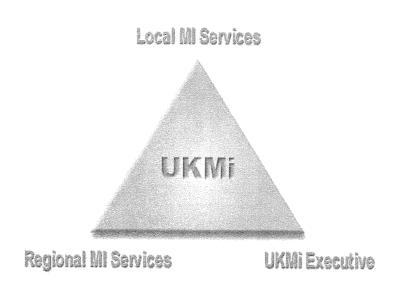
# ノースウィックパーク

- 病院の医薬品情報室(Local MIC)に地域センター(Regional MIC)が併設
- 知 薬剤師 10名
  - 。 ダイレクター: UKMi エグゼクティブ
  - 。マネジャー:新薬レビューリード/教育/運営
  - 。 問い合わせ担当:6人 (band6以上)
- © ロンドン北部 (テムズ川北部) の家庭医からの問い合わせ応対 平日 9:00-17:00
- ∞ 傘下の病院MICとは年2回のRegional Meeting (1日) 勉強会とワークショップ&RegionalからLocalへの伝達事項 新任Local MI ManagerはRegional MICでの1日研修 Local MI Managerの採用面接をRegional MICのスタッフが行うことも

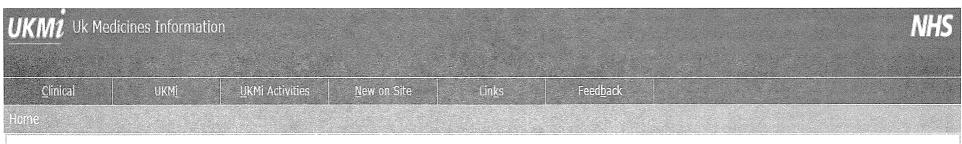
# UK Medicines Information (UKMi)

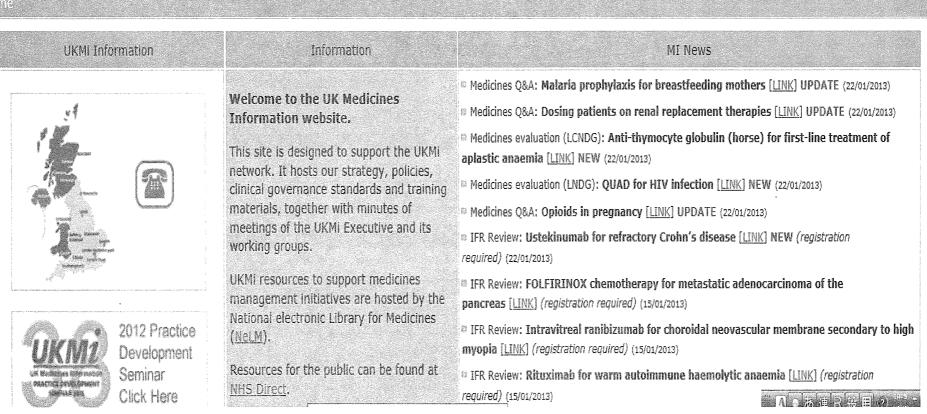
- ワーキンググループ
- ■業務スタンダード
- ■教育
- ■医薬品情報リソース
- ■MiDataBank
- ■研究
- **■**Website

www.ukmi.nhs.uk www.nelm.nhs.uk



## www.ukmi.nhs.uk





## www.nelm.nhs.uk

#### National electronic Library for Medicines

NHS

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#### Search the NeLM

Search

Medicines A-Z

Find key information about medicines by name (prototype)

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Formularies

#### Medicine news and library updates

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#### Spotlight on...

The updated version of A guide to responding to requests for information about medicines management or use, made under the Freedom of Information Act 2000 has been published.

