



Royal College  
of Physicians

**N=1**

## **Why people matter in medicines**

Recommendations of a subgroup  
of the Royal College of Physicians  
Medicines Forum

June 2011



Royal College  
of Physicians

# N=1

## Why people matter in medicines

Recommendations of a subgroup  
of the Royal College of Physicians  
Medicines Forum

June 2011

## Royal College of Physicians

The Royal College of Physicians is a registered charity that aims to ensure high quality care for patients by promoting the highest standards of medical practice. It provides and sets standards in clinical practice and education and training, conducts assessments and examinations, quality assures external audit programmes, supports doctors in their practice of medicine, and advises the government, public and the profession on healthcare issues.

Citation for this report: Royal College of Physicians. *N=1: Why people matter in medicines*. Recommendations of a subgroup of the Royal College of Physicians Medicines Forum. London: RCP, 2011.

## Copyright

All rights reserved. No part of this publication may be reproduced in any form (including photocopying or storing it in any medium by electronic means and whether or not transiently or incidentally to some other use of this publication) without the written permission of the copyright owner. Applications for the copyright owner's written permission to reproduce any part of this publication should be addressed to the publisher.

Copyright © Royal College of Physicians 2011

ISBN 978-1-86016-445-3

Royal College of Physicians  
11 St Andrews Place, London NW1 4LE

[www.rcplondon.ac.uk](http://www.rcplondon.ac.uk)

Registered Charity No 210508

# Contents

Members of the subgroup	iv
Foreword	v
Acknowledgements	vii
Gathering the evidence	viii
Terms of reference	ix
1 Introduction	1
2 People matter	2
3 Service matters	5
4 Research matters	9
5 Conclusions	12
6 Recommendations	14
References	16
Appendix A; Those who gave oral evidence to the subgroup	17
Appendix B: The Yellow Card Scheme of the MHRA	19

## Members of the subgroup

**Harry Cayton** (chair) chief executive, Council for Healthcare Regulatory Excellence

**Susan Shepherd** (secretary) Royal College of Physicians

**Peter Ashley** expert patient, ambassador, Alzheimer's Society

**Katherine Darton** information officer, Mind

**James Davies** pharmacist, The School of Pharmacy, University of London

**Simon Denegri** chief executive, Association of Medical Research Charities

**Richard van Mellaerts** GP, Kingston-upon-Thames

**Mike O'Donovan** trustee, National Voices

**June Raine** director of vigilance and risk management of medicines, Medicines and Healthcare products Regulatory Agency

**David Taylor** professor of pharmaceutical and public health policy, The School of Pharmacy, University of London

**Kate Webb** senior policy analyst, Council for Healthcare Regulatory Excellence

## Foreword

Medicines used well do a huge amount of good. Medicines misused, mis-prescribed or misunderstood are either ineffective or harmful. In accepting the invitation from the Royal College of Physicians Medicines Forum to look at access to medicines from a patient perspective, we sought as a subgroup to try to understand the barriers to effective use of medicines by patients so that they can realise the benefits and minimise the risks for themselves.

People's beliefs about medicines have an enormous and underestimated impact on their use of them in practice. How we think about possible benefit and possible risk of harm, our reactions to adverse effects, our use of patient information, our relationship and quality of communication with prescribing professionals, all affect our adherence to an agreed course of treatment. Time after time we heard from witnesses and saw in our visits that the context of people's daily lives was more important in effective use of medicines than merely prescribing the right medicine and explaining how to take it.

One of the most important steps in the acknowledgement of the validity of patients' experience of medicines was the decision in 2004 to open reporting – through the Yellow Card Scheme – directly to patients themselves. We were struck by the evidence from the Medicines and Healthcare products Regulatory Agency (MHRA) of the value of such reporting as an indicator of risk and of its contribution to patient safety.

Access to medicines is greatly affected by the unevenness of their availability. The supply and choice of medicines we learned is not primarily driven by clinical need but by economics and opportunity. We heard from the Motor Neurone Disease Association that there was only one medicine of limited efficacy for that rare but devastating disease and that even its availability was distorted by high cost and parallel trading in Europe; in contrast, Breakthrough Breast Cancer told us that there was an abundance of more and more medicines for increasingly 'personalised' treatment and that the challenge was finding and using exactly the right one; and we heard from Mind that medicines in mental health were often viewed by patients with suspicion and mistrust because adverse effects could be so damaging to quality of life, and because preferred alternative therapies were often not available. So the first problem of access from a patient perspective is that supply is mismatched to need, with similar medicines competing with each other in some areas of clinical practice and none being available in others.

The evidence we received also confirmed that there is a great deal of misunderstanding about how medicines work and how they should be used. However, it is false to assume that more information is required to correct ignorance. Misunderstandings about medicines are based on beliefs, on rational responses to real experience and perhaps on some basic uncertainties about how medicines work, which are a feature of a scientifically illiterate culture.

It is not only the general public but journalists, commentators and those celebrities who endorse unscientific claims for the causes of illness, for diets, therapies and cures who all compound this problem. Sadly they are sometimes assisted by researchers themselves who in their desire for public recognition and more funding sometimes promulgate or, more often, do not contradict claims about their work which they know to be exaggerated or unfounded. It is not surprising that the public is confused. We suggest at the very least that if all journalists understood that a correlation is not necessarily a cause, and that all doctors understood and could explain the probability of benefit and the risk of harm, and that all scientists and researchers describing their work to the public used whole numbers rather than percentages to describe risk, and if all patients understood dose effects, we would have made a start.

The overall message of this report is that the value of effective use of medicines will not be realised merely by doing more of the same. We need a change in approach that relates medicines use to people's daily lives, acknowledges the importance of concerns about unwanted effects, and radically changes the way we communicate about medicines and the information we provide.

**Harry Cayton**  
Chair, subgroup

## Acknowledgements

The chair and members of the Medicines Forum subgroup would like to thank all those who gave up their time to attend meetings in order to provide oral evidence, and to those who were so hospitable to us on our site visits. These are listed in Appendix A.

