

Tough Decisions

Local decision-making about medicines

Issue 06 January 2012

Local decision-making news...in brief

Since our last newsletter in August, several papers and reports have reiterated the importance of effective systems and processes for making decisions about the funding and commissioning of medicines and treatments. As the NHS reforms continue to develop it is essential that commissioners and clinicians continue to make population and individual patient funding decisions in a manner that is robust, rational and defensible.

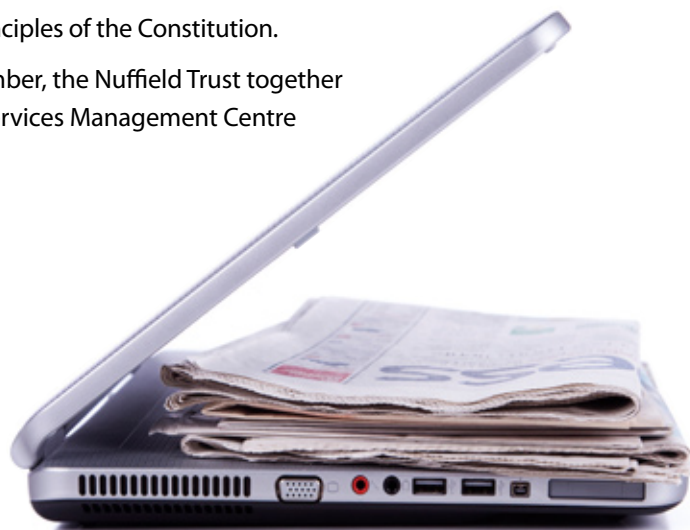
In September, the Department of Health published *Developing clinical commissioning groups — Towards authorisation* <http://tinyurl.com/tdi6-a>. This indicates that it is likely that clinical commissioning groups will have to demonstrate a number of core requirements including “acting with a view to securing that health services are provided in a way which promotes the NHS Constitution <http://tinyurl.com/tdi6-c>, and to promote awareness of the NHS Constitution amongst patients, staff and the public”. Transparent local decision-making systems and processes that include active patient and public involvement are intrinsic within the principles of the Constitution.

Also in September, the Nuffield Trust together with Health Services Management Centre

(HSMC) at the University of Birmingham published the outcome of an extensive review of the priority setting and decision-making processes of eighty primary care trusts (PCTs). The aim of the review was to consider how decisions about funding priorities are made by commissioning organisations. The report, *Setting priorities in health* <http://tinyurl.com/tdi6-d>, confirms that while most PCTs have established robust systems in relation to funding new services and exceptional treatments, in some cases the same rigour may not be applied to core spending. The report highlights a need for tackling disinvestment locally by commissioners.

The following summary has been provided by HMSC and further information can be found on their website <http://tinyurl.com/tdi6-e> and the commissioning pages of the Nuffield Trust website <http://tinyurl.com/tdi6-f>.

“Several of the PCTs that took part reported good progress in respect of their priority-setting activities. However, the majority identified more weaknesses than strengths.



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Obstacles to effective priority setting included:

- Finding sufficient evidence on which to base decisions;
- The tendency for priority setting to take place at just one point in the financial year;
- A typically narrow focus that fails to reach across health economies;
- A lack of involvement from local authorities, patient groups and the public;
- The seeming reluctance to tackle significant disinvestment decisions, despite this being acknowledged as a key priority.

The report's authors conclude that priority setting has proved difficult for PCTs, and that to succeed in future, GP commissioners in clinical commissioning groups will need to move this activity beyond the comfort zone of new and marginal expenditure, and tackle the core spend for which they are responsible".

Dr Suzanne Robinson, Lecturer in Health Economics and Health Care Policy at HSMC and lead author comments:

'Priority setting is moving centre-stage. However changes brought about as a result of the Health and Social Care Bill mean there is a

risk that knowledge around priority-setting tools and processes will be lost as organisations disband and staff scatter into new posts.'

'The issue here is to make sure that the learning is transferred to the new world of clinical commissioning. While politicians may want to move away from past government policy, the expertise and learning from the evolution of commissioning over the last ten to fifteen years is crucial to meeting the efficiency challenge.'

