Improving Medicines Management

www.1000livesplus.wales.nhs.uk
Acknowledgements

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Date of publication

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The purpose of this guide

This guide has been produced to enable healthcare organisations and their teams to successfully implement a series of interventions to improve the safety and quality of care that their patients receive.

This ‘How to Guide’ must be read in conjunction with the following:

- Leading the Way to Safety and Quality Improvement
- How to Improve

Further guides are also available to support you in your improvement work:

- How to Use the Extranet
- A Guide to Measuring Mortality
- Improving Clinical Communication using SBAR
- Learning to use Patient Stories
- Using Trigger Tools
- Reducing Patient Identification Errors

These are available from the 1000 Lives Plus office, or online at www.1000livesplus.wales.nhs.uk

We are grateful to The Health Foundation for their support in the production of this guide.
Improving care, delivering quality

The 1000 Lives Campaign has shown what is possible when we are united in the pursuit of a single aim: the avoidance of unnecessary harm for the patients we serve. The enthusiasm, energy and commitment of teams to improve patient safety by following a systematic, evidence-based approach has resulted in many examples of demonstrable safety improvement.

However, as we move forward with 1000 Lives Plus, we know that harm and error continue to be a fact of life and that this applies to health systems across the world. We know that much of this harm is avoidable and that we can make changes that reduce the risk of harm occurring. Safety problems can’t be solved by using the same kind of thinking that created them in the first place. To make the changes we need, we must build on our learning and make the following commitments:

- Acknowledge the scope of the problem and make a clear commitment to change systems.
- Recognise that most harm is caused by bad systems and not bad people.
- Acknowledge that improving patient safety requires everyone on the care team to work in partnership with one another and with patients and families.

The national vision for NHS Wales is to create a world class health service by 2015: one which minimises avoidable death, pain, delays, helplessness and waste. This guide will help you to take a systematic approach and implement practical interventions that can bring that about. The guide is grounded in practical experience and builds on learning from organisations across Wales during the 1000 Lives Campaign and also on the experience of other campaigns and improvement work supported by the Institute for Healthcare Improvement (IHI).

Where reference is made to 1000 Lives Plus, this includes the work undertaken as part of the 1000 Lives Campaign and the second phase of this improvement programme - 1000 Lives Plus.

The guide uses examples from the former NHS organisational structures, and where possible this has been acknowledged.
Improving Medicines Management

Introduction

The fourth report from the Patient Safety Observatory details that 60,000 medication incidents were reported to the NPSA via the National Reporting and Learning System (NRLS) between January 2005 and June 2006. The report reviews 92 of these medication incidents in detail, 38 of which resulted in death. The report finds that the medicines most frequently associated with severe harm were:

- Anticoagulants
- Injectable sedatives
- Opioids
- Insulin
- Antibiotics (allergy related)
- Chemotherapy
- Antipsychotics
- Infusion fluid

What are high risk medicines?

High risk medicines are medicines that are most likely to cause severe harm to the patient, even when used as intended. The Institute for Safe Medication Practices (ISMP) reports that, although mistakes may not be more common in the use of these medications, when errors occur the impact on the patient can be significant. As common or expected adverse effects and system or process problems tend to be under-reported there is a difference between the reported drugs and the drugs selected for this guide.

<table>
<thead>
<tr>
<th>Medicine group</th>
<th>Risks to the patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticoagulants (Warfarin and Heparin)</td>
<td>Narrow therapeutic index; potential for clot or bleed; interactions with other medicines including herbal medication; over the counter products and food.</td>
</tr>
<tr>
<td>Opioids</td>
<td>Sedation; respiratory depression; confusion; lethargy; nausea; vomiting; constipation.</td>
</tr>
<tr>
<td>Insulin</td>
<td>Achieving blood sugar control without causing hypoglycaemia particularly in patients who are not eating and drinking as usual. Incorrect selection of product at prescribing or dispensing stage leading to over/under dose.</td>
</tr>
<tr>
<td>Thiazide diuretics</td>
<td>Risk of hypokalaemia; cardiac arrhythmias; muscle weakness and paralysis.</td>
</tr>
<tr>
<td>Gentamicin in neonates</td>
<td>Narrow therapeutic index; potential for hearing impairment; kidney damage.</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>Extremely long half-life; Multiorgan toxicity including lungs, liver, eyes.</td>
</tr>
</tbody>
</table>
NSAIDs (Non Steroidal Anti Inflammatory Drugs) | Risk of gastrointestinal bleeding; increased cardiovascular risks.
---|---
Antipsychotics in elderly dementia | Risk of cerebrovascular adverse events and death.

**Why focus on reducing harm from high risk medications?**

High risk medications are more likely to be associated with harm than other medications. Although any medication used improperly can cause harm, high risk medications cause harm more commonly and the harm they produce is likely to be more serious.\(^2,3\) The harm leads not only to patient suffering, but also to additional costs associated with care of these patients.\(^4,5,6\) Known safe practices can reduce the potential for harm.

The prescribing, preparation, dispensing and administration of medicines requires focused concentration from the individuals involved in all parts of these processes and, whilst there may be guidelines or policies in place to ensure safe practice, there are many stages in these processes where errors may occur or where safeguards are not in place.

Understanding the role human factors play in these circumstances is crucial to understanding how medication practice can be made safer. Historically, improving medication safety involved actions concentrated mainly on ways to identify issues, increase staff awareness of these and encourage greater vigilance. However in recent years there is a growing recognition that more attention is required on designing more reliable systems and processes that prevent and mitigate human error.

The 1000 Lives Campaign aimed to improve patient safety by implementing interventions developed by clinicians in Wales. The improvement methodology promotes doing the simple things reliably and right, using the Model for Improvement and measuring progress. Measurement allows us to determine what the current position is, and provides the means by which we can evaluate how successful we have been in our efforts.

The implementation part of this document is divided into two sections:

- overarching actions to reduce harm from all high risk medicines
- actions to reduce harm in each of the specific medicines included in this intervention.

Where changes have been suggested, it is indicated whether they relate to identification, prevention or mitigation of error.

Based on evidence, the findings from use of the Global Trigger Tool and experience nationally with the Safer Patients Initiative and the 1000 Lives Campaign, this guide has chosen to focus on six groups of high alert medications because they represent areas of greatest harm and greatest opportunity for improvement.
Anticoagulants
opoids
insulins
thiazide diuretics
antipsychotics in dementia
NSAIDS

and two specific drugs
• gentamicin
• amiodarone

The most common types of harm associated with these medications include
• hypotension
• respiratory depression
• bleeding
• hypoglycemia
• delirium
• lethargy
• bradycardia
• renal failure
• cardiac failure

1. Anticoagulants

Management of warfarin therapy spans across primary and secondary care and this can make the pathways complex. Whilst management takes place largely in the outpatient/GP practice setting, problems frequently occur when these patients are transferring between the community and hospital setting. This can be due to issues around medicines reconciliation, failure to communicate effectively or failure to stop or start therapy appropriately when patients are admitted for surgical procedures. A lack of current information has the potential for serious harm, for example where an International Normalised Ratio (INR) is unavailable or communication systems are flawed. Incidents from interactions with warfarin can also be problematic, so safeguards are required in order to avoid patient harm.

Harm events with warfarin and heparin have been associated with a lack of dosing guidelines, appropriate monitoring, poor numeracy and failure to record basic information such as the patient’s weight. Risk assessment of patients commencing anticoagulation is beneficial, to consider selection of a lower dose regimen. Studies have shown that strategies to improve prescribing and monitoring have the potential to reduce adverse events such as bleeding or thromboembolic events.
Standardising steps to initiate and maintain treatment is one of the strategies that may be helpful. In the case of heparin, hospitals may use two types of low molecular weight heparin. Dosage calculations vary between the two and according to the condition being treated. This can lead to confusion and increase the likelihood of error.

In April 2008, the NPSA published a Rapid Response Report relating to the use of intravenous heparin flushes which were widely used in healthcare to keep both indwelling and peripheral lines patent. Risks with heparin flushes are not well recognised by practitioners. Risk of harm to patients can be caused through poor practice such as inappropriate use, the use of heparin flushes which are not formally prescribed or subject to a patient group direction, mis-selection for other poorly differentiated commercial medicine products, mis-calculation and mis-preparation when a dilution of concentrated heparin product is required and mis-selection for other prepared products when placed in an unlabelled syringe before administration.

NPSA guidance relating to anticoagulant use is available at www.nrsls.npsa.nhs.uk/resources

A separate How to Guide has been developed specifically to address preventing Hospital Acquired Thrombosis.

2. Opioids

Opioid overdose or underdose may be associated with respiratory depression or poor pain control respectively. As with other medicines, differing strength medicines in similar packaging can increase the likelihood of human error. Delays in administering a reversal agent in cases of overdose may also lead to more serious harm.

NPSA guidance is available to reduce risk of harm (www.npsa.nhs.uk/nrls/alerts-and-directives/notices/morphine-diamorphine/)
Reducing dosing errors with opioid medicines (www.nrls.npsa.nhs.uk/resources)
The MHRA also have guidance on the safe use of fentanyl patches: (www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/CON025631)

3. Insulin

The introduction of new insulin formulations has resulted in potential risks in the care of diabetic patients. Similar packaging and nomenclature has resulted in an increase in reports of patient harm to the NPSA, who will be issuing guidance on the safe use of insulin in 2010.

Errors may also occur from inadequate monitoring and the use of the abbreviation i.u. instead of (international) units. Patients’ blood glucose could be monitored at an incorrect frequency or even not at all before administration of insulin. Again, standardisation of management may help to avoid incidents.
4. Diuretics
Thiazide diuretics, particularly bendroflumethiazide and indapamide are commonly used hypotensive agents and are valuable agents in the treatment of hypertensive disease. However, hyponatraemia is a common side effect and is a common cause of morbidity and mortality, particularly in the elderly with low body mass. Higher doses than the recommended 2.5mg daily of bendroflumethiazide cause more marked biochemical changes with little advantage in blood pressure control. Significant numbers of doses of bendroflumethiazide 5mg daily continue to be prescribed.

5. Gentamicin in neonates
In 2007, 89% of 180 neonatal units in England used intravenous gentamicin, a broad spectrum antibiotic that is widely used in the treatment of neonatal infection. It is associated with a risk of adverse effects, specifically hearing impairment and kidney damage. Gentamicin has a narrow therapeutic range which necessitates its administration within an accurate timing regime and the careful monitoring of blood levels. 15% of all neonatal medication incidents related to the administration of intravenous gentamicin to neonates.

An NPSA Expert Working Group (EWG) concluded that incidents occur because of:
- poor prescribing practice
- a lack of clearly assigned responsibility relating to blood levels
- a lack of clearly assigned responsibility during the preparation, checking and administration phase (failure to identify administration frequency and dosing errors)
- poor communication between medical and nursing staff
- interruptions, particularly during the preparation and administration phase (this is from RCA and EWG experience)
- poor monitoring

In February 2010, the NPSA published a Patient Safety Alert on the Safer use of intravenous gentamicin for neonates: www.nrls.npsa.nhs.uk/resources/

6. Amiodarone
Amiodarone HCl is an anti-arrhythmic agent indicated for the treatment of recurrent, life-threatening ventricular fibrillation and haemodynamically unstable ventricular tachycardia that does not respond to other agents. Because of its propensity for organ toxicities, this agent is generally considered to be a drug of last resort.

The Summary of Product Characteristics (SmPC) was altered in 2004 to state that treatment should be initiated and normally monitored only under hospital
or specialist supervision. Yet, despite the known adverse effect profile of amiodarone and NICE clinical guidelines for atrial fibrillation,\textsuperscript{10} the drug continues to be widely prescribed. It can cause serious side effects that can lead to death including lung and liver damage and can worsen heartbeat problems.\textsuperscript{11}

### 7. NSAIDs

There is overwhelming evidence to reduce prescribing of antiinflammatory drugs especially in the elderly. The Committee on Safety of Medicines (CSM), now the Medicines and Healthcare products Regulatory Agency (MHRA), have issued five warnings to prescribers regarding the gastrointestinal dangers of NSAIDs.\textsuperscript{12,13}

All NSAIDs, including ibuprofen and COX-2 inhibitors are associated with reports of serious gastrointestinal toxicity and NSAIDs remain one of the top 5 drugs responsible for adverse event related admissions.\textsuperscript{9} The elderly and those taking concomitant aspirin are high-risk groups. There is also an increased risk of thrombotic events associated with the long term use of NSAIDs.\textsuperscript{14}

Usage of NSAIDs has changed little over the years indicating that traditional change methods have not been effective.

### 8. Antipsychotics in dementia

A recent review of dementia prescribing in England for the Minister of Health raised concerns about the level of use and risk of antipsychotic drugs for people with dementia.\textsuperscript{15} The evidence suggests that the drugs appear to have only a limited positive effect in treating behavioural and psychological difficulties (e.g. agitation, aggression, wandering, shouting, repeated questioning and sleep disturbance), but can cause significant harm.

It is estimated that approximately 26% of patients with dementia are prescribed antipsychotics and of these only 20% will derive any benefit. However, use at this level equates to an additional 97 cerebrovascular adverse events, around half of which may be severe, and to a further 108 deaths per year on top of those that would be expected in this frail population in Wales.