The chair and members of the subgroup would also like to thank Professor Tim Evans and Dr Richard Horton, the co-chairs of the RCP Medicines Forum, for their support for the work, and also to Simon Denegri who has been a member of both the Forum and the subgroup and acted as a point of liaison between us.

We have been wonderfully looked after by our secretary Susan Shepherd, who has variously chivvied and corralled us to visits, coaxed and coerced us into meetings, efficiently arranged everything despite multiple busy diaries, provided us with research briefings, welcomed our many guests, and who with other members of the subgroup assisted in drafting our report. Special thanks go also to Kate Webb for devising the report structure and for a major contribution to drafting.

Endorsed by the Royal College of Physicians Medicines Forum.

## Gathering the evidence

The group began its work in December 2009, finishing in November 2010. During this time the group took evidence from 17 people, each with special knowledge of or interest in the area of work covered by the group's terms of reference. In order to round out the oral material, three site visits were made: to a hospital pharmacy; to an inner-city GP surgery; and to the regulator. Many of those with whom the subgroup met provided documents and quoted references to support their statements, all of which the group also considered when drawing its conclusions and formulating its recommendations.

Throughout the text of this report, the subgroup has selected quotations from its witnesses to illustrate and amplify points made and conclusions drawn.

## Terms of reference

To consider the barriers to and opportunities to improve people's choice of, access to, and effective use of medicines, with particular reference to:

- people's knowledge, beliefs, and understanding of medicines
- incentives and disincentives to effective medicines use
- incentives and disincentives to people participating in research about medicines.



# 1 Introduction

- 1.1 In February 2009 the Royal College of Physicians (RCP) published *Innovating for health: patients, physicians, the pharmaceutical industry and the NHS*,<sup>1</sup> a report addressing the conditions under which safe and effective medicines can be developed and delivered for the benefit of patients. The report contained 42 recommendations, the penultimate one of which is to convene a Forum to ‘deliver and build on’ report recommendations. The RCP’s Medicines Forum met for the first time in May 2009 at which time it allocated tasks to four subgroups.
- 1.2 This subgroup enquired about factors relating to whether and how people take their medicines, what influences choice, and how decisions around medicines use are made; and gathered information about participation in medicines research. We looked at patient information about medicines and the way professionals communicate about medicines. We also considered the future role of medicines in the context of primary prevention and population health.
- 1.3 This report sets out to understand better the factors that inhibit and facilitate medicines use – whether taken occasionally for an acute event, where a medicine may provide an effective cure, or where they are taken daily or frequently to support a chronic or recurring illness, and for which medicines are considered a benefit. It is set against the background of global demographic and epidemiological transition, in which effective and properly used medicines can do more than ever before to help relatively poor individuals and populations escape the burdens of infectious disease; and in which they are needed more than ever before to enable ageing people and communities in more economically developed parts of the world to live as healthily and productively as possible.
- 1.4 The subgroup summarised its findings in three sections, setting out why, in the context of medicines provision, people, services and systems matter. Our recommendations, which fall out of our findings, are aimed at several parties, but principally at healthcare professionals and the agencies that support them. For change to happen effectively, all these parties will need to enter into partnership – particularly with patients and the public. We hope, therefore, that this report will encourage those involved in medicines provision to engage with patients in order to be at the forefront of shaping change.

## 2 People matter

### Knowledge and beliefs

- 2.1 From his research, Professor Rob Horne provided valuable insight into the impact that individual knowledge and beliefs have on medicines use. What a person thinks about a prescribed medicine and background beliefs about pharmaceuticals as a class of treatment influence how they understand, interpret and experience specific medicines. When making decisions, people apply an internal logic based on an individual understanding of illness:

*None of us actually blindly follows health advice ... we interpret whether the advice makes sense in the light of our understanding of a condition or a risk and this is true even if the advice comes from a trusted source. (Horne)*

Being on medication affects a person's sense of self and how they think they appear to others; often doubts go undisclosed because people believe that the expression of doubt will be interpreted by the prescriber as a doubt in them and their skills.

- 2.2 This is a profoundly important insight if we are to change the way in which we communicate about medicines and improve their use. People's beliefs about medicines are not 'wrong' (though they may be mistaken); they are based on valid personal experience and if we are to achieve anything like the 'agreement' suggested by NICE<sup>2</sup> between patient and clinician, the conversation must start from the patient's personal understanding and experience.

In its *Clinical Guideline 76*<sup>2</sup> the National Institute for Health and Clinical Excellence (NICE) stated that: ' "adherence" presumes an agreement between prescriber and patient about the prescriber's recommendations. Adherence is defined as the extent to which the patient's action matches the agreed recommendations'.

- 2.3 What we should strive for is 'a real educative approach' – one that is about understanding where a patient is coming from first, considering their perspective and their thinking about their condition, and using this to tailor the type and nature of the information provided.

*Providing information in itself has limited effect – what is often missing is an understanding of the underlying beliefs that people might have which will influence the way they will interpret the information and decide whether it is right for them. (Horne)*

- 2.4 An agreement requires mutual understanding, not merely acquiescence to following instructions. But even if real agreement were to be achieved between prescriber and patient, this still falls short of what is needed if people are to engage fully in a partnership about their medication. The assumption that an agreement has been reached between the two parties fails to recognise the multiplicity of factors that influence medicine-taking behaviour and the reality of what actually happens when a person leaves the pharmacy or the consulting room. What we should seek to achieve – but what we often fail in – is 'concordance': the ideal situation that exists when patient and prescriber have an informed discussion and come to an agreement about what the treatment will be and how it will be managed.

