Royal Pharmaceutical Society
of Great Britain

Helping pharmacists achieve excellence

PRACTICE AND QUALITY IMPROVEMENT
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Dear Bijal,

Clinical guideline: medicines concordance, scope consultation.

Please find attached the response of the Royal Pharmaceutical Society to the above consultation.

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.
The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register.

Please do not hesitate to get in touch with any further queries.

Yours sincerely

Paul Gimson
Lead Pharmacist, Long Term Conditions and Public Health

National Institute for Health and Clinical Excellence

Medicines concordance

Comments on the Scope

Stakeholder Comments

Please use this form for submitting your comments to the Institute.

1. Please put each new comment in a new row.
2. Please do not paste other tables into this table, as your comments could get lost – type directly into this table.
3. Please insert the **section number** in the 1st column. If your comment relates to the document as a whole, please put **'general'** in this column. **Please refer to section numbers and not page numbers.**

27 November, 2006

Name:	**Paul Gimson**
Organisation:	**Royal Pharmaceutical Society of Great Britain**
Section number Indicate **section number** or **'general'** if your comment relates to the whole document	**Comments** Please insert each new comment in a new row.
1 General	Overall, we very much welcome the decision by NICE to create a guideline on the topic of medicines concordance and the appointment of the NCC for Primary Care to carry out the work.
1 Guideline title and General COMMENT 1	It is not clear whether the focus of the guidelines is to promote shared decision making about prescribed medicines or to facilitate optimal adherence to medication. This is an important distinction as the processes and outcomes are different. A recent Scoping Exercise conducted for the NHS NCCSDO (http://www.sdo.lshtm.ac.uk/files/project/76-final-report.pdf) found that separating these issues was crucial to identifying a pragmatic way forward in this complex field. There is an implicit assumption that patient involvement in decision making will address the problem of non-adherence, but this has yet to be proven.
1 Guideline title and General COMMENT 2	Getting the most appropriate definitions and targets for the review is crucial to avoid a quagmire. I would suggest that the group consider adherence as the outcome (this term incorporates many of the features of concordance as it describes the degree to which the patients' behaviour matches an agreed recommendation). Adherence is a 'patient-centred' term.

1 Guideline title and General COMMENT 3	This review is likely to be challenging and complex as the evidence base may not be typical of those informing most NICE reviews – identifying the appropriate outcome and terminology is crucial.
1 Guideline title and General COMMENT 4	The key challenge for the formation of guidelines on this topic is to marry the philosophical and ethical imperative of taking account of patient perspectives and preferences with pragmatic interventions to facilities optimal use of medicines.
1 Guideline title and General COMMENT 5	Whereas, it can be argued that increased patient involvement is desirable in its own right, this alone does not solve the problem of non-adherence. The recent SDO review supported the underlying principles of concordance (respect for patient autonomy and need to understand patients' perspectives of illness and treatment and to engage them in decisions affecting their health) but identified key limitations in the concept. These included the difficulties of operationalising the concept in practice and the fact that it addresses only one of the potential causes of non-adherence (the prescribing consultation). This point is much more than semantics as it will determine the scope and content of their value in primary care practice
1 Guideline title and General COMMENT 6	The scope of the guidelines and guidelines title should include the term 'adherence' (this could be in addition to concordance). Section 3 which sets out the clinical need for the guidelines focuses on the problem on non-adherence and much of the text and areas covered actually refer to adherence rather than concordance
1 Guideline title and General COMMENT 7	The SDO review concluded that there was currently no valid and reliable way of measuring concordance (as the concept is complex and there is little agreement over it definition). Chapter 5 (Cribb & Barber) provided an in-depth critique of the concept and application in practice. Given that the NICE guidelines scoping document sets out clear targets for review of studies where concordance is the outcome, the first task for the group will be to agree a definition and measurement criteria for concordance. The SDO Scoping team found this to be a challenging and time-consuming topic, but arrived at some valuable insights which could help inform this process for NICE
1 Guideline title and General COMMENT 8	There is likely to be considerable overlap between the SDO and NICE projects with potential for synergy and it is worth considering how this might best be achieved.

