Key: SH = stakeholder

National Institute for Health and Clinical Excellence

Medicines concordance scope consultation table
30 October – 27 November 2006

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Addenbrookes NHS Trust			This organisation was approached but did not respond.	Noted.
SH	Age Concern England	1	General	We recommend that the scope should be reviewed in general to ensure that the key relevant issues from Medicines and Older People (Department of Health, 2001) will be covered. This document was issued with the National Service Framework for Older People (Department of Health, 2001). It is important to establish that the guideline may need to have a particular focus on the older population. We have highlighted in other comments below some of the specific issues from Medicines and Older People which we recommend are incorporated into the scope for the guideline but recommend that a full review is undertaken.	We will be addressing key issues in the elderly in studies that address this population group exclusively, or in studies that undertake sub-group analysis.
SH	Age Concern England	2	3	We recommend that the clinical need for the guideline should include the fact that as people get older, their use of medicines tends to increase (NSF for Older People, Medicines and Older People) and that four out of five people aged 75 and over take at least one prescribed medicine, with 36% taking four or more medicines (Health Survey for England). This will give some indication of the issues of polypharmacy and, to a lesser extent, co-morbidities which the Department of Health included as specific aspects of its referral to NICE.	We will be addressing key issues in the elderly in studies that address this population group exclusively, or in studies that undertake sub-group analysis.
SH	Age Concern England	3	3	We recommend that the clinical need for the guideline should include the fact that many adverse reactions to medicines could be prevented – they are implicated in 5-17% of hospital admissions (Medicines and Older People, 2001)	We will be addressing key issues in the elderly in studies that address this population group exclusively, or in studies that undertake sub-group analysis.
SH	Age Concern England	4	3d	Additional reasons for non-adherence include poor	We will be including as much information as

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				literacy levels (the English Longitudinal Study on Ageing provides evidence of this as a key factor in determining older people's understanding of written information on medicines), poor vision and manual dexterity, and impact on other important factors in the individual's quality of life. We recommend that these are included.	possible from the relevant evidence, and we will be addressing key issues in the elderly.
SH	Age Concern England	5	4.1.1	We recommend that the population to be covered should state a particular focus on older people (for the reasons stated above – that increasing age brings increasing use of medicines) and should explicitly state that it will focus on those taking more than one drug.	We will be addressing key issues in the elderly in studies that address this population group exclusively, or in studies that undertake sub-group analysis.
SH	Age Concern England	6	4.3	We recommend that polypharmacy should be included explicitly as an area to be covered in considering both concordance and effectiveness of interventions to promote adherence. Polypharmacy is a key issue in the referral from the Department of Health and in the problems faced by both older people and prescribers. It therefore needs to be explicitly included.	We will revise scope to add more detail on polypharmacy.
SH	Age Concern England	7	4.3 a	Barriers to concordance should include low literacy levels, physical barriers such as low vision or poor manual dexterity, and impact on other important aspects of quality of life.	Noted, and we do not intend the barriers as listed in the scope to be comprehensive. However, this is an important issue and therefore has been added to the Scope.
SH	Age Concern England	8	4.3 a and b	Barriers should include poor two-way communication between hospitals and primary care. This is again highlighted as a key issue in Medicines and Older People.	Communication between healthcare professionals, although a vital component, is outside the scope of this guideline.
SH	Age Concern England	9	4.3 c and d	The targets for intervention should include carers – this should include both informal/family carers, who often provide the main help and support to people taking medication, and paid carers. Medicines and Older People identified the fact that the potential contribution of carers and their needs are often not addressed. The guideline should ensure that the	Noted. Have revised.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				needs and contribution of carers are addressed.	
SH	Amgen UK Ltd			This organisation was approached but did not respond.	Noted.
SH	Anticoagulation Europe			This organisation was approached but did not respond.	Noted.
SH	Anticoagulation Specialist Association	1	General	ASA welcomes the opportunity to review this draft scope	Noted. Thank you for your comments.
SH	Anticoagulation Specialist Association	2	General	We are pleased that NICE is looking into developing guideline on concordance for patients on long term medication. However we it could be difficult to address all aspects due to the varies elements that affect medication intake	Noted. Thank you for your comments
SH	Anticoagulation Specialist Association	3	3a	Every prescriber have a duty of care to Assess the patient, carry out medication review and achieve concordance, only then we might be able to reduce the percentage of patients not taking medicines This practice might enable the prescriber to identify patients who have not been taking all the other medication before a new medication is prescribed Identification of a problem is critical, hopefully the guideline will help to achieve this 2. Following identification there has to be mechanism to refer patient to the GP highlighting the problem	Thank you for your comments. We will guide the development work as much as possible from the available evidence.
SH	Anticoagulation Specialist Association	4	3b	Consequences of 3b Ill health and reduced quality of life Reduced expectancy Avoidable health care cost Economic loss to society Therefore a guideline is definitely welcomed	Noted. Thank you for your comments.
SH	Anticoagulation Specialist Association	5	General	Part of developing the guideline is about addressing issues like education and training for prescribers, especially for medics Hopefully through this work the above can be achieved	Noted. Thank you for your comments.
SH	Anticoagulation Specialist	6	4.2b	Excluding tertiary is worrying-	In light of the stakeholder comments we have