## The Yellow Card Scheme and the words people use

- 2.5 One of our first visits was to the Medicines and Healthcare products Regulatory Agency (MHRA), to better understand how people's views and experiences are collected, analysed and used to improve the use of medicines. This is done principally through a mechanism known as the Yellow Card Scheme – a scheme that health professionals and members of the public can access to raise a suspicion that there is an adverse effect relating to a particular medicine. Through the Scheme, symptom data are gathered and reviewed and in the past have led to notification of significant concern and subsequent action. An explanation of the Scheme and some case studies are set out in Appendix B.
- 2.6 However, our visit to the regulator led us to the conclusion that much more needs to be done to capture the experience of patients in real-life language, and yet more to explain adequately the logic underpinning how a signal becomes an identified risk. Only when we achieve this will patients' experiences be of benefit to other medicines users – often the main reason behind a patient sending in their report.

## Information about medicines

*A well-designed leaflet is a shop window for medicine and is actually an aspect of medicine; when you consider its potential to encourage – or otherwise – medicine-taking, it is actually a very active constituent. (Dickinson)*

- 2.7 One of the major ways in which people learn about their medicines is through information leaflets provided with prescriptions. These inform about adverse reactions and what to look out for, but provide little or no information about why something might be happening. David Dickinson, an expert in leaflet design who has advised the MHRA and undertaken work for a number of pharmaceutical companies, told us that patients do value the patient information leaflets enclosed with their medicines – not because of their inherent quality but because they get so little information from other sources. Although there is clearly difficulty in catering for everyone's preferences all at once, enough is known about how to present information clearly to improve the current situation. Salient issues are twofold: basic leaflet design, and using language that people commonly use themselves to talk about medicines.
- 2.8 We learnt during our visit to St Thomas' Hospital that all literature relating to medicines goes through a scrutiny committee for readability. However, a problem identified by the hospital was getting information to minority communities, disabled people, those with sight problems, and those who have difficulty with reading. Mind told us that there is an urgent need to write information specifically for prisoners, people with low literacy skills, and for those with poor concentration levels. Our visit to the MHRA reinforced the fact that many patients do not have easy or automatic access to the information they need about their medicines.

## Summary

- 2.9 We need to acknowledge the reality of the patient experience in areas of medicines use, starting from a point that has meaning for the patient. We need to foster better partnerships – issuing a prescription is not simply a technical act; the partnership is between the patient, the health

practitioners, the pharmacist, the health system and industry. We need to acknowledge and legitimise the terms that patients use to describe their experience and expectations of medicines; ‘translations’ made by professionals are not always into words that patients use. It is unclear how colloquial language use should be – but it appears that patient reporting is becoming professionalised and converted into words that no patient would recognise. More could be done to improve the way information about medicines is designed and provided – bearing in mind the particular needs of some groups – and to widen its scope, bringing in issues that will inform discussion and assist with choice in areas where decision making can be complex. Conversations need to be derived from what the public wants and needs to know about medicines and their effects – not from what professionals want to tell them.

### Recommendations for more effective engagement

- The pharmaceutical industry, medicines regulators, commissioners and prescribers need to capture and appreciate what patients say about medicines more thoroughly and comprehensively, and to understand the stories that people tell about medicines – how they use them; the benefits they experience; and the adverse reactions that can arise – so that we can make the most of this area of healthcare.
- Start the process with a collection of patient terms and descriptors, collected throughout the medicines system – in clinical trials; regulatory decisions; technical appraisals; the consulting room; the pharmacy – in order to help health professionals work with patients to get the most from a medicine they have decided to take.
- Create new opportunities to capture and react to patients’ views and experiences about medicines. The current opportunity to report suspected adverse drug reactions through the Yellow Card Scheme needs greater use and a higher profile. We need to explore other options to report – for example, developing a patient formulary and using initiatives like [healthtalkonline.com](http://healthtalkonline.com).<sup>3</sup>
- The Expert Patients Programme should explore how it could further develop expert medicine users to provide support and advice to people about their medicines.
- To build further on existing achievements, more sustained effort needs to go into the quality and design of medicine information leaflets, addressing a range of needs, and using a range of formats and approaches – including exploiting opportunities offered by new communication tools.

## 3 Service matters

### Support for patients and the public

- 3.1 As the majority of prescriptions are written in the community, our starting point was a visit to an inner-city GP surgery. The subgroup was impressed to learn about the amount of time and effort that goes in to collating practice prescribing data and the high scores achieved in ‘patient satisfaction surveys’. However, the use of modern technology falls far short of what is provided in other service sectors. Practice staff spoke about the need to improve the ability of patients to request prescriptions online or via email. Community pharmacists believed that patients should be provided with the opportunity to acquire prescriptions from multiple sources, and that better use should be made of medicines use reviews. Medical staff spoke about the need for information leaflets to discriminate better between risks and side effects.

**Medicines use reviews** (MURs) were introduced as part of the new pharmacy contract in 2005. An MUR is an appointment with a pharmacist in which patients can discuss how they are getting on with their medicines, and allows a private consultation to ask questions and for medication issues to be discussed. Recommendations may be made to the GP. Nearly 1.4 million MURs were conducted in England between April 2008 and April 2009.<sup>4</sup>

**Patient group directions** (PGDs) have been in existence since August 2000. They constitute a legal framework that allows certain healthcare professionals to supply and administer medicines to groups of patients that fit the criteria laid out in the PGD. So, a healthcare professional could supply (provide an inhaler or tablets) and/or administer a medicine (give an injection or a suppository) directly to a patient without the need for a prescription or an instruction from a prescriber. PGDs allow the supply and administration of specified medicines to patients who fall into a group defined in the PGD; using a PGD is not a form of prescribing. Unlike nurse and pharmacist prescribing, healthcare professionals entitled to work with a PGD require no additional formal qualification. However, for a PGD to be valid, certain criteria must be met both in terms of the patient group for which the PGD can be used, and in how the PGD itself is drawn up. Organisations also have a responsibility to ensure that only fully competent, trained healthcare professionals use PGDs.

