Gentamicin is the seventh most commonly used antibiotic in Irish hospitals, with approximately 15,000 patients treated per annum with the drug. It is a potentially life-saving drug, used to treat Gram-negative infection in amongst the sickest cohort of patients cared for in our hospitals.

It is strategically important as it retains good sensitivity rates at a time when Gram-negative resistance continues to increase, especially in other agent classes. Moreover, Gentamicin has a low relative propensity for inducing the emergence of Clostridium difficile-associated diarrhoea in comparison to alternative agents such as fluoroquinolones or cephalosporins.

Usage of Gentamicin is likely to increase in the future, as the pipeline of new drug discovery to treat Gram-negative infection is scant. Gentamicin has a narrow therapeutic index. This means that there is only a small difference between optimal and toxic dosing.

Safe and effective therapy requires accurate dose selection, and time sensitive serum level monitoring. Failure to achieve optimal dosing runs the risk of increased patient morbidity and mortality, and increased resistance. Over-dosage can cause temporary or permanent kidney toxicity, or loss of hearing or balance functions.

The reported incidence of nephrotoxicity ranges from 10% to 25%. It is usually mild and reversible but in extreme cases can result in the need for renal replacement therapy. Ototoxicity severity may be subclinical, but it is nearly always irreversible and in some cases can lead to complete hearing or balance loss. The reported incidence of hearing loss ranges from 0% to 27%.

Conversely, fear of toxicity can result in sub-therapeutic dosing and error in therapeutic drug monitoring equal performance can also lead to unintended dose omission or delay. Both of these factors present a risk of treatment failure and the emergence of Gentamicin resistance.

IMPROVEMENT GUIDE DEVELOPMENT

The development and testing of this improvement guide was prompted by frontline healthcare workers across the Irish healthcare system. Optimal Gentamicin usage is a regular focus for improvement, and there have been a number of examples of such improvement to date across the Irish Healthcare service.

In the interest of shared learning and innovation, an initiative was developed in the belief that a collective approach to problem solving between healthcare workers across settings can yield rapid and sustained improvement.

Through this initiative and the co-operation between frontline clinicians, support staff and national quality improvement expertise, this improvement guide was developed.

It is intended that the improvement guide may be applicable in cases where patients are receiving once daily Gentamicin therapy (adult or paediatric), with the exception of patients receiving renal replacement therapy, pregnant patients or those with burns.

It should be noted that this guideline document relies upon appropriate patient selection in choosing to use this drug. Careful consideration of the potential risks and benefits of usage of the drug should occur for every patient. This risk assessment should continue throughout therapy. Review of local guidelines and consultation with expert advice should be considered in aiding this risk assessment as appropriate.

WHY USE THIS GUIDE?

This improvement guide will aid you through the process of improving the quality of prescribing and usage of Gentamicin. As with all quality improvements, you must be prepared for possible deviations and adaptations to the process when implementing it within your area or organisation. Through referring to the improvement guide throughout the process it will help you to maintain focus and momentum with the improvements.

PATIENTS

By making the quality improvements suggested in this guide you may create the following benefits for your patients:

- Better patient outcomes in treating Gram-negative sepsis, including potentially reduced mortality
- Reduced need to escalate to broader spectrum antibiotics, thereby preserving their utility for more complex infective cases
- Reduced time spent in hospital due to sub-therapeutic use of Gentamicin
- Reduced rates of harm from inappropriate use
- Increased multidisciplinary team work in their care
- Improved work practices around their care

STAFF

Patients are not the only people who will potentially benefit from this. There may also be benefits for your staff:

- Less numbers of patients requiring Nephrology or Critical Care referral
- Increased awareness of the potential for harm from inappropriate use of Gentamicin
- More effective and reliable multi-disciplinary team work
- Shared learning across the organisation in quality improvement

ORGANISATION

Finally there are potential benefits to the organisation overall:

- Potentially reduced costs associated with harm from Gentamicin, including reduced direct treatment costs, renal replacement therapy costs and litigation costs
- Potentially reduced length of stay for patients treated with Gram-negative sepsis
- Becoming a leader in Gentamicin medication safety
- Decreased length of stay for Gentamicin patients
- Increased quality improvement skills and expertise in the organisation
- Reduced costs in association with underdosing
STEP ONE: ESTABLISHING STRUCTURE

A. ESTABLISHING YOUR OVERSIGHT GROUP

Strong local senior clinical and management support (governance) for this project will be required to ensure the best chance of success. Effective Gentamicin dosing and therapeutic drug monitoring requires many different staff members and groups to work together in harmony to provide optimal therapy.

MEMBERS OF OVERSIGHT GROUP

It is vital to garner support for this improvement guide with the following key representatives before starting:

- Antimicrobial stewardship team (including Consultant Microbiologist and Antimicrobial Pharmacist where present)
- Drugs and Therapeutics (D&T) committee
- Hospital manager/CEO
- Clinical director(s)
- Director(s) of Nursing
- Laboratory management
- Phlebotomy management
- Chief Pharmacist

Also where present you should involve:

- Consultant in Infectious Diseases
- Consultant in Nephrology

ROLE OF OVERSIGHT GROUP

Your local D&T committee should provide the majority of governance oversight for the project and provide support and advice throughout the process. The role of the oversight group is to provide visible support for the improvement project and to lead in enabling changes to happen.