In October the Royal College of General Practitioners (RCGP) published Making Difficult Choices — Ethical Commissioning Guidance for General Practitioners <http://tinyurl.com/tdi6-g>. The document focuses on challenging ethical dilemmas for GPs as they become commissioners, but the principles stated within the guidance are applicable to all personnel involved in setting priorities for funding allocations at a population level, as well as making decisions for individual patients.

Also of interest was the publication *Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS*, December 2011. The document outlines a number of themes to improve uptake of innovation in the NHS. One of the key themes is reducing variation in the NHS and driving greater compliance with NICE guidance.

How the NPC and NICE can help you and your commissioning groups

The documents outlined above reinforce the need to ensure all members of decision-making committees and panels are appropriately trained and have the knowledge and skills to contribute to the decision-making process.

The **Local decision-making** www.npc.nhs.uk/local_decision_making/ pages on the NPC website contain a range of tools and resources to support training and development.

e-Learning resources

The e-learning resources can be particularly helpful for new committee members to understand the principles of priority setting, the legal and ethical framework in which to make decisions, basic terminology and concepts of health economics www.npc.nhs.uk/local_decision_making/elearn_health.php.

The resources can also be used as part

of structured training and development sessions for established committees.

There are also two short guides <http://tinyurl.com/tdi6-h> and <http://tinyurl.com/tdi6-i>

that provide a brief summary of the principles of local decision-making, including the requirement to set priorities as part of the annual commissioning round and the need to develop funding policies. The guides also outline the requirement for commissioning organisations to have a mechanism for clinicians to apply for funding for a medicine for an individual patient where the funding policy is to not routinely fund that medicine in accordance with Secretary of State Directions March 2009.

Competency framework for local decision-makers

There is currently no national resource

outlining/ describing the skills and knowledge required by members of local decision-making committees, or to enable the assessment of training needs for committee members.

The NPC has recently started to develop a framework guidance document that will set out the skills and knowledge needed for senior and operational managers, professionals, clinicians and lay people directly involved in making local NHS commissioning decisions. The framework will support the development of individuals in decision-making groups and provides a basis for organisation, group or self-assessment.

Local decisions need to be made by local NHS commissioners;

- As part of the overall setting of priorities for healthcare spend at the

local level

- When considering specific questions of investment and disinvestment whether at a population, care group or individual level.

The guide will support priority decision-making on a population basis, whether as part of the annual commissioning round, or in-year policy decisions that cannot wait for forthcoming planning rounds, as well as individual funding requests (IFRs) submitted by clinicians.

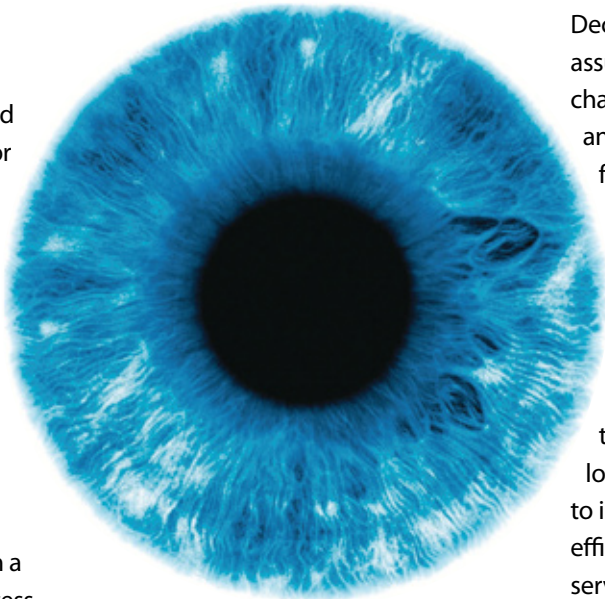
The framework will be available on the NPC website in Spring 2012.