- 3.2 At the pharmacy at St Thomas’ Hospital, as much verbal support as possible is given when prescriptions are collected. However, this is often an isolated opportunity. The hospital operates a telephone helpline for medicines advice; experience shows that patients are relatively content with their treatment regimen at the time of discharge but subsequently feel unsure and make contact six to seven weeks post-discharge. From retail pharmacy witnesses we heard about a new medicines service that is being developed in community pharmacy to help address this issue. It is on this advice that we believe patients should be given an after-care call to follow up their use of a new medicine, to allow them to discuss any medication-related issues with a healthcare professional – nurse, doctor or pharmacist. We were told that issues that modify acceptance of treatment regimens are often dealt with poorly: ‘There are consistent reports that things such as side effects, particularly those that affect sexuality, lifestyle, the use of complementary medicines [are] “not being well discussed and well explained”’. (Breakthrough Breast Cancer)

- 3.3 The approach taken by a leading UK retail pharmacy chain is one of ‘opening up more channels to our customers’ and one of ‘providing access to product and accompanying service and the professional advice that goes along with that’ (Bennett and Gilbert). Services to support wider accessibility of medicines and improved use include: the use of the internet and remote access to make product and services available; professional services including a number of patient group directives and medicines use reviews; and WebMD – an internet health portal to support choice.

*It is not only about product but it is also about the supporting service and the information to go alongside that so that the consumer can make an informed choice in their selection of product.*  
(Bennett and Gilbert)

**P to GSL:** From pharmacy-only to general sales list.<sup>5</sup>

**Pharmacy (P)** medicines can only be obtained from a pharmacy and are sold under the supervision of a pharmacist.

**GSL:** general sales list. This is a category of medicines that may be sold without the supervision of a pharmacist, equivalent to over-the-counter sales. They are suitable for sale and normal use without supervision or advice from a pharmacist or doctor.<sup>5</sup>

**OTC:** over-the-counter products. For example, aspirin tablets bought in a chemist shop. Encompasses both pharmacy (P) and GSL status in the UK. Not necessarily kept behind a counter.<sup>5</sup>

**POM:** prescription-only medicine, ie medicine available only on prescription from a doctor, dentist, pharmacist, or nurse independent prescriber, or, subject to certain limitations, an optometrist independent prescriber.<sup>5</sup>

**POM to P:** The means by which a prescription-only medicine can become a pharmacy medicine (ie available only from a pharmacist). It is also known as ‘de-pomming’.<sup>5</sup>

In the UK, the use of pharmaceutical products (both OTC and POM) is extensive. In 2009 about 17 items were dispensed in primary care for every person in England at a cost to the NHS of £8.5 billion.<sup>6</sup> These numbers only include medicinal use in primary care and will be less than the total number of items prescribed, as not all prescriptions are filled and many prescriptions are issued in secondary care. This number also fails to include the £2.4 billion spent by patients on a number of products bought ‘over-the-counter’ as part of a regimen of ‘self-medication’.<sup>7</sup>

- 3.4 Retail pharmacy witnesses also recognised the power of personalisation in the provision of advice and services – ‘the care that we give and the products should be personalised’. Calls to the information service provided by the charity Mind confirm the value of personalisation – ‘there is nothing like a one-to-one conversation’. The ability to share experiences about the progress of a condition and its treatment was an important aspect of personalisation described by the Motor Neurone Disease Association (MNDA).
- 3.5 There is now wider accessibility to medicines than ever before. This has been seen through the greater availability of over-the-counter (OTC) products brought about by deregulation of the legal

status of medicines, making former prescription-only products available in pharmacies (POM to P switching) and making more products generally available outside pharmacy in supermarkets and other retail outlets (P to GSL switching).

- 3.6 Efforts have been made by organisations such as the National Institute for Health and Clinical Excellence (NICE) to improve the access to high-cost medicines by creating guidance and advice to both prescribers and payers on which high-cost medicines are cost effective – although this process is often lengthy and creates the tensions that we heard about. However, pharmaceutical products are not always available when and where needed, nor in a form most suited to patient need – both of which constitute a barrier to access. The most compelling evidence about this was provided by representatives of the MNDA where the only medicine currently available for the treatment of motor neurone disease is riluzole (Rilutek).<sup>8</sup> Motor neurone disease is difficult to diagnose in its early stages often creating a delay in access to medication. Parallel exporting of Rilutek means that substantial quantities of the drug leave the supply chain, leading to local shortage.

A **parallel import** (PI) is a medicinal product which is imported into one member state of the EU from another following the principle of the ‘free movement of goods’, a cornerstone of the ‘common market’. This takes place with the knowledge of the owner of the trademark and/or intellectual property rights (typically the medicine’s manufacturer) who have a right to comment on the proposed marketing and, in certain circumstances, the right to prevent it. Parallel imports occur when the price levels of the same product are significantly different between countries, where lower priced markets sell to higher priced ones, and where prices can vary as much as threefold. Once the competent authority in the destination country has confirmed that the imported product is therapeutically equivalent to the domestic product, the medication is imported and certain changes are needed to meet the requirements of the importing market, such as patient information leaflets in the local language, which will involve an appropriately licensed company repackaging the medicines. This practice has led to the shortage of medicines in some European countries as medicines are freely traded within the boundaries of the European Union. Parallel trade is an enterprise that is actively encouraged by governments of several member states such as the UK, Sweden, Denmark, Germany and the Netherlands due to their overall price levels being higher than the European average – nearly 20% of the total UK market, 14% of the Dutch, 10% of the Danish and Swedish markets, and 7% of the German market in 2002. However, since the pound sterling has become weaker against the Euro, the UK has become a net exporter, as opposed to its previous position as an importer, leading to shortages in certain medications in the UK.

## Support for prescribing professionals

- 3.7 Professor Philip Routledge described initiatives to ensure and restore prescribing competence – which in his view cannot be done without a basic understanding of pharmacology. We were told that pharmacists have a very good pharmacological education and that we need to make sure that all future prescribers – including doctors and nurses – have this knowledge in order to deliver better patient care. Only in this way will prescribers have the ability to communicate information about medicines. In the view of the subgroup, this ability is fundamental, and underpins not only safe practice but also adequacy in partnering patients and the public in understanding the part that medicines can play in their lives.

