

# Perspectives on *'Communicating evidence about medicines'*

A report of a one-day workshop held by  
the Academy of Medical Sciences on 6  
June 2016

**Disclaimer**

This report does not represent a formal Academy of Medical Sciences position on how best to communicate evidence about medicines. Rather this document reflects the wide-ranging discussions that took place at the workshop. The report of this meeting will feed into the Academy's workstream on '*How can we all best use evidence to judge the potential benefits and harms of medicines?*'.<sup>1</sup>

We hope that this report will also encourage wider discussion about communicating evidence about medicines. We would therefore welcome feedback on the report. For further information, please contact Dr Rachel Brown, Policy Officer at the Academy of Medical Sciences ([rachel.brown@acmedsci.ac.uk](mailto:rachel.brown@acmedsci.ac.uk), 020 3141 3223).

We are most grateful to Professor Theresa Marteau FMedSci for Chairing this workshop and to Professor Sir David Spiegelhalter OBE FRS for his helpful contributions in the development of this workshop. We are also especially thankful to Dr Paul Robinson, Dr Jacintha Sivarajah, and Dr Catherine Harvey for their contributions to the workshop which were given at short notice, and to all other individuals who contributed to the event.

All web references were accessed in June/July 2016.

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1. Led by Professor Sir John Tooke FMedSci, the workstream also includes workshops on evaluating evidence in health, conflicts of interest, and communicating evidence about medicines in the media. For further information, please see: <http://www.acmedsci.ac.uk/policy/policy-projects/how-can-we-all-best-use-evidence/>

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# Executive summary

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**To make informed choices about treatment options, individuals require accurate, balanced, and accessible information about the potential benefits and harms of medicines. Notably, in order to make a truly informed decision, it is imperative that people are able to understand this information as it is communicated to them and feel it can be trusted.**

*As part of a wider project exploring 'How can we all best use evidence to judge the potential benefits and harms of medicines?', the Academy of Medical Sciences convened a one-day multidisciplinary workshop on 'Communicating evidence about medicines'. The aim of the workshop was to explore the available evidence on how the presentation of quantitative health-related information impacts on the understanding and perceived trustworthiness of such information. Several key themes emerged:*

- **The principal aim of communicating quantitative evidence about medicines to the public and patients is to support both informed choice and shared decision-making with doctors.** Consistent with this non-directive approach, communication should be based on openness, honesty, and clarity. Communication should also cover both the potential benefits and potential harms of a medicine, and uncertainty. Ideally, it should also cover the potential benefits and harms of alternative treatments or, where relevant, preventive options.
- **To help support this aim, several forms of guidance and recommendations have been developed on good practice in risk communication.** These highlight the importance of, for example, using absolute risk figures, and tables and graphics in order to improve understanding of the information, as well as the dangers of using qualitative terms (such as 'low risk') which are open to interpretation and can lead to confusion. Although such guidance is often highly consistent, delegates were unaware of formal (or enforceable) guidelines dictating how best to communicate evidence. They noted, however, that the development of such guidelines could better promote consistent good practice and ensure credibility.
- **There are a range of generic communication practices that can be used to enhance understandability.** Techniques such as 'layering' of information – including summaries followed by increasingly detailed tiers of information – can enable readers to grasp key concepts before exploring issues in more depth. In addition, breaking information into smaller clearly differentiated sections, greater use of subheadings, font choice, and use of colours to highlight key points can all enhance understanding and readability. The web and digital tools are offering more dynamic and interactive ways to present information, and could enable more personalised benefit–harm assessments to be developed. There are also opportunities for interdisciplinary research (e.g. clinicians, psychologists, cognitive neuroscientists, educationalists, designers, writers, information architects, public/patient representatives) to establish a firmer theoretical basis for communication and to further enhance communication practice.
- **It is highly valuable to involve potential users throughout the development process for information materials.** It is beneficial to involve patients and the public (or other users of information) from the beginning of the development process, initially to identify needs and preferences. At later stages, representatives of target audiences can provide feedback on materials, such as draft text or designs or possible graphical materials, as part of an iterative development process.
- **There are numerous channels through which individuals receive information about medicines, each of which is subject to particular constraints (but each also offering opportunities for improved communication).** There are a range of information providers, including healthcare professionals, government bodies, regulatory bodies, charities, pharmaceutical companies and the media, but also friends, family and social networks. The perceived trustworthiness of such sources is a crucial factor affecting how the information is perceived, and therefore ultimately used in decision-making.
- **A particular focus of discussion was that the mainstream media can have an important role to play in shaping perceptions about medicines and other treatments.** Delegates agreed it would be helpful if media reports routinely placed new information about the benefits and harms of a medicine in the context of existing knowledge about that treatment and alternative approaches. Information providers may need to invest time in dialogue with journalists and other mediators to promote more nuanced reporting.
- **Explaining about the process of evidence generation could improve individuals' ability to evaluate information about medicines.** Communicating information about medicines to the public is challenging – information may be inherently complex, and the contingent nature of science means that knowledge is constantly evolving (even after drugs are available on the market), often resulting in uncertainty and expert

disagreement. While much of the workshop focused on how to present quantitative information about specific medicines, it was recognised that a wider focus on health literacy, and developing public knowledge of scientific processes and critical appraisal skills, could empower individuals to better interpret information about medicines. Delegates suggested that progress might be best achieved if this education began at early ages, during formal schooling.

- **There are limitations to what can be achieved even with adoption of good practice.** Recipients of information are not blank slates, but interpret information and make decisions based on a multitude of factors. For example, personal values, preconceptions, and perceptions of information sources all impact on decision-making. In addition, constraints on GPs' time may be a barrier to truly informed, shared decision-making. Other healthcare professionals, such as practice nurses, could potentially become more involved in provision of information or discussions with patients before final decisions are made with GPs.
- **This perspective also emphasises the importance of public trust in the provider of information.** Some concern was raised that communication to correct misperceptions could be inadvertently interpreted as an attempt to manipulate, which risks undermining trust in the information provider. Furthermore, there are occasions when communication is explicitly intended to persuade or influence behaviour, for example to promote public health messages (e.g. vaccine use, smoking cessation, medication adherence).
- **Communication of information about medicines to the public should be based on a distillation of all relevant information.** Communication based on incomplete information risks misinforming patients and the public, emphasising the need for full public scrutiny of medicines-related data.

# Introduction

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**Patients are playing an increasingly active role in discussions with doctors about treatment choices. To contribute meaningfully to these discussions, and to make genuinely informed choices, patients need accessible and accurate information about the potential benefits and harms of medicines. It is important that individuals both understand and trust the information provided to them.**

As part of a wider project exploring '*How can we all best use evidence to judge the potential benefits and harms of medicines?*' the Academy of Medical Sciences convened a one-day workshop on '*Communicating evidence about medicines*'.<sup>2</sup> As introduced by the Chair **Professor Theresa Marteau FMedSci**, Director of Behaviour and Health Research Unit at the University of Cambridge, the aims of the workshop were to explore the available research on how the presentation of quantitative evidence about the potential benefits and harms of medicines impacts on the understanding and trustworthiness of such evidence.

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2. The Academy of Medical Sciences (2015). *How can we all best use evidence to judge the potential benefits and harms of medicines?*  
<http://www.acmedsci.ac.uk/policy/policy-projects/how-can-we-all-best-use-evidence/>

The workshop also aimed to review existing best practice guidance on the communication of evidence. The participant list and agenda for the workshop are provided in Annex 1 and Annex 2 respectively.

To foster discussions, the workshop made reference to three exemplar medicines used by large proportions of the population: hormone replacement therapy (HRT), statins, and vaccines. Each case study also formed the basis of a breakout session which provided an opportunity for participants to discuss challenges to effective communication and methods to overcome them. Summaries of the discussions held during the breakout sessions are provided in Annex 3.