NHS Evidence — information portal

Funding decisions about medicines and treatments, whether for a population or as an individual funding request need to be made based on consideration of the best available evidence. **NHS Evidence** launched in April 2009 and provided by NICE, is a web-based information portal that provides access to high quality, evidence-based literature and examples of best practice. The service was expanded in May 2011 and now brings together a greater range of clinical resources, with a key focus on medicines. It provides access to more than 250,000 resources from 1,500 sources — including guidelines, systematic reviews, evidence summaries, commissioning guides, policy documents and on-going trials.

As well as providing resources to support the management of established medicines within pathways and new medicines that may impact patient care, NHS Evidence can support the equitable commissioning, or decommissioning of services. For example, when considering the evidence for commissioning a new or redesigned service, NHS Evidence can provide access to disease prevalence models, health profiles and interactive maps produced through the Association of Public Health Observatories. The *Patients at Risk of Re-hospitalisation* (PARR) risk prediction system to identify patients at high risk of hospital re-admission can also be accessed from the site.

NHS Evidence includes carefully selected submissions from organisations which can be relied on for providing good quality information. Specific organisations whose guidance processes meet the exacting standards set by NHS Evidence are approved under its accreditation scheme. Thirty three guidance development processes have been accredited between 2009 – 2011, including the National Patient Safety Agency (for rapid response reports) and the Medicines and Healthcare products Regulatory



Agency (for Pharmacovigilance Public Assessment Reports, Device Bulletins and Public Assessment Reports). Accredited guidance development processes are clearly denoted on all search returns through an accredited mark (right), so are easily identifiable to users.



For the development of Quality Standards, the national markers of high-quality, cost-effective patient care covering the treatment and prevention of different diseases and conditions, NICE uses evidence sources accredited by NHS Evidence. Quality Standards will be reflected in the new Commissioning Outcomes Framework and will inform payment mechanisms and incentive schemes such as the Quality and Outcomes Framework (QOF) and Commissioning for Quality and Innovation

(CQUIN) Payment Framework.

Through the NHS Evidence portal, the UK Cochrane Centre provides details of newly published reviews that contain a conclusion indicating that an intervention is harmful, ineffective, or not supported by sufficient good quality evidence and therefore should not be used outside of research. Information provided through this source can support commissioners when making local disinvestment decisions, and reducing patients' exposure to treatments of unproven benefit.

Decision-makers need to make confident, assured decisions about the ever-changing needs of the local population and deliver a sustainable system in the face of the most challenging financial and organisational environment seen in decades. Now more than ever, it is important that commissioners and providers have access to a quality-assured evidence base. In one place, NHS Evidence provides the most up-to-date quality medicines information, local data and commissioning tools to inform the development of effective, efficient and appropriate high quality services.

For further information email:

www.evidence.nhs.uk/contact-us

Supporting the disinvestment of low-value interventions

The constant challenge for commissioners of healthcare is the balance between the increasing need to control costs, to contribute towards the £15-20 billion in efficiency savings required by the NHS by March 2015, whilst protecting the quality of healthcare delivered and patient safety.

Disinvestment is the explicit process of stopping or restricting the use of low-value healthcare practices to enable resources to be shifted to higher-value care. The Coalition Government has reaffirmed the need to place quality of care at the heart of the NHS through the **Quality, Innovation, Productivity and Prevention (QIPP)** agenda.

NICE is committed to support the QIPP

agenda and provide disinvestment guidance to the NHS, including PCTs and local commissioners, by identifying disinvestment opportunities within its existing guidance programmes and making them accessible for the NHS.

To aid local commissioners and NHS professionals to identify interventions that are not effective/cost-effective, or are harmful, NICE has engaged in a range of initiatives:

- **QIPP case studies**, also available on **NHS Evidence**, are a collection of real-life examples of how health and social care staff are improving quality and productivity across the NHS and social care. The case-studies help inform local initiatives to address the quality and productivity challenge.
- **Database of do not do (DNDs) recommendations** collates the disinvestment recommendations where intervention should be discontinued completely, or should not be routinely used in clinical practice. These are abstracted from

NICE clinical guidelines, cancer service guidelines, technology appraisals and interventional procedures guidance. The stand-alone database is available on the NICE website via the "Putting guidance into practice" tab, as well as via each guidance page.