The NICE clinical guidelines for dementia include advice on the appropriate use and ongoing monitoring of antipsychotics for non-cognitive symptoms and behaviour that challenges.\textsuperscript{16}
References


13. www.mhra.gov.uk


Improving Medicines Management

Driver Diagram

**Content Area**

- Improve Medicines Management
  - Prevent
  - Identify
  - Mitigate

**Drivers**

- Reliable Medicines Management of High Risk Medicines
- Co-ordination of care
- Patient and family Involvement

**Interventions**

- Use standardised protocols, scales and recovery protocols for high risk meds: guided dose algorithms
- Routine and reliable laboratory monitoring
- Identify High risk areas using FMEA
- Pharmacy Consultation Service
- Accuracy of Medicines at the interface (verification, validation, classification); Medication reconciliation
- Education and training
- Reliable in-hospital handoffs
- “One Stop” delivery systems
- Communication between Primary care and Secondary care (GP/Community Pharmacy)
- High Risk management services
- Patients and family education
- Self management protocols

**Prevent**

- Identify
- Mitigate
Getting Started

Have you set up your team?
You need to consider three different dimensions:

- Organisational level leadership
- Clinical or technical expertise
- Frontline leadership and team membership

See the ‘Leading the Way to Safety and Quality Improvement’ How to Guide; and Appendix 9 for further information.

Do you know how you will measure outcomes?
For this content area, you should use the following outcome measures:

- % of Warfarin tests with INR results above 5*
- % of Warfarin tests with INR results above 8*
- % tests within 0.5 of target INR
- % Heparin tests outside protocol limits
- Anticoagulant adverse event rate (suitable for both Warfarin and heparin)
- Narcotic adverse event rate
- % patients treated with Naloxone
- Insulin adverse event rate

See Appendix 8 for further information.

Do you and your team understand how to apply the Model for Improvement?
The Model for Improvement is a fundamental building block for change and you need to understand how to use it to test, implement and spread the interventions in this guide.

See the ‘How to Improve’ Tools for Improvement guide and Appendix 10 for further information.

How are you going to measure process reliability?
In order to improve outcomes for your patients you need to demonstrate you are using these interventions reliably. This means that all the elements of the interventions are performed correctly on 95% or more of the occasions when they are appropriate. You need to do this by using the process measures in this guide.

See the ‘How to Improve’ Tools for Improvement guide and Appendix 10 for a summary of all process measures.

How will you share your learning?
Contact 1000 Lives Plus for details of mini-collaboratives and other ways to share your learning and to learn about the progress of other teams.
Drivers and Interventions

Some interventions apply to either primary or secondary care and some apply to both. The high risk medicines included in this How to Guide are:

- Anticoagulants: Warfarin
- Anticoagulants: Heparin
- Opioids
- Insulin
- Diuretics
- Gentamicin in neonates
- Amiodarone
- NSAIDs
- Antipsychotics in elderly dementia

Three suggested actions that can reduce harm from high risk medicines are based on approaches to developing safer systems: identification, prevention and mitigation.

On commencement of this work, organisations (Health Boards, Hospitals, GP practices, Community pharmacies etc) should review their systems and incident reports in order to assess the local position regarding the most common causes of medication-related clinical incidents. Whilst warfarin is associated with the highest medicines related harm, reduction of harm from its use is also the most complex to resolve. As referenced in the previous section, detailed guidance on this has been provided by the NPSA.

Complying with these interventions may require focusing on the use of a care bundle to reduce harm in different areas of clinical practice. Care bundles in general are groupings of best practices with respect to an intervention or a disease process that, when applied individually, can improve care, but when applied collectively may result in substantially greater improvement. A bundle is a means to designing a standard approach when delivering elements of care.

A number of hospitals were involved in the Safer Patients Initiative (SPI) and they have found it helpful to maintain their focus on one medicine before embarking on efforts to improve another. It may be possible in your organisation to commence work on other medicine groups in parallel if you can appoint a lead who specialises in a related care area such as diabetes or anaesthesia. Your approach needs to be determined locally based on your preference, your local experience of relevant incidents, or processes and the resources available to you.
Interventions 1a
Warfarin Care Bundle - Primary Care

The interventions that make up the care bundle for Warfarin are shown below. Some may differ in one area from those in another. For example some of the components in a GMS practice undertaking the level 4 Anticoagulant Near Patient Testing enhanced service may differ from those in an area where the local acute hospital runs an out-patient anticoagulant clinic, or those of a community pharmacy applying the recommendations of the NPSA.
Every patient on warfarin should have a minimum dataset of information recorded on GP records

- Record indication for warfarin
- Record target INR (a value not a range)
- Record expected duration of therapy
- Record who is responsible for monitoring and dosing (e.g. GP, hospital clinic etc)

Every patient on warfarin should have their INR monitored regularly and warfarin dosage adjusted to achieve target INR

- Record INR results on GP records
- Ensure INR monitored at least every 12 weeks (minimum)
- GP to check recent INR result prior to signing prescription
- Ensure dosage adjusted to achieve target INR

Every patient on warfarin should have a prescription for appropriate strengths and quantities of warfarin according to individual dose

- Record recent dose of warfarin
- Use tablet strengths suitable for the dose
- Issue quantity for a 28 day supply
- Avoid 5mg tablets unless absolutely necessary

Establish the level of INR control for each patient over the last 12 months (or since the start of therapy, if less than one year)

- Record number of INRs > 8 in last 12 months
- Record number of INRs > 5 in last 12 months
- Record number of INRs < 2 in last 12 months
- Record number of INRs in last 12 months

Every patient should have a documented annual risk versus benefit assessment of warfarin therapy

- Review benefit of warfarin therapy versus risks taking into account physical, medical and social circumstances and history of INR control
- Record outcome of review and discussion with patient

Ensure patient education and encourage patient involvement in warfarin therapy

- Use of yellow book/alert card
- Carer information
- Patient self monitoring/management
- Community Pharmacy support
Measures:
For this Bundle, use the following measures:
- INR >5 and INR >8
- INR within 0.5 of target INR
- Anticoagulant adverse event rate

Applying the Model for Improvement

What are we trying to achieve?
In order to agree an aim, you need to understand the current situation. This may mean undertaking one or more of the following to identify the priority areas for your organisation and to set a realistic time frame for your goal:
- A baseline audit in a particular setting e.g. GP practice or community pharmacy
- A review of local incident reports in your hospital
- An exercise in process mapping
- A Failure Modes Effects Analysis (FMEA)

An example of an aim statement could be:
Within 1 year, 95% of patients in this practice will have a record of indication, target INR and expected duration of treatment for Warfarin and a record of an INR result (in range) within the last 12 weeks.

How will we know a change has been an improvement?
Measurement is the only way to know whether a change represents an improvement.
Decide which measures will inform you of your progress and how you are going to collect them. These are the measures to monitor compliance with the recommended interventions (see care bundle above). Examples of measures used during the 1000 Lives Campaign were:
- % patients with no INR
- % patients treated within anti-coagulant protocol
**What changes can we make that will result in an improvement?**

The management of warfarin is particularly complex. It is often initiated and managed in a secondary care environment, although primary care assumes the responsibility for prescribing and increasingly the monitoring as well. It therefore often requires interventions in different parts of the care pathway. As systems, processes and service delivery can differ widely between organisations, implementation of improvements can be challenging.

Some resources developed during the campaign may help with process improvement. These can be found in Helpful Resources.

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Hywel Dda Health Board’s (Ceredigion) aim was “To ensure all patients to whom a prescription for warfarin is dispensed receive appropriate counselling on warfarin and its side-effects, and their most recent INR is noted prior to dispensing”. A community pharmacy was recruited to test a PDSA of the NPSA recommendation that the pharmacist should ensure that the patient had a recent INR, which was within safe levels before dispensing a repeat prescription for warfarin.

The first test did not achieve the 95% reliability target because not all patients carry their yellow book, or collect their prescription themselves. Some patients send a relative or a carer, or are resident in care homes, or have their prescriptions delivered.

Further PDSA cycles were developed and then tested to include alternative strategies to encourage patients or their representatives to present a recent INR result.
1b Anticoagulants: Warfarin Care Bundle - Secondary Care

**Primary outcome**

Prevent harm from anticoagulation by implementing the bundle of care

**Care bundle**

Every patient on warfarin should have a minimum dataset of information recorded in their notes

Every patient on warfarin should have their INR monitored regularly and warfarin dosage adjusted to achieve target INR

Every patient should have a prescription for appropriate strengths and quantities of warfarin according to individual dose

Establish the level of INR control for each patient or area

Every patient should have a documented annual risk versus benefit assessment of warfarin therapy

Ensure patient education and encourage patient involvement in warfarin therapy

**Interventions**

- Record indication for warfarin
- Record target INR (a value not a range)
- Record expected duration of therapy
- Record who is responsible for monitoring and dosing (e.g., GP, hospital clinic etc)

- Record INR results on prescription chart and in patients’ hand held record
- Ensure INR monitored at appropriate intervals
- Prescriber to check recent INR result prior to prescribing
- Ensure INR results available and actioned in a timely manner

- Record recent dose of warfarin
- Use tablet strengths suitable for the dose
- Avoid 5mg tablets unless absolutely necessary

- Record percentage of INRs > 8 each month
- Record percentage of INRs > 5 each month
- Record percentage of INRs < 2 each month

- Review benefit of warfarin therapy versus risks taking into account physical, medical and social circumstances and history of INR control
- Record outcome of review and discussion with patient

- Use of yellow book/alert card
- Carer information
- Patent self monitoring/management
- Community Pharmacy support
Improving Medicines Management

**Measures:**
For this Bundle, use the following measures:
- % INR >5 and % INR >8
- Anticoagulant adverse event rate

**Model for Improvement Example**

**What are we trying to achieve?**
In order to agree an aim, you need to understand the current situation. This may mean undertaking one or more of the following to identify the priority areas for your organisation and to set a realistic time frame for your goal:
- A baseline audit in a particular setting e.g. ward, division or directorate, hospital
- A review of local incident reports
- An exercise in process mapping
- A Failure Modes Effects Analysis (FMEA)

**An example of an aim statement could be:**
Within 1 year, 95% of patients initiated on warfarin within this hospital will have a record of indication, target INR and expected duration of treatment for warfarin and a record of at least 3 INR results, which is communicated effectively to primary care when the patient is discharged.

**How will we know a change has been an improvement?**
Measurement is the only way to know whether a change represents an improvement.

Decide which measures will inform you of your progress and how you are going to collect them. These are the measures to monitor compliance with the recommended interventions (care bundle).

**What changes can we make that will result in an improvement?**
The management of warfarin is particularly complex. It is often initiated and managed in a secondary care environment, although primary care assumes the responsibility for prescribing and increasingly the monitoring as well. These patients may be admitted to any part of a secondary care organisation, during their warfarin therapy, resulting in many transfers of care (handovers), which are known to be high risk processes. It therefore often requires interventions in
different parts of the care pathway. As systems, processes and service delivery can differ widely between organisations, implementation of improvements can be challenging.

The components that make up the care bundle for warfarin are listed below. Some components may differ in one area from those in another. For example, depending whether patients have their INRs monitored in primary or secondary care and how doses are prescribed and communicated based on these results.

At Glan Clwyd Hospital (Betsi Cadwaladr University Health Board), staff redesigned their warfarin prescribing and monitoring chart using a series of PDSA cycles. Their aim was “To develop a more user-friendly warfarin chart and improve the recording of target INRs, indications and durations of therapy”.

Tests began using just one ward, then escalated to simultaneous testing on multiple wards within different specialties before the chart was adopted throughout the hospital. Three months after the chart was launched, the target INR, indication and duration of therapy were all recorded for 76% of warfarin patients.

The resulting chart was well liked by doctors, nurses and pharmacy staff. It has been shared with a number of other organisations who have used it to develop their own local charts using PDSA cycles, as well as in work being undertaken to develop a standard chart throughout Wales.
1c Anticoagulants: Heparin

**Primary outcome**

Prevent harm from heparins by implementing the bundle of care.

**Care bundle**

**Policies**
- Review use of heparins (including flushes) on general and specialist wards
- Ensure NPSA Rapid Response on heparin flushes fully implemented
- Review compliance with local heparin dosing and monitoring guidance

**Communication**
- Ensure communication between medical and nursing staff
- Assign responsibility for checking monitoring results

**Patient education**
- Patient counselling at initiation
- Information for patients self-administering LMWH or heparin flushes

**Monitoring side-effects**
- Regular monitoring of clotting time (APTT or similar) for UFH
- Monitor for bruising/bleeding
- Platelet counts for patients on long-term therapy

**Record keeping**
- Record of patient weight (for LMWH) and indication
- Record of expected duration of treatment or treatment plan
- Record of dosing plan including loading dose as appropriate
**Measures:**

For this intervention, use the following measures:

- % patients treated with appropriate LMWH (Low Molecular Weight Heparin) dose
- % patients with weight recorded on prescription chart
- % patients treated within UFH (Unfractionated Heparin) protocol, including monitoring & dose adjustment
- Heparin adverse event rate

**Applying the Model for Improvement**

**What are we trying to achieve?**

Find out what your current policies are relating to heparins (both Low Molecular Weight and Unfractionated Heparins). Include investigation into the policy/protocol for prescribing and monitoring as these are points in the patient pathway where heparin errors may occur.