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Association			In patients are initiated on new long term medication, so excluding this group of patients have implications: 1. Ideal opportunity to assess patients medication, a medication review can be conducted 2. Concordance should be achieved when new medications are started and not to wait until the patient is discharged into the community or seen in out patient	revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	Anticoagulation Specialist Association	7	4.3b	Barriers should be identified and can be identified so the issues can be communicated to GP in primary care	Noted. This will be done whilst developing the evidence reviews.
SH	Asthma UK	1	General	Asthma UK welcomes the opportunity to comment on the *scope of the Medicines Concordance Guideline*. Good quality outcomes in asthma hinge not just on availability of medications but also on their appropriate use by patients. In asthma, low rates if adherence to prophylactic medication are associated with higher rates of hospitalisation and death It has been estimated that one quarter of asthma patients in the UK have a compliance rate of 30 per cent or less. Asthma UK believes the issues that surround lack of concordance are extremely complex and guidelines on how this should be addressed would be welcome and could have a major impact on the lives of people with asthma particularly the 81% of people with asthma who fail to meet the international standards of care	Noted. Thank you for your comments and we will try to address this as appropriate.
SH	Asthma UK	2	3 c	The definition of concordance as stated in the scope, as a wider concept which stretches from prescribing	We have tried to follow closely the work done by the SDO report. Also, please bear in mind that

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				communication to patient support in medicine taking' does not fully encapsulate its wider meaning. We would recommend a definition similar to that used in the British Guideline on the Management of Asthma (BTS/SIGN); "The term concordance is intended to convey a respect for the aims of both the health professional and the patient, and signifies a negotiated agreement between the two. Non-concordance describes an inability of both parties to come to an understanding, not merely a failure of the patient to follow the health professional's instructions"	they are working definitions, and as an iterative process they may be subject to change.
SH	Asthma UK	3	4.1.1	Asthma UK welcomes the fact that people with co-morbidities will be included in the guidelines as 60% of older people with asthma say that they also have other long-term health problems.	Noted. Thank you for your comments.
SH	Asthma UK	4	4.1.2 a	Whilst Asthma UK acknowledges the breadth of this scope we would urge some consideration to include young people under the age of 18 years. The reasons why adolescents fail to comply with their regimen are not well understood and 75% of children in the UK with asthma fail to meet international standards of care The impact of poorly controlled asthma can have huge implications for young people, e.g. 24% of children with asthma miss 6 or more days of school as a result of their asthma The Blue Peter/Asthma UK Survey is the largest survey of the views of children with asthma in the world and the results from this survey suggest that 1 in 5 of those who participated in the survey are using their reliever inhalers 9 times or more per week (more	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				than 3 times the recommended amount)	
SH	Asthma UK	5	4.1.2 b	The scope does not cover patients being treated in specialist or tertiary centres, or undergoing specialist treatment or regimes not normally delivered in a generalist primary or secondary care setting. Asthma is a variable condition and people with asthma may need to spend time within specialist care where concordance is as an important issue as in generalist primary or secondary. Therefore we would encourage all of the spectrum of care to be included.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medicines.
SH	Asthma UK	6	Areas covered 4.3	An important contributor to poor concordance with treatment instructions may be a discrepancy between the goals of the clinician and those of the person with asthma. This may result in a failure to integrate the medical agenda with the person's perspective. Concordance is only possible if both the clinician and the patient have shared goals. Some people with asthma prioritise lifestyle issues ahead of disease specific concerns and therefore clinicians and clinical guidelines should recognize this and consider the goals of both the clinician and the patient Will the scope address whether shared goals are reached? Also will the scope take into account follow-up care (such as regular asthma reviews, medicines use reviews etc) and its impact on concordance? The scope states that the guideline will focus on the facilitators (including structural or procedural factors). Would this include written information and personal written action plans and the impact they may have on concordance? There is very good evidence to suggest that the	We will be guided by the available evidence and the expertise of the Guideline Development Group during the development of the guideline. In addition, we anticipate that medication review and self-management (as related to concordance/adherence) will be included.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				undertaking of self-management education and the issuing of self management plans increases concordance with inhaled medication in asthma	
SH	Asthma UK	7	Areas not covered 4.3 a	Respiratory disease is the most common illness responsible for an emergency admission to hospital yet an estimated 75% of admissions for asthma are avoidable. There were over 72,000 hospital admissions in the UK in 2003, which equates to 198 per day on average. Asthma costs the NHS an average of £889 million per year, caring for people who experience an asthma attack costs over 3.5 times more than for those whose asthma is well managed it would therefore be beneficial for those receiving emergency treatment to be included in the scope of these guidelines.	Noted. Thank you for you comments. However, the issues in emergency situations are very different to those of 'involving adults in decisions on prescribed medications'. Therefore, uses of drugs administered in an emergency setting are to be excluded. However, we are not excluding by setting, so if a prescription is initiated in the emergency setting, this will be reviewed as appropriate.
SH	Asthma UK	8	4.3 b	Asthma is a variable condition and if asthma symptoms become severe short courses of steroid tablets may be prescribed. It is very important that the course of steroids is taken until the person's asthma is fully controlled. We would therefore ask you to consider including medicines prescribed for acute (short-term) conditions this in the scope.	We have revised the scope and will now include prescribed medications for all conditions, regardless of duration.
SH	Asthma UK	9	General	Will the length of time a patient has been diagnosed be taken into consideration as concordance issues may vary over the life span of a person with a long-term condition? There is quite a strong scientific literature to suggest that the longer the duration of the disease and the older the patient, the better the concordance.	Noted as an important issue, and we will consider this, guided by the available evidence.
SH	Asthma UK	10	General	This is a very wide scope and we do have some concerns as to whether the issues around concordance can be generalised for all conditions.	We are aware of these concerns and we will be guided by the expertise of the Guideline Development Group, and co-opted experts on when/how issues can be generalised.