- **Cochrane QIPP** topics summarise disinvestment recommendations that have been identified through systematic reviews, written by health professionals working internationally and published by the Cochrane Collaboration. NICE adds value to these reviews by contextualising the evidence to the NHS, and by providing an estimate of productivity savings, the potential impact on quality of patient care and ease of implementation of these disinvestment recommendations. These summaries are available on **NHS Evidence**.
- **Database on referrals advice (RA) recommendations** supports the NHS to reduce inefficiencies due to inappropriate referrals and to assist the appropriate and timely referral

of patients to secondary services in order to improve quality of care. Recommendations of referrals advice are abstracted from NICE clinical guidelines, cancer service guidelines and public health guidance. The stand-alone database is available on NICE website via the "Putting guidance into practice" tab, as well as via each guidance page.

NICE is continuing to develop these products through its NHS Evidence service to allow for better integration and alignment with other existing NICE products, such as NICE pathways, and to communicate and present disinvestment information in a more meaningful way for local clinicians and commissioners.

For more information about how NICE and NHS Evidence can help support local disinvestment decisions, please visit the cost savings page of the NICE website at: <http://tinyurl.com/tdi6-k> and the QIPP pages of NHS Evidence at: www.evidence.nhs.uk/qipp, or contact the Research and Development team at NICE at R&D@nice.org.uk

New medicines – are you prepared?

The well-established New Medicines Programme of work at the National Prescribing Centre (provided by NICE) aims to provide advanced information to the NHS to support the managed introduction of key new medicines. In this issue of the newsletter we identify some developments occurring in the treatment of diabetes.

In September 2011 the European Committee for Medicinal Products for Human Use (CHMP) adopted a change to the Summary of Product Characteristics (SmPC) for insulin detemir (Levemir) to state that the drug, "can be used alone as the basal insulin or in combination with bolus insulin. It can also be used in combination with oral antidiabetic medicinal products or as add-on therapy to liraglutide treatment".

<http://tinyurl.com/tdi6-l>



However, the same month the CHMP considered an application for a new indication for liraglutide ▼ (Victoza) for the "treatment of type 2 diabetes mellitus in combination with insulin".

Although the CHMP did not consider the study results submitted were sufficient to recommend the addition of a new indication for liraglutide, the Committee concluded that the new data were of importance to healthcare professionals involved in treating type 2 diabetes and recommended that they be included in the product information for liraglutide.

Another development to watch out for is insulin degludec, a once daily insulin analogue depot, for which a licence application for possible use in type 1 and type 2 diabetes mellitus was recently submitted to the European Medicines Agency. Look out for a review of this from the NPC in the Spring.

Managing medicines across a health community – Is your Area Prescribing Committee (APC) fit for purpose?

In the last edition of Tough Decisions, we highlighted the Government's continued commitment to the rights in the NHS Constitution and therefore the need for Clinical Commissioning Groups (CCGs) to have in place robust arrangements for their local decision-making groups. For many health communities, an Area Prescribing Committee (sometimes known as a Medicines Management Committee or equivalent) is one of the key mechanisms used to help make local decisions about the availability of medicines for their patient populations.

As the commissioning landscape develops Area Prescribing Committees (APCs) need to ensure that they remain relevant and fit for purpose.

The NPC Fitness for purpose framework, extracted from the NPC guidance document *Managing medicines across a health community* <http://tinyurl.com/tdi6-m> provides a structure against which APCs can be reviewed. This article outlines the key steps in the framework and describes how three APCs have recently used the framework in practice.

The NPC fitness for purpose framework
Area Prescribing Committees have a long history in promoting cooperation between healthcare providers across a health community. Typically APCs have had a strong local clinical input and the ultimate aim of providing patients with consistent and safe access to medicines across care interfaces.

In recognition of the key role that effective APCs can play, in 2007 the Department of Health (DH) commissioned a fitness for purpose (FFP) framework. The framework was updated in 2009 to reflect the requirements of the NHS Constitution and

the DH guiding principles (<http://tinyurl.com/tdi6-n>) that underpin processes for local decision making about medicines.