In order to agree an aim, you need to understand the current situation. This may mean undertaking one or more of the following to identify the priority areas for your organisation and to set a realistic time frame for your goal:

- A baseline audit in a particular setting e.g. GP practice or community pharmacy
- A review of local incident reports in your hospital
- An exercise in process mapping
- A Failure Modes Effects Analysis (FMEA)

**An example of an aim statement could be:**

Within 1 year, we will reduce by 40% the number of events where patients receive more than 30% more Enoxaparin than the ideal dose. This will be achieved by initial focus on ensuring all patients have a current weight recorded on their prescription chart and/or clerking notes.

Create your operational definition. In the example above this means establishing criteria for ‘current weight’.

Who can record the patient’s weight? Exactly where should it be recorded? Do you have to weigh the patient or can they self-report their weight? Are facilities available to weigh larger or immobile patients?
How will we know a change has been an improvement?

Measurement is the only way to know whether a change represents an improvement.

Decide which measures will inform you of your progress and how you are going to collect them. These are the measures to monitor compliance with the recommended interventions (care bundle).

What changes can we make that will result in an improvement?

The management of heparins may be complicated, as the dose is often related to the patient’s weight and the indication for the medication (as mentioned previously). There are a number of references to weight-based dosing protocols for UFH in the literature, mainly from America. The risks and benefits of adopting this approach in contrast to a standard loading dose then dose adjustment based on continued monitoring e.g. APTT, (as is more commonly used in the UK) would need to be balanced for each individual organisation.

You may wish to follow the How to Guide for ‘Preventing Hospital Acquired Thrombosis’ concurrently with this document.
High Risk Medicine 2: Opioids in Secondary Care

**Primary outcome**

Prevent harm from opioids by implementing the bundle of care.

**Care bundle**

**Policies**
- Minimise or eliminate multiple strengths of the same drug where possible
- Have procedures for safely prescribing, labelling, supplying, storing, preparing and administering opioids
- Provide ongoing staff training

**Communication**
- Consider agreeing pain score with patient prior to procedure
- Confirm recent doses and formulations prior to prescribing/administering
- Ensure does changes are clearly communicated

**Patient education**
- Patient counselling at initiation or dose changes
- Confirm recent doses and formulations with patients or carers

**Monitoring side-effects**
- Ensure guidelines include monitoring of pain score and vital signs
- Ensure naloxone is available and consider establishing a regime which can be given before calling a prescriber

**Record keeping**
- Record of dosing plan including planned increases as appropriate
- Record risk versus benefit discussion
- Record independent infusion pump check
Measures:

For this Bundle, use the following measures:

- The number or proportion of patients receiving opioids who receive subsequent treatment with naloxone
- % patients treated within opioid protocol
- Opioid adverse event rate

Applying the Model For Improvement

What are we trying to achieve?

Find out what your current policies are relating to opioids. Include investigation into the policy/protocol for prescribing and communicating post-operative pain management on transfer from theatres to the ward as this is a point in the patient pathway where opioid errors may occur.

An example of an aim statement could be:

Within 1 year we will reduce the number of events where naloxone is administered to counteract opioid overdose by 40%. This will be achieved by initial focus on ensuring all post operative patients transferring to ward settings have standard pain management regimes in place.

Create your operational definition. In the example above this means establishing criteria for ‘standard pain management regimes’ and ‘in place’.

‘Standard pain management regimes’ - what does this look like in your hospital? (Pre-printed signed prescription, signed sticker, description of ongoing regime with doses and limits that can be administered).

‘in place’ - What you would expect to have happened prior to transfer? e.g. documentation of first dose and subsequent doses given prior to transfer. Where is this to be documented? Theatre notes, prescription chart or somewhere else? Can this be easily accessed by all who may need to?

How will we know a change has been an improvement?

Measurement is the only way to know whether a change represents an improvement.

Decide which measures will inform you of your progress and how you are going to collect them. Some examples of measurements are shown above and in the Care Bundle.
What changes can we make that will result in an improvement?

Opioids may be used either acutely or chronically with different products used for each situation. You may therefore wish to “segment” your population and target just one of these areas initially. Some areas to consider are:

- Acute pain in the peri-operative period: are appropriate doses given, recorded and effectively communicated? How are patients with high opioid requirements (e.g. those taking opioids chronically, or opioid addicts/abusers) managed?

- Responding to dose-related side-effects: is naloxone readily available in all required locations? Do staff know how and when to use it? Is it used appropriately if a long-acting opioid has been used? Is it prescribed with the opioid or is there a potential delay as naloxone must be prescribed on each occasion it is required?)

- Chronic pain: are gastro-intestinal side-effects minimised/managed appropriately? What criteria are used to decide whether a dose should be increased or decreased? Are they followed?
High Risk Medicine 3: Insulin

**Primary outcome**

Prevent harm from insulin by implementing the bundle of care

**Care bundle**

**Interventions**

- **Policies**
  - Develop, implement and monitor protocols for diabetic emergencies
  - Up-to-date protocols and procedures in all clinical areas
  - Risk assess products and procedures to identify high risk areas and action them
  - Provide ongoing staff training

- **Communication**
  - Confirm recent doses, formulations and devices prior to prescribing, dispensing or administering
  - Communicate above details at all transfers of care
  - Co-ordinate meal and insulin times

- **Patient education**
  - Patient counselling at initiation
  - Agree care plan with patients or carers and involve them in day to day care

- **Monitoring side-effects**
  - Independent double-checks of IV insulin infusions
  - Protocols for treatment of diabetic emergencies
  - All agents (including non-pharmaceuticals) to treat hypoglycaemia readily available

- **Record keeping**
  - Annual audit of practice
  - Care plan for each patient
  - Record of insulin, dose and device communicated effectively at transfers of care
Measures:
For this Bundle, use the following measures:

- Percentage of patients treated within insulin protocol
- Insulin adverse event rate

Applying the Model For Improvement

What are we trying to achieve?
In order to agree an aim, you need to understand the current situation. This may mean undertaking one or more of the following to identify the priority areas for your organisation and to set a realistic time frame for your goal:

- A baseline audit in a particular setting e.g. GP practice or community pharmacy
- A review of local incident reports in your hospital
- An exercise in process mapping
- A Failure Modes Effects Analysis (FMEA)

An example of an aim statement could be:
Within 1 year, 95% of diabetic patients in this organisation who are Nil by Mouth (NBM) will have their blood sugar maintained within an appropriate range.

How will we know a change has been an improvement?
Measurement is the only way to know whether a change represents an improvement.
Decide which measures will inform you of your progress and how you are going to collect them. These are the measures to monitor compliance with the recommended interventions (care bundle).

What changes can we make that will result in an improvement?
Insulins may be administered regularly as part of a patient’s chronic requirements or given using a ‘sliding scale’ when requirements are less predictable. You may therefore wish to ‘segment’ your population and target just one of these areas initially. Some areas to consider are:

- Is hypoglycaemia well-defined and recognised? Are nursing and medical staff all using the same definition? How is it managed and are all the components readily available in all locations (including non-drug measures such as sugary drinks or starchy foods)?
Improving Medicines Management

- How are patients’ usual insulins managed during a stay in hospital? Who administers them and what happens if a change is required (e.g. a change in the number of units to be injected or temporarily withholding while the patient is on a sliding scale or similar)?

- How are selection errors minimised (electronic selection on prescribing/dispensing software or physical selection)?

An example of an insulin prescription chart for ward use can be found in Appendix 6.
High Risk Medicine 4: Diuretics

Measure:
For this Bundle, use the following measure:
- Diuretic adverse event rate

Applying the Model For Improvement

What are we trying to achieve?
To reduce the number of patients who are admitted to hospital as a result of their diuretic therapy.

How will we know a change has been an improvement?
The outcome measure will be a full count (not sample) of patients whose cause of admission is related or probably related to overdosage, adverse reaction to, or complication arising from their diuretic therapy.

Decide which measures will inform you of your progress and how you are going to collect them. These are the measures to monitor compliance with the recommended interventions (care bundle).

This intervention has not yet been evaluated but is the subject of testing in at least two hospitals and their communities in Wales. The measure will be of bundle compliance in participating practices based on 3 bundles (diagnosis, selection and management) measured monthly from a sample of 20 patients taking diuretics in each practice.

What changes can we make that will result in an improvement?
Practices will be fed their bundle compliance data plus a qualitative review of non-compliance and hospital admissions in order to identify system level changes in the practice and patient-specific interventions. It is assumed that compliance with these bundles will have a beneficial effect on the outcome measure because Howard et al. analysed the nature of drug-related admissions and identified that, in the case of diuretics, the cause was almost always adverse reaction or overdosage (almost never under-dosing).
High Risk Medicine 5: Gentamicin in neonates

**Primary outcome**
Prevent harm related to administration of i/v gentamicin to neonates by implementing the bundle of care

**Care bundle**

**Policies**
- Gentamicin protocol should be available where neonatal services are provided.
  - 24 hour clock format should be used and unused time slots on prescription chart blocked out
  - Prevent interruptions during preparation and administration by wearing coloured disposable apron
  - A double checking prompt should be used during preparation and administration
  - The prescribed dose of gentamicin should be given within 1 hour of the prescribed time

**Communication**
- Ensure communication between medical and nursing staff
- Assign responsibility for checking blood level results

**Education**
- Training should be provided to all staff involved in prescribing and administration of i/v gentamicin
- Peak gentamicin level approx 1 hour post i/m or i/v administration concentration
- Trough gentamicin level just before the next dose
- Serum-aminoglycoside concentrations must be done in neonates
- In patients on single daily dose regimens it may become necessary to prolong the dose interval to more than 24 hours if the trough concentration is high

**Monitoring**
- Ensure patient’s weight is recent and realistic
- Each checker to confirm correct dose has been prescribed based on weight
- Ensure dosing regimen and frequency correct for gestational age
- Ensure prescription is signed

**Record keeping**
- Ensure prescription is signed
**Measures**

For this Bundle, use the following outcome measure:

A short-term outcome measure, which can be measured on neonatal units, would be:

- The percentage of non-therapeutic gentamicin blood level results

- A longer term outcome, measuring actual harm would be the number of neonates with hearing loss as monitored by the Neonatal Hearing Screening Programme.

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**Applying the Model For Improvement**

**What are we trying to achieve?**

Find out what your current policies are relating to neonatal gentamicin prescribing and administration. They should be developed or revised to state that intravenous gentamicin should be administered to neonates incorporating the following four elements of the care bundle. Construct a clear aim statement.

**An example might be:**

We will achieve 100% compliance with all elements of the gentamicin care bundle by March 2010.

**How will we know a change has been an improvement?**

Measurement of your process and outcomes will tell you if the changes you have made have resulted in an improvement. Using a selection of measures helps give the whole picture.

Decide which measures will inform you of your progress and how you are going to collect them. These are the measures to monitor compliance with the recommended interventions (care bundle).
Process measures tell you how individual parts of the system are performing. For example:

- The percentage of gentamicin doses compliant with all four components of the neonatal gentamicin care bundle.

A double checking prompt checklist and care bundle compliance form developed as part of the NPSA resource pack can be found in Appendices 4 and 5.

Balancing measures tell you what has happened elsewhere in the system when you made the change - any consequences. For example, the impact of gentamicin assay requests on local laboratory processes.

**What changes can we make that will result in an improvement?**

Once a protocol has been agreed, compliance against the care bundle can be measured and the data input onto run charts, which will demonstrate whether a change has resulted in an improvement. The data should be reviewed and analysed by the multi-disciplinary implementation team.
High Risk Medicine 7: Amiodarone

**Primary outcome**

Prevent harm from amiodarone by implementing the bundle of care.

**Care bundle**

- Policies
- Communication
- Patient education
- Monitoring side-effects
- Record keeping

**Interventions**

- Review use of amiodarone on general wards
- Implement NICE Atrial Fibrillation guidelines
- Monitor and control initiation of amiodarone
- Informed consent of patient
- Shared care agreement
- Patient counselling at initiation
- Patient hand held information and monitoring booklet
- Regular monitoring of ECG, LFT’s, TFT’s, Chest X Ray, Eye tests
- Record of indication for amiodarone
- Record of expected duration of treatment or treatment plan
- Record of dosing plan including loading doses as appropriate
Improving Medicines Management

**Measure**

For this intervention, use the following process measure:

- % of patients with a documented, recorded indication, expected duration of therapy and a record of monitoring

---

**Applying the Model For Improvement**

**What are we trying to achieve?**

In order to agree an aim, you need to understand the current situation. This may mean undertaking one or more of the following to identify the priority areas for your organisation and to set a realistic time frame for your goal:

- A baseline audit in a particular setting e.g. GP practice or community pharmacy
- A review of local incident reports in your hospital
- A Failure Modes Effects Analysis (FMEA)

**An example of an aim statement could be:**

Within 1 year, 95% of patients in this practice taking amiodarone will have a record of indication, expected duration of treatment and a record of regular monitoring.

**How will we know a change has been an improvement?**

Measurement is the only way to know whether a change represents an improvement.

Decide which measures will inform you of your progress and how you are going to collect them. These are the measures to monitor compliance with the recommended interventions (care bundle).

