NHS England

Regional Medicines Optimisation Committees – Workshop Outputs from 20 April 2016

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Please note this document is a summary of a meeting discussion and is for information only. Whilst acknowledging that the document raises more questions than provides answers, a more focused discussion document is in preparation and will form the basis of wider engagement moving forward.

Contents

1 Introduction

The Accelerated Access Review highlighted the need to reduce unnecessary barriers to patients receiving the medicines they need. A long held concern is how new medicines, or some new indications of existing medicines, which are not evaluated by the NICE TA programme, are instead evaluated many times across the NHS. NHS England has committed to help eliminate unnecessary duplication of effort, and instead refocus scarce resources towards implementation activities, and in particular, achieving best value and patient outcomes from all medicines through implementation of medicines optimisation – achieved in a manner that integrates medicines optimisation into the Right Care programme.

The best way to achieve this is to bring those activities to a regional level, and to ensure any evaluation activity is co-ordinated and shared across the four regions. This approach should free up pharmaceutical and other staff at CCG and Trust level to focus on implementation duties, it will also ensure medicines are evaluated once only, whether by NICE or regional committees, and results shared.

The committees must be established in a way which engages hospitals, CCGs and other key stakeholders and there must be confidence in the membership, workings and outputs of the committees. The outputs must not undermine the financial and clinical governance duties that rest with individual hospitals and CCGs. The committees must also have the confidence of pharmaceutical manufacturers so that they feel their products are being treated fairly though processes which are transparent and objective.

2 Workshop

As a first step towards establishing Regional Medicines Optimisation Committees (RMOC), NHS England held a workshop, on 20th April 2016, with a broad range of NHS colleagues, to begin the process of agreeing the principles which will form the foundations of the committees. The main focus of the workshop was for attendees to discuss the following key issues:

2.1 What are the principles under which the RMOCs will operate?

- Will they provide clear guidance on the place in therapy of a medicine within a pathway?
- What are the committees not doing and leaving to local Drug and Therapeutic Committees?
- If decision making, will they categorise medicines in a manner similar to our and other APCs?
- Will there be a phased approach for implementation?
- Will financial decisions be taken?

2.2 What does the governance structure look like?

- Will the regional committees be decision making or will they only produce evaluations for local consideration?
- If the regional committees will be decision making, is there anything in place that would mean CCGs have to implement as CCGs are free standing statutory organisations?
- Are the outcomes mandatory or recommendations in terms of choice for local implementation?
- Outcome may be an option to use, in this context, in this patient population etc. Where will responsibility for implementation sit?

2.3 What does the membership of the Committees look like?

- What is the right structure for the groups?
- How to achieve wide scale engagement across the regions – what are the communication channels for achieving this.
- How will the Committees work with Industry?
- How will the groups ensure wide scale engagement across the regions?

2.4 How will the work plan be allocated?

- Every geographical area has different priorities, how will the work plan/areas of focus for the regional committees be decided?
- Will the regional Committees share work and make single decisions on news drugs/indications for the whole of England?
- What's the interface with NICE/NHSE/DH?
- How is Conflict of Interest managed?

3 Next step

Whilst there is still much to do, NHS Clinical Commissioners and NHS England will be working together to take forward the establishment of the Committees. As an immediate next step, a write up of the discussions from the workshop is provided below which will form the basis of our next phase of consultation.

We would welcome comments in relation to the discussions on the four key issues that will underpin the establishment of the Committees.

4 Workshop discussion

4.1 What are the principles under which the RMOCs will operate?

There was clear discussion on each of the tables regarding the role of the committees and that these should “recommend and not mandate”. The committees must “add value” to the service to gain credibility. They should look at the gaps in the current system and fill these.

Underpinning these recommendations, each region MUST work to the same process with a possible peer review of the process. There should be:

- a clear evaluation process;
    - a clear process of prioritisation for the committee (s) –
    - so all relevant organisations know how to put proposals forward and publish a clear forward work plan and say what is NOT included; and
- which allows the system to help prioritise i.e. CCGs/Trusts and national feed in to the work plan process.
- responsive timescales, which are published. Evaluations should be timely, not dragged out and comprehensive;
- a process which allows for local implementation;
- recognition that the process of horizon scanning is key. New drugs / treatments not in the NICE pipeline should be prioritised;
- a clear statement on the governance of these committees, where they report nationally and how the work will be evaluated.

Where shared decision making or shared care guidance would seem sensible, it would be appropriate for the committees to co-produce, with one another, and either commission a template or signpost to available resources, to help CCGs and support local implementation–where ever possible. Decisions should allow for local implementation.

There should be a balance between recommendations which are pragmatic and those suggested by "purist" health economics? Recommendations should be clear about how they were formulated and methodology should be published.
In addition to recommendations derived from medicines review/evaluation, the RMOCs should identify and address "topics for review" i.e. identify examples of apparently unwarranted variation or specific clinical topics and produce guidance for APCs on them? This should link to the recommendations of the Carter Review and the Right Care programme.

The Committees should not be seen as a performance management system but variation across the system could be highlighted and commented upon. The Committees should help, guide and steer the local NHS. For positive recommendations – the Committees should follow up to see the impact. For negative recommendations - Committees should publish details of observed variation and ask the question of the system, inviting justification?

RMOCs should develop a role of assuring best practice in use of high-cost medicines which are not subject to review by NICE.