The FFP framework itself has typically been used to identify where improvements to functioning APCs might be made, review and restate the roles of APCs in abeyance and to help establish an APC where one does not exist. Given the changes to the commissioning environment and the emergence of new commissioners with different structures and stakeholders, the fitness for purpose review provides health communities with an ideal mechanism to review the ongoing role of their APC.

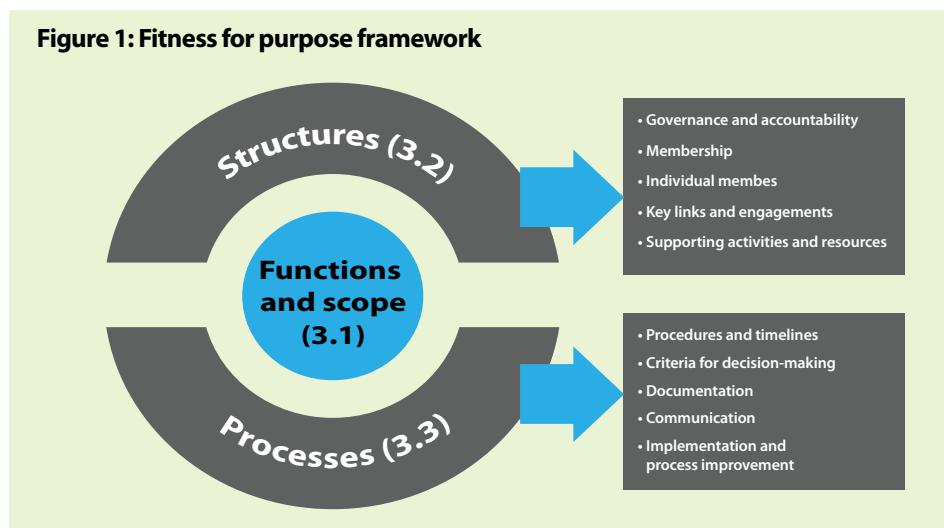
The full FFP framework document can be downloaded from the local decision-making pages of the website (<http://tinyurl.com/tdi6-o>), its structure is summarised in **Figure 1** and described briefly here.

The **first step** in the review is for APCs to define their scope and functions. In this process APCs develop a stakeholder map of all the organisations and groups involved in medicines management. The map helps the APC to understand

its scope and also highlights stakeholder relationships relative to each other. For example, where an APC is making recommendations or decisions about the use of medicines in a health community, it needs to be clearly linked into the wider commissioning and prioritisation processes.

Once the APC's scope is defined a full discussion of its functions follows. The FFP framework lists the functions that APCs can undertake which can be used as a basis for discussions along with the APCs terms of reference, where they exist. At this point the interaction between other existing advisory and decision-making groups needs to be explicitly discussed, such as clinical networks. There needs to be a clear understanding of each others' roles and terms of reference.

The **second step** is a review of the structures that are needed to support the effective delivery of the APCs functions. This step covers areas like governance and accountability, to ensure amongst other things that there is clarity about the status of APC decisions, recommendations or guidance.



The second step also covers membership of the APC and the roles and responsibilities of individual members. This includes a discussion of how to identify the training and development needs of group members (in particular new members) and how patients and lay input might be obtained.

Finally it considers the wider links that APC need to make in their health

communities and importantly the resources needed to support the effective functioning of an APC.

The **third step** is a focus on the processes that underpin the work of the APC. The NHS Constitution requires commissioners to be transparent about local decision-making. APCs therefore need have the resources available to fully document and communicate both their decisions and

the basis on which they were made. This part of the FfP framework (the processes review) is closely linked to the DH guiding principles for local decision-making groups. It covers the need for procedures and timeliness, criteria for decision-making, documentation, communication mechanisms, and implementation and process improvement.

Case Study — Nottinghamshire APC.

The APC review day was attended by around 70% of APC members representing 100% of stakeholder organisations and was held as an additional APC meeting. The report of the review day was discussed at the following APC meeting for actions to be agreed, prioritised and allocated to APC members to take forward.