**What changes can we make that will result in an improvement?**

Amiodarone is initiated in a secondary care environment, although primary care assumes the responsibility for prescribing and increasingly the monitoring as well. Initiation should be by physicians experienced in the use of amiodarone and according to national shared care guidelines and/or local care pathways protocols. There should be informed consent from the patient after counselling, and the patient should be encouraged to participate in ongoing management. This can be achieved by use of a patient held record of monitoring (see Helpful Resources).
Compliance with monitoring requirements should be in accordance with the All Wales Medicine Strategy Group (AWSMG) Shared Care Agreement which outlines each physician’s role and responsibilities.

Where the indication for amiodarone is not clear and patients are no longer under the care of a Secondary Care physician it is recommended that a medication review is undertaken with the aim of compliance with national and local policies.

An example of a data collection sheet can be found in the Helpful Resources.
High Risk Medicine 8: NSAIDs

**Primary outcome**
Reduce the harm caused by the use of Non-steroidal anti-inflammatory drugs (NSAIDs)

**Care bundle**

**Policies**
- Issue acute prescriptions for NSAIDs only
- Select the lowest dose for the shortest duration to reduce GI and CV risks
- Co-prescribe a PPI to patients at high risk of developing GI complications
- Diclofenac 150mg daily has similar thrombotic risk profile to that of at least one coxib (etoricoxib) and possibly others
- Aspirin and other NSAID combination substantially increases GI risk
- Switching between NSAIDs should not be done without careful consideration of the overall safety profile of the products, a patient’s individual risk factors, and patient’s preference
- Implement NICE Osteoarthritis and Rheumatoid Arthritis guidelines

**Communication**
- Detailed ongoing communication between primary and specialist services and patient/carer

**Patient/carer involvement**
- Formulate and agree a management plan with patient
- Full discussion on benefit versus risk of medication including increased risk of GI, renal liver and cardiovascular adverse events
- Review regularly

**Monitoring side-effects**
Assess and monitor patient risk factors for gastrointestinal, liver and cardio-renal toxicity:
- Active Peptic ulcer disease
- Renal function
- Ischaemic heart disease
- Heart Failure
- Active liver disease

**Record keeping**
- Record of indication for NSAID
- Record risk/benefit assessment
- Record efficacy
- Record side-effects
- Record rationale for continuing, changing or stopping medication

For full prescribing information please consult current BNF and Summary of Product Characteristics for individual drugs.
Measures
For this Bundle, use the following process measures:

- % of patients taking long term NSAIDs with a documented record of indication and assessment/discussion of risk/benefit and a record of renal function in the last 12 months
- DDD per 1,000 PUs
- Ibuprofen and Naproxen as % of NSAIDS items

Applying the Model For Improvement

What are we trying to achieve?

In order to agree an aim, you need to understand the current situation. This may mean undertaking one or more of the following to identify the priority areas for your organisation and to set a realistic time frame for your goal:

- A baseline audit in a particular setting e.g. GP practice or community pharmacy
- A review of local incident reports in your hospital

An example of an aim statement could be:

Within 1 year, 95% of patients in this practice taking long term NSAIDs will have a documented record of indication and assessment/discussion of risk/benefit and a record of renal function in the last 12 months.

How will we know a change has been an improvement?

Measurement is the only way to know whether a change represents an improvement.

Decide which measures will inform you of your progress and how you are going to collect them. These are the measures to monitor compliance with the recommended interventions (care bundle).

What changes can we make that will result in an improvement?

Because NSAIDS in single doses have analgesic activity comparable to paracetamol and in regular full dosage have both a lasting analgesic and anti-inflammatory effect they are often prescribed early on in treatment for both acute pain and chronic inflammatory conditions. However it is recommended that non-pharmacological methods, regular paracetamol and topical NSAIDs should be tried first and documented.
Where an anti-inflammatory is being considered, careful selection of an appropriate NSAID, following a documented assessment of previous analgesia use, patient risk factors and discussion with the patient on the benefits and risks of long-term NSAID use should be combined with regular follow up and monitoring for early detection of adverse effects and opportunities to take a break from treatment.
### High Risk Medicine 9: Antipsychotics in dementia in Primary and Secondary Care

#### Primary outcome
- Reduce the harms caused by the use of antipsychotic medication in patients with dementia

#### Care bundle

#### Interventions suggested

- **Policies**
  - Implement NICE Dementia guidelines
  - Antipsychotics should NOT be 1st line treatment except where there is risk of extreme risk and harm
  - Identify and treat co-morbidities e.g. pain, depression, infection
  - Consider psychological and alternative therapies first
  - Atypical antipsychotics preferred
  - Prescribe lowest dose for shortest duration possible
  - Review continuation regularly

- **Communication**
  - Detailed ongoing communication between primary and specialist services and patient/carer

- **Patient/carer involvement**
  - Patient/carer involvement at initiation
  - Full discussion on benefit versus risk of medication including increased risk of cardiovascular adverse events

- **Monitoring side-effects**
  - Regular monitoring for side-effects
  - Sedation
  - Agitation/behaviour changes
  - Extrapyramidal effects
  - Weight gain
  - Hypotension
  - Hyperglycaemia
  - Poor temperature control

- **Record keeping (At least 3 monthly)**
  - Record indication for antipsychotic
  - Record risk/benefit assessment
  - Record efficacy including changes in symptoms and behaviour
  - Record side-effects
  - Record rationale for continuing, changing or stopping medication

---

For full prescribing information please consult current BNF and Summary of Product Characteristics for individual drugs.
Measures
For this Bundle, use the following process measures:

- % of patients with a diagnosis of dementia with a documented record of indication for antipsychotic
- % of patients with a diagnosis of dementia prescribed an antipsychotic
- DDD/1000 PUs for an agreed basket of antipsychotics

Applying the Model for Improvement

What are we trying to achieve?
In order to agree an aim, you need to understand the current situation. This may mean undertaking a baseline audit in a particular setting e.g. GP practice or care home to identify the priority areas for your organisation and to set a realistic time frame for your goal.

An example of an aim statement could be:
Within 1 Year 95% of dementia patients prescribed antipsychotics in this practice will have a documented record of indication and of monthly reviews for continued benefit and adverse event monitoring.

How will we know a change has been an improvement?
Measurement is the only way to know whether a change represents an improvement.

Decide which measures will inform you of your progress and how you are going to collect them. These are the measures to monitor compliance with the recommended interventions (care bundle).

What changes can we make that will result in an improvement?
Identifying high prescribers of antipsychotic medications. Where an antipsychotic is being considered, careful risk assessment should take place in consultation with patient/carers. Alternative therapies should be first choice. Antipsychotic choice, when necessary, should be individually tailored to the patient with the lowest dose possible prescribed for the shortest duration. Ongoing monitoring of the patient is essential.
**Critical Success Factors**

1. Get the right team; ensure that there is a good representation from medical and non-medical staff involved in the process (which may span different sectors).
2. Recruit a patient onto the team (see below).
3. Establish a clear aim and an operational definition.
4. Don’t try and tackle everything at once. Use tools such as FMEA or Pareto to identify where the greatest risks are.
5. Choose a champion to start the work.
6. Make sure that measurements are quick and easy to do.
7. Identify someone responsible for collecting the data.
8. Share any improvement graphs with those involved with the PDSAs, so they can track progress over time.
9. Set challenging, but realistic timetables.
10. Meet regularly to maintain the momentum.

**How to Engage a Patient**

Having a patient involved in your team adds value to the improvement work. Not only are they able provide a patient’s perspective to an existing process or service, but they can also act as a sounding board for proposed changes, a champion for the improvement work and keep the team ‘patient-focused’.

The most likely way to recruit a patient onto the team, would be to ask an anticoagulant nurse or a practice nurse to approach someone via an anticoagulant clinic or alternatively go to the local PPI group.
Helpful Resources

NPSA Actions that can make anticoagulant therapy safer: Alert and other information
www.nrls.npsa.nhs.uk/resources

NPHS Quality Improvement Toolkit/ AWMSG anticoagulant audit:
http://nww2.nphs.wales.nhs.uk:8080/primarycareqitdocs.nsf/

FMEA:
www.ihi.org/ihi/workspace/tools/fmea/

WeMeReC Things to know about amiodarone November 2008
Bibliography


Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. JAMA. 1997;277:312-317.


NPSA Patient Safety Resources; Rapid Response Report: Intravenous Heparin Flush Solutions
www.nrls.npsa.nhs.uk/resources/


### Glossary

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cox-2</td>
<td>Cyclo-oxygenase-2 selective inhibitors</td>
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<tr>
<td>CSM</td>
<td>The Committee on Safety of Medicines</td>
</tr>
<tr>
<td>CV</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>DDD</td>
<td>Divided Daily Dose</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiograph</td>
</tr>
<tr>
<td>EWG</td>
<td>Expert Working Group</td>
</tr>
<tr>
<td>FMEA</td>
<td>Failure Modes Effects Analysis</td>
</tr>
<tr>
<td>GI</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>GMS</td>
<td>General Medical Services</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>INR</td>
<td>International Normalised Ratio</td>
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<tr>
<td>LFT</td>
<td>Liver Functions Tests</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and Healthcare Regulatory Authority</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
</tr>
<tr>
<td>NMC</td>
<td>Nursing and Midwifery Council</td>
</tr>
<tr>
<td>NPSA</td>
<td>National Patient Safety Agency</td>
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<tr>
<td>NRLS</td>
<td>National Reporting and Learning System</td>
</tr>
<tr>
<td>NSAID</td>
<td>Non Steroidal Antiinflammatory Drug</td>
</tr>
<tr>
<td>PCQIS</td>
<td>Primary Care Quality Information Service</td>
</tr>
<tr>
<td>PDSA</td>
<td>Plan Do Study Act</td>
</tr>
<tr>
<td>PPI</td>
<td>Proton Pump Inhibitor</td>
</tr>
<tr>
<td>PU</td>
<td>Patient Units</td>
</tr>
<tr>
<td>RCA</td>
<td>Root Cause Analysis</td>
</tr>
<tr>
<td>RLS</td>
<td>(National) Reporting and Learning System</td>
</tr>
<tr>
<td>SmPC</td>
<td>Summary of Product Characteristics</td>
</tr>
<tr>
<td>SPI</td>
<td>Safer Patients Initiative</td>
</tr>
<tr>
<td>TFT</td>
<td>Thyroid Function Test</td>
</tr>
<tr>
<td>TIA</td>
<td>Transient Ischaemic Attack</td>
</tr>
</tbody>
</table>
Appendices

Appendix 1

Annual Risk/Benefit Assessment for Patients on Anticoagulant Therapy

Guidance: This tool is for use when carrying out the annual risk/benefit assessment for patients on warfarin. It is an aide memoire for any possible changes to the patient’s medical and social circumstances that might have occurred in the last 12 months. There is no specific scoring scheme. The decision to continue therapy is the responsibility of the prescribing clinician.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Action/Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the patient &gt; 75 years?</td>
<td></td>
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<tr>
<td>Has the patient a history of uncontrolled hypertension (systolic &gt;180 &amp; diastolic &gt;100mm Hg)?</td>
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<tr>
<td>Is there any evidence of alcohol excess?</td>
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<td></td>
</tr>
<tr>
<td>Is there any evidence of liver disease?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Are the LFT’s normal?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Is there any evidence of active bleeding lesions? (i.e. gastrointestinal blood loss, peptic ulcer disease or cerebral haemorrhage)</td>
<td></td>
<td></td>
<td>Contraindicated</td>
</tr>
<tr>
<td>Has the patient any bleeding tendencies? (including coagulation defects and thrombocytopaenia)</td>
<td></td>
<td></td>
<td>Discuss with Consultant Haematologist</td>
</tr>
<tr>
<td>Is the patient taking antiplatelet drugs?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Is there a commitment to use non-steroidal anti-inflammatory drugs and antibiotics?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the patient being investigated for or receiving treatment for cancer?</td>
<td></td>
<td></td>
<td>LMWH not Warfarin</td>
</tr>
<tr>
<td>Active VTE + Cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there any evidence of previous trips and falls?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Is the patient illiterate?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If the patient has been previously on Anticoagulant therapy, is there any evidence of non compliance or instability of INR control?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there any evidence of Alzheimer’s or possible problems with Mental Capacity?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has the patient had any cardiovascular events in the last 12 months?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has there been a new diagnosis of heart failure in the last 12 months?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signed: ____________________________ Date: ____________

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Appendix 2

After completion this document should be scanned into the patient’s record as evidence of Annual Review.