- 3.8 The Royal Pharmaceutical Society of Great Britain told us it is doing much to improve standards across the pharmacy profession – a multi-faceted sector that encompasses community, primary care, hospital, academia and industry. We were told that the pharmacy profession has patient care at its heart, but has a ‘job to do’ in articulating more widely its ‘offering’. We were told that the profession needs to be more outward-looking; find ways to engage with the new healthcare agenda, and make the public better aware of the service it provides. In particular, providing access to individual patients’ healthcare records and improving the relationship between general practice and community pharmacy were key goals in the near future.
- 3.9 Records about patient care are an important tool for communication between healthcare professionals. We heard how the ownership of the records is an important part of understanding disease progression and of empowering patients to understand their illness better. We believe, therefore, that patients should be in the lead in deciding with whom they wish to share their records.

## Summary

- 3.10 We cannot emphasise enough the need for collaboration between health professionals, and between doctors and pharmacists. However, throughout our discussions we heard about the barriers created in communicating advice between professions. We also heard how relationships and quality of communication between patients and prescribers affect adherence to an agreed course of treatment. In order to improve this, greater effort should be made to facilitate cooperation between health professionals in all aspects of prescribing practice – with patient need at its heart. We heard how the current system of supplying repeat prescriptions is a complicated and cumbersome process. Evidence seen at the GP surgery that we visited suggests that patients would prefer the option of requesting repeat medications via a variety of technologies, including email and the telephone.<sup>9</sup> Professional regulators need to continue to adapt to changes in clinical practice and ensure that they do not act as a barrier to improvements in patients’ access to care relating to medicines use by impeding innovation.

## Recommendations for service improvement

- GP consortia, in collaboration with local networks of pharmacists, nurses and other healthcare professionals, should introduce a proactive system of aftercare to allow patients to be contacted in the first few weeks after starting a new medicine. Some people may need longer-term support. We welcome the planned introduction of the Department of Health’s ‘new medicines service’ which may be an opportunity to improve the management of medicines use.
- Every GP practice in the country should have access to a local pharmacist adviser, to whom they can refer patients with medication problems, and who can be used as a source of advice for both patients and GPs on medication related issues.
- Patients should control access to their care record and, if they wish, allow pharmacists and other healthcare professionals to access and input into their electronic NHS patient record.
- There should be a better use of information technology in GP surgeries to assist the public in requesting and obtaining prescriptions.

## 4 Research matters

- 4.1 We heard that considerable effort is focused on gathering and collating evidence for evidence-based practice, but that we are bad at disseminating this evidence – to doctors, health professionals, and to the public. We heard about a number of distorting features that generate misunderstandings and incorrect beliefs about the efficacy of medicines. A critical factor is the way clinical trials research is reported – which is often selective and lacking in transparency at various stages in the trials process.
- 4.2 If the situation is confused for prescribers, then how much more is it so for the public? We heard that there are many situations when we do not know what the best treatment is and the only way we know whether something works or not is because in most cases we have conducted a clinical trial. In the view of Ben Goldacre, if people were more aware of this, and if the whole process of how we gather evidence and how we use it were more transparent, we would have an easier job discussing with people the claims made about medicines, and an easier job recruiting people into clinical trials. In support of these aims, the subgroup endorses efforts to improve reporting transparency contained in the ‘six principles of transparent reporting’, which are being developed by the transparent reporting subgroup of the Medicines Forum.

### Medicines and the media

- 4.3 The Science Media Centre was set up in 2000 to work with the scientific community when controversial science stories hit the headlines. Making respected scientists and clinicians, who can be relied on to take an evidence-based approach, available to the media is a powerful way to improve coverage so that the public has access to accurate information. For those members of the public who wish to delve deeper into scientific issues, information, including specialist journals, is readily available on the internet. However, this facility is not always first choice and, for many, views about new drugs or treatments will be determined solely by what is seen on TV or in the press.

*The media does not see it as its role to communicate accurate information to help patients get an unbiased view. The media's role is to sell papers and entertain, and somewhere along the way to inform. (Fox)*

- 4.4 In truth, many treatments that feature in the media are the subject only of very preliminary research, and will not be available to the public for decades. This then becomes an issue of balance: one of providing information without raising expectations needlessly. In the view of the subgroup, this will only be improved by facilitating a better understanding of the nature of scientific research and its complexities, through honest debate about its limitations, and by freeing up professional time so that individual patient need can be handled sensitively.

### Medicines research and the public

- 4.5 There is no progress without research. By and large, members of the public are sympathetic to the need to gather knowledge through experiment; however, their participation in research needs to be brokered through open and honest discussion. The incentive is often altruism; the disincentive, lack of information and opportunity.

*Our regular surveys of people with motor neurone disease show that research and taking part in research is at the top of their priority list every time. People with motor neurone disease see taking part in research as a way of fighting back and ultimately and hopefully sparing others from their own experience of this devastating and terminal disease. There is also a recognition that taking part in, for example, a clinical trial can offer regular clinical monitoring, which gives reassurance.* (Knox)

- 4.6 From NHS INVOLVE we heard about the importance of public involvement in research, which serves to improve research quality and ultimately quality of care: ‘When patients, carers and the public are involved in research they highlight issues that are important to them both in terms of their treatment and care, and in identifying outcome measures that are important to them’. If they have the opportunity to influence design methods, the acceptability of research to patients is increased: ‘patients can often recommend ways in which research is done, which in turn gets more people interested in research’. (Buckland)

