Minutes: Confirmed

Guideline Development Group Meeting 1

Sepsis: The recognition, diagnosis and management of severe sepsis

Date and Time: Friday 11 July 2014 1000 - 1600

Place: Rosenheim and Pickering Room, Royal College of Physicians, 11 St Andrews Place, London NW1 4LE

Present:
- Saul Faust (Chair) (SF) Professor of Paediatric Immunology & Infectious Diseases & Director, NIHR Wellcome Trust Clinical Research Facility, University of Southampton
- Richard Beale (RB) Clinical Director of Perioperative, Critical Care & Pain Services and Consultant in Intensive Care Medicine
- John Butler (JB) Consultant in Emergency Medicine & Critical Care Medicine
- Enitan Carrol (EC) Chair in Paediatric Infection/Honorary Consultant, University of Liverpool Institute of Infection and Global Health
- Simon Nadel (SN) Consultant/Reader in Paediatric Intensive Care
- Julian Newell (JN) Corporate Matron, Patient Safety
- Jenny O’Donnell (JOD) Patient member
- Rachel Rowlands (RR) Consultant in Paediatric Emergency Medicine
- Alison Tavare (AT) General Practitioner
- Louella Vaughan (LV) Senior Clinical Research Lead, Northwest London CLAHR
- James Wenman (JW) Clinical Development Manager
- Saskia Cheyne (SC) Research Fellow, NCGC
- Margaret Constanti (MC) Health Economist, NCGC
- Lina Gulhane (LG) Joint Head of Information Science, NCGC
- Yasmina Hedhli (YH) Project Manager, NCGC
- Norma O’Flynn (NOF) Guideline Lead, NCGC
- Silvia Rabar (SR) Senior Research Fellow, NCGC
- Julie Robinson (JR) Information Scientist, NCGC

Apologies:
- Jill Cobb (JC) Information Scientist, NCGC
- Mark Simmonds (MS) Consultant in Acute and Critical Care Medicine
- Vicki Pollit (VP) Senior Health Economist, NCGC
- Catherine White (CW) Patient member

In attendance:

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<th>NICE Staff:</th>
<th>Caroline Keir, Guidelines Commissioning Manager</th>
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<td>Emma Chambers, Public Involvement Programme Lead</td>
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Observers:
NCGC staff | Quyen Chu, Senior Project Manager
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**Notes**

1. **Welcome, introductions and declarations of interest**
   SF welcomed the group to the first meeting of this guideline development group. Each member of the group introduced themselves and their interest in Sepsis.

   The declarations of interest for the group were covered under item two.

   Apologies were received from JC, MS, VP and CW.

2. **Introduction to NCGC and declarations of interest**
   The GDG was given introductory presentations on working with NICE, the NCGC guidelines programme and the NICE declarations of interest policy.

   Individual declarations of interest made on application were declared and discussed by the group.

   **Saul Faust**
   Non-personal pecuniary interests: Clinical Trial investigator for commercial clinical trials (acting on behalf of the University of Southampton and University Hospital Southampton NHS Foundation Trust), all NIHR portfolio commercial studies. Any grants, honoraria or fees paid to University or Trust. Two of these trials are: In 2012-2014 he was UK Chief Investigator for GSK quadrivalent influenza vaccine paediatric clinical trials (QIV004 and 009) and in 2014-2016, UK Chief Investigator for Cubist trial of antimicrobial agent in paediatric bone and joint infection. SF is co-investigator on a Pfizer-funded investigator led study in pneumococcal molecular epidemiology. SF attended a meeting of experts in April 2013 arranged by equal convenors: Astellas, Cubist & Actelion, to discuss generic issues related to C difficile infection in infants.

   Personal non-pecuniary interests: involved in sepsis research since 1996, as an investigator and co-investigator in MRC and pharma-funded clinical research and trials in paediatric sepsis. Current Chief Investigator on a UK AMRC Charity (Meningitis Research Foundation) funded, NIHR MCRN adopted, pilot phase 2 study of corticosteroids in paediatric sepsis, which will report in Q4 2014.

   **Richard Beale**
   Non-personal pecuniary interests: consulting work for industry with funds paid to departmental research budget. Recent work has been for infection diagnostics for the Waters Corporation and a Technology Strategy Board (TSB) grant was received in partnership with Edinburgh and Newcastle Universities and BD biosciences, to develop new sepsis biomarkers.

   Personal non-pecuniary interests: current member of the Steering Committee of the Surviving Sepsis Campaign. Previous Chair of Research Committee of European Society of Intensive Care Medicine (2010 - 2013), and Executive Committee Member. Attended a Waters Scientific Advisory Board meeting on 10 December 2013.

   **John Butler**
   Personal pecuniary interest: In January 2013 received travel and accommodation from Thermofisher to discuss biomarkers and experience with PCT in clinical practice.

