A regional approach to the implementation of the NPSA gentamicin alert

A National Patient Safety Agency alert to promote the safe use of gentamicin in neonates was issued in February 2010. The mandate included the requirement for implementation where all neonatal patients are treated in England within one year of the alert being issued. Implementing the alert required significant changes in practice involving a number of disciplines and departments. This article describes how the East of England Perinatal Network adopted a region-wide, network approach to implementing the alert.

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Key points

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1. A region-wide approach was used for implementation of the gentamicin alert, encouraging network integration.
2. This approach avoided duplication of effort and enabled effective use of resources.
3. The implementation was completed within the required NPSA time frames.

There seems to be a wide variation in the response of individual units to prospective change. Some units are early adopters of change whereas others find difficulties in implementing innovation. Research suggests that without an understanding of the complexity of different organisations and the support required to implement change, this will not happen effectively. This article explores how units of the East of England Perinatal Network worked together to implement the National Patient Safety Agency (NPSA) alert for gentamicin, using an innovation model approach and allowing adaptation.

Background to the alert

Gentamicin is a broad spectrum aminoglycoside antibiotic widely used in neonatal units in England for the treatment of neonatal sepsis. A review of National Reporting and Learning System[1,2] (NRLS) data showed that in 2008, fifteen percent of all neonatal medication incidents involved gentamicin. This finding led to the development of a care bundle to reduce gentamicin incidents. The Institute for Health Improvement describes a care bundle as a group of evidence-based interventions related to a disease or care process that, when implemented together, result in better outcomes than when implemented individually[3].

The project was piloted in the south of England and the findings led to the NPSA producing a Patient Safety Alert for implementation nationally, by February 2011.

The alert included four care bundle elements:

1. Wearing a disposable coloured apron to indicate that staff should not be disturbed when preparing and administrating gentamicin.
2. Use of the 24-hour clock when prescribing gentamicin.
3. Use of a double checking prompt when preparing and administering gentamicin.
4. Giving the dose one hour either side of when it was due.

As well as a requirement to implement the four care bundle elements the alert stipulated that:

- A local gentamicin protocol must be available in all units.
- The alert was to be implemented using small cycles of change using Plan, Do, Study, Act (PDSA) methodology.
- Compliance must be measured daily.
- Staff must be provided with appropriate training[1,2].

The East of England Perinatal Network

The East of England Perinatal Network is made up of two networks: Eastern and Bedfordshire and Hertfordshire network with two units also belonging to the North East London network. At the time, eighteen units were managed within these networks, covering a wide geographical area, with a land size of approximately ten percent of England and with a birth rate of around seventy thousand babies per annum.

An Innovation Lead post had been created in May 2010, shortly after the alert had been issued. One of the remits of the post holder was to support teams to implement the alert.

Drivers for a regional approach

The main driver for adopting a network

approach to implementation was to reduce variations in practice through standardisation of key aspects of the alert, avoiding duplication of effort through the appropriate use of resources and ensuring that every unit implemented the alert within the required NPSA time frames, with appropriate support.

Facilitating the change process

Plesk describes how many healthcare organisations use multidisciplinary teams to bring about change, recognising that good care and quality improvements often require the coordinated efforts and skills of different people and disciplines[5]. The rapid-cycle test-of-change improvement methodology, advocated principally by the Institute for Healthcare Improvement, is already widely used to support change efforts in healthcare organisations, nationally and internationally[3].

This cycle of change model, known as the PDSA cycle was advocated by the NPSA to aid implementation and provide a model for delivery of the required changes[1]. Each unit identified a local champion with responsibility for representing unit's views on the regional approach, implementing the required changes and facilitating the PDSA cycle in their own unit.

The alert stipulated availability of a protocol clarifying the dose and frequency of drug administration, blood level monitoring requirements and arrangements for any adjusted doses based on blood level results. Allowing each team to write and agree a local protocol would have resulted in duplication of effort, wasted time and avoidable complexity.

The need to maintain quality and safety throughout as well as after implementation were other important drivers. Junior doctors rotate four to six monthly, having to adjust to different working environments, staff and local practices. Standardising practices across a region reduces the number of changes doctors face, resulting in safer processes being adopted. This notion is especially valid when applied to the prescribing and administration of medication to newborns.