Affix Addressograph label or complete all details below:

- Full Name
- DOB
- Hospital Number
- NHS Number

Warfarin/Anticoagulation Therapy Patient Checklist

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I have been given a yellow NHS/NPSA Oral Anticoagulation Therapy Record Book and I understand the arrangements that have been made to monitor my INR.</td>
</tr>
<tr>
<td>2</td>
<td>I have been given a NHS/NPSA Oral Anticoagulation Therapy Patient Information Pack</td>
</tr>
<tr>
<td>3</td>
<td>I have been advised to inform my GP and my Dentist that I am on warfarin /anticoagulation therapy</td>
</tr>
<tr>
<td>4</td>
<td>I have been given advice about drugs that may affect my warfarin/anticoagulation treatment, and I understand that these include drugs that I am able to buy without a prescription</td>
</tr>
<tr>
<td>5</td>
<td>I have been advised to inform the Pharmacist when I buy over the counter medicines, or collect my prescription medicines, that I am on warfarin /anticoagulation therapy</td>
</tr>
<tr>
<td>6</td>
<td>I understand the different colours and strengths of my warfarin tablets.</td>
</tr>
<tr>
<td>7</td>
<td>I have been given advice and information regarding possible side affects of the warfarin/anticoagulation therapy</td>
</tr>
<tr>
<td>8</td>
<td>I have been given advice and information regarding my diet and the possible affect that it may have on the warfarin/anticoagulation therapy</td>
</tr>
<tr>
<td>9</td>
<td>I have been given advice and information on the consumption of alcohol and the possible affect that it may have on the warfarin/anticoagulation therapy</td>
</tr>
<tr>
<td>10</td>
<td>I have been advised <strong>not</strong> to become pregnant whilst undertaking warfarin/anticoagulation therapy <em>(indicate if not applicable)</em></td>
</tr>
<tr>
<td>11</td>
<td>I am aware of signs to look out for if my blood is becoming “too thin” and will seek urgent advice from the INR clinic, my GP or the A&amp;E Department</td>
</tr>
<tr>
<td>12</td>
<td>I have been given the opportunity to ask questions about my warfarin/anticoagulation treatment</td>
</tr>
</tbody>
</table>

Details of Health Professional who provided anticoagulation advice and information:

- Name: 
- Designation: 
- Signature: 
- Date: 

- Patient’s signature: 
- Date:
Appendix 3 - Amidoarone Audit Sheet and Patient Information

### Amidoarone Audit Sheet

**DATA COLLECTION**

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Date of Birth</th>
<th>NHS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Who initiated the amiodarone? (i.e. hospital speciality)

When was the amiodarone initiated?

If no date, has the patient been taking the amiodarone for > 5 years / > 10 years (From repeat prescription)?

<table>
<thead>
<tr>
<th>Is there an indication?</th>
<th>Atrial Fibrillation</th>
<th>VT or VF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial Flutter</td>
<td>Other; specify</td>
<td></td>
</tr>
<tr>
<td>SVT</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

If no accurate indication, write to initiating physician and request details of the original indication and expected duration of treatment.

Is there any evidence of regular monitoring?

<table>
<thead>
<tr>
<th>SYSTEM</th>
<th>MONITORING</th>
<th>Y/N</th>
<th>SYSTEM</th>
<th>MONITORING</th>
<th>Y/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac</td>
<td>Baseline ECG</td>
<td></td>
<td>Hepatic</td>
<td>%12 AST or ALT</td>
<td></td>
</tr>
<tr>
<td>Pulmonary</td>
<td>Baseline chest x-ray</td>
<td></td>
<td>Neurological</td>
<td>Exam if symptomatic</td>
<td></td>
</tr>
<tr>
<td>Pulmonary</td>
<td>Documented absence of respiratory symptoms</td>
<td></td>
<td>Ophthalmic</td>
<td>Annual eye exam or if symptomatic</td>
<td></td>
</tr>
<tr>
<td>Endocrine</td>
<td>%12 Thyroid Function Tests</td>
<td></td>
<td>Dermatological</td>
<td>Exam if symptomatic</td>
<td></td>
</tr>
</tbody>
</table>

**ACTION**

**FOR ATRIAL FIBRILLATION AND FLUTTER INDICATIONS**  
(For other indications, seek advice)

Confirm current heart rhythm by ECG

Is patient still in AF?

**YES**
Stop amiodarone  
If patient is still symptomatic, seek advice for further management.

**NO**
For decision on whether to discontinue amiodarone and initiate alternative treatment, use algorithm over leaf and refer to the accompanying guidance document.

Assess response at 1, 3 and 6 months to ensure condition remains stable.
Improving Medicines Management

When taking amiodarone you should have a blood test at least every 6 months to check your thyroid gland and liver function. You should also have an annual eye test and a chest X-Ray before starting treatment.

Whenever you have a blood test, eye test or chest X-Ray please ask your doctor or optician to fill in the monitoring record below. If you haven’t had these tests please ask your GP to arrange them for you.

<table>
<thead>
<tr>
<th>Date</th>
<th>Thyroid Test</th>
<th>Liver Test</th>
<th>Eye Test</th>
<th>Chest X-Ray</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example: 26/6/09</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

For further advice about this medication please ask your Pharmacist, GP or cardiology clinic.

This leaflet is available in Welsh, large print and other formats on request.

Adapted from a leaflet produced by Dr J Munro of Kingsmill GP practice, Lanarkshire & Lanark Patient Participation Group.

About your tablets

Your tablets contain amiodarone hydrochloride. Your doctor will decide which strength of tablet is suitable for you. You may start the medication on a high dose which is then adjusted to suit your condition.

What your tablets are for

Amiodarone is used to control an irregular or fast heartbeat.

How they work

Your tablets correct the electrical impulses of the heart when their ‘timing’ goes out of control.

It is very important that healthcare professionals know that you are taking Amiodarone. Please take an up-to-date list of your medicines whenever you attend hospital, the dentist, the opthalmic or other clinics either routinely or in an emergency.

Medicines which interfere or cause problems with your tablets

Amiodarone can affect the way certain medicines work and can also be affected by some medicines that you can buy and foods.

These can include herbal and Chinese remedies, so make sure that your doctor knows that you take them.

Other advice:

- Try to use the same Community Pharmacy on a regular basis.
- Do NOT buy medicines over the Internet.
- You should not take amiodarone if you are allergic to iodine.

Side-effects

Amiodarone can cause a number of unwanted side-effects. These are described in the Patient Information Leaflet with your tablets. Tell your doctor if you have or develop any of the following:

- Breathlessness or a new or unexplained cough that does not resolve as expected.
- A deterioration in your eyesight.
- A rash or skin changes
- Sunburn on exposure to sun. To prevent this cover your skin, use sunblock and wear a hat. This may occur after you have been taking the tablets for a while.
- A tremor, headaches, difficulty sleeping, unsteadiness.
- Numbness, pins & needles.
- Symptoms of an underactive thyroid (tiredness, weight gain, constipation, feeling cold, dry skin, depression.)
- Symptoms of an overactive thyroid (increased appetite, weight loss, excessive sweating, nervousness.)

Side-effects and interactions can last for up to six months and possibly longer after stopping amiodarone.

More information about medicines which interact can be found in the Patient Information Leaflet.
Appendix 4

DOUBLE CHECKING PROMPT FOR THE PREPARATION AND ADMINISTRATION OF INTRAVENOUS GENTAMICIN TO NEONATES

- Please use this prompt every time a dose of gentamicin is prepared and administered.
- Both members of staff are to use the prompt.
- Ultimate responsibility for the process lies with Checker One whose ADDITIONAL responsibilities are highlighted in bold.

| Blood level monitoring: Any actions required in the section below should be prioritised to ensure doses are not delayed |
|---|---|
| 1. Check the date and time of the next blood level required. Are any blood levels required prior to or post administration? |
| 2. Do any blood level results need action prior to administration of this dose? i.e results chasing or results interpreted. |
| 3. If yes to question 2 has the person responsible for the interpretation of result been informed? |
| 4. Has the blood level result been interpreted correctly? If not escalate as per local policy. |
| 5. Does the dose or dosing interval need changing as a result of the blood level result? If yes ensure this is actioned as per local policy. |

<table>
<thead>
<tr>
<th>Prescription chart details:</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Check the time recorded when dose last given and the frequency prescribed. Is a dose due now?</td>
</tr>
<tr>
<td>7. Is the patient’s current weight recorded on the prescription chart correct? Caution: Ensure the weight is recent and realistic</td>
</tr>
<tr>
<td>8. Has the correct dose been prescribed based on the weight? Each checker to calculate the dose separately.</td>
</tr>
<tr>
<td>9. Is the dosing regimen and frequency correct for gestational age? Check against local neonatal gentamicin policy. Caution: Any deviation from approved prescribing practices should be escalated as per local policy.</td>
</tr>
<tr>
<td>10. Has the prescription been signed by the prescriber?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vial or CIVAS details:</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Is this the correct medication?</td>
</tr>
<tr>
<td>12. Is this the correct strength of gentamicin ie 20mgs/2mls? (N/A for CIVAS)</td>
</tr>
<tr>
<td>13. Has the correct volume been drawn up? Each checker to calculate dose separately.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Administration:</th>
</tr>
</thead>
<tbody>
<tr>
<td>14. Does the patient’s identity match the patient details on the prescription chart?</td>
</tr>
<tr>
<td>15. Has the prescription chart been signed by the administrator with details of the time of administration?</td>
</tr>
</tbody>
</table>
Appendix 5

Neonatal gentamicin care bundle compliance chart

- Complete a SEPARATE form for each dose of gentamicin administered
- Circle the appropriate answer

Patient ID: ________________________________

Date: __________________________ Time drug administered: __________________________

Care bundle elements:

1. Use of the 24 hour clock format and blocking out of unused time slots when prescribing  Y / N
2. No interruptions during preparation and administration of gentamicin  Y / N
3. Use of the double checking prompt  Y / N
4. *Gentamicin dose given within 1 hour of prescribed dose time  Y / N

* If you circle No to this question please complete the audit chart overleaf

Compliant with all 4 elements of the care bundle  Y / N
Appendix 6

### Treatment of Hypoglycaemia – Adult In-patient Care

Hypoglycaemia is a blood glucose of 4 mmol/L or less. Wherever possible, check blood glucose level prior to treatment. If patient asymptomatic, repeat test.

<table>
<thead>
<tr>
<th>4mmol/L</th>
<th>3mmol/L</th>
<th>2mmol/L</th>
<th>1mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MILD</strong> Patient conscious and able to swallow. Trembling, sweating, hungry, tingling, headache, anxiety, palpitations, nausea, faintness.</td>
<td><strong>MODERATE</strong> Patient conscious and able to swallow, but in need of assistance. Difficulty concentrating, confusion, weakness, giddiness, drowsiness, unsteadiness, headache, dizziness, difficulty focusing and speaking.</td>
<td><strong>SEVERE</strong> Patient unconscious and unable to swallow. Unconscious, fitting.</td>
<td></td>
</tr>
</tbody>
</table>

#### STEP 1

- Administer 10g – 30g fast acting glucose<sup>9</sup>
  - 3-5 x GlucoTabs (8g glucose per tablet) or
  - 1 x 50ml bottle of Glucose Liquid Base or Llucosan
- Administer 1-2 tubes of GlucoGel<sup>10</sup> (15g glucose per tube). Ensure gag reflex is present.
- Check always. Place patient in recovery position. Intramuscular injection of Glucagon 1mg.
- Call for emergency assistance if required.

#### STEP 2

- Wait 15 minutes and recheck glucose levels, and record.
  - If reading is still below 4 mmol/L, or if no physical improvement, repeat STEP 1
  - Once patient is conscious, give ag of Glucose Liquid Base or Llucosan.
  - Recheck glucose level every 15 minutes to ensure increase to at least 4 mmol/L.

---

**Always follow up with a slowly digested/starchy carbohydrate**

Check glucose level. Once it is at 4 mmol/L, or over and patient is recovered, eat a minimum of 15g slowly digested/starchy carbohydrate. Eg 1 x elevator sandwich of low GI bread (ideally multigrain or granary); two digestive biscuits, grass of milk, banana, small carton of fruit juice. Recheck glucose levels after 15 minutes.

---

**Note:**

Do not omit next dose of insulin in type-1 diabetic patients (seek advice from medical team or Diabetes Nursing Team) unless blood glucose <4 mmol/L or persistently symptomatic. Make sure BMI is checked hourly until next injection is due if insulin is omitted.

**NB:** Professional judgement will always be necessary.

Next dose of insulin / oral agent should be reviewed before given in type-2 diabetic patients (seek advice from medical team or Diabetes Nursing Team).

**NB:** Professional judgement will always be necessary.

---

<sup>9</sup> British National Formulary, 2007

<sup>10</sup> Type 1 Diabetes: Diagnosis and Management of Type 1 Diabetes in Children, young people and adults. NICE Clinical Guideline No 14, July 2004

---

### Treatment Record for Hypoglycaemia

<table>
<thead>
<tr>
<th>Date/Time blood glucose taken</th>
<th>Blood glucose value</th>
<th>Treatment used</th>
<th>Date/Time treatment administered</th>
<th>Administered by</th>
<th>Blood glucose after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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</tbody>
</table>

If unsure seek advice immediately.
Appendix 7

**DIABETIC MONITORING CHART**

Guide to frequency of monitoring:
- All diabetic patients' blood glucose should be monitored four times a day for the first 48 hours.
- Thereafter monitor appropriately (if unsure seek advice from medical team or Diabetic Nurse Specialist).

<table>
<thead>
<tr>
<th>Date</th>
<th>Date</th>
<th>Date</th>
<th>Date</th>
<th>Date</th>
<th>Date</th>
<th>Date</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
</tr>
</tbody>
</table>

Specify frequency of monitoring & timings

Date
Signature bleep

Test Times
- 0 am
- 10 am
- 4 pm
- 10 pm

Glucose Levels:
- Normal
- High
- Low
- Borderline

Hypoglycaemia:
- None
- Reassurance
- Corrective action

Hyperglycaemia:
- None
- Reassurance
- Corrective action

Notes:
- Any relevant notes or comments should be recorded here.
ADULT INSULIN ADMINISTRATION RECORD

- This chart is for prescribing of regular INSULIN only.
- For all other medications see standard Prescription Chart.
- This chart is NOT to be used for sliding scale insulins.
- On standard chart write "On Insulin – see Insulin chart".