This '*Communicating evidence about medicines*' workshop followed an earlier roundtable meeting, also held as part of the wider workstream, which discussed issues specifically related to the communication of health-related information through the mainstream media.<sup>3</sup>

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3. The Academy of Medical Sciences (2016). *Communicating evidence in the media*. <http://www.acmedsci.ac.uk/policy/policy-projects/communicating-evidence-workshop/>



# Initiatives in presenting the evidence about potential benefits and harms of medicines

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**The workshop began with a series of presentations from academics, regulators, and industry representatives in order to examine a range of approaches that have been used to communicate the potential benefits and harms of medicines to the public and other audiences.**

Setting the scene, **Professor Sir David Spiegelhalter OBE FRS**, Winton Professor of the Public Understanding of Risk at the University of Cambridge, outlined several reasons why it is important to communicate such information. He suggested it is an ethical necessity to communicate information that could influence people's health and wellbeing. A key aim is to enable patients to make informed choices about treatments, to improve the quality of the discussion between professionals and patients, and to develop what he described as 'immunity to misleading anecdote'.

Crucially, he suggested, the aim should not be to persuade or coerce individuals but to enable them to come to an informed decision. As an example, he detailed a recent redesign of a breast cancer-screening leaflet which was developed in order to provide a balanced picture of the potential benefits and risks, without promoting a specific course of action.

Professor Spiegelhalter suggested that understandability is key to public communication. Information needs to be accurate and balanced but also understandable to non-expert audiences. Several authors (including Professor Spiegelhalter) have developed good practice guidance on risk communication (summarised in the workshop background document).<sup>4</sup> These sources of guidance cover how best to express quantitative risk information, for example through use of natural or expected frequencies ('x out of a 100 people') and absolute rather than relative risk, and highlight the drawbacks of qualitative descriptions (e.g. 'low-risk'), which may mean different things to different people. They also emphasise the importance of visual design and graphical representations of data in order to ensure that individuals better understand the information being presented to them. Ideally, for such materials to be most useful, they should be developed in collaboration with users, cater for variation in numeracy among readers, and acknowledge uncertainty and limitations of evidence.

One notable model for communicating information about medicines to the public is the US-based 'Drug Facts Box', developed by speakers **Dr Steven Woloshin** and **Dr Lisa Schwartz**, Co-Directors of Medicine in the Media Program, Dartmouth Institute for Health Policy and Clinical Practice, USA. Unlike the UK, the USA allows direct-to-consumer marketing of pharmaceutical products. Advertisements may include assertions of benefit (e.g. celebrity endorsement), data on popularity/usage, and occasionally simple data on clinical benefit – typically expressed in terms of relative risk reduction, which generally gives an impression of greater effect.

Accompanying each glossy advertisement is a one-page 'brief summary' of possible side-effects. Typically this information is detailed and difficult to interpret. It may tick the transparency box, suggested Dr Woloshin and Dr Schwartz, but it does little to aid consumer understanding of risks.

Dr Woloshin and Dr Schwartz noted that documents submitted to regulators such as the US Food and Drug Administration (FDA) are a rich source of publicly available data on potential benefits and risks. However, these documents are dense and poorly summarised, and hence are challenging to interpret. This information forms the basis of direct-to-consumer advertisements and drug box leaflets, which are produced by pharmaceutical companies themselves. Companies may also publish medicines-related data in academic papers. However, Dr Woloshin and Dr Schwartz highlighted several examples in which important information had been lost or communicated misleadingly as information flowed through the 'medicines evidence pipeline' and into advertisements, leaflets, academic papers and clinical guidance.

Inspired by the simple tables of nutrition-related information included on breakfast cereal boxes, Dr Woloshin and Dr Schwartz developed the concept of Drug Facts Boxes to provide information about the potential benefits and harms of medicines in a way that was appealing, easy to understand, and useful to consumers. However, as inclusion of drug fact boxes with

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4. The background paper to the '*Communicating evidence about medicines*' workshop is available to download at [www.acmedsci.ac.uk/more/events/communicating-evidence-about-medicines-workshop/](http://www.acmedsci.ac.uk/more/events/communicating-evidence-about-medicines-workshop/)

medicines would require congressional approval, the FDA challenged Dr Woloshin and Dr Schwartz to establish that there was a public demand for such an approach. In a series of experimental studies, they showed that Drug Facts Boxes were popular with the public and also enabled them to make better judgements about the merits of drugs.<sup>5,6,7,8</sup> The Affordable Care Act has since included a section (3507) that called on the FDA to review the evidence for the Drug Facts Box summaries and to produce them if they were convinced that the format was helpful. However, after more than five years, and despite replicating many of the findings published by Dr Woloshin and Dr Schwartz, the FDA concluded that they are unable to implement such boxes.

Dr Woloshin and Dr Schwartz are therefore working independently to develop Drug Facts Boxes.<sup>9</sup> They have also established formal mechanisms and criteria for Drug Facts Box production, to promote transparency and replicability.

With a background in design, **Dr Sarah Rosenbaum**, Senior Advisor and Information Designer at the Norwegian Institute of Public Health, described how visual design and language use can enhance the understanding and readability of materials for the public or other target groups.

Dr Rosenbaum noted that communication challenges with end users are related to factors emerging at multiple stages along the evidence pipeline. She also pointed out that while target audiences have typically been divided into 'expert' and 'lay', it may be more appropriate to distinguish those with a research background from all other groups, including policy-makers and healthcare professionals as well as more traditional lay audiences.

A range of principles can be applied to enhance how well materials are understood, such as layering of information (i.e. going from simple to more complex); for example the '1:3:25' report format is based on a one-page outline of the main messages, a three-page executive summary, and a 25-page full summary. Understanding can also be enhanced by the use of colours to highlight key text, dividing text into clearly differentiated sections, and avoiding acronyms or terms that require prior knowledge for interpretation. Quantitative information should be provided in multiple representations – textual and graphical – to cater for different user preferences, but also to enable readers to cross-check their interpretations and gain confidence they have understood the information. Even with good templates and established processes, Dr Rosenbaum agreed that user testing is highly beneficial.

Dr Rosenbaum pointed to examples where these principles have been applied.<sup>10</sup> One initiative is the development of templates for plain language summaries for Cochrane systematic reviews, to help authors write understandable and consistent summary texts for anybody

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5. Schwartz LM, Woloshin S & Welch HG (2009). *Using a drug facts box to communicate drug benefits and harms: two randomized trials*. *Ann Intern Med* **150**(8), 516–27.
  6. Woloshin S, Schwartz LM (2011). *Communicating data about the benefits and harms of treatment: a randomized trial*. *Ann Intern Med* **155**(2), 87–96.
  7. Schwartz LM & Woloshin S (2011). *Communicating uncertainties about prescription drugs to the public: a national randomized trial*. *Arch Intern Med* **171**(16), 1463–8.
  8. Schwartz LM & Woloshin S (2013). *The Drug Facts Box: Improving the communication of prescription drug information*. *Proc Natl Acad Sci USA* **110** (Suppl 3), 14069–74.
  9. <http://www.informulary.com>
  10. <http://www.cochrane.no/scope-our-work>

interested in the review topic.<sup>11</sup> Through the EU DECIDE project, which has been exploring ways to improve the dissemination of evidence-based recommendations, Dr Rosenbaum and colleagues have been developing digital tools to provide new ways to present information, including interactive summaries of findings.<sup>12</sup> The DECIDE project has also developed an 'interactive evidence to decision' framework (iEtD) to bring evidence and structure to complex discussions and decisions in health care.<sup>13</sup>

Dr Rosenbaum is also involved in initiatives to enhance the capacity of the public or other audiences to interpret information about medicines. These include the GET-IT glossary of plain language definitions of health research terms and resources to enable schoolchildren and the public to appraise claims made about health.<sup>14,15</sup>

A key challenge in decision-making about medicines is the need to consider both potential benefits and potential harms. **Professor Deborah Ashby OBE FMedSci**, Co-Director of the Imperial Clinical Trials Unit, described an approach taken by the PROTECT project run by the Innovative Medicines Initiative (IMI), a public–private partnership supported by the European Commission and the European pharmaceutical industry.<sup>16</sup> The wider PROTECT project is examining how post-licensing data can be collected and used to inform regulatory decision-making. Professor Ashby described a stream of work aiming to develop a methodology to present quantitative information on benefits and harms in a visual form to support more effective decision-making.