   Personal non-pecuniary interests: Member of the Faculty of Intensive Care Board, as the College of Emergency Medicine Representative, with full voting rights. Member of the UK Sepsis Trust and has utilised their Survive Sepsis educational material to conduct Sepsis study days within his Trust. Attended a Houses of Parliament meeting in September 2013 following an invitation from the UK Sepsis Trust, to Lobby MPs on the importance of sepsis as a major healthcare issue. Involved in evaluation of the biomarker PCT in critical care
Enitan Carroll
Non-personal pecuniary interests: TSB grant holder for the development of a point of care test for sepsis with two UK SMEs. Institution (university) has filed a patent on her behalf, for a biomarker combination for sepsis.

Personal non-pecuniary interests: working in collaboration with Biomerieux and Brahms. EC’s publications usually end with a statement stating that development of tools for early diagnosis of sepsis are a research priority. EC is also a member of two NIHR panels; RfPB and i4i. In addition, EC is a co-opted member of a NICE diagnostic assessment committee, which is looking at Procalcitonin. EC has personal experience of septicaemia.

Simon Nadel
Personal pecuniary interest: consultant and advisory board member for Novartis Vaccines. SN also sits on advisory boards for Novartis, Pfizer, Baxter and Abbvie and receives money for expenses and travel.

Non-personal pecuniary interests: SN is in receipt of an educational grant and a research grant from Pfizer.

Personal non-pecuniary interests: member of Scientific committee for Meningitis Research Foundation and Meningitis Now charities, Scientific committee for British Paediatric Surveillance Unit, Writing Committee for American Academy of Pediatrics, Sepsis Guidelines Group, Secretary of the European Society for Paediatric and Neonatal Intensive Care.

Julian Newell
Personal non-pecuniary interests: advisor to NCEPOD Study: Sepsis and volunteer for the UK Sepsis Trust.

Jenny O’Donnell
Personal non-pecuniary interest: lead volunteer for the UK Sepsis Trust.

Rachel Rowlands
Personal non-pecuniary interests: department’s audit lead and paediatric governance lead. RR also has a clinical interest in improving the process to better outcomes in septic children.

Alison Tavare
Personal family interest: her husband is in receipt of grants from the Wellcome Trust, Cancer Research UK, EPSRC and Diabetes UK.

Personal non-pecuniary interests: personal experience of sepsis and also involved in raising awareness of sepsis amongst clinicians at North Bristol Trust, GP practices in Bristol and Eastwood Park Prison, Gloucester.

Louella Vaughan
Non-personal pecuniary interests: LV is a collaborator in a research project which has received non-financial support, in the form of equipment, from Thermofisher. LV also works on NIHR research projects that have received funding from industry partners (Thermofisher).

Personal non-pecuniary interest: Council Member and Research Lead for the Society for Acute Medicine and has publicly supported the National Early Warning System (NEWS).

James Wenman
Non-personal pecuniary interest: in 2012/13, his employer, the South Western Ambulance Service (SWASFT) embarked on a joint project with Daiichi Sankyo (pharmaceutical company), developing the first electronic referral pathway for patients with atrial fibrillation. This project was funded partly by Daiichi Sankyo (£10,000) matched with the equivalent of unit 4 years ago. Has presented his departmental experience at meetings and has received travel and accommodation expenses from Thermofisher. Involvement in meeting organised by Advancing Quality Alliance to produce a set of clinical standards which could be used to assess clinical performance in the management of patients with sepsis.

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Professional managerial input and training by SWASFT. The £10,000 was spent directly on the project, purchasing the licence for the required software to facilitate to the pathway. JW negotiated the funding and the payment was made directly to the Trust.

The remaining GDG members all declared that they knew of no personal specific, personal non-specific, non-personal specific or non-personal non-specific interest in the development of this guideline.

3. **Sepsis scope**
The GDG was given a presentation on the scope.

4. **Searching for the evidence**
The GDG was given a presentation on the methods used to search for the evidence.

5. **Reviewing the evidence and protocol setting**
The GDG was given a presentation on the methods used to review the evidence and set protocols.

6. **Health economics**
The GDG was given a presentation on health economic methods used in clinical guidelines.

7. **Introduction to NICE**
The GDG was given an introductory presentation on the NICE Centre for Clinical Practice’s guidelines programme and the NICE patient and public involvement programme.

8. **Review protocols**
The GDG discussed the following review protocols:

   a) What is the most effective way of improving the recognition and diagnosis of sepsis and severe sepsis?
   
   b) What is the prognostic value of different symptoms and signs, alone or in combination (including signs & symptoms scoring systems) compared to a reference standard in the diagnosis of sepsis?

   c) What is the diagnostic and prognostic accuracy of blood tests (blood gas [arterial, venous or capillary]; glucose; lactate; full blood count [haemoglobin, platelets, white cell count and differential]; urea and electrolytes; clotting screen; C-reactive protein [CRP]) compared to a reference standard in the diagnosis of sepsis?

9. **Summary of next steps**
The GDG was given an overview of what areas the remaining meetings would cover.

10. **Any other business**
None.

**Date, time and venue of the next meeting**
Friday 5 September 2014 from 1000 - 1600
Rosenheim and Pickering Room, Royal College of Physicians, 11 St Andrews Place, London NW1 4LE