In smaller hospitals where some of the supports or structures may not be fully available, adaptation to include key opinion forming clinicians at the outset of the process may assist with project foundation. In addition, pairing up with another larger hospital or hospitals in your group may also aid with project foundation and ongoing support.

B. ESTABLISHING YOUR TEAM

Your team is the second crucial part in driving this improvement project and gaining buy-in within the organisation. There are a number of key members you must have as a minimum within your core team before starting.

MEMBERS OF CORE PROJECT TEAM

- Consultant in relevant specialty
- Pharmacist
- Consultant Microbiologist or Infectious Diseases
- Clinical Nurse Manager and/or Senior Nurse with a remit for Nurse Training and Development

There are also additional groups that will be central to achieving sustainability following the process; they may also be included in the Core Project Team.

- Gentamicin prescribers (Intern/Senior House Officer/Registrar)
- Clinical Risk Manager and/or Medication Safety Officer
- D&T committee members
- Senior leadership team members
- Relevant Laboratory staff who are involved in assay result determination
- Phlebotomy staff
- Patients and families
- Any other key staff involved in the Gentamicin dosing and monitoring process

ROLE OF CORE PROJECT TEAM

This team will be responsible for planning and implementing the improvements within their unit or the organisation. They will:

- Measure the data and plan what changes are priority
- Coordinate small tests of change in line with the improvement guide
- Study the results of the changes before implementing others or further tests
- Action any successful changes so that they become imbedded in practice
ESTABLISHING URGENCY FOR CHANGE
HOW TO INCENTIVISE INVOLVEMENT

Gentamicin is used across a wide range of medical and surgical patient specialties. It is likely that a high proportion of staff members will be both familiar with use of this medicine, and the complexity involved in ensuring an optimal treatment course. It is also likely that some staff members may have experienced difficulty in using the drug, particularly around the process of dosing and monitoring.

All improvement requires some degree of change, and given the number of potential staffing groups who may need to be involved to facilitate effective improvement, a shared sense of the need to work together to address this issue will be required.

Change theory suggests that creating a sense of urgency for change at the outset of project such as this will foster the necessary impetus for improvement. Moreover, as has been demonstrated in many change settings, our experience so far has found that selling the need to change may be best approached by appealing to key staff members' logical and, more crucially, emotional side. This may be done by use of real life examples of situations where perhaps performance may have been better in your hospital, and effective use of such examples in a transparent yet just manner could act as an effective prompt for action.

STEP TWO: ESTABLISHING AN AIM

DEVISE A SMART AIM STATEMENT FOR YOUR PROJECT

Our suggested aim for this improvement package can be amended to suit your situation and organisation. Our SMART aim is:

‘TO REDUCE THE INCIDENCE OF GENTAMICIN ASSOCIATED TOXICITY BY ‘INSERT %’, WHILST ENSURING OPTIMAL THERAPY (AS PER LOCAL/NATIONAL GUIDELINES) 100% OF THE TIME BY ‘INSERT DATE’ IN ‘INSERT WARD/AREA NAME’

SMART AIMS ARE:

<table>
<thead>
<tr>
<th>Specific</th>
<th>clearly states what topic you are focusing on and where</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurable</td>
<td>what percentage/amount/level you aim to reach</td>
</tr>
<tr>
<td>Actionable</td>
<td>can be actioned in your area</td>
</tr>
<tr>
<td>Realistic</td>
<td>is achievable</td>
</tr>
<tr>
<td>Timely</td>
<td>is able to be achieved within a specific frame</td>
</tr>
</tbody>
</table>

STEP THREE: HOW TO START MEASURING

In order to start measuring you will need to identify what to measure. This guide provides a number of key measures that have been tested in a variety of acute settings and the results have been shown to produce reliable, safe and effective use of Gentamicin.

FIVE SUGGESTED KEY MEASURES

On what to collect data on as you move through the improvements

1. Renal function (the project group recommend the use of the Cockcroft and Gault equation for measuring renal function) recorded for all patients on prescribing Gentamicin
2. Correct dose prescribed for weight, height and renal function
3. First serum trough level is taken in the correct time window
4. No inadvertently missed or delayed doses due to TDM error
5. In patients who require more than 7 days therapy, the rationale for continuing therapy beyond this time point is recorded
BASELINE MEASUREMENT

At the outset of the project, a baseline measurement exercise across your patient population will be necessary to get a full picture of underlying performance, and any variance in practice in the area. The amount of data required will depend on the needs of each hospital and the frequency of usage of the drug in each area. A balance will need to be struck between getting a good picture of performance and the amount of time required to capture the data.

As a general rule of thumb however, measurement of performance in 20-30 consecutive patients will be sufficient, although it is acknowledged that it may not be possible to capture this many practically in some areas. Rapid identification of patients can be achieved from laboratory records of patients who have had Gentamicin serum levels processed. An example of a possible data collection form is outlined at the bottom of the page. A run chart can help you to display this data and easily monitor changes as you progress, see below.