As a case study, Professor Ashby discussed work on natalizumab, a drug licensed for the treatment of relapsing–remitting multiple sclerosis (MS). Following FDA approval, the drug was voluntarily withdrawn from the market after some patients taking natalizumab developed a rare neurological condition, progressive multifocal leukoencephalopathy (PML). However, as the drug provided good symptom relief, many individuals with MS pressed for its return to the market and it was subsequently relicensed in the USA. It was also approved in the EU for relapsing–remitting MS.

Weighing up the benefits and risks of natalizumab is challenging. As well as the risk of severe events such as PML, natalizumab use is associated with other side-effects of lower severity. These risks have to be weighed against the symptomatic relief offered by the drug. In addition, it is also important to assess how the benefits and harms of natalizumab compare with those of other MS drugs. However, head-to-head comparison studies have not been carried out, with most trials being placebo-controlled. Comparisons between drugs therefore have to be inferred from trial data.

The PROTECT project team has reviewed a range of methodologies to analyse and provide visual representations of benefits and harms data, using weighting systems to enable effects of very different impact to be combined.<sup>17</sup> These can generate relatively easy to interpret risk–benefit representations and scores (which suggest that in MS natalizumab's benefits do

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11. <http://www.cochrane.no/plain-language-summary-format>

12. <https://isof.epistemonikos.org/#/>

13. <https://ietd.epistemonikos.org>

14. <http://getitglossary.org>

15. <http://www.informedchoices.healthcare>

16. <http://www.imi-protect.eu>

17. Ashby D (2013). *Benefit-risk assessment and communication: A case study of natalizumab and PML*. <http://www.imi-protect.eu/documents/AshbyDBenefit-riskassessmentandcommunicationICPEMontreal26-29August2013.pdf>

outweigh the risks associated with its use).<sup>18</sup>

The methodology generates information of value to regulators. The project is also exploring how its visual outputs could be used to support communication with patients and the public. The project has also made recommendations about appropriate methodologies and visualisation techniques that could be used more widely (which are being reviewed by regulatory and other bodies).<sup>19</sup>

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18. Nixon R, *et al* (2013). *IMI PROTECT WP5 IMI Report 2: b: iv* <http://www.imi-protect.eu/documents/NixonetalBenefitRiskWave2CasestudyReportNatalizumabMarch2013.pdf>
  19. Hughes D, *et al*. *IMI PROTECT Benefit-Risk Group Recommendations Report*. <http://www.imi-protect.eu/documents/HughesetalRecommendationsforthemethodologyandvisualisationontechniquetobeusedintheassessmentto.pdf>

# Perspectives from industry and regulators

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**Two potentially important sources of information about medicines are regulatory agencies and the pharmaceutical industry.**

**Dr Priya Bahri**, who is leading on pharmacovigilance guidelines and use of evidence from risk communication research at the European Medicines Agency (EMA), suggested that recent years have seen a major drive towards increased transparency, in terms of the processes used to evaluate medicines and the information published about their potential benefits and harms. Increasing efforts are also being made to acquire more evidence about the risks and safety of medicines through post-licensing pharmacovigilance activities – including through better understanding of how medicines are used – with a view to inform regulatory decision-making on risk minimisation measures and other product-related action. She also advocated gaining a better understanding of the communication needs of patients and healthcare professionals in order to tailor risk minimisation measures accordingly.

The EMA creates a European Public Assessment Report (EPAR) for each medicine it regulates.<sup>20</sup> EPAR summaries are published on the EMA website, with a specific landing page for each medicine. Each EPAR includes a summary in language understandable to the general public.

The EMA is working with healthcare professionals, patients, and the public to improve the communication of medicines information. For example, when it was due to publish revised information about contraceptives and risk of thromboembolism, it consulted both professional and public groups to assess their needs and preferences. Interestingly, the two groups did not necessarily share preferences: consumers preferred information in tabular form, finding graphics too complex, while healthcare professionals preferred graphical representations which would also visualise relative risks. In addition, unlike healthcare professionals, consumers did not believe it was appropriate to make comparisons between pregnancy and thromboembolism risk, as the likening of pregnancy to a disease was deemed inappropriate.

The result of these deliberations was an accessible risk table, developed using principles of good communication practice and with very pragmatic aims. Dr Bahri acknowledged it was not perfect but was a good starting point and could be refined in the future. She also encouraged pharmacoepidemiology researchers to consider, when designing their studies, how data and results could be communicated meaningfully to the public.

Looking to the future, Dr Bahri suggested that there is a need to improve the reporting of potential adverse events, and to continue exploring ways to enhance the presentation of information, following the principles of good communication practice, involving users and exploring different ways of conveying numerical information (including graphical approaches). More thought was needed on how to communicate the robustness of data and uncertainty. The EMA is planning to develop its EPAR web pages, particularly to enhance accessibility to public audiences, and to promote their wider use.

Providing an industry perspective, **Dr Paul Robinson**, Executive Director, Scientific Medical and Patient Perspective, Merck Sharp & Dohme, noted that pharmaceutical companies have limited communication with the public about medicines, particularly in Europe, where direct-to-consumer advertising is not permitted. Although patient information leaflets for participants in clinical trials provide one point of contact, Dr Robinson suggested that their main function is as a kind of legal contract rather than as a communication tool. Similarly, the content of drug box leaflets is dictated by legal requirements; wording must also be agreed with regulators. Dr Robinson argued that these constraints make it challenging to develop materials that better meet patient needs (although even minor changes to typography and design can make a difference to readability). A third source of patient information is the risk management plan submitted to regulatory agencies. The EMA publishes public summaries of risk management plans of approved medicines, which can include useful material, but patients would tend to access this information only once decisions had already been made about treatment.

These comments were reiterated by **Dr Jacintha Sivarajah**, Head of Medical Affairs at the Association of the British Pharmaceutical Industry (ABPI), who added that the communication of information by companies to healthcare professionals and the public was also covered by

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20. [http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar\\_search.jsp&mid=WC0b01ac058001d125](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d125)

the ABPI code of practice.<sup>21</sup> While the pharmaceutical industry is able to communicate information on the benefits and risks of medicines directly to healthcare professionals (which is an ongoing process as information is constantly accumulating), she noted that communication with patients is most obviously done via healthcare professionals and patient charities. She also emphasised the importance of data collection in the post-licensing period and the importance of self-reporting of side-effects via the 'Yellow Card' reporting system run by the Medicines and Healthcare products Regulatory Agency (MHRA).<sup>22</sup>

Echoing this latter point, **Dr Catherine Harvey**, Director of Pharmacovigilance at GlaxoSmithKline, cautioned against relying solely on the original data submitted as a licence application to regulatory agencies when developing communications materials for the public. She pointed out that clinical trial participants in such studies, which are designed to achieve licence status, do not necessarily resemble the patients who take drugs in routine practice. Further, trials often focus on specific endpoints that are dictated by regulators and may not necessarily be the ones most relevant to patients. These factors, she suggested, emphasised the value of data from pragmatic studies and global post-marketing data collected after launch; there is a need to incorporate such evidence in patient communication by regularly updating information. She also argued that information about medicines was better provided by an independent body rather than directly to patients by companies, thus ensuring the focus of communication is informing rather than advertising.

