Observatory
August 2015
Observatory of recent safe medication practice research, reports, and publications
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Recent regulator and statutory body activity

NHS England

MHRA
Regulating Medicines and Medical Devices

European Medicines Agency
Science Medicines Health

FDA
U.S. Food and Drug Administration

UKMi
UK Medicines Information
Stage Two: Resources

Addressing antimicrobial resistance through implementation of an antimicrobial stewardship programme
NHS/PSA/Re/2015/007

• Jointly issued by Health Education England, NHS England and Public Health England (PHE) to highlight the challenge of AMR and to signpost the toolkits developed by PHE to support the NHS in improving antimicrobial stewardship in both primary and secondary care.

• **Primary care resource**
  – TARGET (Treat Antibiotics Responsibly, Guidance, Education, Tools)
    (www.rcgp.org.uk/clinical-and-research/target-antibiotics-toolkit.aspx)

• **Secondary care resource**
  – Start Smart then Focus (www.gov.uk/government/publications/antimicrobial-stewardship-start-smart-then-focus)
Stage Two: Resources

Addressing antimicrobial resistance through implementation of an antimicrobial stewardship programme

NHS/PSA/Re/2015/007

When: To commence immediately and be completed by 31 March 2016

1. Bring this Alert to the attention of those holding leadership roles for antimicrobial stewardship

2. Review the resources signposted in the Alert - link with organisational or cross-system antimicrobial stewardship teams/committees, or equivalent, identify how the resources can be used to support your local antimicrobial stewardship programme.

3. By circulating the Alert or through local alternatives (e.g. newsletters, local awareness campaigns etc.) ensure that staff are aware of the key antimicrobial stewardship messages and resources relevant to their clinical practice.
Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use

- www.nice.org.uk/guidance/ng15
- The guideline covers the effective use of antimicrobials (including antibiotics) in children, young people and adults. It aims to change prescribing practice to help slow the emergence of antimicrobial resistance and ensure that antimicrobials remain an effective treatment for infection.
- The guideline includes recommendations on:
  - antimicrobial stewardship programmes
  - antimicrobial prescribing
  - introducing new antimicrobials
Recent regulator and statutory body activity

Class 4 - medicines defect information:

**Pregabalin 75mg capsules incorrect strength printed in one area of foil blister pack**

- 25mg has been incorrectly printed in one position of the affected foil packs however it is correct in other positions
• **Simeprevir with sofosbuvir** (treatment for hepatitis C): **risk of severe bradycardia and heart block when taken with amiodarone**

• When treating patients with both heart rhythm disorders and hepatitis C:
  – closely monitor patients taking amiodarone if they start simeprevir + sofosbuvir; sofosbuvir + daclatasvir; and sofosbuvir + ledipasvir (particularly during the first weeks of treatment)
  – in patients taking these antiviral combinations only start amiodarone when other antiarrhythmics are not tolerated or contraindicated; monitor closely (particularly during the first weeks of treatment)
  – monitor patients at high risk of bradyarrhythmia continuously for 48 hours in an appropriate clinical setting when starting concomitant amiodarone and antiviral treatment
  – due to the long half-life of amiodarone monitor patients who stopped it within the last few months and need any of the antiviral combinations
  – advise patients to watch out for signs and symptoms of bradycardia and heart block, and to get medical help urgently if they experience any of these symptoms:
    • shortness of breath
    • light-headedness
    • Palpitations
    • fainting
Introducing biosimilar versions of infliximab: Inflectra and Remsima

- Use of biosimilars can reduce costs, allowing more treatment with new medicines but appropriate follow-up and monitoring systems must be in place to manage risk and patient needs and expectations.
- Developed to provide practical information and advice on the use of biosimilar versions of infliximab (Inflectra and Remsima).
- Presents learning gained from NHS organisations that have introduced biosimilars.
- Examples not presented as best practice but as real-life examples of how NHS sites have planned and managed the introduction of biosimilars.
This months’ papers

• How to make medication error reporting systems work - Factors associated with their successful development and implementation
  Health Policy. 2015; 119: 1046-1054

• Using the Theory of Planned Behaviour to examine health professional students' behavioural intentions in relation to medication safety and collaborative practice
  Nurse Educ Today 2015; 35: 935-40
  http://www.ncbi.nlm.nih.gov/pubmed/25935666

• Medication Safety Climate Questionnaire: Development and Psychometric Analysis
  Journal of Health Science 2015; 3: 1-10
  http://www.davidpublisher.org/index.php/Home/Article/index?id=11287.html  (free full text)