SAMPLE DATA COLLECTION FORM

GENTAMICIN QUALITY IMPROVEMENT PROJECT
PILOT DATA COLLECTION FORM

Patient Address:
Age:
Sex:
Weight (in KG):
Height:

1. Was there documentation of estimated renal function in the patient's medical record at the time of prescribing Gentamicin (Estimated creatinine clearance using Cockcroft and gault, or eGFR using MDRD, or serum creatinine)?  Y / N

2. Was the correct dose for weight and renal function prescribed as per local guidelines?  Y / N

3. Was the first serum pre-dose level taken in the correct time window as per local guidelines?  Y / N

4. How many (if any) doses were unintentionally missed, or inadvertently delayed by in excess of 4 hours, due to TDM process related error as a proportion of total planned doses?
   No. of doses planned:
   No. of doses missed or delayed:
   Missed or delay doses/planned doses:

5. In patients who require in excess of seven days therapy, was there a documented reason in the patient medical record outlining the clinical rationale for continued treatment beyond this time point?  Y / N
Following getting your baseline measurement results, you can now look at how to start improvements against each of the measures. In order to clarify the improvements needed it is suggested to use a driver diagram to firstly capture what is needed and secondly to identify priority areas to address. Please see a sample driver diagram below. The driver diagram is a pictorial version of improvement concepts available. This is a useful diagram to refer to quickly throughout the process. It is also very useful when presenting or explaining the process to others.

**PROJECT AIM**

**Aim**

To reduce the incidence of Gentamicin associated toxicity, while ensuring optimal therapy, every time.

**Target Aim** – ‘By April 2014, 100% of patients in enrolled units treated with IV Gentamicin safely and effectively.’

**MEASURES**

1. Renal function recorded for all patients on prescribing Gentamicin
2. Correct dose prescribed for weight, height and renal function
3. First serum trough level is taken in the correct time window
4. No inadvertently missed or delayed doses due to Therapeutic Drug Monitoring (TDM) error
5. In patients who require more than 7 days therapy, the rationale for continuing therapy beyond this time point is recorded

**PROJECT AIM PRIMARY DRIVERS**

Ensure Gentamicin patient selection is appropriate, and that the drug is dosed correctly

Ensure that patient monitoring, including therapeutic drug monitoring, is effective and reliable throughout therapy

**SECONDARY DRIVERS**

- Clear, concise, unambiguous and agreed dosing guidelines. These should include clarity around dosing in patients of all ages, weights, degrees of renal function and by indication.
- Routine assessment of patient factors associated with potential toxicity prior to prescribing Gentamicin e.g. underlying renal function, hearing difficulty, concurrent nephrotoxic drugs.
- In patients where these risk factors are present, review the relative risks and benefits of treatment. Where therapy is adjudged to be required, mitigate for risks e.g. hold additional nephrotoxins, ensure adequate hydration.
- Routinely record patient renal function and indication for Gentamicin use in patient medical chart or drug kardex at the time of prescribing the drug.
- Routine measurement of weight and height on admission, with results recorded on the patient’s drug kardex.
- Ready access to required measurement equipment.
- Use of ulna length to estimate height where needed.
- Use of electronic dosage calculators and dedicated Gentamicin dosing forms.
- Label Gentamicin boxes to flag required safety checks prior to Gentamicin administration.

**BUILDING YOUR DRIVER DIAGRAM**

**PROJECT AIM**

The box on the left details the overall aim and you can include your measures here as well if you wish.

**PRIMARY DRIVERS**

The middle ‘primary drivers’ are the areas that impact the aim and Gentamicin usage.

**SECONDARY DRIVERS**

The boxes on the right provide detail per primary driver and this is where you identify what is the first priority. Begin your project by addressing the secondary drivers. For example ‘Ready access to required measurement equipment’ may be a priority if there are no weighing scales on the ward, therefore you need to address this first.

As with any local environments, you may find there are other issues that you feel also need to be addressed and so additional measurements or improvements may be required to capture performance. In practice, a review of patients at 5–7 days after their first level has been taken allows for a timely review of performance with a high chance of medical chart availability for rapid review on the ward. Most patients will have also completed their Gentamicin therapy at that point. For those who require a longer course, further follow-up may be necessary. An example of a possible data collection form is outlined on the previous page.
In approaching this project, it is suggested that a methodical approach to the sequence of activities may aid in ensuring seamless execution. The suggested steps are detailed below with suggested timeframes.