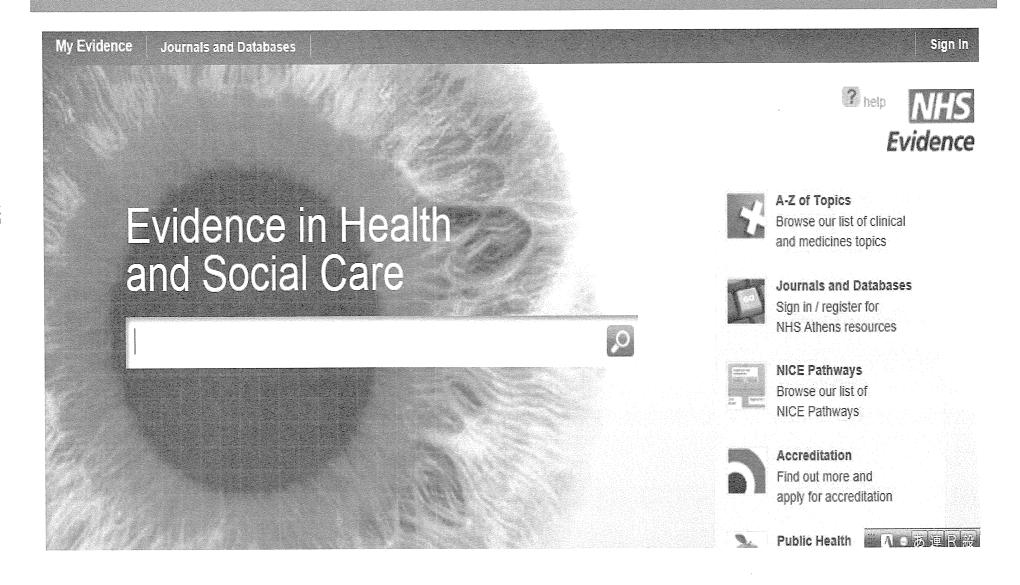
A new Medicines Management Overview on 'Inhaler use technique and related interventions' has been published.

Reminder that the **PGD** (Patient Group Directions) Website can be accessed by clicking the link or going to www.pgd.nhs.uk.





## NHS Evidence



# 問い合わせ記録のデータベース化 MiDatabank

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# 問い合わせDBから副作用報告

# Mi Databank



Home About ADRE



MiDatabank i Help & Support FAQ Documentation Contact



You are here: ADRs > Electronic Yellow Cards/ADR Reporting

Register Login

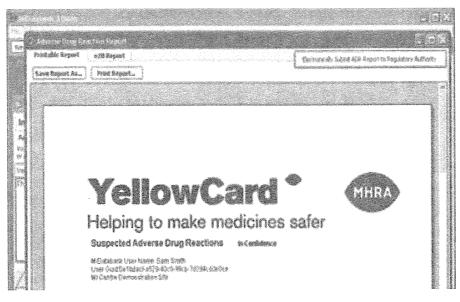
Electronic Yellow

Cards/ADR Reporting

**Development History** 

Useful Resources

#### Electronic Yellow Cards/ADR Reporting in MiDatabank



Version 3.1 of MiDatabank now has the facility to electronically submit an ADR report directly to the MHRA.

By clicking on the button in the to the button in the to the button in the total and the button in the total and the button in t right, the ADR report is electronically transmitted to the MHRA.

The first electronic Yellow Card (eYC) was sent on 28th February 2011 by the North West Medicines Information Centre in Liverpool.

In September 2011 the UKMI Evacutive nave annewal for the

# 医薬品情報提供業務スタンダード

- ∞医薬品情報提供業務に必要な設備
- ∞必須情報源リストの書籍、データベース所蔵
- ∞業務に必要な薬剤師の配置
- ∞問い合わせに対して迅速な対応
- 窓業務向上の為のユーザーアンケートの実施
- 50問い合わせ記録の保存状態
- ∞医薬品情報問い合わせ内容

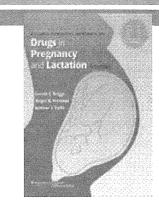
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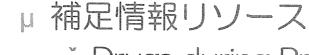
- ® Regional MICが3年に1回Local MICを業務スタンダードをもとに評価
  - 。 結果の公表 (センター名は匿名)
- 知 Peer review 1年に1回
  - \* Local MIC Manager同士がお互いの業務を評価・共有
- 80 Internal QA
  - \*毎月20の問い合わせ履歴を抽出し、担当者以外が問い合わせ を評価し、お互いの業務の質を評価・共有