Further issues and questions raised:

- Will all evaluation be done solely by SPS staff or will other potential partners be invited to be involved?
- What about disinvestment – will the RMOC address this issue and produce recommendations? – this would be valued;
- Can medical devices and branded medicines be included in the remit?
- Recommendations should be clear and concise;

- Are we developing a national formulary?
- Biosimilars – can the committees provide guidance for managing adoption by local health economies?

4.2 What does the governance structure look like?

Discussions in this section considered issues of how the RMOCs would interface with the existing NHS Structure, the status of outputs from the committees, committee management and performance management and membership of the committees and communications.

4.2.1 Issues around relationships with the existing NHS structure

- Clarity of DH/NHSE/NHSCC expectations is essential. Should RMOCs work to a mandate?
    - About scope
    - For RMOCs
    - For APCs
    - Is there a potential conflict with sub-regional initiatives such as Devo Manchester or with STPs?
- RMOCs are in a legislative vacuum; they are not statutory bodies; whereas CCGs are:
    - but there are legal flexibilities.
- RMOCs have distinct categories of work and audiences with different priorities:
    - Acute v Primary Care;
    - Non-NICE vs NICE gap vs other meds;
    - Old as well as new;
    - National vs Regional vs Local vs Individual;
    - But the real audience should be whole health economies.
- ROMOCs will work & engage across big geographies:
    - Local engagement, interpretation & implementation should be through/managed by re-tasked APCs;
    - RMOC/APC relationship critical;
    - RMOC/CCG relationship is secondary to that.

4.3 The status of the outputs from the committees

- Outputs must be authoritative & credible advisory but not mandatory:
    - “You can’t appeal against a recommendation” even if 100% CCGs happen to accept it!
- Appraisals and advice must reflect care pathways and context of medicines use, not medicines in isolation:
    - Appraisals should look at groups of meds wherever possible;
    - How to frame advice where there are legit treatment options rather than yes/no recommendations;
    - Concepts of “minimum effective treatment”, “prudent treatment”, “comply or complain and justify”;
    - About value not about cost;

- Clinical efficacy & safety vs affordability & funding;
- How would Avastin vs Lucentis be addressed by an RMOC?

4.4 Committee Management and Key Performance Indicators

- Need high and lower level KPIs & monitoring of local impact:
  - Level of local compliance should be a good indicator of RMOC performance?
- Peer Review for QA of RMOC processes performance.
- Use examples of existing good practice and replicate them:
  - SMC sets many good examples;
  - The English Medicines Optimisation Committee EMOC (r x 4)?
  - North East Technology Advisory Group.
- What are the levers to manage (GP) compliance/not?
  - Especially Dispensing GPs!
- Incentives to do the right thing preferred to sanctions for having done the wrong thing:
  - Should/could compliance be linked to access to STP funds?

4.5 Committee Membership and Communication

- Credibility of RMOC membership, processes, advice will be critical to success:
  - Transparency;
  - "Build it in public";
  - Build on and engage existing structures, functions and expertise;
  - Wisdom vs evidence;
  - "Earned authority";
  - Timeliness;
  - Equity & engagement:
    - Pharma, via ABPI?
    - Citizens vs patients.
  - Two way communications:
    - It hasn't started as well as it might have done;
    - Some CCGs already feel excluded;
    - Adequate time for effective consultation;
    - Draft – Consult – reflect-revise-publish;
    - Flexibility for rapid review e.g. for NICE gap meds; and
    - Escalation & feedback.

4.6 What does the membership of the Committees look like

Discussions around membership considered a Core membership vs variable membership. Core membership should have no conflicts of interest.
The following groups were identified:

- Patient and public voice should be represented;
- Nice regional leads should be utilised;
- Membership of the RMOCs should mirror that of the SMC;
- Should it be an English Medicines Consortium (EMC) --- do you need RMOCS?

- Industry standing or invited;
- Health economic expertise;
- CCGs;
- Trusts; and
- NHS England.

4.7 How will the work plan be allocated?

Four steps were identified as being key to this development. These were setting priorities for the committees, sharing of information and decisions, the interface and interests.

4.7.1 Setting Priorities

Horizon scanning would form part of this process. The Specialist Pharmacy Service should lead on this. The process of horizon scanning should take into account all stakeholder views. The process this should be linked to the planning round and should take a feed from national organisations.
The process should be both flexible and timely.

4.7.2 Sharing of Information and decisions

The priority setting process should be signed off and shared. Each review of medicines should have a single decision making process which applies nationally. The review should issue a priority statement “best practice recommendation with teeth”. It should be a recommendation in context which links with the Right Care programme and link to pathways. Implementation plans and support tools should be issued with the recommendations and decision making process.

4.7.3 Interests

The committees require clinicians from the front line – free of conflicts of interests. Declarations of interest need to be transparent.
Representatives from trade groups.

4.7.4 Interface

Key metrics should be available.
The RMOCs should interface with the following areas:

- Royal Colleges;
- Local Authorities;
- PHE;
- NHSI;
- DH;
- NHS CC;
- NHSE; and
- APCs and their engagement should be maintained.

This process was described as a medicines hopper with medicines falling into the completion of a NICE TA, other medicines are passed into the committee and a decision is made around keeping this medicine and review and pass out.

4.8 Concluding Comments from the workshop

NHS CC and NHS England would work together to promote and consult on the work. This would be conducted via a time limited working group. This group would consider where there was agreement on the role of the RMOCs, the principles and governance and where there is not. To enable this some examples would be taken and "walked through". This would be an iterative process using a semi-delphi technique.