Scoping of practice

Key to reaching regional consensus and approach was the need to understand current practice in each unit. This was achieved through a scoping exercise undertaken at the start of the project in May 2010, using an on-line Survey Monkey questionnaire. Information was collected on gentamicin dose, frequency of administration based on gestational age, use of a specific gentamicin prescription chart, blood level monitoring practices and use of a formal protocol. Units were asked whether any aspects of the alert had already been implemented. This allowed for effective planning of support required according to specific unit needs. As advised in the "how to" guide issued by the NPSA as part of the supporting documentation, a named champion and senior leads, both at unit level and within governance departments were asked to be involved in the approach to ensure the project received the senior leadership and support it required.

Findings from the scoping exercise confirmed the variations in practice. Seven different gentamicin doses were in use across the region, all within the range of 4 to 5mg/kg/dose as advised by the British National Formulary for children (BNFc 2009)[6] with some variation according to gestational age. Over ten different regimens were employed. Seven units had developed their own gentamicin prescription chart with a further three units in the process of designing one.

Blood level monitoring policies were largely based around laboratory provision. In many units assays were run once every 24 hours, leading to delays in babies receiving their next gentamicin dose dependent on the particular regimen. One unit had no weekend laboratory provision for gentamicin assays and weekend doses were given following discussion with their consultant microbiologist.

Eleven units had already adopted a policy of no interruptions during the checking and administration process, either through the use of the coloured apron or through use of a separate room to prepare the drugs. Fourteen units had a policy of using the 24-hour clock when prescribing and four units had a policy of administering the dose one hour either side of when it was due. No unit had a formal gentamicin protocol in place or had fully implemented the alert.

Results of the scoping exercise were presented to clinicians and leads outlining the aim of achieving regional consensus on all aspects of the alert. This was an important part of the change process. Engaging leaders through their recognition of variations in practice, allowed for consideration of local change to support achievement of the aim of wider regional consensus and approach.

Achieving consensus across the region

A multidisciplinary team meeting was arranged for mid July 2010 to which neonatologists, pharmacists, neonatal nurses, managers and unit champions were invited. The aim of the meeting was to agree a single dose, a regimen for dose frequency dependent on corrected gestational age, arrangements for monitoring gentamicin levels, a regional gentamicin prescription chart and a regional apron colour. Unit champions were invited to represent their unit's views on all the above aspects.

Discussions on these areas for consensus had been clarified prior to the meeting. A draft protocol and a proposed gentamicin prescription chart had been circulated to key stakeholders prior to the meeting. Local unit meetings had been held to discuss which aspects could be incorporated into a regional approach and which aspects each unit did not want to change. These views were then brought to the regional multidisciplinary meeting.

It is widely assumed that enabling changes in professional practice are less likely to succeed unless barriers are identified and taken into account as part of the change process[7]. Local barriers to implementation were discussed at the meeting: individual Trusts had specific laboratory restrictions and governance requirements which required consideration. Three units were to undergo relocation later in the year. They requested support for implementation ahead of their move to minimise the number of changes their staff faced and ensure the alert was part of everyday practice prior to relocation, while supporting regional implementation by the end of December 2010. Awareness of these barriers proved to be an important part of the engagement and change process and ensured all units had fully implemented the NPSA aspects within the regional time frames.

The rationale for implementation by December, was to ensure there was time to "iron out" any specific issues ahead of the NPSA February 2011 deadline. Secondly, a different large innovation project involving significant changes in practice was being implemented regionally at the start of

NAME OF YOUR UNIT TO GO HERE

East of England Perinatal Networks

Addressograph

PRESCRIPTION CHART FOR IV GENTAMICIN ONLY – (Staple to main Drug Chart)
DOSING AND MONITORING OF IV GENTAMICIN

Dose and frequency: 4.5mg/kg/dose <32 weeks corrected gestational age – ONE dose every 36 hours
≥32 weeks corrected gestational age – ONE dose every 24 hours

Monitoring: Trough level pre 2nd dose (and give 2nd dose if renal function satisfactory) and pre-5th dose unless more frequent monitoring is indicated.
Generally, levels should be checked every 3rd dose.