For Multiple Medication Charts
Chart No. .........................

<table>
<thead>
<tr>
<th>DATE</th>
<th>INSULIN (APPROVED NAME)</th>
<th>DOSE</th>
<th>ROUTE</th>
<th>TIME TO BE GIVEN</th>
<th>PRESCRIBER’S SIGNATURE</th>
<th>PHARMACY</th>
<th>DATE</th>
<th>TIME GIVEN</th>
<th>GIVEN BY</th>
<th>CHECKED BY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

AS REQUIRED INSULIN

MORE FREQUENT USE OF "AS REQUIRED" INSULIN NEEDS TO BE REVIEWED

<table>
<thead>
<tr>
<th>DATE</th>
<th>MEDICINE (Approved Name)</th>
<th>Dose</th>
<th>Route</th>
<th>Frequency</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MORE FREQEUNT USE OF "AS REQUIRED" INSULIN NEEDS TO BE REVIEWED

NON-ADMINISTRATION OF MEDICINES
When a patient does not receive a prescribed dose, the nurse should enter one of the code numbers given below in the administration box, to explain the reason for non-administration. Please attempt to obtain any unavailable medicines.

X. Doctor’s request
3. Patient unable to receive medicine or no access
2. Patient not on ward
4. Patient refused medicine
5. Medicine unavailable
6. See Note

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## Appendix 8 - Measures and Definitions

### Components of the Anticoagulant Care Bundle

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review practice anticoagulant policy</td>
<td>% compliance with policy</td>
<td>Does the policy meet the NPSA recommendations? Does the policy include a recognised dosing protocol? Does it include recommended actions in the event of high INR result (vitamin K, admission)?</td>
</tr>
<tr>
<td>Recorded Target INR</td>
<td>% of patients with recorded target INR</td>
<td>This should be a value rather than a range. This should help maintain Time in Therapeutic Range &gt;65%.</td>
</tr>
<tr>
<td>Recorded Indication for warfarin</td>
<td>% of patients with recorded indication</td>
<td>All patients should have an indication recorded to allow risk/benefit analysis and help ensure appropriate discontinuation.</td>
</tr>
<tr>
<td>Recorded duration of therapy</td>
<td>% of patients with a recorded duration of therapy</td>
<td>Some conditions require warfarin therapy for limited periods (3 to 9 months) compared to lifelong therapy. Important to define it for each patient.</td>
</tr>
<tr>
<td>Record who is responsible for monitoring and dosing</td>
<td>% of patients with a record of where monitoring is taking place</td>
<td>Can be a shared approach or a service delivered wholly by a GP or other provider. Incidents have occurred as patients “have slipped through the monitoring net”.</td>
</tr>
</tbody>
</table>
### Intervention Measure Rationale

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR in last 12 weeks is documented</td>
<td>% of patients with record of INR in previous 12 weeks</td>
<td>All INR results should be easily accessible to the prescriber. This may require a local arrangement with the Path Lab (downloading the results from online database e.g. ICE). Point-of-care test results must be on the GP records. 12 weeks is the maximum period between INR tests many providers prefer to monitor more frequently even in stable patients.</td>
</tr>
<tr>
<td>PRIMARY CARE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INR is documented</td>
<td>% of patients with record of INR on prescription chart</td>
<td>All INR results should be easily accessible to the prescriber at the time of prescribing. INRs may be checked too frequently (e.g. daily in a stable patient) or not often enough.</td>
</tr>
<tr>
<td>SECONDARY CARE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current/recent warfarin dose is recorded</td>
<td>% of patients with a recorded warfarin dose.</td>
<td>After initiation, the dose of warfarin may vary slightly due to changes in medication, diet etc but most of these changes are small (within 1mg).</td>
</tr>
</tbody>
</table>
### Components of the Anticoagulant Care Bundle

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>SECONDARY CARE</td>
<td>% of patients with at least 3 warfarin doses recorded in their yellow book on discharge</td>
<td>Individual dosage requirements between patients can vary from 1mg daily to 20mg daily. To ensure continued safe warfarin use, prescribers responsible for warfarin dosing in primary care often require a number of INR results and doses. Likewise, on admission to hospital, details of recent doses and INRs can reduce the need for unnecessary blood tests and dose changes.</td>
</tr>
<tr>
<td>Prescription to be reconciled to dose</td>
<td>% of patients with reconciled prescription</td>
<td>Traditionally most patients have received bulk supplies of warfarin of several strengths to allow for dosage variations. However, as we have discussed these variations are usually minor. Patients often have sufficient medication to last for a number of months. This represents a significant harm as patients could be failing to attend for monitoring without the GP’s knowledge and would be able to use the wrong strength of tablet with dangerous results. Manufacturers original packs of 28 tablets are colour coded to the same colour as the tablets and are clearly labelled. Use of these should minimise the risk of harm. A chart is available in Helpful Resources to assist GP practices reconcile prescriptions to dose. We recommend that 5mg tablets are not prescribed unless the patient’s dose deems this absolutely necessary and they should never be prescribed with 0.5mg tablets as this represents a significant risk. Dosage schedules should be as simple as possible.</td>
</tr>
</tbody>
</table>
### Improving Medicines Management

**Intervention Measure Rationale**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients supplied with appropriate quantities and strengths of tablets during admission and on discharge</td>
<td>% of patients with required strengths specified</td>
<td>Patients often have sufficient medication to last for a number of months. Where possible, supply only those strengths already used by the patient. We recommend that 5mg tablets are not prescribed unless the patient’s dose deems this absolutely necessary and they should never be co-prescribed with 0.5mg tablets as this represents a significant risk. Dosage schedules should be as simple as possible.</td>
</tr>
<tr>
<td>Number of INRs &gt; 8 each month in last 12 months</td>
<td>% of INRs &gt; 8 in last 12 months (may be expressed as a % of tests done or % or patients)</td>
<td>Whilst not a direct measure of harm an INR &gt; 8 significantly increases the risk of potentially fatal intracranial bleeding.</td>
</tr>
<tr>
<td>Number of INRs &gt; 5 each month in last 12 months</td>
<td>% of INRs &gt; 5 in last 12 months (may be expressed as a % of tests done or % or patients)</td>
<td>Whilst not a direct measure of harm an INR &gt; 5 increases the risk of potentially fatal intracranial bleeding.</td>
</tr>
<tr>
<td>Number of INRs &lt; 2 each month in last 12 months</td>
<td>% of INRs &lt; 2 in last 12 months (may be expressed as a % of tests done or % or patients)</td>
<td>Underdosing represents as great a risk as overdosing. Time in Therapeutic Range needs to be &gt; 65% of time to convey a therapeutic benefit to the patient. Less than this value and the patient is at risk of a thrombotic event which can have high morbidity.</td>
</tr>
<tr>
<td><strong>Number of INRs in last 12 months</strong></td>
<td>PRIMARY AND SECONDARY CARE</td>
<td>This measure may give an indication of the stability of the warfarin treatment, compliance with monitoring and allow an approximate calculation of Time in Therapeutic Range (if this is not otherwise available).</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-----------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Annual risk/benefit assessment</strong></td>
<td>PRIMARY AND SECONDARY CARE</td>
<td>% of patients who have had risk/benefit assessment in previous 12 months                                                                                                                                  At least annually, and more frequently if necessary, the benefit of warfarin therapy should be reviewed versus the risks of bleeding. Each patient’s personal circumstances, compliance with therapy and co-morbidities should be balanced and discussed. If appropriate, alternative therapies can be discussed. A risk/benefit tool which may be used to aid this process is attached (See Helpful Resources). A record should be made of this review which can be completed in primary or secondary care.</td>
</tr>
<tr>
<td><strong>Yellow Book &amp; Alert Card</strong></td>
<td>PRIMARY AND SECONDARY CARE</td>
<td>% of patients with Yellow Book at admission or on discharge                                                                                                                                           All patients should have a Yellow Book as a hand held record of their therapy and carry an Alert Card at all times.</td>
</tr>
<tr>
<td><strong>Carer information</strong></td>
<td>PRIMARY AND SECONDARY CARE</td>
<td>Many patients have either formal or family carers and they need good information about warfarin therapy</td>
</tr>
<tr>
<td><strong>Patient self monitoring/management</strong></td>
<td>PRIMARY AND SECONDARY CARE</td>
<td>% of Warfarin dispensed in line with NPSA guidance                                                                                                                                                    Some patients may be suitable and wish to self monitor and/or self manage. This should be supported and training provided.</td>
</tr>
<tr>
<td><strong>Community Pharmacy support</strong></td>
<td></td>
<td>Community Pharmacies can play a key role in improving the safety of patients on warfarin. They are the frontline in ensuring that monitoring is taking place, patients understanding of dosing, MURs and checking for interactions.</td>
</tr>
</tbody>
</table>
## Components of the Heparins Care Bundle

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure correct dose of LMWH prescribed and administered</td>
<td>% of patients with correct dose</td>
<td>Doses may differ depending on the indication, LMWH used and patient weight. Doses requiring partial syringes of medication may not be practical to measure, particularly when an air bubble is present in the manufactured syringe.</td>
</tr>
<tr>
<td>Record patient weight</td>
<td>% of patients with recorded weight</td>
<td>All patients requiring weight-based doses should have their bodyweight recorded to allow dose checking. Patients may be weighed as part of an admission nutritional assessment (as per NICE clinical guidance 32: Nutritional Support in Adults).</td>
</tr>
<tr>
<td>Review local policies/guidance for prescribing, preparing and administering heparins</td>
<td>% compliance with policy&lt;br&gt;Record of protocols and procedures with review dates</td>
<td>Protocols and procedures should be clear and easily accessible. A simple flow chart may help highlight important points if the full document is very large or complex.</td>
</tr>
<tr>
<td>Ensure information available at point of prescribing and administration</td>
<td>Record of information available and review date</td>
<td>Ensure essential technical information on injectable medicines is available and accessible to healthcare staff in clinical areas at the point of use.</td>
</tr>
<tr>
<td>Risk assess all heparins and LMWHs (low molecular weight heparins)</td>
<td>Record of risk assessments undertaken</td>
<td>Undertake a risk assessment of UFH/LMWH procedures and products in all clinical areas to identify high risks, and develop an action plan to minimise them.</td>
</tr>
<tr>
<td>Minimise use of heparin flushes</td>
<td>Number of flushes issued/used</td>
<td>Review local policies to minimise the use of heparin flush solutions in all devices, including complex central venous or arterial catheters. This should take into account the evidence reviewed by UK Medicines Information (UKMi) which confirms that heparin flushes should not normally be used to flush peripheral intravenous catheters.</td>
</tr>
<tr>
<td>Intervention</td>
<td>Measure</td>
<td>Rationale</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Ensure all heparin flushes are prescribed</td>
<td>% of heparin flushes which are prescribed (or administered under PGD)</td>
<td>All flush solutions should only be administered following a prescription or patient group direction (PGD).</td>
</tr>
<tr>
<td>Train and supervise all relevant staff</td>
<td>Record of training/competency assessment</td>
<td>Provide training for, and supervision of, all healthcare staff involved in prescribing, administering and monitoring heparins.</td>
</tr>
<tr>
<td>Implement a “purchasing for safety” policy</td>
<td>Policy in place</td>
<td>Promote procurement of heparins with inherent safety features such as ready to use injections and infusions.</td>
</tr>
<tr>
<td>Annual audit of practice</td>
<td>Record of audit and resulting actions</td>
<td>As part of the annual injectable medicines audit.</td>
</tr>
</tbody>
</table>
### Components of the Opioids Care Bundle