<table>
<thead>
<tr>
<th>SUGGESTED STEPS</th>
<th>SUGGESTED TIMEFRAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Ensure support for the project with strong advocacy for change through establishing Oversight Group</td>
<td>Weeks 1 - 4</td>
</tr>
<tr>
<td>2. Build your Core Project Team</td>
<td>Weeks 3 - 5</td>
</tr>
<tr>
<td>3. Develop a SMART project aim</td>
<td>Weeks 3 - 5</td>
</tr>
<tr>
<td>4. Conduct baseline measurement exercise of performance against the measures. Analyse the results of the exercise, and confirm or establish the Gentamicin dosing and TDM process in your hospital - who is involved, and how does each process step interrelate? Does this process vary on different wards, for different types of patients (eg patients with long lines), or at weekends?</td>
<td>Weeks 5 - 6</td>
</tr>
<tr>
<td>5. Review your dosing guidelines in tandem with your current TDM to determine if amendment might yield better performance. If serum level timing accuracy is a particular problem, significant change in the timing window for serum levels may be required (see below).</td>
<td>Weeks 6 - 10</td>
</tr>
<tr>
<td>6. Undertake improvement following the secondary drivers and suggestions outlined below.</td>
<td>Weeks 7 - 12/16</td>
</tr>
</tbody>
</table>

The table below outlines possible improvement tests that can be used in order to address each of the primary drivers and ultimately help the project achieve its aim:

<table>
<thead>
<tr>
<th>PRIMARY DRIVER: ENSURE GENTAMICIN PATIENT SELECTION IS APPROPRIATE, AND THAT THE DRUG IS DOSED CORRECTLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>SECONDARY DRIVERS</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>Clear, concise, unambiguous and agreed dosing guidelines. These should include clarity around dosing in patients of all ages, weights, degrees of renal function and by indication.</td>
</tr>
<tr>
<td>Routine assessment of patient factors associated with potential toxicity prior to prescribing Gentamicin e.g. underlying renal function, hearing difficulty, concurrent nephrotoxic drugs. In patients where these risk factors are present, review the relative risks and benefits of treatment. Where therapy is adjudged to be required, mitigate for risks e.g. hold additional nephrotoxins, ensure adequate hydration.</td>
</tr>
</tbody>
</table>
**PRIMARY DRIVER:** ENSURE GENTAMICIN PATIENT SELECTION IS APPROPRIATE, AND THAT THE DRUG IS DOSED CORRECTLY

<table>
<thead>
<tr>
<th>SECONDARY DRIVERS</th>
<th>SUGGESTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routinely record patient renal function and indication for Gentamicin use in patient medical chart or drug kardex at the time of prescribing the drug.</td>
<td>Physically recording the patient’s renal function at the time of prescribing the drug acts as a prompt for prescribers to consider this critically important parameter before commencing Gentamicin. Providing a place for renal function to be recorded as part of standard patient documentation may increase the likelihood of this occurring – either through a designated place on the drug kardex, in the medical notes, or through the use of a Gentamicin prescriber checklist sticker or form. The need to undertake this step should be emphasised as part of the training of all new prescribers, and re-emphasised throughout their practice.</td>
</tr>
<tr>
<td>Routine measurement of weight and height on admission, with results recorded on the patient’s drug kardex.</td>
<td>Ready access to required measurement equipment. Use of ulna length to estimate height where needed in adults (see below). In Children, use estimated weight from height charts (see below).</td>
</tr>
<tr>
<td>Use of electronic dosage calculators and dedicated Gentamicin dosing forms.</td>
<td>There are a number of apps in development. Check your organisations intranet for other calculators and resources.</td>
</tr>
<tr>
<td>Use of a Gentamicin prescriber checklist sticker.</td>
<td>See sample sticker below.</td>
</tr>
</tbody>
</table>

**ESTIMATING A CHILDS WEIGHT FROM THEIR HEIGHT CHART**

Screening Tool for the Assessment of Malnutrition in Paediatrics (STAMP) tool (www.stampscreeningtool.org) can be used to estimate ideal weight for height in children.

The download section gives instruction how to use the tool, information on how to measure correctly, as well as a centile quick reference table for children 2-18 years:


**SAMPLE GENTAMICIN STICKER**

Complete at the time of prescribing Gentamicin.

Serum Cr _________ micromol/L
Weight _________ kg
Height if obese _________
Gentamicin calculator on T drive used?
Trough level ordered 18-24 hrs after first dose?
Sig _________ MCN _________ Date _________

This image has been reproduced with kind permission of BAPEN.

BAPEN is a Charitable Association that raises awareness of malnutrition and works to advance the nutritional care of patients and those at risk from malnutrition in the wider community. The ‘Malnutrition Universal Screening Tool’ (‘MUST’) was developed by the Malnutrition Advisory Group, a standing committee of BAPEN and it has been reviewed regularly since its launch in 2003. It is supported by many governmental and non-governmental organisations including the British Dietetic Association (BDA), the Royal College of Nursing (RCN) and the Registered Nursing Home Association (RNHA) and is the most commonly used screening tool in the UK. It is also used in many other countries in Europe and the rest of the world. http://www.bapen.org.uk/pdfs/must_page6.pdf

**ESTIMATING HEIGHT FROM ULNA LENGTH**

This image is from the British Association for Parenteral and Enteral Nutrition (BAPEN) resource ‘Alternative measurements (illustrations)’ and it describes how to estimate height using ulna length.

This image has been reproduced with kind permission of BAPEN.