# 必須医薬品情報リソースリスト



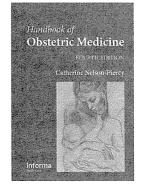
- · 妊婦·授乳婦
  - μ <u>必須情報リソース</u>
    - Medication and Mothers' Milk
    - \* Drugs in Pregnancy and Lactation

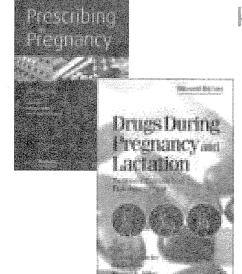




- \* Drugs during Pregnancy and Lactation
- \* Handbook of Obstetric Medicine
- \* Prescribing in Pregnancy







# 教育リソース

- めワークブック
- Meb base training
- 知 研修
  - ITスキル
  - 。Medline/Embase検索
  - 。Critical Appraisal 批判的吟味 年会(学会)







**Training Workbook** 

Angela Emerson Simon Wills

Wessex Drug & Medicines Information Centre Southampton University Hospitals NHS Trust





Medicines Information Computer Aided Learning (with MiDatabank Trainer)

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Welcome to Medicines Information Computer Aided Learning (MiCAL) with MiDatabank trainer

### MI Pharmacists 研修プログラム 2006年7月



- ・3日間の滞在研修 (年2回開催)
- ・全国のMI Pharmacistsとの交流





# Medicines Q&A

#### ∞ よくある問い合わせ集

- 。 妊娠中のオピオイド鎮痛薬について
- 。 授乳中のマラリア予防内服の選択について
- 。 フェンタニルパッチ製剤への変更時の換算量
- 。 クロピドグレルとPPIの相互作用
- め 執筆マニュアル
- ∞ 査読システム
- め 発行から2年改訂
- ® NeLMにて公開



Medicines Q&As₁



Q&A 268.3.

Can breastfeeding mothers take paracetamol?

Prepared by UK Medicines Information (<u>UKMi</u>) pharmacists for NHS healthcare professionals *↔*Date prepared: 14 January 2013 *↔* 

# 新薬レビュー

- The UKMi New Product Working group (NPWG)
  - 。全国ネットワークをコーディネイトした新薬 レビューを提供
  - National Horizon Scanning Centre
  - National Prescribing Centre
  - o NICE

#### 新薬承認から患者への処方まで 臨床家 患者グループ New Horizon Drugs新薬 意見 国民の意見 scanning レビュー 臨床試験 NICE 経済評価 新薬 患者への の承認 処方 病院 予算 臨床的

採用選定

制限

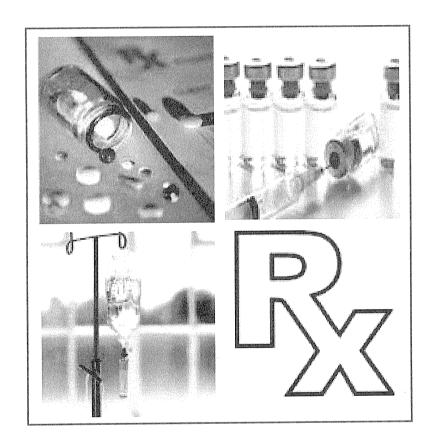
判断

# 英国の薬剤師による 医薬品情報

- っ病院だけでなく、家庭医に対しての薬剤師による る医薬品情報センターが配置されている
- 地域医薬品情報センターによるネットワークを 利用したセンター同士の実務の共有と合理化が 図られている
- w UKMiエグゼクティブが政府や他の機関と交渉、 連携し、情勢に応じた医薬品情報サービスを計 画している

# Prescribing Outlook New Medicines

September 2012



A resource for the NHS to help with budget setting, prescribing planning and medicines management.





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#### Managing new medicines

Managing new treatments is different from managing other service developments. The NHS Constitution gives patients the right to expect local decisions about funding medicines and treatments to be made rationally, so there is a need for high-quality, evidence-based and systematic decision making. The number of high-cost treatments makes the task of allocating resources one of the most politically sensitive and complex issues facing the NHS.