During wider participant discussion, it was suggested that more could be done to involve patients in medicines development and evaluation (for example, providing input into trial design and outcome measures or acceptable risk–benefit discussions). The rare disease field may be the area where patients have the strongest voice. It was also noted that the IMI is also running initiatives examining ways to improve public and patient involvement.<sup>23</sup>

Several drawbacks in the current systems for reporting potential side-effects were also acknowledged. It was suggested that awareness of the Yellow Card reporting system is low among the public (and even among UK physicians and pharmacists). While gaining greater insight into the existence of potential side-effects was widely seen as important, it was also acknowledged that reporting might raise public concerns about a medicine, even in the absence of a confirmed link to harm. It was suggested that a period of uncertainty was inevitable, but it is important that all potential adverse reactions should be openly communicated and investigated.

Reflecting on the wide-ranging presentations, audience discussions also touched on which organisations were appropriate sources of information. It was recognised that pharmaceutical companies could be perceived as biased and may not be trusted sources. Charities and patient groups may be better placed to assimilate information and offer advice to healthcare professionals and the public. Bodies such as the EMA might also have a role, although it was suggested that EPAR information is currently quite complex (it is currently aimed mostly at healthcare professionals rather than the public).

For decisions to be truly informed, some participants pointed out that they needed to be based on a true picture of medicines' potential benefits and harms, and hence on an analysis of all relevant data. Standard output formats might ensure that complete data from clinical trials entered the public domain for independent analysis.

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21. <http://www.pmcpa.org.uk/thecode/Pages/default.aspx>

22. <https://yellowcard.mhra.gov.uk>

23. <https://www.imi.europa.eu/content/eupati>



Wider discussions of the morning session also emphasised the considerable challenges in communicating quantitative information about medicines. All medicines have potential benefits and harms, which may be difficult to compare. In addition, knowledge of benefits and harms is constantly evolving. There are also inevitably trade-offs between simplicity and comprehensiveness.

While drug box leaflets do offer one possible route for public communication, it was suggested that this might be too late in the process, as patients would access this information only after they have already chosen a treatment. It may be more helpful to provide different information in drug box leaflets, such as how to take the medication safely. Ideally, patients need access to information before they discuss treatment options with their GP.

It was also noted that the media plays an important role in shaping perceptions about the potential benefits and harms of medicines. There is a risk that media stories focus only on potential harms (or potential benefits) in isolation rather than considering the balance of benefits and harms. Such a polarised view could lead to inappropriate use of an overhyped drug or under-utilisation of a drug that might offer important benefits. On the other hand, devoting time to engagement with the media can lead to more nuanced reporting. It was suggested that the subtleties of the conclusions of several Cochrane Reviews were reported well after media events held at the Science Media Centre. A similar event also led to balanced coverage of issues related to proton beam therapy for cancer.

Freelance journalist **Michael Blastland** noted that the BBC has guidelines on risk communication which suggest it is important '*not to worry the audience unduly*'.<sup>24</sup> The BBC guidance has a strong emphasis on health and includes a checklist to encourage good practice. However, Mr Blastland was unsure whether a checklist would be widely used by busy journalists, although he acknowledged its existence could filter through to influence journalistic practice.

A particularly strong theme to emerge from discussions was the vital need to consider potential benefits and harms together rather than in isolation, for example in effects tables. New technologies are providing growing opportunities to personalise effects tables, so that the information is more directly relevant to individuals.

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24. <http://www.bbc.co.uk/editorialguidelines/guidance/reporting-risk>

# Understanding and trustworthiness among publics

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**The presentations were followed by a panel discussion that provided an important opportunity to examine the public's perception of medical evidence and sources of information.**

First to speak was **Dr William Matthews**, Senior Lecturer at the University of Cambridge, who applies the principles of social psychology to consider how people's perceptions of such sources affect how information is interpreted. While the morning session had focused on how aspects such as the numerical presentation of quantitative information can affect how it is understood, Dr Matthews added a valuable insight into how basic psychological factors and interpersonal interactions can also impact on how information is perceived, often unknowingly to the individual concerned.

He highlighted three key dimensions that can influence how people form opinions of other people or sources of information – competence, warmth (or likeability) and trustworthiness. He also noted that such factors can influence opinions very rapidly (and often subconsciously), can be deep-seated, and have long-lasting impact.

**Helen Baker**, an Associate at the Community Health and Learning Foundation, noted that the ability to act upon quantitative information about medicines was part of the broader issue of health literacy – having the skills to make informed choices about one’s health. She suggested that health literacy levels among the general public were typically low – 43% of adults do not have health literacy skills to fully understand typical text-based health information, a figure that rises to 61% if materials include numerical information – which information providers needed to take into account.<sup>25</sup> She echoed the importance of good communication practice, including providing information in multiple formats, testing materials with users, and carrying out tests to check comprehension. She also emphasised the need to develop general health literacy to empower individuals to make more informed decisions about their health.

**Dr Emma Smith**, Science Communications Manager at Cancer Research UK (CRUK), suggested that CRUK is a trusted source known for the quality, accuracy, and clarity of its materials. CRUK recognises the importance of accuracy and of not overselling research – its overriding aims in public communication are to be transparent, honest, and clear. To address some of the challenges associated with the communication of cutting-edge science, such as scientific uncertainty and expert disagreement, it aims to include aspects of science as a process in its communications. Although focusing on individuals can create compelling stories and capture attention, Dr Smith cautioned that this approach can also divert attention from important issues and create misleading perceptions. She also suggested that financial factors can significantly influence public perceptions – the pharmaceutical industry can be seen as having an interest only in making money and NICE may be perceived to be a mechanism for saving money.

**Suzie Shepherd**, Outgoing Chair of the Royal College of Physicians Patient and Carer Network, pointed out that the public was a very varied group, with widely varying levels of knowledge and skills. Each patient is likely to have a unique set of characteristics and co-morbidities and may be taking other medications. Understanding how population-level benefits and risks relate at an individual level can therefore be challenging. It is also difficult to find time to research these issues, and consultations offer limited time for genuinely informed discussions with GPs. She also commented that mutual trust between the public and the pharmaceutical industry is imperative for effective communication.

In wider participant discussions, it was suggested that conflicts of interests (both real and perceived) can have a significant impact on how trustworthy information is thought to be. This was considered most obviously the case for financial interests, but over-selling of health-related research findings by researchers or their institutions, to enhance their public profiles through greater media exposure, could also undermine trust in scientists. Recent research has shown that many examples of over-selling are not the result of journalistic misreporting but reflect statements made in original media releases.<sup>26</sup> It was emphasised that all parties (including researchers, press officers and journalists) need to take responsibility for accurate

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25. Rowlands G (2014). *Health literacy*. *Hum Vaccin Immunother*. **10**(7), 2130–5.

26. Sumner P, *et al* (2014). *The association between exaggeration in health related science news and academic press releases: retrospective observational study*. *BMJ* **349**:g7015.

and balanced reporting of health-related research findings in the media.

It was noted that public perceptions, once established, are hard to shift. It was raised that a two-step process could be needed to address this issue, first to secure public attention then to apply techniques to shift perceptions (approaches more typically associated with advertising and marketing). However, it was also noted that this runs the risk of being perceived as coercive and manipulative, rather than corrective and done out of concern for accuracy. Although the communication of information about medicines would generally be non-directive, where there is a strong public health justification – such as vaccination – more persuasive approaches are appropriate.