BAPEN is a Charitable Association that raises awareness of malnutrition and works to advance the nutritional care of patients and those at risk from malnutrition in the wider community. The ‘Malnutrition Universal Screening Tool’ (‘MUST’) was developed by the Malnutrition Advisory Group, a standing committee of BAPEN and it has been reviewed regularly since its launch in 2003. It is supported by many governmental and non-governmental organisations including the British Dietetic Association (BDA), the Royal College of Nursing (RCN) and the Registered Nursing Home Association (RNHA) and is the most commonly used screening tool in the UK. It is also used in many other countries in Europe and the rest of the world. http://www.bapen.org.uk/pdfs/must/must_page6.pdf

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**Alternative measurements: instructions and tables**

If height cannot be obtained, use length of forearm (ulna) to calculate height using tables below. (See ‘The MUST’ Explanatory Booklet for details of other alternative measurements (knee height and demispan) that can also be used to estimate height).

**Estimating height from ulna length**

Measure between the point of the elbow (olecranon process) and the midpoint of the prominent bone of the wrist (styloid process) (left side if possible).

<table>
<thead>
<tr>
<th>Height (cm)</th>
<th>Ulna length (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men (&lt;65 years)</td>
<td>1.49</td>
</tr>
<tr>
<td>Men (≥65 years)</td>
<td>1.57</td>
</tr>
<tr>
<td>Women (&lt;65 years)</td>
<td>1.41</td>
</tr>
<tr>
<td>Women (≥65 years)</td>
<td>1.54</td>
</tr>
<tr>
<td>Men (&lt;65 years)</td>
<td>1.60</td>
</tr>
<tr>
<td>Men (≥65 years)</td>
<td>1.58</td>
</tr>
<tr>
<td>Women (&lt;65 years)</td>
<td>1.52</td>
</tr>
<tr>
<td>Women (≥65 years)</td>
<td>1.55</td>
</tr>
</tbody>
</table>
### PRIMARY DRIVER: ENSURE THAT PATIENT MONITORING, INCLUDING THERAPEUTIC DRUG MONITORING, IS EFFECTIVE AND RELIABLE THROUGHOUT THERAPY

<table>
<thead>
<tr>
<th>SECONDARY DRIVERS</th>
<th>SUGGESTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure ability to identify time of pre-dose trough sample taken from reported result.</td>
<td>Work with laboratory and phlebotomy colleagues to identify ways to improve the reliability of sample time recording on assay samples prior to processing. Electronic systems which automatically record the time of sample may aid with this.</td>
</tr>
<tr>
<td>Prescriber’s given responsibility for and trained to order levels in advance, at the time of prescribing Gentamicin.</td>
<td>Establish a ‘process roles and responsibility chart’ which clarifies everyone’s expected role in the process.</td>
</tr>
<tr>
<td>Nurses trained to check first level is ordered at time of first administration, and intervene if forgotten.</td>
<td>Establish a ‘process roles and responsibility chart’ which clarifies everyone’s expected role in the process.</td>
</tr>
<tr>
<td>Clarity and awareness of which staff member is available, competent and responsible to take serum samples at the required time in that unit.</td>
<td>Establish a ‘process roles and responsibility chart’ which clarifies everyone’s expected role in the process. Where possible, try to forward plan to avoid having to get levels processed at weekends. In situations where this cannot be avoided, forward plan with weekend staff to avoid unintended delays.</td>
</tr>
<tr>
<td>Expansion of time window for trough level, for example 16-18 hours post dose to improve capability.</td>
<td>Sampling system designed to be time sensitive either through a dedicated phlebotomist, nurse led, or with dose time adjustment to facilitate reliability.</td>
</tr>
<tr>
<td>Design system so that results are available in the time between sampling and next dose administration. Introduce automatic added serum creatinine measurement with each TDM serum sample.</td>
<td>Awareness of laboratory result turnaround time and daily cut-off times for same day results will be required to aid in this planning phase. Standardisation of administration time for the drug to later in the day may aid in same day sampling and assay result availability prior to drug administration.</td>
</tr>
<tr>
<td>Monitor ongoing need for Gentamicin throughout therapy, and discontinue as soon as clinically appropriate (nephrotoxicity risk is increased in patients who receive more than 7 days therapy). Where more than 7 days is required, record rationale for continued therapy in the patient medical chart.</td>
<td>Consider the introduction of an automatic stop date for Gentamicin at day 7. This may need to be service or condition specific to avoid inadvertent discontinuation for conditions/patient populations where longer course durations are the norm. Clinical Pharmacist or Nurse intervention for ongoing prescriptions may aid with this. Use of alert stickers or alarms in electronic prescribing systems may also be of benefit.</td>
</tr>
<tr>
<td>Introduce alerts into system to flag therapy approaching the 7 day mark.</td>
<td></td>
</tr>
</tbody>
</table>