There are a number of new government initiatives that will impact the way medicines are managed in the NHS. Underpinning the strategic direction for managing new medicines is the recently published Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS document. This outlines the importance of early adoption and diffusion of clinically and cost effective innovative practices, including medicines. Among other initiatives it recommends establishing new relationships with industry, based on partnerships that deliver mutual value.

Inevitably, an important aspect of uptake of new medicines by the NHS is cost. In *Prescribing Outlook* we try to predict the financial impact a new medicine may have. There are many factors, including market and political factors, that determine how much a new medicine will cost. The current <a href="Pharmaceutical Price Regulation Scheme (PPRS)">Pharmaceutical Price Regulation Scheme (PPRS)</a>, a voluntary scheme agreed between the Department of Health (DH) and the pharmaceutical industry, comes to an end in 2013. Following a wide-ranging consultation on future pricing structures, the <a href="government's response">government's response</a> is to move to a value-based pricing scheme that reflects value to the NHS. The objectives for value-based pricing are to:

- improve outcomes for patients through better access to effective medicines;
- stimulate innovation and development of high value treatments:
- improve the process for assessing new medicines, ensuring transparent, predictable and timely decisionmaking:
- include a wide assessment, alongside clinical effectiveness, of the range of factors through which medicines deliver benefits for patients and society;
- ensure value for money and best use of NHS resources.

As with any new scheme, a phased introduction is necessary so value-based pricing will focus primarily on new medicines marketed from January 2014. There will be a successor scheme for medicines licensed before 2014 that will operate under a similar framework to earlier PPRS agreements. Exactly how value-based pricing will operate is yet to be decided; discussions between the pharmaceutical industry and the government are ongoing. However, it is likely that where drugs have different indications there will be different pricing strategies based on the assessed 'value' of the drug for each indication. There are a number of drugs listed in this edition of *Prescribing Outlook* with an anticipated launch date of 2014. The introduction of value-based pricing makes the

task of assessing the potential financial impact of new medicines available after 2013 more difficult. There are already situations where the same medicine has a different pricing strategy for different indications. This is especially true for medicines that have an <u>orphan</u> designation for one or more indications. In this case, the medicine will have a different brand name for the non-orphan and orphan indications, and different price tag attached. This further adds to the complexity of estimating the financial impact of new medicines and indications.

With the high cost of bringing a new drug to the market it is inevitable that the pharmaceutical industry will put more effort into looking for new uses or formulations for licensed products. This trend is reflected in the content of *Prescribing Outlook* where 43% of entries this year are for licence extensions or new formulations compared to around 30% in previous years. These applications are processed through licensing systems faster as less safety and technical data are required. In addition, there is generally less publicity about licence extensions and new formulations so they are less likely to feature in horizon scanning systems.

Another mechanism aimed at delivering value from new medicines to the NHS is the patient access scheme (PAS). PASs, also known as risk sharing schemes, may allow NICE to recommend treatments that it might otherwise have found not to be cost effective. PASs are increasingly being used as a mechanism to manage entry of new and expensive medicines into the NHS and can be either cost (discounts, free stock etc) or outcome (price variation is linked to patient outcomes) based. Manufacturers may submit a PAS proposal for any technology in the NICE appraisal process. Since 2009, PAS proposals have been considered by the NICE Patient Access Scheme Liaison Unit (PASLU), which advises the DH on the feasibility of PAS, within the NHS. Further information on the work of PASLU, together with a list of NICE technologies with an approved PAS can be viewed on the NICE website. Implementation of PASs can be complex. Research into the uptake and challenges of operation of PASs has been published. In this edition of Prescribing Outlook current PAS schemes are highlighted if they are relevant to a new medicine in the same therapeutic area.

Details of a scheme which would allow patients access to new medicines prior to licensing were put out for consultation by the Medicines and Healthcare products Regulatory Agency (MHRA) in July 2012. The intention of the scheme, which is part of the government's life sciences strategy, is to widen access to "promising new medicines that will treat, diagnose or prevent life threatening, chronic or seriously debilitating conditions without adequate treatment options". Other regulatory schemes that allow earlier access to medicines in the EU and UK include 'individual patient supply' and 'conditional approval'. Where relevant, details of these are included in Prescribing Outlook. These schemes make predicting UK availability dates more difficult.