Expected trough level: Level ≤ 2mg/L

Dose adjustments if levels >2mg/L: If on 24 hourly dosing extend interval to 36 hourly (level and hold before next dose – level must be ≤2mg/L before next dose given)
If on 36 hourly dosing extend interval to 48 hourly (level and hold before next dose – level must be ≤2mg/L before next dose given)

Weight: .... **Corrected gestational age at start of treatment:..............weeks**

Date	Time to be given	Drug	I.V Dose	IV route i.e. PVL or LL	Frequency of administration	Signature of Prescriber	Printed Name of Prescriber	Write **'LEVEL and GIVE'** or **'LEVEL and HOLD'**.	Double checking prompt used*	Given by		LEVELS		Pharm
										Initials*	Time	Initial when level taken	Result of level	
-- /-- /--	-- : --	Gentamicin	mg								-- : --			
-- /-- /--	-- : --	Gentamicin	mg					**LEVEL AND**			-- : --			
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*** Lead checker to sign uppermost section of box.**

Date: 13/07/10. Version: 1.3
Name of your hospital here

File: Neonatal Services/Pharmacy Ext: XXXX
File: Under the Prescription Charts divider in date order – most recent on top.

Approved by:

FIGURE 1 Prescription chart for IV gentamicin.

Name of your unit in here

East of England Perinatal Networks

Double-checking prompt for the preparation and administration of intravenous gentamicin to neonates

- Both members of staff are to use the prompt every time a dose of gentamicin is prepared and administered.
- Ultimate responsibility for the process lies with the lead checker whose additional responsibilities are highlighted in red.

Blood level monitoring: The actions below are to be prioritised to ensure doses are not delayed:
1. Check the date and time of the next blood level required. Are any blood levels due?
2. Do any blood level results need action prior to administering 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, action according to instructions on regional chart.
Apron and Prescription chart details:
6. Are you wearing a purple coloured apron?
7. Check the time recorded when the dose last given and the frequency prescribed. Is a dose due now?
8. Has the 24 hour clock been used to prescribe this dose?
9. Is the weight recorded on the prescription chart correct? *Ensure the weight is recent and realistic.*
10. Has the correct dose been prescribed based on the weight? Each checker to calculate the dose separately.
11. Is the dosing regimen and frequency correct for gestational age? Check against gentamicin prescription chart. *Caution: Any deviation from approved prescribing practices should be escalated.*
12. Has the prescription been signed by the prescriber?
Vial or CIVAS details:
13. Is this the correct medication?
14. Is this the correct strength of gentamicin, ie 20mg/2mL? *(N/A for CIVAS)*
15. Has the correct volume been drawn up? Each checker to calculate dose separately.
Administration:
16. Does the patient's identity match the patient details on the prescription chart?
17. Has the prescription chart been signed by the administrator with details of the time of administration?
18. Was the dose given one hour either side of when it was due?
19. If any aspect of the double checking prompt was not complied with, have you completed the audit form on the reverse side of the gentamicin drug chart?

FIGURE 2 Checklist for gentamicin administration.

2011. The project lead wanted to minimise the number of changes units were undergoing simultaneously, but also to have some success in implementing the change so success could be celebrated.

With these factors in mind, the network was able to agree a single dose (4.5mg/kg) and regimen for the dose frequency, blood level monitoring and dosing adjustment practices, specific prescribing chart and single apron colour (**FIGURES 1 AND 2**). Adopting a regional apron colour (purple) as part of the medication safety process was seen as an important part of improving the parent experience. Parents could become familiar with a single apron colour, the significance of which was explained to them by regionally-produced information posters, each carrying individual Trust logos to meet governance requirements.

Evidence-based practice was used to inform decision making as far as possible and in the absence of this regional consensus was adopted. The draft protocol was reviewed and amended to reflect regional agreement.

Training toolkit

A core objective when planning quality improvement changes is the need to disseminate the desired outcomes of the project to key stakeholders involved in the delivery of the outcomes. This will only be achievable and successful if, from the outset, every member of the team has a shared understanding of the requirements and rationale. Clearly articulating what changes are required and what these changes offer is essential to ensure the wider team has a shared understanding of what is required and how it will be delivered[8].

An initial formal teaching session involving local multidisciplinary teams was carried out by the project lead inviting opportunities for discussion of the project, local changes required and what impact this may have which required consideration. Following this initial teaching, the locally-based champion continued to cascade the information, using pre-prepared teaching tools and supporting teams to implement the alert using the PDSA cycle of change.