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk assess and have procedures for safely prescribing, labelling, supplying, storing, preparing and administering opioids</td>
<td>Procedures in place with review dates</td>
<td>Minimise or eliminate multiple drug strengths where possible. Lower strengths (e.g. 5mg and 10mg morphine) are required for acute care, and higher strengths are usually required for syringe drivers or parenteral infusions. If both are required in the same area, use separate storage locations e.g. cupboards, shelves, bags or boxes for low and high strength products. Raise awareness of the similarities of packaging of different strengths of the same products. Where possible, use a second independent check to confirm the identity of the drug, strength, dose to be administered and expiry date of the product. Consider inviting patients and/or carers to carry out a second check if another healthcare professional is not available.</td>
</tr>
<tr>
<td>Review opioid guidelines, including post-administration observation of patients who haven't previously received them</td>
<td>% patients treated within opioid protocol</td>
<td>Include dose calculations, maximum bolus doses, monitoring guidelines (vital signs and pain score, particularly in the 1st hour after administration), options for non-opioid analgesics and non-pharmacologic interventions. Also include information about which strengths should be used to prepare doses e.g. diamorphine 5mg or 10mg ampoules for bolus doses and patients newly commenced on infusions; diamorphine 30mg ampoules reserved for patients already receiving infusions and requiring higher daily doses. Use pre-printed prescriptions where possible</td>
</tr>
<tr>
<td>Provide ongoing training for healthcare staff</td>
<td>Records of training/assessments of competence</td>
<td>Ensure that all staff prescribing, dispensing or administering opioids are familiar with their starting dose, dose titration and usual dose, frequency of administration, common side effects and symptoms of overdose, as well as safe systems for product selection, preparation, administration and monitoring.</td>
</tr>
<tr>
<td>Intervention</td>
<td>Measure</td>
<td>Rationale</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Ensure naloxone is available % of opioid-treated patients who receive naloxone</td>
<td>Supplies are required in the same clinical locations where opioid injections are stored. Consider establishing a standard naloxone regime that can be given before calling prescriber.</td>
<td></td>
</tr>
<tr>
<td>Confirm recent opioid doses and formulations prior to prescribing, dispensing or administering non-emergency opioids % opioid doses unreconciled</td>
<td>Ensure accurate details of previous opioid therapy (including concordance) are available prior to continuing or changing treatment.</td>
<td></td>
</tr>
<tr>
<td>Ensure intended dose increases are safe for the patient (e.g. no more than 50% higher than previous dose) Number of dose increases greater than 50% of previous dose</td>
<td>Larger dose increases may put patients at greater risk of adverse effects.</td>
<td></td>
</tr>
<tr>
<td>Independently double-check all pumps delivering opioid infusions (including PCA and epidural pumps) Proportion of “near misses” to reported incidents</td>
<td>Independent double checks can be an important method of detecting errors before they reach the patient.</td>
<td></td>
</tr>
<tr>
<td>Consider agreeing a pain score between patient &amp; clinicians prior to procedures</td>
<td>Patients may have unrealistic expectations of zero pain post-operatively.</td>
<td></td>
</tr>
</tbody>
</table>
# Components of the Insulins Care Bundle

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure all patients with diabetes admitted to hospital receive effective care of their diabetes and involve patients/carers in their day-to-day care</td>
<td>% of blood glucose measurements outside desired range</td>
<td>Wherever possible, patients should continue to be involved in decisions concerning the management of their diabetes. Have patients manage their own insulin if they are capable. Co-ordinate meal and insulin times.</td>
</tr>
<tr>
<td>Develop, implement and monitor protocols for treatment of diabetic emergencies</td>
<td>Protocols in place with review dates</td>
<td>Protocols should include the management of acute complications and procedures to minimise the risk of recurrence.</td>
</tr>
<tr>
<td>Ensure supplies of glucose products and non-pharmacological agents used to treat hypoglycaemia</td>
<td>% of patients treated within hypoglycaemia protocol % of blood glucose levels outside “normal” range</td>
<td>Supplies are required in the same clinical locations where insulin injections are administered. Consider establishing a standard hypoglycaemia regime that can be given before calling prescriber.</td>
</tr>
<tr>
<td>Confirm recent insulin doses and formulations/devices prior to prescribing, dispensing or administering</td>
<td>% insulin doses unreconciled</td>
<td>Except in emergencies, ensure accurate details of previous insulin therapy (including concordance) are available prior to continuing or changing treatment.</td>
</tr>
<tr>
<td>Agree a care plan with the patient in an appropriate format and language</td>
<td>% of patients with care plan</td>
<td>Encourages partnership in decision-making, supports them in managing their diabetes and helps them adopt and maintain a healthy lifestyle including optimising the control of their blood glucose, blood pressure and other risk factors for developing complications of diabetes. Encourage patients to question doses and timing of insulin.</td>
</tr>
<tr>
<td>Intervention</td>
<td>Measure</td>
<td>Rationale</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Risk assess insulin procedures and products in all clinical areas to identify high risks and develop an action plan to minimise them</td>
<td>Procedures in place with review dates</td>
<td>Raise awareness of the similarities of packaging of different products. Where possible, use a second independent check to confirm the identity of the drug, strength, dose to be administered and expiry date of the product. Consider inviting patients and/or carers to carry out a second check if another healthcare professional is not available.</td>
</tr>
<tr>
<td>Ensure up-to-date protocols and procedures for prescribing, preparing and administering insulins in all clinical areas</td>
<td>% patients treated within insulin protocol</td>
<td>Include monitoring guidelines (vital signs and blood glucose) and actions to be taken if results fall outside the expected range. Use pre-printed prescriptions where possible. Ensure essential technical information on insulins is accessible in clinical areas at the point of use.</td>
</tr>
<tr>
<td>Provide training for and supervision of all healthcare staff involved in the prescribing, administering and monitoring of insulins</td>
<td>Records of training/assessments of competence</td>
<td>Ensure that all staff prescribing, dispensing or administering insulins are familiar with their dose titration and usual dose, frequency of administration, common side effects and symptoms of overdose, as well as safe systems for product selection, preparation, administration and monitoring e.g. separate look-alikes and sound-alikes by time and distance.</td>
</tr>
<tr>
<td>Implement a “purchasing for safety” policy</td>
<td>Policy in place</td>
<td>Promote procurement of insulins with inherent safety features. Prepare all infusions in pharmacy and standardise to single concentration of insulin for IV infusions.</td>
</tr>
</tbody>
</table>
## Intervention Measure Rationale

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Require an independent double-check of drug, concentration, dose, pump settings, route of administration and patient identity before administering IV insulin</td>
<td>Proportion of “near misses” to reported incidents</td>
<td>Independent double checks can be an important method of detecting errors before they reach the patient. Use pre-typed diabetic and insulin infusion prescriptions where possible.</td>
</tr>
<tr>
<td>Annual audit of practice</td>
<td>Record of audit and actions taken</td>
<td>As part of the annual injectable medicines audit.</td>
</tr>
<tr>
<td>Community Pharmacy support</td>
<td>Number of insulin related interventions</td>
<td>Community Pharmacies can play a role in improving the safety of patients on insulin. They can be the front line in ensuring that monitoring is taking place, patients understanding of dosing, checking for interactions and health promotion.</td>
</tr>
</tbody>
</table>
**Components of the Gentamicin Care Bundle**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reducing harm related to administration of IV gentamicin to neonates by implementing the bundle of care.</td>
<td>% compliance with neonatal gentamicin care bundle</td>
<td>Adopting the four main components of the neonatal gentamicin care bundle will reduce the risks associated with the administration of intravenous gentamicin to neonates.</td>
</tr>
<tr>
<td>When prescribing gentamicin the 24 hour clock should be used.</td>
<td>% of prescriptions where 24 hour clock format has been used and unused time slots blocked out.</td>
<td>RLS data highlighted that 36% of gentamicin incidents related to the administration of the drug at the incorrect time. The NPSA Expert Working Group (EWG) experience suggested that the use of the 24 hour clock was good practice to avoid confusion over timing although this has not been formally evaluated in a research setting.</td>
</tr>
<tr>
<td>Interruptions during the preparation and administration of Gentamicin should be minimised by the wearing of a coloured apron by staff.</td>
<td>Recorded ‘no interruptions during preparation and administration of gentamicin’ as % of all gentamicin preparation and administration.</td>
<td>Interruptions by patients, staff and visitors are a common source of distraction to those involved in drug administration and there are a number of studies to support this. Methods to prevent or reduce interruption such as the wearing of a coloured apron are reported to have good effect but no formal evaluations have been reported.</td>
</tr>
<tr>
<td>A double checking prompt should be used during the preparation and administration of gentamicin (See Appendices)</td>
<td>% of recorded double checking prompts used during preparation and administration of gentamicin.</td>
<td>Root cause analysis identified that incidents occurred because of a lack of clearly assigned responsibility during the preparation, checking and administration of gentamicin. There are a number of studies to support the use of double checking, and the assignment of responsibility to one checker within the checking process. Double checking is also advocated by the Nursing and Midwifery Council (NMC).</td>
</tr>
</tbody>
</table>
**Intervention** | **Measure** | **Rationale**  
--- | --- | ---  
The prescribed dose of gentamicin should be given within an hour either side of the prescribed time. | % of gentamicin doses given within 1 hour of prescribed dose time. | Gentamicin has a narrow therapeutic range and the potential for toxicity or non efficacy if prescribed timing intervals are not adhered to. RLS data highlighted that 36% of gentamicin incidents related to the administration of the drug at the incorrect time. In addition the survey of neonatal units indicated variation in practice of blood level monitoring and in assigning responsibility for obtaining the results of levels from the laboratory. Lack of clarity about blood level monitoring may contribute to administration delays or omissions.
## Components of the Amiodarone Care Bundle

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implement NICE clinical guidelines for Atrial Fibrillation</td>
<td>% compliance with guidelines</td>
<td>Amiodarone is not a first choice for treatment. Other pharmacological and non-pharmacological treatments are preferred.</td>
</tr>
<tr>
<td>Review use of amiodarone on general wards</td>
<td></td>
<td>Amiodarone should only be initiated by cardiologists or clinicians experienced in its use. By restricting access to the supply, prescriptions can be reviewed for appropriateness.</td>
</tr>
<tr>
<td>Monitor and control initiation of amiodarone.</td>
<td></td>
<td>Amiodarone should only be initiated by cardiologists or clinicians experienced in its use.</td>
</tr>
<tr>
<td>Informed consent of patient.</td>
<td></td>
<td>Informed consent should be obtained from the patient prior to initiation of this medication.</td>
</tr>
<tr>
<td>Shared Care Agreement</td>
<td>% of patients with Shared Care Agreement in place</td>
<td>Shared Care Agreement should be in place between primary and secondary care physicians. If GP is not clear on the indication for amiodarone or treatment plan this should be resolved as soon as possible.</td>
</tr>
<tr>
<td>Full discussion on benefit versus risk of medication.</td>
<td>% of patients with an assessment of risk/benefit recorded in their notes</td>
<td>The risks as well as the benefits of amiodarone treatment should be assessed and communicated to the patient and recorded. These include liver, thyroid, dermatological and pulmonary adverse effects.</td>
</tr>
<tr>
<td>Patient education</td>
<td>% of patients with hand held information and monitoring booklet</td>
<td>Patients should be counselled carefully about the medication and be issued with a hand-held record of monitoring requirements to encourage concordance.</td>
</tr>
<tr>
<td>Monitoring side-effects</td>
<td>% of patients with record of regular monitoring requirements</td>
<td>Patients should have tests at least every 6 months to check TFTs and LFTs as amiodarone is associated with potentially fatal thyrotoxicity and hepatotoxicity. ECGs are necessary to monitor efficacy. If the patient develops changes to respiratory function this may be pneumonitis caused by amiodarone which can be fatal. Changes in vision may be caused by corneal micro-deposits (reversible) or optical neuritis or neuropathy which can lead to blindness if amiodarone is not discontinued.</td>
</tr>
<tr>
<td>Intervention</td>
<td>Measure</td>
<td>Rationale</td>
</tr>
<tr>
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<td>----------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Record keeping</td>
<td>% of patients with a complete record as set out in the driver diagram</td>
<td>Amiodarone is only initiated in secondary care so it is essential that the GP responsible for ongoing prescribing has a record of the indication for amiodarone, the expected treatment plan including dose, responsibilities for monitoring and a record of the risk/benefit discussion with the patient.</td>
</tr>
</tbody>
</table>
## Components of the NSAID Care Bundle

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implement NICE clinical guidelines for osteoarthritis and rheumatoid arthritis</td>
<td>% compliance with guidelines</td>
<td>Clinical guidelines include rationale for use of NSAIDs alongside other NSAID-sparing strategies for pain relief.</td>
</tr>
<tr>
<td>Is treatment with NSAID appropriate?</td>
<td>Has alternative treatment been tried? E.g. Paracetamol (regular dosing may be required. Risk factors: &gt; 65 years; IHD; CVD; PVD; Past history of PUD; Diabetes; hypertension; interacting drugs.</td>
<td></td>
</tr>
<tr>
<td>Risk assess suitability of NSAID</td>
<td>Is the NSAID prescribed the one with the lowest cardiovascular/GI risk suitable for this patient?</td>
<td></td>
</tr>
<tr>
<td>Issue acute prescriptions for NSAIDs only</td>
<td>% of patients with NSAIDs on acute prescription</td>
<td>Offers practice some control of patients’ use of NSAIDS. Discourages chronic self-administration of NSAIDS.</td>
</tr>
<tr>
<td>Recorded Indication for NSAID</td>
<td>% of patients with recorded indication</td>
<td>Good clinical practice and continuity of care.</td>
</tr>
<tr>
<td>Select the lowest dose for the shortest time</td>
<td>DDD/1000 PUs</td>
<td>Reduced risk of developing GI and CV complications.</td>
</tr>
<tr>
<td>Co-prescribe a PPI to patients with high risk of developing GI complications</td>
<td>% of patients with risk factors taking long term NSAIDs with prescription for PPI</td>
<td>Patients with risk factors e.g. &gt; 65 years should be co-prescribed a PPI.</td>
</tr>
<tr>
<td>Ibuprofen and Naproxen should be used 1st line</td>
<td>Ibuprofen &amp; naproxen as % of NSAIDs</td>
<td>Ibuprofen and naproxen are associated with the lowest GI and CV risks (although neither are without risk).</td>
</tr>
<tr>
<td>NSAID should not be co-prescribed with aspirin</td>
<td>% of patients taking NSAID also taking aspirin</td>
<td>Aspirin and another NSAID combination substantially increases GI risk. Patients taking aspirin should be reminded not to purchase over the counter NSAIDS.</td>
</tr>
</tbody>
</table>
## Intervention Measure Rationale