## Medicines and public health

- 4.7 Although ‘medicines are almost as old as medicine itself’<sup>1</sup> it is only within the last century that we have seen the mass production of pharmaceuticals and their consequent increasing availability to the public. However, the benefits of a population-based approach to medicines use, whereby the primary focus of attention is reducing the level of risk incurred by every member of a community rather than only those at the ‘high end’ of the risk distribution curve, do not appear to be widely understood, even by health professionals and policy makers. We were told that there are as yet unexploited opportunities for improving health outcomes, especially in contexts such as the primary prevention of vascular and related diseases: ‘We need to bring medicines into public health and engage public health people in the field’. (Wald)
- 4.8 It was suggested to us by Professor Sir Nicholas Wald that the use of medicines in a preventive context tended to be seen as a public health ‘failure’. Medicines are historically associated with the treatment of disease rather than its prevention, and prevention is seen primarily as a matter of environmental and lifestyle interventions. We noted the improvement in dental health associated with water fluoridisation in some parts of the UK, along with the controversy that has surrounded this issue. The more extensive use of fluoride in self-purchased dental products has not been subject to the same concerns, although as a public health measure it is less likely to be effective amongst some of the most at-risk sections of the population.
- 4.9 Professor Wald’s particular evidence related to one type of primary prevention for one class of disease,<sup>10</sup> but the thrust of his argument rested on the need for a new model of access in order to confer wider population benefit – the problem being one of people

*... not getting access to simple, inexpensive and safe means that could protect them from very serious events ... We need to find a proper framework for this that protects the public but which is not denying them access to something that will benefit them.* (Wald)

## Summary

- 4.10 In certain circumstances, patients and the public are keen to be involved in clinical research and we believe that ways should be found to facilitate this. However, we remain concerned that the partial disclosure of research evidence means that important uncertainties about the effects

of treatments remain unidentified and that patients are at risk from medicine usage which is inappropriate and potentially harmful. We believe that the ‘six principles of transparent reporting’, being developed by the transparent reporting subgroup of the Medicines Forum, will go some way to address this issue.

- 4.11 Although it is not the place of the subgroup to recommend the use of one particular approach, we do believe an exploration is needed of the role and value of medicine use at population level to improve public health.

### **Recommendations for improving research for the benefit of the public**

- Reporting guidelines on patient and public involvement in medicines research should be developed to: improve standards of reporting of patient and public involvement (PPI); strengthen the evidence base for PPI in medicines research; and encourage its inclusion in research design and conduct. These guidelines should be aimed primarily at scientists writing up their research for publication or involved in peer review, and at academic journals.
- The health departments across the UK should collaborate and fund initiatives to improve public awareness and understanding of the importance and role of research in delivering quality care. We would like to see public involvement in health research extended to include their involvement in the development of new medicines.
- The new National Institute for Health Research (NIHR) School for Public Health Research, and the NIHR Policy Research Unit on Behaviour and Health, to be established as part of the government’s white paper proposals on public health, should investigate public health-orientated approaches to the use of medicines, alongside conventional applications of pharmaceutical technologies.
- Regulatory approaches should also support consideration of the population benefits of medicines use. The outcomes of regulatory decisions should be evaluated in terms of population health benefit, together with an evaluation of the acceptability of such an approach to the public.

## 5 Conclusions

- **We all have lives beyond illness or medicines.**
- **We need a shared language for a better conversation.**
- **Prescribing is the beginning not the end of effective medicines use.**
- **We need real patient engagement in science and research.**
- **People do not need to be patients to take medicines.**

- 5.1 The barriers and opportunities that affect choice, access, and effective use of medicines are both personal and organisational. Access is not just about availability, and barriers are not always obvious. Individual and cultural constructs of health and disease are powerful drivers and influencers of behaviour. The part that knowledge, belief and understanding of medicines play in determining whether or not a medicine is taken as directed – or taken at all – cannot be underestimated.
- 5.2 Belief in the efficacy of medicines and the trust invested in those who prescribe and dispense them is enormous. We learned there is often a gap between what the medicines system is set up to deliver and public understanding of it, and in engaging people adequately in understanding the part that medicines can play in their lives. We believe there can be a professional over-reliance on prescription medicines that sometimes runs counter to patient wishes and welfare, and that there is often misunderstanding about what is available to the public in terms of life-changing therapeutic products and what modern medicine is able to offer in the present.
- 5.3 Safe and effective medicines play an important part in the relief of disease and suffering. However, not all prescriptions that are written are dispensed and not all dispensed medicines are either taken as directed or taken at all. In some circumstances multiple medicines are given which interact to the detriment of the person taking them. These are issues of concern – not just because of harm caused and waste,<sup>11</sup> but because of lost opportunity for improved individual and population health and well-being.
- 5.4 There is no doubt that modern medicine and medicines can be life-enhancing and (along with complementary environmental and social improvements) life-extending. Medicines can confer hope and opportunity to people living with illnesses that disable and kill. As social objects, therefore, medicines have great significance and it is perhaps not surprising that there are ambiguities in public, professional, and regulatory approaches to their supply and use. Medicinal drugs that are inherently hazardous and costly in relation to the benefits they confer need careful controls around them. However, many modern drugs are relatively safe, and most are now available at very low cost. As populations grow more educated and the people in them more skilled and self-confident in self-care, there will be a continuing trend towards the ‘normalisation’ of more forms of medicines use. The role of health professionals should shift further towards one of encouragement and the facilitation of rational personal choice, rather than discouraging the self-directed taking of medicines.