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As part of the government's initiatives for the NHS, the central role of NICE is to be strengthened. A new department dedicated to supporting implementation of NICE guidance is to be established. Where relevant, links are provided in Prescribing Outlook to NICE pathways, commissioning guidance and quality standards. Quality standards are designed to drive and measure priority quality improvements within a particular area of care. They will be reflected in the 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. The National Prescribing Centre (NPC), now the NICE Medicines and Prescribing Centre (MPC), produced a number of documents to support medicines management in local decision making. They can be accessed through the 'Local decision making' section of the archived NPC website and include a bulletin entitled 'Tough Decisions'. The MPC has recently been commissioned to develop good practice guidance on formularies.

Implementation strategies include how and where medicines are delivered to the patient. Hospital medicine homecare services deliver ongoing medicine supplies and, where necessary, associated care, initiated by a hospital prescriber, direct to a patient's home. The annual value of medicines supplied by this route is estimated to be over £1billion and is increasing year on year. Procurement guidance for provision of homecare delivery service of medicines and a DH review "Homecare Medicines - Towards a Vision for the Future" into the supply of homecare services have been published. There are a number of factors that increase the likelihood of homecare delivery. The medicine is:

- for a therapy area/condition which is currently treated through homecare,
- currently distributed to patients' homes for another indication.
- suitable for ongoing outpatient administration,
- expensive,
- initiated in secondary care,
- generally safe to administer.

#### About Prescribing Outlook

The aim of the annually published Prescribing Outlook series is to assist NHS organisations in planning. implementing and budgeting for new medicines or licence extensions and national guidance. It provides support to commissioners and providers by highlighting new medicines and service developments that may require dialogue about financial and operational resource implications. The Prescribing Outlook series is produced for primary and secondary care with a national perspective. This document is the first in the series that comprises Prescribing Outlook - New Medicines and Prescribing Outlook - National Developments, and is supported by an electronic Cost Calculator. These are all available at www.nelm.nhs.uk >evidence>horizon-scanning. NeLM registration is required and is available to all with an NHS email address. The component documents of the

Prescribing Outlook series are published each autumn in line with annual budget planning timeframes and key outputs from NICE. Updates on the progress of individual medicines at other times throughout the year can be found on the UKMi New Drugs Online database.

The content and presentation of the *Prescribing Outlook* series has evolved following consultation with users of the documents. Due to the nature of these documents they are all now only published electronically but are formatted to make them suitable for printing. Further specialist information on medicines not included in the series can also be obtained from local and regional medicines information centres. See www.ukmi.nhs.uk for details.

Prescribing Outlook – New Medicines is produced by UK Medicines Information (UKMi). It aims to provide advance information about new medicines (and new licensed indications) with anticipated market launches in the next 18 to 24 months. In addition, brief details of drugs launched in the last 12 months are included as this is useful for local planning purposes. The content is not comprehensive but focuses on medicines with the potential for significant clinical or financial impact on the NHS. Estimates of potential uptake, patient, service and financial implications are included where possible. Reference is made to relevant national guidance and links to in-depth independent reviews are included, where available.

#### How is the content decided?

Various criteria are applied to prioritise those medicines in the pipeline likely to have the largest impact. These include considering whether:

- the medicine is expected to provide a significant improvement in disease management,
- the medicine is first in class or has a major new indication.
- there are limited other alternatives,
- the medicine cost will be high.
- the target population is large,
- there is likely to be a significant effect on service implications e.g. route/ formulation/ method of delivery,
- the medicine or disease area is considered an NHS priority,
- the medicine has significant additional indications in the advanced pipeline stage,
- the medicine is in the EU licensing process.
- there is likely to be significant media interest.

There will be additional, unquantifiable, factors that have implications for the NHS such as local demographics and prescribing preferences which cannot be accommodated in a national document.

More detailed information on the medicines listed can be obtained from the UKMi *New Drugs Online* (NDO) database which can be accessed directly from the generic name hyperlink in this document.

#### Payment by Results (PbR)

Payment by Results (PbR) is the national tariff based system for paying trusts for activity. However, as standard tariff prices do not always allow fair reimbursement of some interventions a list of drugs and services excluded from the