Some examples of recommendations identified

As the commissioning function moves from the PCT to Clinical Commissioning Groups (CCG):

- Reconfirm the APCs mandate with stakeholder organisations
- Review the stakeholder map to ensure that organisations and their local decision-making groups are linked with the APC
- Update membership, for example to include a public health representative from the Local Authority, to ensure CCGs are appropriately represented

Other actions identified included:

- Improve communication through the website by adding the dates of the meetings and FAQs for members of the public and patients that describe the APC and its functions
- Evaluate how well APC decisions are implemented and develop effectiveness measures. A brainstorm identified some potential measures to be developed into an options paper for the APC.

One action that might be facilitated through the National Prescribing Centre Local Decision-Making (LDM) programme was to link with the NPC's East Midlands facilitator to help raise awareness in provider trusts about the role of the APC and LDM more generally

Feedback following the review day

"These vision things can often be a bit lame but I thought it was really well focused and derived from our input. The action plans seemed really relevant." GP member of APC

What has happened since the review

The Nottinghamshire APC (NAPC) was formed in 2007 and has been fully supported by all member organisations (secondary and primary care). The NAPC has an active Joint Formulary Group (JFG) where two interface pharmacists were recently recruited to take forward the work of the JFG/NAPC. Their posts are jointly funded by all of the member organisations.

We wanted to build on the findings of a stakeholder survey in May 2010, by undertaking the NPC fitness for purpose review. The review allowed us to look at the current systems and processes of the APC to reflect the NHS changes. The review was very timely for us in that the PCTs had moved to shadow form in April to support the emerging clinical commissioning groups.

Some of the actions identified are very pertinent to the ongoing future of the APC, the main one being to agree the mandate of the APC for future decision-making on behalf of the other organisations. Other actions include improving the breadth of information available on the website www.nottsapc.nhs.uk and making it more patient friendly. We are currently in the process of taking of the actions forward and hope to have them completed in the next 12 months.

For more details about what has happened since the review day contact: Nicky Bird (Nicky.Bird@nottspct.nhs.uk)

Case Study — NHS Norfolk and NHS Great Yarmouth & Waveney Therapeutic Advisory Group (TAG)

The APC review day was attended by 83% of APC members, representing 100% of stakeholder organisations. The review was held on the same day as a scheduled APC meeting. The business for the meeting was concluded before the review began. It was agreed that the actions identified at the review day would be taken forward and, that in the future, an agenda item would be included at TAG meetings to enable feedback on progress.

Some examples of recommendations identified

It was agreed that the profile of the TAG should be raised with Clinical Commissioning Groups (CCG), new providers and some Boards of existing member organisations. Actions identified included:

- Production of an annual report of the TAG's activities including the costs associated with running TAG.
- Individual TAG members to ensure that their representative Boards are aware of the TAG's functions and activities. This will include circulating the annual report to key individuals.
- Review of organisations and individuals routinely receiving the minutes of TAG meetings to ensure maximum impact and profile for TAG work.

Feedback following the review day

"It gave us a chance to critically look at what we do and how we do it. This is important as the Group has been around for a while and we don't get the chance to consider our purpose during the usual course of our meetings." Chief Pharmacist Acute Provider Trust

What has happened since the review

The first TAG Annual Report has been completed for circulation to local organisations and stakeholders. The TAG has also reviewed and updated its circulation list for notes, recommendations and for distribution of the Norfolk Prescriber throughout stakeholder organisations

The stakeholder map has already been taken forward within locally developing CCGs as part of discussions around core functions for future commissioning responsibilities. The TAG has received expressions of interest to attend and observe future meeting from local CCG managers.

Internal working groups are being created to look at developing in-house decision-making frameworks and a review and update of the Declaration of Interest policy and the New Medicines Policy. In addition the TAG has begun debating on how to consider and manage the increasing number of NICE-recommended "options" for treatment within Technology Appraisals.

The TAG Lead Pharmacist now has admin support for note taking and production of written records of TAG meetings.

For more details about what has happened since the review day contact: Fiona Marshall (Fiona.Marshall@norfolk.nhs.uk).

Using the framework in practice:

There are a range of uses for the guidance document in practice, including the following two options for using the framework for a fitness for purpose review.