- 5.5 We noted exceptions, however. In the context of pharmaceutical treatment for mental ill health, for example, for some people the best course of action may be the right to refuse medication, or to accept it at its lowest effective dose for the shortest amount of time possible, or to seek alternative treatments. Evidence gathered by the subgroup also raised concern about promoting the use of pharmaceuticals in providing solutions to issues that are largely lifestyle-based.
- 5.6 We are concerned that systems for medicines access and information are able to fail patients too easily. Perhaps this reflects that no one person or authority is taking a sufficiently patient-centred perspective of the system. Naturally, objectives and responsibilities vary for each player at each stage of the process, but the failing poses a serious question – is there adequate and consistent focus on getting a good outcome for the individual? Many patient groups are able to ‘fill the gaps’ for those who feel they have not been provided with adequate support from conventional sources. However, sadly this is only an option for those conditions that have patient advocacy, for those who have support from a third party, or for those who feel sufficiently empowered themselves to ask questions and probe further.
- 5.7 Clearly there are many conversations going on and everyone whom we met had a story to tell about medicines. However, often those making medicines available are unable to listen and act on what the people using the medicines want to say. This is in part a failure to see the use of medicines as one element of a collaborative approach to managing and treating diseases – but it is also about the nature of evidence about medicines and our attitudes to this, and how this influences the system governing choice, access and efficient use of medicines. Often these factors prevent us from exploring wider benefits from medicines, some examples of which we heard in evidence and which are reflected in this report. In order to make the best use of what modern pharmaceuticals can offer, these barriers will need to be overcome. Our recommendations for doing this are set out in the final chapter of this report.

## 6 Recommendations

### Recommendations for more effective engagement

- The pharmaceutical industry, medicines regulators, commissioners and prescribers need to capture and appreciate what patients say about medicines more thoroughly and comprehensively, and to understand the stories that people tell about medicines: how they use them; the benefits they experience; and the adverse reactions that can arise, so that we can make the most of this area of healthcare.
- Start the process with a collection of patient terms and descriptors, collected throughout the medicines system: in clinical trials; regulatory decisions; technical appraisals; the consulting room; the pharmacy, in order to help health professionals work with patients to get the most from a medicine they have decided to take.
- Create new opportunities to capture and react to patients' views and experiences about medicines. The current opportunity to report suspected adverse drug reactions through the Yellow Card Scheme needs greater use and a higher profile. We need to explore other options to report – for example developing a patient formulary and using initiatives like [healthtalkonline](#).<sup>3</sup>
- The Expert Patients Programme should explore how it could further develop expert medicine users to provide support and advice to people about their medicines.
- To build further on existing achievements, more sustained effort needs to go into the quality and design of medicine information leaflets, addressing a range of needs, and using a range of formats and approaches – including exploiting opportunities offered by new communication tools.

### Recommendations for service improvement

- GP consortia in collaboration with local networks of pharmacists, nurses and other healthcare professionals should introduce a proactive system of aftercare to allow patients to be contacted in the first few weeks after starting a new medicine. Some people may need longer-term support. We welcome the planned introduction of the Department of Health's 'new medicines service' which may be an opportunity to improve the management of medicines use.
- Every GP practice in the country should have access to a local pharmacist adviser, to whom they can refer patients with medication problems, and who can be used as a source of advice for both patients and GPs on medication related issues.
- Patients should control access to their care record and, if they wish, allow pharmacists and other healthcare professionals to access and input into their electronic NHS patient record.
- There should be a better use of information technology in general practices to assist the public in requesting and obtaining prescriptions.

### Recommendations for improving research for the benefit of the public

- Reporting guidelines on patient and public involvement in medicines research should be developed to: improve standards of reporting of patient and public involvement (PPI); strengthen the evidence base for PPI in medicines research; and encourage its inclusion in research design and conduct.

These guidelines should be primarily aimed at scientists writing up their research for publication or involved in peer review, and at academic journals.

- Health departments across the UK should collaborate and fund initiatives to improve public awareness and understanding of the importance and role of research in delivering quality care. We would like to see public involvement in health research extended to include their involvement in the development of new medicines.
- The new National Institute for Health Research (NIHR) School for Public Health Research and NIHR Policy Research Unit on Behaviour and Health to be established as part of the government's white paper proposals on public health should investigate public health-orientated approaches to the use of medicines, alongside conventional applications of pharmaceutical technologies.
- Regulatory approaches should also support consideration of the population benefits of medicines use. The outcomes of regulatory decisions should be evaluated in terms of population health benefit, together with an evaluation of the acceptability of such an approach to the public.

## References

- 1 Royal College of Physicians. *Innovating for health: patients, physicians, the pharmaceutical industry and the NHS*. London: RCP, 2009.
- 2 National Institute for Clinical Excellence. *Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence*. Clinical Guideline 76. London: NICE, 2009.
- 3 Health talk online. [www.healthtalkonline.org](http://www.healthtalkonline.org) [Accessed May 2011]
- 4 Department of Health. *Medicines use review: understand your medicines*. London: DH, 2005. [www.mhra.gov.uk/publications/consumer/con2023071](http://www.mhra.gov.uk/publications/consumer/con2023071) [Accessed May 2011]
- 5 Glossary of MHRA terms. [www.mhra.gov.uk/searchhelp/glossary/index.htm](http://www.mhra.gov.uk/searchhelp/glossary/index.htm) [Accessed May 2011]
- 6 The Health and Social Care Information Centre. *Prescriptions dispensed in the community: England statistics for 1999 to 2009*. Prescribing Support Unit, July 2010.
- 7 The Proprietary Association of Great Britain. Market figures 2009. [www.pagb.co.uk/information/marketfigures.html](http://www.pagb.co.uk/information/marketfigures.html) [Accessed May 2011]
- 8 Motor Neurone Disease Association. *Riluzole: questions and answers*. Information sheet no 9. Northampton: MNDA, 2010.
- 9 My repeats. [www.myrepeats.com](http://www.myrepeats.com) [Accessed May 2011]
- 10 Wald NJ Law MR. A strategy to reduce cardiovascular disease by more than 80%. *BMJ* 2003;326:1419–25.
- 11 York Health Economics Consortium / School of Pharmacy. *Evaluation of the scale, causes and costs of waste medicines: final report*. York: YHEC, 2010.
- 12 McLernon DJ, Bond CM, Hannaford PC *et al*. Adverse drug reporting in the UK: a retrospective observational comparison of yellow card reports submitted by patients and health care professionals. *Drug Safety* 2010;33(9):775–88.

