Introduction

- The National Institute for Health and Clinical Excellence (NICE) commissioned the National Clinical Guidelines Centre (NCGC) to produce a rapid update of the anaemia management in people with chronic kidney disease (AMCKD) guideline (2006)
- New updated guideline published 2011
- This presentation will describe the lessons leant

New evidence

- Evidence emerged with safety implications to two original recommendations
  - Threshold for commencing anaemia treatment in question –
    Hb ≤ 11 g/dl (C) (or 10 g/dl if younger than 2 years of age).
  - Maintenance cut offs in questions –
    Hb 10.5 - 12.5 g/dl for adults and children older than 2 years of age, and between 10 - 12 g/dl in children < 2 years of age.
    Achieved by:
    - Adjusting treatment when Hb > 12.0 or < 11.0 g/dl.
    - Taking patient preferences, symptoms and comorbidities into account and revising the aspirational range and action thresholds accordingly.

Partial & rapid update – differences in time scale

Partial update	Rapid update
When: Review for update takes place	
3 yrs post publication	New safety evidence impacts upon the recommendation
Timeline: Months from commission ➔ publication	
18	10
Development period: Number of GDG meetings to review evidence	
~ 8	~ 3

Partial & rapid update – differences in development process

Partial update	Rapid update
Scope	
Scope goes out to stakeholder consultation when new key areas have been identified	No scope public consultation period
Guideline development group	
Recruit a new GDG (original members can apply)	Original GDG reconvened
Question development	
Develop clinical questions with GDG	Developed clinical questions with clinical advisor

Challenges and solutions?

- **Time**
- **Methodology**
- **Process**

Time issues

Time issues	
Issue	**Solution**
Presented clinical review at first GDG In full guidelines or partial updates spend the first GDG determining the questions with the GDG	Met with clinical advisor in advance of the first meeting and completed the clinical reviews
Health economics (HE) model was also discussed at the first meeting In full guidelines or partial updates would discuss the HE model once clinical reviews completed	Existing model could not be simply updated and had to be rebuilt Very important to have careful up front specification and agreement of HE model structure, data sources and assumption to ensure was deliverable

Time issues continued

Time issues	
Issue	**Solution**
For the second GDG Had to make any changes to the clinical review Build the HE model and present	Health economist and clinical reviewer worked closely to determine how clinical data would be analysed; meant health economist was involved with clinical reviewing Involved limiting the scope of the HE analysis so could be achieved in the timelines
Limited time to make corrections Clinical corrections had to be done between 2 meetings Limited opportunity to make changes to the HE model	Discussion and agreement to changes was outside of GDG meetings with HE subgroup, most decisions were made upfront at GDG meeting

Methodological issues

Methodological issues	
Previous guideline	**Rapid update**
Guidelines Manual, 2005 - no GRADE, narrative summaries to present evidence	Using GRADE profiles to summarise evidence and present evidence following Guideline Manual, 2009
	Differences in quality grading
	Difficulties incorporating old & new evidence
	Time taken to explain new methods to the original GDG members at first GDG meeting
	Augment / re build HE model in limited time

Process issues

Process issues	
Issue	**Solution**
Integrating new recommendations with original guideline - new recommendations contradicting existing ones	Work with clinical advisor to identify where new recommendations will affect existing recommendations to ensure consistency
Style and format - only had a digitised version of the guideline without headings, tables figures etc.	Formatting is easier and faster with the new NCGC template
Validation - stakeholders commenting on non-updated parts of the guideline	

Final guideline

- Reworded recommendation reflecting safety evidence
- HE model – update of 2 recommendations
- A guideline that the GDG were happy with and reflected current evidence

Final guideline continued

- Threshold for commencing anaemia treatment
  - their Hb level falls to 11 g/dL or less (or 10.5 g/dL or less if younger than 2 years) or,
  - they develop symptoms attributable to anaemia (such as tiredness, shortness of breath, lethargy and palpitations).
- Maintenance cut offs in questions –
  - Hb 10 - 12 g/dl for adults and children older than 2 years of age, and between 9.5 – 11.5 g/dl in children < 2 years of age. Achieved by:
    - Adjusting treatment before Hb level is outside the aspirational range before adjusting treatment
    - Taking patient preferences, symptoms and comorbidities, the required treatment
- Consider accepting differing Hb levels above or below the agreed aspirational range depending on individual patient situations and treatment response

Conclusion

- When new evidence emerges, recommendations may need rapid update
- Factor in time to account for:
  - methodological changes
  - building HE model in short space time
  - re-educating GDG in changes
  - style and format – integrating old into new to ensure one product
- Beware of short timelines: adapt process accordingly
- Save time by trying to re-recruit original GDG