### PRIMARY DRIVER: DATA

<table>
<thead>
<tr>
<th>SECONDARY DRIVERS</th>
<th>SUGGESTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify methods (and who is responsible) for the easy capture and visible display of data.</td>
<td>Data needs to be presented in a timely fashion, and to the frontline workers who are involved in this process. Integration of feedback of performance with Gentamicin usage into established clinical team meetings should be considered.</td>
</tr>
<tr>
<td>Create a meeting structure to address problems locally.</td>
<td></td>
</tr>
</tbody>
</table>

### PRIMARY DRIVER: ANTIMICROBIAL STEWARDSHIP

<table>
<thead>
<tr>
<th>SECONDARY DRIVERS</th>
<th>SUGGESTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support of D&amp;T and local antimicrobial stewardship group.</td>
<td>Meet/present your improvement project and this guide to the group. Involve members on the Oversight Group and/or Core Project Team. Update regularly with the group.</td>
</tr>
<tr>
<td>Ready availability of expert local advice to support practice.</td>
<td>Involve relevant representatives in the project. Identify and involve trained quality improvement experts within the organisation (contact the National Quality Improvement Programme for further information, <a href="mailto:orlamullally@rcpi.ie">orlamullally@rcpi.ie</a>).</td>
</tr>
<tr>
<td>Education and training of all Gentamicin usage process stakeholders.</td>
<td>Use this improvement guide as a resource to train quality improvement techniques. Contact the National Quality Improvement Programme if additional training or support is required, <a href="mailto:orlamullally@rcpi.ie">orlamullally@rcpi.ie</a>.</td>
</tr>
<tr>
<td>Ensure the ability of the local antimicrobial stewardship team to readily oversee Gentamicin dosing and therapeutic drug monitoring practice, to easily identify patients who further expert involvement, and to rapidly intervene where necessary.</td>
<td>Consider establishing an alert system which prompts automatic review of Gentamicin therapy in patients who have high levels reported from the laboratory. Ongoing audit of performance may also be aided by automatic recording of patient names from laboratory records of assay measurement.</td>
</tr>
</tbody>
</table>
**KEY DRIVER: MANAGEMENT AND LEADERSHIP**

<table>
<thead>
<tr>
<th><strong>SECONDARY DRIVERS</strong></th>
<th><strong>SUGGESTIONS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure safety is at the top of every agenda.</td>
<td>Ensure this initiative is aligned with the hospital's strategic plan for patient safety. Involve senior leadership within the oversight group – Clinical Director, Director of Nursing, CEO, etc.</td>
</tr>
<tr>
<td>Align with the Risk Register.</td>
<td>Contact relevant area within the organisation.</td>
</tr>
<tr>
<td>Advocate for explicit management and clinical leadership support.</td>
<td>Provide feedback on performance and improvement efforts to the clinical and managerial leadership teams.</td>
</tr>
<tr>
<td>Ensure D&amp;T committee oversight and support.</td>
<td>Ensure support at the outset and maintain ongoing communication and feedback to the committee throughout.</td>
</tr>
</tbody>
</table>

**NATIONAL QUALITY IMPROVEMENT PROGRAMME**

The National Quality Improvement (QI) Programme was formally established between the Quality and Patient Safety Division in the Health Service Executive and the Royal College of Physicians of Ireland in 2012. The programme aims to build leadership skills and expertise in quality improvement, to develop a common language between management and clinicians and to help them achieve their common goal of improving Irish healthcare.

The programme is made up of a number of educational initiatives including the Diploma in Leadership and Quality in Healthcare and the Pressure Ulcers to Zero Collaborative. The programme is also involved in other QI initiatives such as the development of this Gentamicin Improvement Guide, research, and hospital-based quality and leadership development.

One of the most significant elements to the programme is it is driven by clinicians working and teaching with other clinicians and all of the content is specific to healthcare. Since starting in mid-2012 the programme has produced estimated annual savings for the health service amounting to over €3.5 million, trained over 700 healthcare professionals and positively impacted the lives of Irish patients in the system. For further information please contact Orla Mullally, Programme Manager. orlamullally@rcpi.ie.

**SUPPORT**

This improvement guide was designed by the Gentamicin Project Improvement Group as part of the National Quality Improvement Programme, HSE/RCPI. It aims to support the development and implementation of best practice usage of Gentamicin in hospital settings. This guide is also supported by the:

- National Hospital Antimicrobial Stewardship Committee
- Hospital Pharmacists Association of Ireland
- State Claims Agency
- Irish Nephrology Society
- National Specialty Director for the Higher Specialist Training Programme in Clinical Pharmacology and Therapeutics

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**REFERENCES**

A Problem Shared: Adopting a Collaborative Approach to Improve Gentamicin Use in Irish Hospitals


INTRODUCTION

Gentamicin is a potentially life-saving antibiotic which is used to treat serious infection in approximately 15,000 patients per annum in hospitals across the Republic of Ireland. Rising Gram-negative resistance rates have seen its importance as a treatment option increase. Accuracy in dosing and monitoring are required to optimise efficacy and reduce toxicity. Deviation from protocol can increase the incidence of kidney damage, hearing loss or poor treatment outcomes.