## Appendix A

### Those who gave oral evidence to the subgroup

#### 22 January 2010

**Duncan McRobbie** associate chief pharmacist for clinical services, and **pharmacy staff**, St Thomas' Hospital NHS Trust

#### 12 March 2010

**Staff** of the Vigilance and Risk Management of Medicines division of the Medicines and Healthcare products Regulatory Agency

#### 21 May 2010

**Rob Horne** professor of behavioural medicine, head of Department of Practice and Policy, The School of Pharmacy, University of London

**Paul Bennett and Robert Gilbert** Alliance Boots Public Development Team

#### 27 May 2010

**Kirstine Knox** chief executive, Motor Neurone Disease Association

**Katherine Darton** information officer, Mind; member of the subgroup

**Maggie Alexander** head of policy, Breakthrough Breast Cancer

**Hilary Thomas** oncologist and trustee, Breakthrough Breast Cancer

#### 2 September 2010

**Ben Goldacre** writer, broadcaster and medical doctor

**Fiona Fox** director, Science Media Centre

**Gillian Leng** chief operating officer, NHS Evidence

#### 15 September 2010

**Staff** of Globe Town Surgery, Roman Road, Bethnal Green

**Tak Wa Chung** community pharmacist, Roman Road, Bethnal Green

**Moira Coughlan** prescribing adviser, Tower Hamlets PCT

#### 19 October 2010

**Helen Gordon** chief executive, Royal Pharmaceutical Society of Great Britain

**Catherine Duggan** director of professional development and support, Royal Pharmaceutical Society of Great Britain

#### 9 November 2010

**Sarah Buckland** director, NHS INVOLVE

**David Dickinson** health communication designer; director, Consumation Limited

**Philip Routledge** professor of clinical pharmacology (School of Medicine), Cardiff University; president-elect, British Pharmacological Society

**17 November 2010**

**Sir Nicholas Wald** director, Wolfson Institute of Preventive Medicine, Barts and the London

**Edward Andersson** deputy director, NHS INVOLVE

## Appendix B

### The Yellow Card Scheme of the MHRA

- B1 In the UK, the Yellow Card Scheme allows health professionals and patients to report suspected Adverse Drug Reactions (ADRs) on a voluntary basis to the Medicines and Healthcare products Regulatory Agency (MHRA). The Scheme was introduced in 1964 in the wake of the thalidomide tragedy and acts primarily as an early warning system for the identification of previously unrecognised adverse reactions. It also provides valuable information on recognised ADRs, allowing the Commission on Human Medicines (CHM) and the MHRA to identify and refine the understanding of risk factors that may affect the clinical management of patients.
- B2 Like any voluntary scheme, reports received via the Yellow Card Scheme cannot be used to determine the true incidence of ADRs nor the total number of patients who may have suffered a true ADR, as some suspected ADRs are not reported. In addition, the reporting of a suspected ADR via the Scheme does not necessarily mean that the medicine caused the event. Suspected ADRs are often reported even if the association may be coincidental and the condition would have occurred anyway in the absence of the drug. ADR reporting rates may be influenced by the seriousness of reactions, their ease of recognition, extent of use of a particular drug, and promotion and publicity about a drug.
- B3 The MHRA typically receives around 25,000 Yellow Card reports of suspected side effects annually, and patients have contributed some 7,000 reports since a pilot reporting scheme started in 2005. The value of the Scheme has been demonstrated many times and it has helped to identify numerous important safety issues. Examples include:
- **Muscle damage associated with statin treatment**  
Four Yellow Card reports of muscle breakdown occurring with a statin (rosuvastatin) used to lower blood lipids, and a further case of kidney damage, alerted MHRA to the fact that some patients had been started on a high dose rather than working up to it if necessary. This was despite the fact that muscle damage is a well-recognised side effect of statin treatment. The MHRA was able to advise prescribers to start treatment on the lowest dose, and to reduce the dose in patients who had been started on a higher dose.
  - **Interaction between warfarin and cranberry juice**  
Five Yellow Card reports indicated that starting to drink cranberry juice had interfered with the blood-thinning effect of warfarin, in one case resulting in a fatal haemorrhage. The MHRA was able to advise on the need to limit or avoid cranberry juice, since this interaction was biologically plausible.
- B4 Recent research into patient ADR reporting has helped elucidate the contribution of patient reports and in particular patients' own descriptions of how an ADR has affected quality of life.<sup>12</sup> In 2010, patient ADR reports contributed to the identification of around a quarter of drug safety signals. Recent examples include:
- **Oral contraceptive pill and hair loss**  
A young woman who suffered 80% hair loss after taking oral contraception sent in a Yellow Card. The MHRA investigated other cases and found a lack of information in the patient leaflet, enabling this gap to be addressed.

- **Lung fibrosis with an antibiotic**

A carer whose 86-year-old mother was treated with an antibiotic (nitrofurantoin) for a year, and developed lung fibrosis, sent in a report. Although lung reactions were mentioned extensively in the product information, there was no specific mention of pulmonary fibrosis.

In February 2009, the Royal College of Physicians (RCP) published *Innovating for health: patients, physicians, the pharmaceutical industry and the NHS*, a report addressing the conditions in which safe and effective medicines can be developed and delivered for the benefit of patients.

This new report continues the work initiated by the RCP, and sets out to understand better the factors relating to whether and how people take their medicines, what influences choice, and how decisions around medicines use are made.

Members of the subgroup producing this report were concerned that systems for medicines access and information fail patients too easily, reflecting that no one person or authority is taking a sufficiently patient-centred view of the system. It is hoped, therefore, that this report will encourage those involved in medicines provision to engage with patients and the public in order to be at the forefront of shaping change.

ISBN 978 1 86016 445 3

Royal College of Physicians

11 St Andrews Place  
Regent's Park  
London NW1 4LE

[www.rcplondon.ac.uk](http://www.rcplondon.ac.uk)



**Royal College  
of Physicians**