# Existing guidance for communicating risk, and are these 'fit for purpose?'

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**In a presentation by Professor Adrian Edwards, Director of the Institute of Public Health and Primary Care at Cardiff University, it was raised that no guidance for healthcare professionals had yet secured formal approval status, although a range of recommendations have been developed (summarised in the workshop's briefing materials).<sup>27</sup>**

Professor Edwards suggested that the key purpose of risk communication guidance is to support informed shared decision-making between patient and clinician.<sup>28</sup> In this context, both patients and clinicians could be seen as being part of extended networks of contacts – professional and personal – likely to influence perceptions, attitudes to risk, and decision-making.

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27. The background paper to the '*Communicating evidence about medicines*' workshop is available to download at [www.acmedsci.ac.uk/more/events/communicating-evidence-about-medicines-workshop/](http://www.acmedsci.ac.uk/more/events/communicating-evidence-about-medicines-workshop/)

28. Elwyn G, *et al* (2012). *Shared decision making: a model for clinical practice*. *J Gen Intern Med* **27**(10), 1361–7.

A range of conceptual frameworks have been developed for shared decision-making. Methods of risk communication are pivotal to such frameworks.<sup>29,30</sup> Researchers have also proposed core skills that doctors require for shared decision-making (which include the ability to communicate the potential benefits and harms of medicines).

In addition, much work has been put into developing principles to guide healthcare professionals' communication of risk information to patients. Some authors have proposed a series of competencies, covering both the content and the process of risk communication.<sup>31</sup> Given that the guidance is relatively detailed, Professor Edwards queried the practicalities of its routine use, although he acknowledged it could have particular value in training and in evaluation. Simplified versions and practical tools (including risk communications scripts) are widely available.<sup>32,33,34,35</sup>

Following Professor Edwards's presentation, participants noted that most communication focuses on the initiation of treatment, but there is also a need to consider communication about stopping medicines. For example, older patients may end up taking multiple medications and over time may cease to gain benefit from some. There is relatively little guidance on how to discuss ending treatment or switching to non-pharmaceutical alternatives with patients, and it was noted that this may be an area in which greater focus should be placed in order to make progress.

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29. Paling J (2003). *Strategies to help patients understand risks*. *BMJ* **327**(7417), 745–8.
  30. Trevena LJ, *et al* (2013). *Presenting quantitative information about decision outcomes: a risk communication primer for patient decision aid developers*. *BMC Med Inform Decis Mak* **13**(Suppl 2), S7.
  31. Han PK, *et al* (2014). *Development and evaluation of a risk communication curriculum for medical students*. *Patient Educ Couns* **94**(1), 43–9.
  32. <http://effectivehealthcare.ahrq.gov/index.cfm/tools-and-resources/patient-decision-aids/>
  33. <http://www.cincinnatichildrens.org/service/j/anderson-center/evidence-based-care/decision-aids/>
  34. [http://dartmed.dartmouth.edu/spring08/html/disc\\_drugs\\_we.php](http://dartmed.dartmouth.edu/spring08/html/disc_drugs_we.php)
  35. <http://shareddecisions.mayoclinic.org/decision-aid-information/decision-aids-for-chronic-disease/>

# Key conclusions and next steps

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**The key aim of communicating quantitative information about medicines is not to coerce individuals but rather to support informed decision-making. Communicating such information effectively and in a non-directive manner will better enable patients to discuss treatment options with their doctors and come to a genuinely informed decision.**

Delegates at the meeting agreed that there is now a wealth of research into how best to communicate evidence about medicines, resulting in a good deal of guidance about how materials should be developed to ensure that information is understandable. It may also be helpful to consider whether efforts are needed to enhance wider health literacy skills, including people's capacity to interpret such information by developing an appreciation of the processes involved in the generation of evidence about medicines. Such work would raise awareness of factors such as the reliability of information, uncertainty, contingency, and the likelihood of changes to benefits or risks as new data emerge. This latter point is particularly important as the evidence of potential benefits and risks of medicines grows after initial licensing approval, as data emerge from routine clinical use and other large studies are carried out.

However, it is important to recognise that many factors – preconceptions, personality, life experiences – affect how information is understood and interpreted, beyond simply how quantitative evidence is presented. Furthermore, researchers, experts and regulatory authorities differ in their conclusions about benefits and risks, even if they are using the same information and have fully understood it. There may be a range of interpretations of data and how they should influence clinical practice.

As well as the quality and accessibility of information provided, perceptions of the source of information (for example, whether sources are perceived to have a financial interest in use of a medicine) will also have a significant impact on how it is interpreted. For communication to be effective, it is important that information sources are seen as trustworthy as well as competent.

While the communication of quantitative information about medicines tends to focus on the transfer of information from a trusted source directly to a patient, it is also important to recognise the importance of alternative routes of information flow, particularly through social networks and the mainstream media. Echoing the discussions at the earlier roundtable meeting on '*Communicating evidence in the media*', delegates at this workshop agreed the importance of balanced reporting of potential benefits and harms in the media, and the need for those involved in the generation of scientific evidence to contribute to media processes, for example by recognising their responsibility to be balanced and accurate in press releases, and when necessary to devote time to dialogue with journalists.



# Annex 1 Participant list

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- **Dr Jeffrey Aronson**, Consultant Physician and Clinical Pharmacologist, Nuffield Department of Primary Care Health Sciences, Medical Sciences Division, University of Oxford
- **Professor Deborah Ashby OBE FMedSci**, Co-Director, Imperial Clinical Trials Unit; Deputy Head, School of Public Health, Imperial College London
- **Dr Priya Bahri**, Pharmacovigilance Lead for Guidelines and Risk Communication, European Medicines Agency
- **Helen Baker**, Associate, Community Health and Learning Foundation
- **Diane Beddoes**, Director, Deliberate Thinking
- **Christa Biervliet**, Information Resources Editor, Multiple Sclerosis Society UK
- **Michael Blastland\***, Freelance journalist
- **Naomi Boal**, Research Manager, Ipsos MORI
- **Tracey Brown**, Director, Sense About Science
- **Professor Chris Chambers**, Head of Brain Stimulation, CUBRIC Cardiff University
- **Seil Collins**, Media Relations Manager, The Lancet
- **Professor Sarah Cunningham-Burley\***, Professor of Medical and Family Sociology, University of Edinburgh
- **Professor Adrian Edwards**, Director, Institute of Public Health and Primary Care, Cardiff University
- **Harry Evans**, Senior Research Executive, Ipsos MORI
- **Dr Fiona Godlee**, Editor in Chief, The BMJ
- **Margaret Goose OBE**, Governor, The Health Foundation; Vice-President, The Stroke Association
- **Dr Rosa Gonzalez-Quevedo**, Communication Department, European Medicines Agency
- **Professor Bruce Guthrie**, Professor of Primary Care Medicine and Honorary Consultant NHS Fife, University of Dundee
- **Dr Catherine Harvey**, Director of Pharmacovigilance, GlaxoSmithKline
- **Claire Heard**, Research student, King's College London
- **Marie-Agnes Heine**, Head of Communication, European Medicines Agency
- **Professor Rob Horne\***, Professor of Behavioural Medicine, University College London
- **Eluned Hughes**, Head of Public Health and Information, Breast Cancer Now
- **Kate Kelland**, Health and Science Correspondent for Europe, Middle East and Africa, Reuters
- **Professor Ann Louise Kinmonth CBE FMedSci**, Emeritus Professor of General Practice, Fellow and Director of Clinical Studies, St John's College, University of Cambridge
- **Dr Fiona Lethbridge**, Senior Press Officer, Science Media Centre
- **David Leung**, '*How can we all best use evidence to judge the potential benefits and harms of medicines?*' public dialogue participant
- **Professor Theresa Marteau FMedSci (Chair)\***, Director of Behaviour and Health Research Unit, University of Cambridge
- **Dr William Matthews**, Senior Lecturer, University of Cambridge
- **Laura Norburn**, Senior Manager, Public Involvement Programme, National Institute for Health and Care Excellence
- **Professor Peter Openshaw FMedSci**, President, British Society for Immunology
- **Mike Pearson**, Centre for Mathematical Sciences, University of Cambridge