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				While we have suggested ways in which this scope could be more inclusive of issues and areas that would make it more relevant to people with asthma we are pleased that the issue of concordance is being considered and we look forward to the resulting guidelines.	
SH	Asthma UK	11		Horne R (2006) Compliance, adherence, and concordance: implications for asthma treatment. *Chest, 2006; Jul;130(1Suppl):65S-72S* Dasgupta R, Guset JF (2003) Factors affecting UK primary care costs of managing patients with asthma over five years. *Pharmacoeconomics. 21, 5, 357-369* Asthma UK 2006 National Asthma Panel. British Thoracic Society, Scottish intercollegiate Guidelines Network (2004) British Guideline on the Management of Asthma. A national clinical guideline. Revised edition. Asthma UK 2006 National Older People's Asthma Panel. Buston KM, Wood SF 2000 Non-compliance amongst adolescents with asthma: listening to what they tell us about self-management. *Family Practice* Asthma UK 2005 National Asthma Panel. Asthma UK 2005 National Children's Asthma Panel. Asthma UK 2005 The Blue Peter Survey. Steven K, Marsden W, Nevilee RG, Hoskins G, Sullivan FM, Drummond N (2004). Do the British Guidelines for Asthma Management facilitate concordance? *Health Expectations, 7, 74-84* Gallefoss F, Bakke PS. Am J Respir Crit Care Med 1999; 160: 2000-2005) Anon 2000 PCG cash limits mean asthma remains a neglected disease. Primary Care Report; Partridge M 1991 Self care plans for people with asthma. The Practitioner p 715–21 Hospital Episode Statistics, Department of Health; Scottish Morbidity Record, Information Statistics	Noted. Thank you for your suggestions.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				Division; Health Solutions Wales; Hospital Inpatients System, Department of Health, Social Services & Public Safety Calculated from estimated prevalence of treated asthma in National Asthma Campaign 2001 Out in the Open: a true picture of asthma in the United Kingdom today. Asthma J 6 (suppl), and unpublished data from Hoskins G, McCowan C, Neville RG et al 2000 Risk factors and costs associated with an asthma attack. Thorax 55:19–24	
SH	AstraZeneca UK Ltd	1	General	At the stakeholder meeting there was a lot of discussion regarding the similarities and differences between concordance and adherence / compliance. Whilst Horne's definitions of the three terms is given in the scope it is important that within the final scope / guideline that clear definitions of these different yet related topics are available, to ensure that all readers are aware of exactly what is being discussed. For ease of understanding, perhaps a Venn diagram would be useful, this could have the key concepts for each term in the relevant circle with interrelated concepts in the areas of overlap. This would hopefully facilitate better understanding of what each term does and does not encompass and how the terms relate to each other.	We will consider this for inclusion in the full guideline. We have tried to follow closely the work done by the SDO report. Please bear in mind that they are working definitions, and as an iterative process they may be subject to change.
SH	AstraZeneca UK Ltd	2	General	At the stakeholder meeting there was also a lot of discussion regarding the implication of treatment being provided via specialist or in-patient routes. It is important to remember that medicines are often initiated in the in-patient setting, thus it follows that concordance should be aimed for at the start of the treatment pathway, rather than part-way through. Further, concordance in these different areas may have to be approached differently, and the guidelines should adequately reflect this.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	AstraZeneca UK Ltd	3	General and 4.3	There was discussion about the use of proxy measures to assess the levels of adherence. Perhaps	Noted. We have revised the title to the guideline, and the section on reviews (4.3) has been