ASSESSMENT AND ANALYSIS

Despite clear recommendations to support use of aminoglycosides in most hospitals, variation in usage performance persists, and a new approach to facilitate the spread of good practice is required. A national point prevalence study confirmed anecdotal evidence of widespread scope for improvement. Advocacy for change from frontline staff led to the establishment of a nationally supported multidisciplinary, multicentre improvement initiative, which combined subject matter and quality improvement expertise.

AIM STATEMENT

By April 2014, 100% of patients in enrolled units are treated safely and effectively with gentamicin.

STRATEGY FOR CHANGE

A national multidisciplinary team was formed and governance structures were established through the national clinical programme for Healthcare Associated Infection and Antimicrobial Resistance. High quality gentamicin usage was defined, and measures which struck a balance between assurance of efficacy and safety were agreed. Two adult and two paediatric hospitals were initially recruited to test these measures, establish baseline performance and undertake small tests of change using a Shewhart (Plan-Do-Study-Act) cycle to inform the formation of a change package. Six weekly group meetings were held to facilitate shared learning and support.

High quality gentamicin usage was defined by the national improvement group through the adoption of five key performance indicators (Table 1). Baseline performance through measurement against these indicators was established. As expected, key areas for improvement locally included dose selection, and documentation of renal function at the time of prescribing gentamicin. Application of the Model for Improvement, through small tests of change using a Shewhart (Plan-Do-Study-Act) cycle informed incremental improvement in each centre.

RESULTS AND OUTCOMES

Whilst this is an ongoing initiative, incremental improvement in practice has begun to emerge. Moreover, testing of change across centres has informed a collective driver diagram (Fig 1) and change package which will further inform improvement nationally. Currently, as has been found in other health systems, there is no agreed approach to dosing and monitoring gentamicin in Irish hospitals. This improvement group is currently exploring the potential for standardisation of dosing and monitoring practice in adult, paediatric and neonatal patients. Such an approach intends to improve reliability in dosing across the health system, as it will make dose selection practice amongst medical staff (who are the most transient of staff members involved in gentamicin usage) more transferrable. Another measure which has been proven to improve dosing practice performance is the adoption of electronic dosage calculators. Whilst these can vary in form, smart-phone accessible calculators appear to have most promise. This initiative has facilitated the development and sharing of such a tool nationally. Should dosing policy standardisation prove possible, rapid adoption of the same tool across centres may become more seamless. Further step-wise recruitment of other hospitals has likewise begun, with a total of seven centres now signed up to participate. It is intended that this initiative continues to organically spread across the health system, with newer entrants learning from the experience of earlier participants to effect ever faster improvement.

LESSONS LEARNED

Our experience so far has demonstrated that a collective approach to improvement can facilitate the rapid spread of innovation between hospitals. A significant initial investment of both time and expertise is required to yield downstream benefit. Availability of on-site quality improvement expertise is also vital in aiding participants in the application of quality improvement methods locally. Given the level complexity associated with gentamicin dosing and monitoring, many different measures are required to promote optimal performance. Through the sharing of innovative ideas and resources, gradual improvement across hospitals can be achieved.
Use of a Prescriber Checklist to Improve the Reliability of Gentamicin Prescribing at Tallaght Hospital
Egan S, Weedle R, Ridgway PF, Wall C
Departments of Pharmacy, Surgery and Nephrology, Tallaght Hospital, A Teaching Hospital of Trinity College Dublin, Dublin 24.

INTRODUCTION
Escalating Gram-negative resistance rates to conventional beta-lactam antibiotics have seen aminoglycoside antibiotics such as gentamicin become more important in the treatment of severe infection. Accuracy in dosing and monitoring are required to optimise efficacy and reduce toxicity. Despite this, gentamicin usage is a common cause of medication error internationally, and variance in the reliability of usage can often be found on audit.

ASSESSMENT AND ANALYSIS
A successful improvement effort to optimise gentamicin dosing and monitoring practice at our hospital had occurred prior to this initiative, with therapeutic drug monitoring (TDM) practice in particular exhibiting significantly higher reliability 

Table 1. Agreed Gentamicin Prescribing Quality Measures

<table>
<thead>
<tr>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Height Function Required for Adherence at the Time of Prescribing the Drug</td>
</tr>
<tr>
<td>2. The Correct Dose is Prescribed at the Right Weight and Renal Function</td>
</tr>
<tr>
<td>3. The First Serum Trough Level is Taken in the Correct Time Window</td>
</tr>
<tr>
<td>4. No Inappropriately Dosed or Delayed Doses Due to TDM Error</td>
</tr>
<tr>
<td>5. The Patient Who was Initially Treated with Gentamicin was Referred for Further Tests Beyond that Time-point Recorded on Days 5-7 of Therapy</td>
</tr>
</tbody>
</table>

This effort also linked in with a national gentamicin quality improvement initiative, which provided support and quality improvement expertise.

RESULTS AND OUTCOMES
Numerous iterations of the POSA cycle were undertaken on a small scale. Due to a relatively low number of patients in this setting, improvement was gauged based on performance against our measures, and through end-user input into the design of interventions. Sustained effort led to the eventual formulation and testing of a gentamicin prescriber checklist sticker. This sticker was applied by the prescriber onto the drug kardex at the time of prescribing the drug.