- **Dr Jo Protheroe**, Chair and Senior Lecturer in General Practice Health Literacy Steering Group, Keele University
- **Professor Julian Reiss**, Director, Centre for Humanities Engaging Science and Society, Durham University
- **Dr Paul Robinson**, Executive Director, Scientific Medical and Patient Perspective, Merck Sharp & Dohme
- **Dr Sarah Rosenbaum**, Senior Advisor and Information Designer, Norwegian Knowledge Centre for the Health Services
- **Stephanie Saltford**, Senior Content Editor, Arthritis UK
- **Dr Lisa Schwartz**, Professor of Medicine and of Community and Family Medicine; Co-Director of Medicine in the Media Program, The Dartmouth Institute, USA
- **Suzie Shepherd\***, Outgoing Chair, Royal College of Physicians Patient and Carer Network
- **Dr Jacintha Sivarajah**, Head of Medical Affairs, The Association of the British Pharmaceutical Industry
- **Dr Emma Smith**, Science Communications Manager, Cancer Research UK
- **Dr Sam Smith**, Cancer Research UK Postdoctoral Fellow, Queen Mary University of London
- **Professor Sir David Spiegelhalter OBE FRS\***, Winton Professor of the Public Understanding of Risk, University of Cambridge
- **Professor Stephen Sutton**, Professor of Behavioural Science, University of Cambridge
- **Dr David Tovey**, Editor in Chief, Cochrane Collaboration
- **Carmel Turner**, Chief Press Officer, Medical Research Council
- **Dr Geoff Watts FMedSci**, Freelance science and medical writer; broadcaster
- **Dr Stephen Webster†**, Director of the Science Communication Group, Imperial College London
- **Dr Rosie Wellesley**, General Practitioner, St Andrews Health Centre, Tower Hamlets
- **Professor Robert West**, Professor of Health Psychology and Director of Tobacco Studies, University College London
- **Dr Steven Woloshin**, Professor of Medicine and of Community and Family Medicine; Co-Director of Medicine in the Media Program, The Dartmouth Institute, USA
  
- **Secretariat**
- **Dr Rachel Brown**, Policy Officer, Academy of Medical Sciences
- **Dr Claire Cope**, Senior Policy Officer, Academy of Medical Sciences
- **Nick Hiller**, Director of Communications, Academy of Medical Sciences
- **Ian Jones**, Independent science writer; Director, Jinja Publishing Ltd
- **Andrew Pountain**, Policy intern, Academy of Medical Sciences
- **Dr Rachel Quinn**, Director of Medical Science Policy, Academy of Medical Sciences
- **Holly Rogers**, Communications Officer, Academy of Medical Sciences
  
- \* Member of the '*How can we all best use evidence to judge the potential benefits and harms of medicines?*' Oversight Group
- † Member of the '*Methods of evaluating evidence*' Working Group

# Annex II Agenda

09.30 - 10.00	<b>Registration</b>
10.00 - 10.05	<ul style="list-style-type: none"> <li>• <b>Welcome from the Chair</b> <b>Professor Theresa Marteau FMedSci</b>, Director of Behaviour and Health Research Unit, University of Cambridge</li> </ul>
<b>Presentations: Initiatives in presenting the evidence about potential benefits and harms of medicines</b> <b>Chair: Professor Theresa Marteau FMedSci</b> , Director of Behaviour and Health Research Unit, University of Cambridge	
10.05 - 10.10	<ul style="list-style-type: none"> <li>• <b>Professor Sir David Spiegelhalter OBE FRS</b>, Winton Professor of the Public Understanding of Risk, University of Cambridge</li> </ul>
10.10 - 10.30	<ul style="list-style-type: none"> <li>• <b>Dr Woloshin and Dr Schwartz</b>, Co-Directors of Medicine in the Media Program, The Dartmouth Institute, US</li> </ul>
10.30 - 10.45	<ul style="list-style-type: none"> <li>• <b>Dr Sarah Rosenbaum</b>, Senior Advisor and Information Designer, Norwegian Knowledge Centre for the Health Services</li> </ul>
10.45 - 11.00	<ul style="list-style-type: none"> <li>• <b>Professor Deborah Ashby OBE FMedSci</b>, Co-Director, Imperial Clinical Trials Unit; Co-ordinator of PROTECT</li> </ul>
11.00 - 11.15	<ul style="list-style-type: none"> <li>• Panel and audience discussion</li> </ul>
11.15 - 11.35	<b>Refreshments</b>
11.35 - 11.40	<ul style="list-style-type: none"> <li>• Re-cap of above talks by <b>Professor Theresa Marteau FMedSci</b></li> </ul>
11.40 - 11.55	<ul style="list-style-type: none"> <li>• <b>Dr Priya Bahri</b>, Pharmacovigilance Lead for Guidelines and Risk Communication, European Medicines Agency</li> </ul>
11.55 - 12.10	<ul style="list-style-type: none"> <li>• <b>Industry perspective</b> provided by:             <ul style="list-style-type: none"> <li>○ <b>Dr Catherine Harvey</b>, Director of Pharmacovigilance, GlaxoSmithKline</li> <li>○ <b>Dr Paul Robinson</b>, Executive Director, Scientific Medical and Patient Perspective, Merck Sharp &amp; Dohme</li> <li>○ <b>Dr Jacintha Sivarajah</b>, Head of Medical Affairs at the Association of the British Pharmaceutical Industry (ABPI)</li> </ul> </li> </ul>
12.10 - 12.45	<ul style="list-style-type: none"> <li>• Panel and audience discussion</li> </ul>
12.45 - 13.30	<b>Lunch</b>
<b>Panel discussion on understanding and trustworthiness among publics</b> <b>Chair: Professor Sarah Cunningham-Burley</b> , Professor of Medical and Family Sociology, University of Edinburgh	
13.30 - 13.50	Each to provide 5 minute introductory remarks: <ul style="list-style-type: none"> <li>• <b>Dr William Matthews</b>, Senior Lecturer, University of Cambridge</li> <li>• <b>Helen Baker</b>, Associate, Community Health and Learning Foundation</li> <li>• <b>Dr Emma Smith</b>, Science Communications Manager, Cancer Research UK</li> <li>• <b>Suzie Shepherd</b>, Outgoing Chair, Royal College of Physicians Patient and Carer Network</li> </ul>
13.50 - 14.20	<ul style="list-style-type: none"> <li>• Panel and audience discussion</li> </ul>