Section 2c	The focus on 'informed decisions' is good. Consideration should be given to how this can be operationalised and assessed in practice. Horne and Weinman have recently linked the process of informed choice to adherence ('informed adherence') and started to develop a pragmatic approach to implementing this in everyday healthcare settings.
Section 3a and b	Although these two paragraphs are not directly linked within the document, the fact that they occur sequentially suggests that the major cost of non-adherence is wasted medicines. However, this is not the case, as most non adherence results in patients failing to get prescriptions dispensed and /or not obtaining repeat prescriptions (or obtaining them less frequently). Therefore the biggest cost of non-adherence is in avoidable healthcare cost and ill-health.
Section 3b	This section points out that '*..nonadherence is often undisclosed by patients and unrecognised by prescribers*'. A fundamental priority for the guidelines should therefore be to addresses methods for improving this situation by facilitating honest and open discussion about adherence and disclosure of non-adherence without fear of sanction by the patient. There is some development work in this area within primary care using simple questionnaire based techniques.
Section 3c	The fact that the document includes definitions of adherence, compliance and concordance is very valuable, as debates over terms can dominate this topic. The definitions of adherence and compliance given here are exact reproductions of phrases from the Horne SDO report and are uncontroversial. However, the definition of concordance given reflects only part of Horne's section on this topic, is far less precise and therefore open to question. It will be extremely important for the group preparing the guideline to agree a tight definition of concordance at the outset. A better starting point, also taken from the Horne report (page 28, final paragraph) would be to say 'Concordance - a term which describes both the process of prescribing consultations (patients should be involved as partners with clinicians in their own healthcare) and the outcome (shared agreement)'.

Section 3e) and 4.3e)	It is true that the Cochrane review referred to suggested that there was little evidence from the relatively few studies which met their criteria for inclusion that approaches to improve adherence were effective. However, there are many methodological difficulties with measuring the effectiveness of interventions in this area, and it is also the case that many of the admissible studies were attempts to improve compliance without addressing concordance (as per section 4.3d) of the scope). Hence it may be that NICE has to look beyond RCTs for evidence of benefit (whilst acknowledging the strict rules of evidence which apply in guideline development). We therefore welcome the statement that the guideline development group will take reasonable steps to identify ineffective approaches to care.
Section 4.1.1a and 4.3 (the second point called 'b' within this section)	It is not clear from the scope why adults with short term illness are to be excluded from the guideline. There is evidence of substantial harm due to antibiotic resistance resulting from partial adherence to short courses of antibiotics. Furthermore, it is likely that the barriers to adherence for short term illness are simply a subset of those relating to long-term adherence. There are also areas where the definition of short vs. long term illness is unclear. For example, tuberculosis could be seen as a relatively short term condition, but should certainly be covered by this guidance as adherence to antibiotic treatment and the prevention of antibiotic resistance is such a major issue. We would propose including short term illness in the analysis.
Section 4.1.2b	Similarly, it is not clear from the scope why patients being treated in specialist or tertiary centres will not be covered by the guideline. Some of these patients (for example those undergoing organ transplants and considering a lifetime of anti-rejection medicines, or those with Multiple Sclerosis considering disease modifying drugs) experience some of the most complex challenges in relation to medicine taking, and some of the most interesting potential solutions have been tested in these settings. We would hope that they could be included.

Section 4.3a, b, c	The phrase 'Concordance in prescribing decisions and medicine taking' is used in each of these sections but the phrase 'concordance in medicine taking' makes no sense when read in conjunction with the definition of concordance which we have suggested above under section 3c). Due to difficulties in defining and operationalising 'concordance' it may better to focus on 'perceptual factors (eg beliefs, attitudes and preferences) influencing *motivation* to start and continue with medication and practical factors (eg capacity and resource limitations) influencing patients' *ability* to adhere to medication. Communication difficulties and cultural issues can affect perceptual and practical factors as can the structure and content of the prescribing consultation.
Section 4.3a	As described above, if the scope is to look at patients' reports of concordance the group would first need to devise a user-friendly definition of 'concordance'. There would also be the need to consider variation in desire for involvement in treatment decisions.
Section 4.3a, b	It is worth noting that in the process of user consultation employed in the SDO scoping exercise found no support for the concept of concordance among the user stakeholders who preferred the concept of 'adherence'
Section 4.3d	Choosing to omit interventions that increase adherence without achieving concordance may pose difficulties and the literature is not always clear on these issues. Moreover, the SDO review of why previous interventions to facilitate adherence have met with limited success identified the need to take an individualised approach addressing perceptual and practical to the optimal use of appropriately prescribed medication to facilitate informed choice and adherence (if the patient chooses medication)
Section 4.3d	The analysis of previous interventions commissioned by the NCCSDO indicated that the best approach is likely to involve combination of simple reminder interventions with more complex interventions to address beliefs and preferences and facilitate informed choice. The key point is targeting to the needs of the individual. Omitting simple pragmatic interventions to remove the practical barriers to adherence might limit the scope and value of the guidelines.

Please add extra rows as needed