LESSONS LEARNED
Whilst our aim was met, spread to other surgical teams has proven less successful so far. Ongoing easy access of the sticker prompted prescribers to correctly record required data and promoted key process step completion at the start of therapy. This included prompt use of a pre-existing electronic dosage calculator located on the hospital intranet, and pre-ordering or forward planning for the first serum trough level to be taken in advance. Introduction of the sticker achieved our local aim.

References:

Figure 1. The Model for Improvement, As Adapted to this Project

Figure 2. The Gentamicin Prescriber Checklist Sticker

Figure 3. Run-Chart Demonstrating performance at Baseline and Post Checkelisted Sticker introduction

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Gentamicin: Reducing Harm and Optimising Use

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Our Lady of Lourdes Hospital, Drogheda, Co. Louth

Introduction

Gentamicin is an important and effective antimicrobial for the treatment of severe infection, however its use may result in irreversible ototoxicity and reversible nephrotoxicity.1,2 Dosing may be complex, particularly for obese patients and those with renal impairment. As mismanagement of gentamicin can lead to patient harm,3 appropriate prescription, administration and therapeutic drug monitoring (TDM) of gentamicin are essential.1

As part of the National Gentamicin Quality Improvement Collaborative,4 a quality improvement team was formed in Our Lady of Lourdes Hospital (OLOL). The quality improvement team aimed to reduce harm from once-daily gentamicin and optimise use by improving the management of gentamicin in the hospital.

Methodology

Quality Improvement Methodology was followed using the Model for Improvement.6

Aim

• To reduce harm and optimise use

Measures

• Stay below for quality improvement process measures recommended by the National Gentamicin Collaborative

Ideas

• New gentamicin once-daily dosing guideline developed
• Electronic gentamicin calculator from Connolly Hospital introduced
• Gentamicin sticker checklist
• Education for doctors and nurses

The ideas were tested using Plan-Do-Study-Act (PDSA) cycles on two pilot surgical wards in Dec 2013.

The ideas were approved hospital-wide in Feb 2014 and rolled out to all wards over a 4 week period between Feb and Mar 2014.

New gentamicin once-daily dosing guideline:

• Regional renal dosing agreed in HSE DNE
• Trough level time window extended from 1 hour pre-dose to 18-24 hours post-dose
• First trough level now due on day 2 rather than day 3

Gentamicin sticker checklist:

• Record serum creatinine, weight, height if obese
• Reminder to use electronic calculator and order first trough level

Quality Improvement Process Measures:

Five measures— each worth 20% compliance:

1. Was renal function documented by the doctor at the time of prescribing gentamicin?
2. Was dose correct for weight, height and renal function?
3. Was first trough level taken on the right day at the right time?
4. No doses missed or delayed by > 4 hours due to TDM error?
5. No more than 7 days duration unless clinical rationale documented?

Exclusions: pregnancy, paediatrics, multiple daily dose regimens

Results

Hospital-wide baseline data was collected for 68 patients. The quality improvement ideas were tested on two pilot surgical wards from Dec 2013 to Mar 2014. In total, 22 patients have received gentamicin on the pilot wards since the new guideline was introduced.

Table 1. improvements in process measures with new guideline

<table>
<thead>
<tr>
<th>Process Measure</th>
<th>Baseline (%)</th>
<th>Pilot of new guideline (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal function documented when gentamicin prescribed</td>
<td>27.9%</td>
<td>86.4%</td>
</tr>
<tr>
<td>Dose correct for weight, height and renal function</td>
<td>55.9%</td>
<td>100.0%</td>
</tr>
<tr>
<td>First trough taken on right day at right time</td>
<td>37.5%</td>
<td>63.6%</td>
</tr>
<tr>
<td>No doses missed or delayed &gt; 4 hours due to TDM error</td>
<td>94.7%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Necrotising soft tissue infection clinical estimate documented</td>
<td>86.4%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

A run chart of % compliance with quality improvement process measures has also been developed for the pilot wards.

![Figure 1. % compliance with quality improvement process measures on pilot wards](image)

The gentamicin sticker was used for 5 of 22 patients (22.7%).

Discussion

The results show that management of gentamicin has improved on the pilot wards since the introduction of the new guideline. The gentamicin sticker was not widely used, possibly because of problems locating the sticker when needed. An alternative would be a dedicated gentamicin prescription section on the drug chart. Targeted early review of patients on gentamicin by the antimicrobial pharmacist may also lead to improved management of gentamicin. These quality improvement ideas will need to be tested in further PDSA cycles.

As the initial quality improvement ideas were considered successful on the pilot wards, they were recently extended hospital-wide. It is anticipated that management of gentamicin will also improve hospital-wide, however additional data collection will be required to verify this.

Conclusion

Management of gentamicin on pilot wards has improved. Additional data collection will be required to verify improvements hospital-wide. Further quality improvement ideas and PDSA cycles are recommended to further improve the management of gentamicin in the hospital.

References