APC internal review — supported by NPC facilitators (www.npc.nhs.uk/npc_facilitators/npc_facilitators.php)

The APC can also be reviewed internally with the support of one of the trained NPC facilitators. The facilitator can work

with a nominated lead from the APC for the review process and provide tools and resources to help plan and deliver the session. The facilitator will be able to provide advice on the formulation of actions although the final review report will be written by the nominated lead for the APC. Contact your local NPC facilitator for more information.

APC internal review — using NPC support materials

The full FfP framework document can

be downloaded from the local decision-making pages of the website (www.npc.nhs.uk/local_decision_making/apc_guide.php), together with a range of additional support resources. The review process can be undertaken internally as part of protected learning and development time for the committee. For further information on how best to approach an internal review contact: Harriet Lewis (harriet.lewis@nice.org.uk) at the NPC.



IFR Manager News

Report from the Individual Funding Request (IFR) Shared Practice & Learning Events (Manchester, Bristol and Leeds)

As part of NPC's on-going support programme for NHS groups making local decisions about the funding of medicines and treatments, we have to-date delivered three shared practice and learning events aimed at those involved in the Individual Funding Request (IFR) process. A fourth event will be held in Leeds on 3rd February 2012.

The feedback and evaluations from the three events have been exceptionally positive, with 95% of the delegates reporting that they found the event useful and will be able to take the learning back to their own organisation.

The events have all followed the same agenda and have included presentations from Jane Williams, Mills and Reeve Solicitors, covering issues related to the legal aspects of IFRs; Dr Amy Ford, Oncology Registrar currently undertaking research into Exceptionality; Jill Russell, Senior Lecturer in Health Policy & Evaluation, Centre for Primary Care and Public Health, Barts and the London School

of Medicine and Dentistry, currently undertaking research into patient and public involvement in IFRs and a representative from the Healthcare Committee of the Faculty of Public Health, providing a public health perspective of Exceptionality.

Delegates at the events have also heard from and had the opportunity to debate with, front line NHS personnel actively promoting the involvement of patients and the public in their decision-making groups.

The afternoon workshop session has been led by Dr Pauline Leonard, National Clinical Lead for the 'Connected' programme from the National Cancer Action Team. This has proved to be a most captivating session. With the assistance of a professional actor, Pauline has been able to demonstrate the challenges of effective communication with patients and clinicians that can occur as part of the IFR process. Delegates have had the opportunity to role play difficult scenarios and analyse where helpful techniques can be applied.

The last of the four events will be held on 3rd February in Leeds. There are still a few places left <http://tinyurl.com/tdi6-p>

Sharing practice

A recent quality and productivity case study has been added to the NHS Evidence QIPP Collection — Improving medicines management: An effective approach to local decision-making. The case study has been provided by NHS Halton and St Helens on behalf of the Mid Mersey medicines Management Board, and has been accredited through the formal processes associated with the collection.

A number of other case studies are available within the QIPP collection that directly relate to systems and processes for local decision-making. They can be accessed through the main search portal or using the following link <http://tinyurl.com/tdi6-q>

Feedback



We welcome your comments about any aspect of this newsletter as well as ideas for contributions for future issues.

Please email the LDM programme manager Harriet Lewis with your suggestions at: harriet.lewis@nice.org.uk

NPC email alerts

The NPC offers a range of dedicated topic areas to which you can subscribe to receive email updates.

After initial registration and selection, the facility allows you to update your contact details and customise and change your selection of email updates to suit your changing and developing needs.

Would you like to subscribe?

Register here:

www.npc.nhs.uk/email_alerts.php

All contributions welcome. Please write to:

National Prescribing Centre, Ground Floor, Building 2000, Vortex Court,
Enterprise Way, Wavertree Technology Park, Liverpool, L13 1FB

Tel: 0151 353 7720, Fax: 0151 220 4334, or email feedback or suggestions to ian.pye@nice.org.uk

The National Prescribing Centre (NPC) is responsible for helping the NHS to optimise its use of medicines. NPC is part of the National Institute for Health and Clinical Excellence (NICE), an independent organisation providing national guidance on promoting good health and preventing and treating ill health.

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