• Primary Care Medication Safety Surveillance with Integrated Primary and Secondary Care Electronic Health Records: A Cross-Sectional Study.
  Drug Saf 2015; 38: 671-82
  http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4486763/  (free full text)
This months’ papers

• Referral letters to the emergency department: is the medication list accurate?
  Irish medical journal  2015; 108: 38-40

• Computerised clinical decision support systems to improve medication safety in long-term care homes: a systematic review.
  BMJ Open. 2015 May 12;5(5):e006539
  http://bmjopen.bmj.com/content/5/5/e006539.long (free full text)

• Color-coded prefilled medication syringes decrease time to delivery and dosing error in simulated emergency department pediatric resuscitations
  http://www.annemergmed.com/article/S0196-0644(14)01661-8/abstract
Antimicrobial-related medication safety incidents: a regional retrospective study in West of Scotland hospitals.


• **Aim**
  – To analyse the characteristics of antimicrobial-related incident reports across a group of secondary care hospitals

• **Methods**
  – Reports were analysed as a full set, and with subset analyses of incidents resulting in patient harm/injury and those included in a multi-variable regression adjusted by occupied bed-days and defined daily doses to better ascertain areas to target for antimicrobial safety.
Antimicrobial-related medication safety incidents: a regional retrospective study in West of Scotland hospitals

• Results
  – 1,345 incidents were reported at a crude rate of 0.98 reports/day (95% CI 0.93 to 1.03 reports/day).
  – Penicillin (371 reports; 27.6%), aminoglycosides (358; 26.6%) and glycopeptides (210; 15.6%) were the most commonly involved classes of medications.
  – Most incidents involved no injury/harm (514; 38.2%), but 72 reports (5.4%) did result in patient harm.
  – The rehabilitation/assessment (RR 2.61, 1.70 to 4.03) and women/childrens (RR 2.04, 1.39 to 2.99) directorates had higher incident reporting rates compared with other directorates, likely as a function of at-risk patient populations.
  – Among the types of incidents reported, those involving issues with administration/supply were most common (RR 2.07, 1.51 to 2.84).
Antimicrobial-related medication safety incidents: a regional retrospective study in West of Scotland hospitals

• Conclusion
  – antimicrobials should be considered as an important focus in improving medication safety due to their widespread use across the clinical spectrum, and significant contribution to medication-related incidents.
  – increased rates of event reporting were identified among the women/childrens and rehabilitation/assessment directorates, and follow-up will be needed to determine if this is a function of increased awareness for reporting or higher overall risk within antimicrobial use.
  – targeting at-risk paediatric and elderly patients may provide a useful focus for efforts to enhance medication safety.
  – Allergy-induced harm events were also identified as an important area for quality improvement
Examining the attitudes of hospital pharmacists to reporting medication safety incidents using the theory of planned behaviour.


• **Aim**
  – To assess the effect of factors within hospital pharmacists' practice on the likelihood of their reporting a medication safety incident.

• **Method**
  – Theory of planned behaviour (TPB) survey.
  – 270 hospital pharmacists in 21 general and teaching hospitals in the North West of England were invited to participate (response rate = 45%)
  – Participants completed a TPB survey, based on a prescribing error scenario that had resulted in serious patient harm.
  – Multiple regression was used to determine the relative influence of different TPB variables, and participant demographics, on the pharmacists' self-reported intention to report the medication safety incident.

• **Outcomes**
  – The TPB variables predicting intention to report: attitude towards behaviour, subjective norm, perceived behavioural control and descriptive norm
Examine the attitudes of hospital pharmacists to reporting medication safety incidents using the theory of planned behaviour

- Results
  - Overall, the hospital pharmacists held strong intentions to report the error
  - Senior pharmacists were more likely to report.
  - Perceived behavioural control (ease or difficulty of reporting), Descriptive Norms (belief that other pharmacists would report) and Attitudes towards Behaviour (expected benefits of reporting) showed good correlation with, and were statistically significant predictors of, intention to report the error \[ R = 0.568, R(2) = 0.323, \text{adjusted } R(2) = 0.293, P < 0.001 \].
Examining the attitudes of hospital pharmacists to reporting medication safety incidents using the theory of planned behaviour

• Conclusions
  – Efforts to improve medication safety incident reporting by hospital pharmacists should focus on their behavioural and control beliefs about the reporting process.
  – This should include instilling greater confidence about the benefits of reporting and not harming professional relationships with doctors, greater clarity about what/not to report and a simpler reporting system.