<b>Presentation: Existing guidance for communicating risk, and are these 'fit for purpose'?</b>	
<i>Chair: Michael Blastland, Freelance journalist</i>	
<b>14.20 - 14.35</b>	<ul style="list-style-type: none"> <li>• <b>Professor Adrian Edwards</b>, <i>Director, Institute of Public Health and Primary Care, Cardiff University</i></li> </ul>
<b>14.35 - 14.50</b>	<ul style="list-style-type: none"> <li>• Audience discussion</li> </ul>
<b>14.50 - 15.50</b>	<p><b>Break-out groups</b></p> <p><i>To use case studies to identify barriers and possible solutions to the effective communication of quantitative evidence about the potential benefits and harms of medicines.</i></p> <p>Each to provide a five minute introduction to a case study in a breakout group:</p> <ul style="list-style-type: none"> <li>• <b>Vaccines</b> - <b>Professor Peter Openshaw FMedSci</b>, <i>British Society for Immunology</i></li> <li>• <b>Statins</b> - <b>Dr Jeffrey Aronson</b>, <i>Consultant Physician and Clinical Pharmacologist, Nuffield Department of Primary Care Health Sciences, University of Oxford</i></li> <li>• <b>Hormone Replacement Therapy</b> - <b>Eluned Hughes</b>, <i>Breast Cancer Now</i></li> </ul>
<b>15.50 - 16.20</b>	Group feedback and general discussion
<b>16.20 - 16.30</b>	<p><b>Key messages for the Oversight Group</b></p> <p><b>Professor Theresa Marteau FMedSci</b>, <i>Director of Behaviour and Health Research Unit, University of Cambridge</i></p>
<b>16.30</b>	<b>Close</b>

# Annex III Breakout session summaries

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## Case study 1: Vaccines

Vaccines represent one of modern medicine's greatest success stories, and effective vaccines are now available for a wide range of infectious organisms. Vaccines share some features with other preventive treatments: they are taken by large numbers of healthy people, and individuals need to weigh up the benefits of long-term disease prevention with the more immediate potential risks associated with treatment (generally the risk of mild reactions following vaccine administration and, in some cases, a very remote risk of more severe adverse reactions).

However, in the case of vaccination, these individual considerations are overlain with wider population-level issues. Control of infectious disease by vaccination depends on high levels of vaccine use to provide 'herd immunity' to those who are not vaccinated. Thus, as well as implications for an individual, a decision to vaccinate or not also has wider public health consequences. There is therefore a public health imperative to promote vaccination, which could include communication that specifically aims to persuade individuals of the need to vaccinate.

Discussions in the breakout group highlighted these key facets of vaccination, as well as the fact that, as a preventive treatment, the benefits of vaccination are unobservable; people receive no confirmation that the treatment has worked. Moreover, many people now have no personal experience of the conditions successfully controlled by vaccines. Against this uncertain benefit can be set the perceived potential for harm, including rare and severe outcomes. The public is also exposed to periodic scares, most notably the spurious MMR–autism link, and to occasional negative comments from celebrities (abetted by coordinated anti-vaccination movements). As vaccination decisions are often made by parents on behalf of their children, decision-making can be a highly emotive issue.

Individuals may have other concerns about vaccines, beyond immediate harm. With the increasing numbers of vaccines given to children, parents may worry about 'overloading' their child's immune system. Some may also believe that exposure to infectious organisms can naturally 'challenge' the immune system and strengthen immune responses.

The public health drive for vaccination may also raise concerns. A sense of coercion may lead to resentment, and non-disclosed conflicts of interest among doctors benefiting financially from meeting vaccination targets have the potential to erode public trust. If communication is intended to persuade or encourage a certain behaviour, individuals may question whether they are receiving complete and balanced information about potential harms.

There is also a risk that individuals who decline vaccination are labelled as 'irrational'. This can alienate people and make it difficult to engage them in conversation. (It is also not necessarily true: choosing not to be vaccinated eliminates any risk of vaccine-related harm but individuals still benefit from herd immunity – unless significant numbers of their peers adopt a similar strategy.)

Participants suggested several ways of overcoming the barrier of unobservable benefit. When outbreaks of previously controlled infections do occur, these could be communicated, emphasising links to local vaccine coverage. Outbreaks may be a better focus than individual cases, which may be more newsworthy but could also be seen as too remote from people's daily lives.

Communicating the benefits of vaccination could stress the potential impact of non-vaccination on vulnerable family members, such as older people, as well as the public good associated with vaccine use. Potentially more could be done to celebrate the successes of vaccine-related disease control – a more positive message about vaccination.

Innovative approaches could be used to engage young children, such as cartoons or board games. More generally, it might be helpful to explore the reasons why people decline vaccination and to develop communications accordingly. It was also suggested that, rather than being labelled irrational, people who decline vaccination could instead be encouraged to feel guilty about not contributing to a public good.

In addition, a range of suggestions were made to address perceptions of coercion. People could be provided with clear, balanced and comprehensive information about the benefits of vaccination. Information about diseases controlled by vaccination and now rarely encountered could be integrated into young people's formal education. Financial incentives for vaccination must be handled carefully, to avoid damaging patient trust in healthcare professionals.

It may be beneficial to work at a local level, to build a sense of community around vaccination. It was also suggested that allied healthcare staff, such as nurses, midwives and receptionists, could also develop skills in communication of vaccine-related information to patients. Balanced reporting by the media was seen as essential, given its power to influence public attitudes and behaviour.

## Case study 2: Statins

Statins are widely used to lower blood cholesterol levels and to reduce the risk of a range of cardiovascular events, including stroke and heart attacks. The benefits of statins are well-established and little disputed. However, there has been extensive discussion about their potential side-effects.<sup>36,37,38,39</sup> In particular, some studies have reported relatively high levels of muscle pain associated with routine clinical use of statins. However, recent studies have suggested that muscle pain may not always arise as a true and direct consequence of statin use, as raising awareness of the possibility of muscle-related side-effects may increase patients' expectation of muscle pain or the likelihood that they attribute such pain to statin use.

One use of statins is for 'secondary prevention' – preventing further events in patients who have already experienced a cardiovascular event. They are also used for 'primary prevention' – preventing cardiovascular events in at-risk individuals who have yet to experience one. This latter use has stimulated much discussion, particularly as low thresholds for starting treatment could see large numbers of currently healthy people (who are nonetheless at risk of experiencing a cardiovascular event) taking statins.

In terms of individual decision-making in primary prevention, people need to weigh up the potential future benefits of a reduced risk of cardiovascular disease against the *potential* for more immediate side-effects associated with statin use. This decision-making takes place against the backdrop of a high media profile.

These issues raise considerable challenges for communication. For example, quantitative information on potential benefits and potential harms is very different: benefits reflect a reduction in risk of a fatal cardiovascular event some years in the future, while possible harms are more immediate side-effects potentially influencing quality of life (as well as a much rarer but well-established risk of more severe side-effects). Furthermore, the degree of benefit depends on factors such as age, sex and underlying risk, raising questions about how tailored information can be to individuals.

In addition, although benefits and harms may be highly context-dependent, important nuances can be lost in broad-brush communication, particularly media reporting that may over-simplify a complex issue or dichotomise debate. This can have unfortunate consequences, for example in influencing the decisions of patients recommended statins for both primary and secondary

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36. Finegold J, *et al* (2014). *What proportion of symptomatic side effects in patients taking statins are genuinely caused by the drug? Systematic review of randomised placebo-controlled trials to aid patient choice*. *Eur J Preventive Cardiol* **21**(4), 464–74.

37. Moriarty P, *et al* (2014). *ODYSSEY ALTERNATIVE: Efficacy and safety of the proprotein convertase subtilisin/kexin type 9 monoclonal antibody, alirocumab, versus ezetimibe, in patients with statin intolerance as defined by a placebo run-in and statin rechallenge arm*. *Circulation* **130**, 2105–26.

38. Moriarty PM, *et al* (2015). *Efficacy and safety of alirocumab vs ezetimibe in statin-intolerant patients, with a statin rechallenge arm: The ODYSSEY ALTERNATIVE randomized trial*. *J Clin Lipidol* **9**, 758–69.