Baseline data were collected prior to implementing the alert, with compliance rates varying depending on whether units had already begun implementing the alert. This was an important part of recognising the improvements in care being made.

Units used the regional protocol as a tool to embed the theoretical aspects of training. Along with the presentation carried out by the project leads and champions, reading the protocol was considered to have fulfilled the specific training requirements of the alert. Staff were then required to sign that they had read and understood it. Queries were directed to local champions and where necessary, escalated to the project lead.

Champions were also responsible for undertaking monthly audits, providing feedback and agreeing action plans using the PDSA cycle. Units were given the option as to whether to register with the Measurement Extranet and eight units continue to log compliance regularly to date. The role of the champion was predominantly undertaken by neonatal nurses, unit managers and pharmacists. Improved multidisciplinary working was reported and the champion role provided development opportunities for staff in a number of units.

Compliance rates

Pre-implementation compliance rates ranged between 0-80%. The mean was 18%. Two months following implementation, a review of results taken from the Measurement Extranet showed that compliance had increased to 90.5%.

Once units reached over 95% compliance and expressed confidence in managing the ongoing requirements of the alert and protocol, they were formally signed off by the network. Quarterly audits are undertaken in units where compliance rates remain greater than 95%. In units where these rates drop, monthly audits are undertaken followed by targeted feedback and an action plan which is formalised through governance meetings.

Basildon and Thurrock neonatal unit has continued monthly auditing as a means of maintaining the profile of the alert and ensuring compliance rates are maintained above 95% (**FIGURE 3**). The unit champion includes an annual update in their mandatory paediatric study day, reviewing the guideline and providing an accurate and fluid account of compliance over time with key areas for action. When specific issues are highlighted these are discussed with individuals on a one-to-one basis with general issues being highlighted through emailed updates.

Audit results show an improvement in prescribing practice. Doctors face significant changes when moving from unit to unit and a standardised

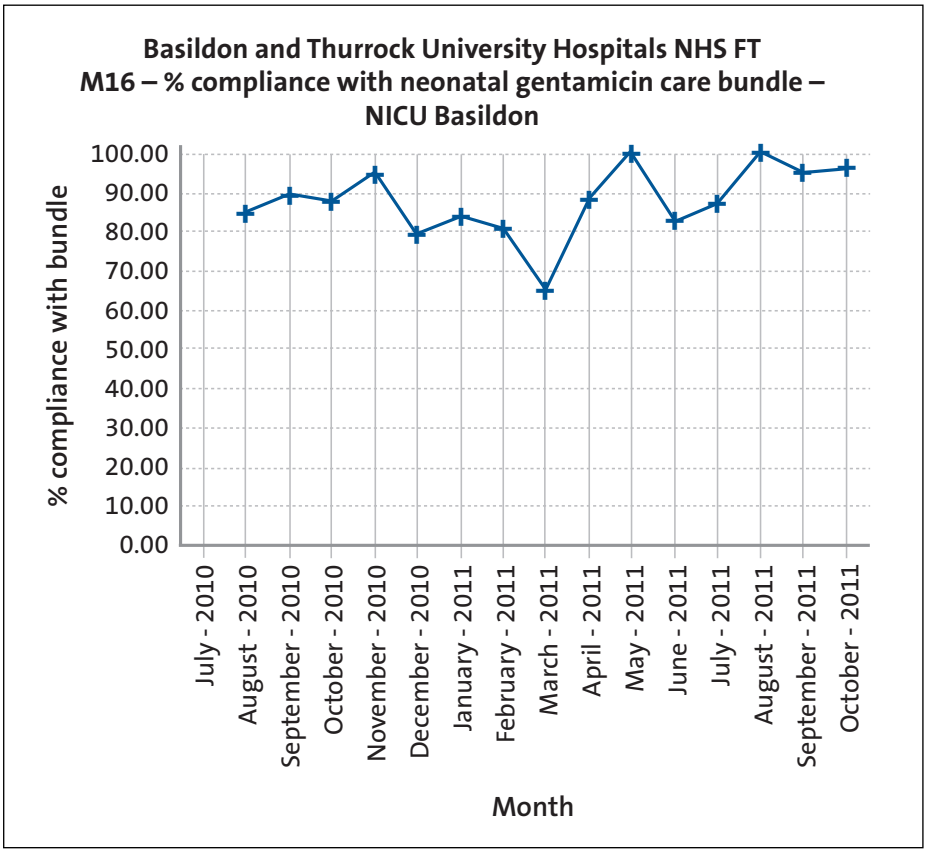

FIGURE 3 Regional double checking gentamicin chart.

gentamicin chart has reduced the number of changes, thus improving safety through familiarity and standardisation of practice. The protocol requires that a copy of the baby's gentamicin prescription chart is sent with the baby at transfer, making it clear to staff in receiving units exactly when levels and doses are due.