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
			d)	the title of the guideline should reflect the dual focus of the guideline (that is, concordance and adherence). Also there is a suggestion that adherence without concordance is acceptable, whilst the Institute has been careful to qualify this as only being acceptable when barriers and beliefs have been addressed, this reasoning should be clarified within the scope / guideline. Patient empowerment plays a big role in concordance, whereas it doesn't appear to feature to the same extent in compliance and adherence; opting for adherence over concordance should be justified within the guideline.	revised.
SH	Avon and Wiltshire Mental Health Partnership NHS Trust			This organisation was approached but did not respond.	Noted.
SH	Barnsley Acute Trust			This organisation was approached but did not respond.	Noted.
SH	Barnsley PCT			This organisation was approached but did not respond.	Noted.
SH	Boehringer Ingelheim Ltd			This organisation was approached but did not respond.	Noted.
SH	Bolton Salford & Trafford Mental Health			This organisation was approached but did not respond.	Noted.
SH	Bristol North PCT (Teaching)	1	4d	We feel that the guideline should seek evidence on the core skills needed to undertake medication reviews with patients. We feel this needs also to be extended to Medicines Use Reviews. The latter are part of the Community Pharmacy contract and are subject of a huge NHS investment, potential £830k in our PCT alone. Yet what is the actual effect of MURs on patient concordance and on improving medicines taking behaviour. We felt that as written the scope has the potential to establish a sound intellectual basis for practice, but may not provide clear guidance on what the NHS should do better or stop doing.	Noted. Core skills may be considered in general, but detailed recommendations on competencies and training are considered by the Implementation team, and are therefore outside the scope of this guideline. However, where national/professional guidelines on competencies are available, we may refer to these. Regarding MURs, we intend to review evidence and interventions related to all healthcare professionals involved in supporting concordance.
SH	Bristol North PCT (Teaching)	2	4d	Given the resources being devoted to the provision of medicines in compliance aids by the NHS, local authorities, care homes and individuals, the NHS	We will be looking at all types of interventions available in the evidence, and will be guided by the available evidence and the expertise of the