39. Taylor F, *et al* (2013). *Statins for the primary prevention of cardiovascular disease*. *Cochrane Database Syst Rev* **1**, CD004816

prevention.<sup>40, 41</sup>

Some participants thought that there remains uncertainty about statin side-effects, adding to this complexity. For example, the issue of muscle-related side-effects has been contested; randomised controlled trials (RCTs) have shown a few, rare side-effects (including myopathy (also termed myositis), new onset type 2 diabetes mellitus, and haemorrhagic stroke). Observational data suggesting a link between statin use and other serious side-effects such as cancer and Parkinson's disease have since been refuted by RCTs. Others question whether side-effects, including muscle-related pain, have been assessed systematically in RCTs.<sup>42,43</sup> This ongoing debate raises questions about how genuine uncertainty can be communicated to patients. One notable aspect of the statin field has been the heated and polarised nature of the debate, which may make it difficult to communicate more nuanced points.

A further complication is that patient decision-making is not solely based on consideration of potential benefits and harms. Taking medication for preventive reasons in the absence of symptoms raises questions about one's sense of self and attitudes to medicines (many people wish to minimise their intake of pharmaceuticals). Similarly, at a societal level, concerns have been expressed about medicalisation and an over-reliance on pharmaceutical solutions. Patients may be exposed to both 'objective' information about potential benefits and harms, but also more subjective comment about medicalisation, with opinion not always distinguished from evidence. There may also be a perception among patients that use of statins is being promoted as a matter of policy, to deliver public health benefits, which may lead some to feel pressured into taking them.

Possible ways forward include more research to resolve scientific uncertainties about side-effects and clarity in communication about possible side-effects that have been suggested in the past but are now discounted (such as increased risks of cancer or suicide). A formal evaluation of the evidence by a well-respected independent body might also help clarify the situation for patients.

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40. Matthews A, *et al* (2016). *Impact of statin related media coverage on use of statins: Interrupted time series analysis with UK primary care data*. *BMJ* **353**, i3283.

41. Bohan H, van Doorn T, Witwicki C, Coulter A (2016). *Perceptions of Statins: Research with patients, GPs and cardiologists*. Picker Institute Europe.  
[https://www.bhf.org.uk/-/media/files/research/p2941-bhf-statins\\_final-report\\_publication.pdf?la=en](https://www.bhf.org.uk/-/media/files/research/p2941-bhf-statins_final-report_publication.pdf?la=en)

42. Of note, in order to provide further clarification of the side-effects that are likely to be caused by statin treatment, the Cholesterol Treatment Trialists' collaboration is currently conducting a reanalysis of the adverse events reported in statin trials. Ebrahim S & Davey Smith G (2015). *N-of-1 approach to determine when adverse effects are caused by statins*. *BMJ* **351**, h5281.

43. The Statin Web-based Investigation of Side Effects Trial (Statin WISE Trial) is currently running a series of N-of-1 randomised double blind placebo controlled trials to provide further information on whether muscle-related adverse events attributed to statin use by patients can be directly attributed to statins.  
<http://www.nets.nihr.ac.uk/projects/hta/1449159>



## Case study 3: Hormone replacement therapy

Hormone replacement therapy (HRT) is prescribed for symptom relief in women undergoing the menopause. There is also some evidence that HRT may in some groups protect against heart disease, although a recent Cochrane Review concluded that the evidence did not support the use of HRT for the prevention of cardiovascular disease.<sup>44,45</sup> Conversely, HRT use is associated with an increased risk of cancer, particularly breast cancer.<sup>46</sup>

Communication with the public about HRT is complicated. An understanding of the benefits and harms of HRT has changed over time, and continues to evolve.<sup>47</sup> Initial studies highlighting the increased risk of breast cancer, which contributed to a significant drop in HRT usage, may have overestimated the risks. Furthermore, benefits and harms are highly context-dependent, depending on multiple factors including which form of HRT is used, when it was started, the duration of usage, and individual factors such as family history, lifestyle and body mass index. It is therefore challenging to relate benefit and risk information to specific individuals.

As well as these complexities, it was also noted that potential benefits and harms are difficult to compare. Major harms, such as the increased risk of cancer, can be readily communicated in quantitative ways. It is less easy to provide meaningful quantitative data on symptom relief. Furthermore, weighing up potential benefits and harms is a very personal decision: some women may feel that short-term symptom relief and improved quality of life is worth the increased risk; others may feel that the potential adverse consequences are too great.

Within this complex landscape, discussions focused on two related issues: the supply of information by multiple bodies, and the absence of a single body responsible for communicating balanced, accessible and up-to-date information.

Cancer charities are among those providing information. Although this may be high quality and useful information, it may have the potential to focus women's attention on cancer and perhaps less on other beneficial or harmful outcomes.

GPs were considered to be a trusted group that women were likely to turn to for advice. However, it is unclear how able they are to provide detailed and nuanced information tailored to the circumstances of individual patients. Bodies such as NICE have an important role to play in providing professional guidance to support GPs' communication in this area.

Websites such as NHS Choices are another possible source of information for patients. The mainstream media are likely to be influential in raising awareness of key issues, and perhaps in establishing general perceptions, but are unlikely to be a suitable source of detailed information to

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44. Schierbeck LL, *et al* (2012). *Effect of hormone replacement therapy on cardiovascular events in recently postmenopausal women: randomised trial*. *BMJ* **345**, e6409.

45. Roberts H & Hickey M (2015). *Editorial - Should hormone therapy be recommended for prevention of cardiovascular disease?* *Cochrane Database Syst Rev* (3), 10.1002/14651858.ED000097

46. Narod SA (2011). *Hormone replacement therapy and the risk of breast cancer*. *Nat Rev Clin Oncol* **8**(11), 669–76.

47. Women's Health Concern (2015). *HRT: The history*. <https://www.womens-health-concern.org/help-and-advice/factsheets/hrt-the-history/>

inform decision-making. Women's magazines may also be a source of information and influence.

It was also noted that informal social networks – both face-to-face and online – provide potentially important channels for exchange of information, with considerable potential to influence attitudes and behaviour. However, it is challenging to assure the quality of information shared through these networks.

Opportunities may also exist to involve allied healthcare professionals in communication with patients. Nurses or other healthcare professionals could be trained to discuss information with patients, before a final decision during GP consultations.

It was suggested that 'celebrity ambassadors' could focus attention on health issues, including HRT. However, it was felt that these needed to be representative of target patient populations, and the media may find exceptional examples more newsworthy, potentially presenting a distorted picture.

This multiplicity of sources presents challenges, and suggests that action might need to be taken on multiple fronts. On the other hand, they offer numerous opportunities to open channels of communication.

In terms of what is communicated, the diversity of primary data also raises challenges. Clinical trial data may be seen as the highest quality, but clinical trial participants may be quite different from the women actually seeking treatment, raising questions about the generalisability of trial data. It may also be challenging to translate risk statistics generated in primary studies into information that is meaningful to patients. One possibility may be to factor public communication into trial design, by including outcome measures that are meaningful to public audiences.

In terms of how information is transferred, it was suggested that there was an abundance of poorly designed or conducted communication studies that may be influencing practice. There may be a need for more formal and rigorously evaluated guidance for effective communication based on high-quality studies.

In terms of who should provide information, public trust in information sources was seen as essential. In this context, peers may be particularly influential. Information could be provided by an NHS body, although it was suggested that not all patients had complete trust in the NHS. A body such as the EMA (or other regulator), which has high levels of public trust, would be another possible source. Independent bodies such as the Cochrane Collaboration could also be a source, particularly for healthcare professionals.

Finally, it was also noted that the impact of high-quality information would depend on the ability of patients to understand and assimilate the information they receive. As well as enhancing flows of information about HRT (or other medicines), it may also be helpful to develop the 'health literacy' of patients so they are better able to make use of this information.





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