The regional prescription chart and embedded auditing tool

In order to achieve simplicity with auditing compliance, several modifications were made to the NPSA double checking prompt. Additional questions were included under the headings of "Prescription chart details" and "Administration."

These questions related to compliance with wearing the apron, prescribing using the 24-hour clock and administration within the one-hour time frame. The final question on the double checking prompt asked that if any aspect of the prompt was not complied with, the checker was to complete the audit form on the reverse side of the gentamicin prescription chart providing relevant details.

This became a simple means of collecting compliance rates and reasons for non compliance. All the information was contained within a single document and cross checking of validity of compliance rates could be made by the auditor by simply reviewing the prescription chart thus avoiding use of multiple forms for completion and cross referencing.

Other changes to the prompt included highlighting the responsibilities of the lead checker in bold red font. The regional protocol stipulates where the lead checker signs on the regional chart to indicate they were lead checker. This clarifies roles should a query need to be made as part of the auditing and safety process.

Reasons for non compliance

Units cited a number of reasons for non compliance. Broadly, these were found to be either patient factors, eg tissuing of line for administration leading to a delay of over an hour while resiting a line; or service-related issues, eg prescription errors, avoidable interruptions and unavailability of blood level results. Many units went to considerable lengths to work with laboratory leads to ensure gentamicin assays were returned within a time frame which avoided the dose being delayed. In several Trusts, processing of gentamicin assays moved from microbiology laboratories to biochemistry laboratories. This supports the view that services should fit around the needs of patients and not patients around the needs of services[9].

Units choosing to "opt out"

Adopting a regional approach required openness and willingness from clinicians, Trusts and units to change local practices in order to achieve network consensus. Whereas all units underwent changes to adopt the regional approach, not all units adopted every aspect that the regional guideline required. As the NPSA alert requirements were mandatory, these were fulfilled by all units and were achieved by December 2010.

Three aspects of the regional approach were not followed by some units. Four units continued to use their local apron colour. Reasons for this related to cost (one unit), another unit was instructed by their infection control team to use a wipe clean tabard in place of the disposable apron and two units had a Trust policy of wearing red aprons across the Trust. It was deemed prudent to continue with the Trust colours in these units.

Two units opted out of using the regional gentamicin chart. One unit had a robust safety system in use regarding the prescribing of gentamicin which incorporated a prescription sticker and auditing system. This unit also had patient flows which saw most of their sickest babies transferred into London. The other unit had designed a local gentamicin chart which incorporated the double checking prompt.

One unit opted out of following the regional approach to blood level monitoring prior to the second dose in favour of prior to the third dose. This decision was based on lack of evidence for taking levels prior to the second dose and the cost implications of having to screen more babies more often than their current arrangements required.

A formal written "opt out" process was followed requiring reasons for opt out and endorsed by the unit Clinical Director as well as the Trust Medical Director.

Outcomes

Current practice has seen improved awareness of the use of gentamicin and the safety issues which are involved when prescribing, preparing and administering the drug. The regional approach has resulted in familiarity with one chart, one protocol, a standardised dose and regimen and a standard process for monitoring blood levels. Adopting a standard apron colour has improved familiarity with and parental awareness of the significance of the apron and its colour – one less change for parents when their babies are transferred for continuing care.

The challenges of implementing a project across a large geographical area and involving changes in locally embedded practices are considerable. Staff working within neonatal units in the east of England showed openness and willingness to change local practices in the interests of patient safety, improved quality and standardised practices. Adopting a regional approach with the gentamicin alert paved the way for a number of other regional innovations which followed. The collaborative working culture and openness to change, acknowledging that some units had to adopt more changes than others, demonstrates that agreeing a network-wide approach is achievable and could be adopted in other networks.

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