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full discussion on benefit versus risk of medication including increased risk of GI, renal liver and cardiovascular adverse events</td>
<td>% of patients with an assessment of risk/benefit recorded in their notes</td>
<td>The risks as well as the benefits of NSAID treatments should be assessed and communicated to the patient and recorded. PCQIS has requested a READ code to describe NSAID risk/benefits assessed (or discussed).</td>
</tr>
<tr>
<td>Assess and monitor patient risk factors for gastrointestinal, liver and cardiovascular toxicity:</td>
<td>% of patients on long term NSAIDs with baseline renal function and test in last 12 months</td>
<td>All patients prescribed long-term NSAIDs with the risk factors of renal or cardiac impairment should have base-line renal functions tests (urea, electrolytes and creatinine) and a record of renal function in the last 12 months.</td>
</tr>
<tr>
<td>• Active Peptic ulcer disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Renal function</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Ischaemic heart disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Heart Failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Active liver disease</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Components of the Antipsychotics in Dementia Care Bundle

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Measure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implement NICE clinical guidelines for dementia</td>
<td>% compliance with guidelines</td>
<td>Antipsychotics appear to be used all too often as a first line response to any behavioural difficulty in dementia rather than a considered second line treatment when other options have failed. Their potential benefit in specific cases is likely to be outweighed by the serious adverse effects of their use in general.</td>
</tr>
<tr>
<td>Is treatment with antipsychotic appropriate?</td>
<td>Have alternative treatments been tried? Are there co-morbidities causing symptoms which could be treated appropriately? Is there a risk of extreme harm to the patient or carer/s? Type of dementia is vitally important as use of antipsychotic in Lewy Body Dementia or related to Parkinson’s Disease is potentially fatal. If multi-infarct dementia antipsychotic may increase stroke risk.</td>
<td></td>
</tr>
<tr>
<td>Risk assess suitability of antipsychotic</td>
<td>Is the antipsychotic prescribed the one with the lowest risk suitable for this patient? Consider previous medical history particularly hypertension and previous stroke/TIA.</td>
<td></td>
</tr>
<tr>
<td>Issue acute prescriptions for antipsychotics only</td>
<td>% of dementia patients with antipsychotic on repeat prescription (Target 0%)</td>
<td>Offers practice some control of patients’ use of antipsychotics. Time limited prescriptions for a maximum of 12 weeks ensures regular medication review.</td>
</tr>
<tr>
<td>Communication</td>
<td></td>
<td>Where patients are moving between secondary/primary care and possibly care home it is vital that there is detailed written communication regarding medication. This should detail treatment plans and review requirements.</td>
</tr>
<tr>
<td>Patient/carer involvement</td>
<td></td>
<td>Before initiation of any antipsychotic medication there should be a full discussion with the patient(if possible) and/or carer about the possible benefit versus risks which include known adverse effects (see below) and risk of cardiovascular events. Patient/carer should be in agreement with treatment choice.</td>
</tr>
<tr>
<td>Intervention</td>
<td>Measure</td>
<td>Rationale</td>
</tr>
<tr>
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<td>-------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Monitoring side-effects</td>
<td></td>
<td>As the benefits of antipsychotics may be only small, the impact of side-effects on this already frail and vulnerable group of patients assumes greater importance. Prescribers should actively check for side-effects as these can severely affect quality of life. In particular, falls and daytime sedation can be attributable to the effect of antipsychotics.</td>
</tr>
<tr>
<td>Record keeping</td>
<td>% of dementia patients on antipsychotics with record of rationale for prescribing antipsychotic</td>
<td>Care of dementia patients requires a multi-disciplinary approach. It is therefore essential that complete, accurate and up to date records are kept such that all ‘team’ members are aware of the type of dementia that has been diagnosed and the indication for the prescribed antipsychotic. There should be a record of the risk/benefit assessment and an ongoing record of the effect of medication - either positive or negative. The reason for any changes in medication must be recorded.</td>
</tr>
</tbody>
</table>
Appendix 9 - Setting up your team

Achieving improvements that reduce harm, waste and variation at a whole-organisation level needs a team approach: one person working alone, or groups of individuals working in an uncoordinated way will not achieve it and this applies equally at all organisational levels.

Whether your improvement priorities relate to 1000 Lives Plus content areas, national intelligent targets or other local priorities, you need to consider three different dimensions in putting your team together:

- Organisation level leadership.
- Clinical or technical expertise.
- Frontline leadership.

There may be one or more individuals on the team working in each dimension, and one individual may fill more than one role, but each component should be represented in order to achieve sustainable improvement.

**Organisation level leadership**

An Executive, or equivalent level Director, should always be given delegated accountability from the Chief Executive for a specific content area; and all staff working on the changes should know who this is. This individual needs sufficient influence and authority to allocate the time and resources necessary for the work to be undertaken.

It is likely that accountability will be further delegated to Divisions, Clinical Programme Groups or Directorates and this can help to build ownership and engagement at a more local level. However, it is essential that the leader has full authority over the areas involved in achieving the improvement aim. As changes spread more widely, crossing organisational boundaries, appropriate levels of delegation will need to be reviewed.

When working with frontline teams, it is essential for organisational level leaders to have an understanding of the improvement methodology and to base conversations around the interpretation of improvement data. Reporting of progress to higher organisational levels should also use a consistent data format so that the Executive level leader can report to the Board on progress.

**Clinical/Technical Expertise**

A clinical or technical expert is someone who has a full professional understanding of the processes in the content area. It is critical to have at least one such champion on the team who is intimately familiar with the roles, functions, and operations of the content area. This person should have a good working relationship with colleagues and with the frontline leaders, and be interested in driving change in the system. It is important to look for clinicians or technical professionals who are opinion leaders in the organisation (individuals sought out for advice who are not afraid to try changes).
Patients can provide expert advice to the improvement team, based on their experience of the system and the needs and wishes of patients. A patient with an interest in the improvement of the system can be a useful member of the team.

Additional technical expertise may be provided by an expert on improvement methodology, who can help the team to determine what to measure, assist in the design of simple, effective measurement tools, and provide guidance on the design of tests.

**Frontline leadership**

Frontline leaders will be the critical driving component of the team, assuring that changes are tested and overseeing data collection. It is important that this person understands not only the details of the system, but also the various effects of making changes in the system. They should have skills in improvement methods. This individual must also work effectively with the technical experts and system leader. They will be seen as a bridge between the organisation leadership and the day-to-day work.

Frontline leaders are likely to devote a significant amount of their time to the improvement work, ensuring accurate and timely data collection for process and outcome measures related to the frontline team.

**Characteristics of a good team member**

In selecting team members, you should always consider those who want to work on the project rather than trying to convince those that do not. Some useful questions to consider are the following:

- Is the person respected for their judgment by a range of staff?
- Do they enjoy a reputation as a team player?
- What is the person’s area of skill or technical proficiency?
- Are they an excellent listener?
- Is this person a good verbal communicator within, and in front of, groups?
- Is this person a problem-solver?
- Is this person disappointed with the current system and processes and do they passionately want to improve things?
- Is this person creative, innovative, and enthusiastic?
- Are they excited about change and new technology?
Appendix 10 - The Model for Improvement

Successful improvement initiatives don’t just happen - they need careful planning and execution. There are many things to consider and techniques to employ, which are captured in the driver diagram on page 81. The rest of this section explains the primary drivers and where to get more help in using them.

In any improvement initiative you need to succeed in three areas. You need to generate the Will to pursue the changes, despite difficulties and competing demands on time and resources. You need the good Ideas that will transform your service. Finally you need to Execute those ideas effectively to get the change required.

Will

The interventions you need to build Will are explained in the ‘Leading the Way to Safety and Quality Improvement’ and ‘How to Improve’ guides. They concentrate on raising the commitment levels for change and then providing the project structure to underpin improvement approaches. Spreading changes to achieve transformative change across the whole health system requires strong leadership. We need to create an environment where there is an unstoppable will for improvement and a commitment to challenge and support teams to remove any obstacles to progress.

Ideas

The interventions in this guide describe ideas which evidence shows to be effective for achieving changes that result in improvements. It gives examples from organisations that have achieved them and also advice based on their experience. Methods and techniques for generating new ideas or innovative ways to implement the evidence can be found in the ‘How to Improve’ guide and other improvement literature.

Execution

However, to bring these ideas into routine practice in your organisation, it is essential that you test the interventions and ensure that you have achieved a reliable change in your processes before attempting to spread the change more widely.

1000 Lives Plus uses the Model for Improvement (MFI) which is a proven methodology as the basis for all its improvement programmes. It requires you to address three key questions and then use Plan-Do-Study-Act (PDSA) cycles to test a change idea. By doing repeated small-scale tests, you will be able to adapt change ideas until they result in the reliable process improvement you require. Only then are you ready to implement and spread the change more widely.
Improving Medicines Management

Model for Improvement
Driver Diagram

Aim

Primary drivers

Secondary drivers

Interventions

Will

To deliver patient safety and quality initiatives for Health Boards and Trusts

Ideas
Evidence Base (The what to)

Create an organisational culture and environment for improvement

Use the relevant content area ‘How to Guide’ to assess the latest evidence of best practice

Use the relevant content area ‘How to Guide’ to assess the latest evidence of best practice

Execution
Improvement Methodology (The how to)

The Model for Improvement

What are you trying to accomplish?

How will you know that a change is an improvement?

What change can you make that will result in improvement?

Establish reliable process

Set SMART aims

Communicate aims

Use project charter to provide structure

Understand what to measure

Use 7 step measurement process

Map the process

Use creative thinking

PDSA cycles:
Test - implement - spread - sustain

Use reliability model

Engage senior Leadership

Make links to organisation goals

Form teams

Build skills

Raise awareness

Appoint clinical champions

Consult Faculty members to agree standards to be achieved

Use critical sub sets of key content areas to improve the outcome

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Improving Medicines Management

Model for Improvement - PDSA Cycle

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?

For more guidance on using the Model for Improvement, see the ‘How to Improve’ guide.

Seven Steps to Measurement

1 Decide aim
2 Choose measures
3 Define measures
4 Collect data
5 Analyse & present
6 Review measures
7 Repeat steps 4-6
One area that bears extra attention is measurement because we have found that this is often the Achilles heel of improvement projects. When measuring your progress, follow the Seven Steps to Measurement shown on page 82 and covered in more detail in the ‘How to Improve’ Guide.

The key is to go round the Collect-Analyse-Review cycle frequently:

- **Collect** your data
- **Analyse** - turn it into something useful like a run chart
- **Review** - meet to decide what your data is telling you and then take action

Successful improvement projects all have clear aims, robust measurement and well-tested ideas. Use the ‘How to Improve’ guide to ensure your projects have all three.

**What are we trying to accomplish?**

You will need to set an aim that is Specific, Measurable, Achievable, Realistic and Time-bound (SMART). Everyone involved in the change needs to understand what this is and be able to communicate it to others.

**How will we know that change is an improvement?**

It is essential to identify what data you need to answer this question and how to interpret what the data is telling you. The improvement methodology ‘How to Guide’ provides detailed information on the tools, tips and information you need to achieve this, and includes the following advice:

<table>
<thead>
<tr>
<th>Plot data over time</th>
<th>Tracking a few key measures over time is the single most powerful tool a team can use.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Seek usefulness, not perfection.</strong></td>
<td>Remember, measurement is not the goal; improvement is the goal. In order to move forward to the next step, a team needs just enough data to know whether changes are leading to improvement.</td>
</tr>
<tr>
<td><strong>Use sampling.</strong></td>
<td>Sampling is a simple, efficient way to help a team understand how a system is performing.</td>
</tr>
<tr>
<td><strong>Integrate measurement into the daily routine.</strong></td>
<td>Useful data is often easy to obtain without relying on information systems.</td>
</tr>
<tr>
<td><strong>Use qualitative and quantitative data.</strong></td>
<td>In addition to collecting quantitative data, be sure to collect qualitative data, which is often easier to access and highly informative.</td>
</tr>
<tr>
<td><strong>Understand the variation that lives within your data.</strong></td>
<td>Don’t over-react to a special cause and don’t think that random movement of your data up and down is a signal of improvement.</td>
</tr>
</tbody>
</table>
Improving Medicines Management

What change can we make that will result in improvement?

The interventions in this guide describe a range of change ideas that are known to be effective. However, you need to think about your current local systems and processes and use the guide as a starting point to think creatively about ideas to test. The improvement methodology guide gives more advice to support you in generating ideas.

Spreading changes to achieve transformative change across the whole health system requires strong leadership. We need to create an environment where there is an unstoppable will for improvement and a commitment to challenge and support teams to remove any obstacles to progress. The guide on ‘Leading the Way to Safety and Quality Improvement’ gives detailed information on interventions that will support this. However, the Model for Improvement, PDSA cycles and process measurement lie at the heart of the transformative change we seek.
Improving care, delivering quality

If we can improve care for one person, then we can do it for ten.

If we can do it for ten, then we can do it for a 100.

If we can do it for a 100, we can do it for a 1000.

And if we can do it for a 1000, we can do it for everyone in Wales.

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