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				needs to know the absolute effectiveness of these devices. Unambiguous guidance on the use of these, as free standing interventions and as part of concordance. The problem being that some practitioners may see the devices themselves as addressing concordance, which I know not to be true, but it needs robust guidance one way or the other.	Guideline Development Group during the development of the guideline.
SH	Bristol North PCT (Teaching)	3	4e	Given the trends towards remote supply (mail order or home delivery) evidence is needed on the impact of the nature of this supply on adherence and he types of communication which accompany this – for example telephone help lines. We would expect there to be evidence from the US on this, where experience of mail order is more extensive.	We will be looking at all types of interventions available in the evidence, and will be guided by the available evidence and the expertise of the Guideline Development Group during the development of the guideline.
SH	Bristol North PCT (Teaching)	4	4e	Does supervised administration of medicines improve adherence and how does the implicit mistrust in this type[of supply impact on patient beliefs, for example with TB patients?	We have amended the scope to include only prescribed medication, and not administered medications, as the issues may be very different in that patient population as noted.
SH	Bristol-Myers Squibb Pharmaceuticals Ltd			This organisation was approached but did not respond.	Noted.
SH	British Association for Counselling and Psychotherapy (BACP)			This organisation was approached but did not respond.	Noted.
SH	British Association for Psychopharmacology			This organisation was approached but did not respond.	Noted.
SH	British National Formulary (BNF)			This organisation was approached but did not respond.	Noted.
SH	British Psychological Society, The			This organisation was approached but did not respond.	Noted.
SH	British Society for Heart Failure			This organisation was approached but did not respond.	Noted.
SH	British Thoracic Society			This organisation was approached but did not respond.	Noted.
SH	Burntwood, Lichfield and Tamworth Primary Care Trust			This organisation was approached but did not respond.	Noted.
SH	Cambridgeshire & Peterborough Mental Health			This organisation was approached but did not respond.	Noted.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Trust				
SH	Chesterfield PCT			This organisation was approached but did not respond.	Noted.
SH	City and Hackney Teaching PCT			This organisation was approached but did not respond.	Noted.
SH	Clinovia Ltd			This organisation was approached but did not respond.	Noted.
SH	Commission for Social Care Inspection			This organisation was approached but did not respond.	Noted.
SH	Connecting for Health			This organisation was approached but did not respond.	Noted.
SH	Continence Advisory Service			This organisation was approached but did not respond.	Noted.
SH	Conwy & Denbighshire Acute Trust			This organisation was approached but did not respond.	Noted.
SH	Cornwall Acute Trust			This organisation was approached but did not respond.	Noted.
SH	Datapharm Communications Ltd			This organisation was approached but did not respond.	Noted.
SH	Department of Health	1	Section 3, paragraph d	Would you please consider swapping the term "medical prescribers" to "prescribed medicines" because there are now a number of non-medical prescribers.	We have revised.
SH	Department of Health	2	Section 3, paragraph d	Under reasons for non-adherence it includes, "poor provider- patient relationship" should it not say, poor communication between health professional and patient. Grateful if you could clarify. Would you please consider adding to the list of reasons for non-adherence that covers: - patients who are confused by what medicine they have been prescribed and its impact on their condition, - a treatment regimen that does not fit in with the patient's daily activities - the decision process that takes into account values and beliefs of the patient , for example no shared	Noted and added.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				decision making about the medicines prescribed."	
SH	Department of Health	3	Section 4.3 para(c)	Should carers be included in the target of the intervention?	Noted and added.
SH	Department of Health	4	Section 4.3 para(d)	The draft scope suggests that multi-compartment compliance aids will only be considered where there is evidence that all the other things that could be done to improve compliance are not adequate and would be a barrier to appropriate medicine taking. In our view, we consider it better to say that an assessment will be made about the level of support a patient may need if they are prescribed a complex regimen and that a multi-compartment compliance aid will only be provided where other methods of support do not meet the patient's needs e.g. compliance charts, labelling medicines in large fonts etc.	Noted and revised.
SH	Department of Health	5	Section on areas that will not be covered	Are there any reasons why medicines for acute short-term conditions excluded within the scope? In our view if patients are not involved in decisions about their medicines, even for short term use, they may not take the medicine as prescribed , which could lead to another visit to their GP, resulting in a waste of the medicine prescribed in the first instance. We also consider It important that a concordant discussion is had about the treatment prescribed to ensure compliance.	We have revised the scope and will now include prescribed medications for all conditions, regardless of duration.
SH	Derbyshire Mental Health Trust	1	General	Our Chief Pharmacist has commented that in his opinion the scope risks being far too general. In his view, different illnesses and different treatments are associated with quite different or particular concordance issues. For example, concordance issues with a mental health diagnosis may or may not be the same as with hypertension. There is the potential complicating factor that someone with both may have different or the same concordance issues in respect of each treatment.	We are aware of these concerns, and we will be guided by the expertise of the Guideline Development Group and co-opted members on when/how issues can be generalised.
SH	Derbyshire Mental Health	2	General	One of our Nurse Consultants asked for assurance	We have sought to ensure that professional

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Trust			that the widest possible range of professionals is involved.	representation is as diverse as possible.
SH	Diabetes UK	1	4.1.2	While the proposed document specifically excludes children and adolescents from its remit, it would be useful to see such a document for children and young people, as evidence of chronic conditions management highlights frequent concordance issues in young people eg diabetes and insulin management. As a group of the population with diabetes for the greatest duration, improvements in concordance or adherence to therapy will have positive health impacts within later life.	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline
SH	Diabetes UK	2	4.1.2	Are the needs of the 12 – 18 year olds going to be considered somewhere as teenagers are a particularly at risk group regarding medicines and chronic conditions such as diabetes.	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline.
SH	Diabetes UK	3	3d	Issues regarding young adults (18 - 25 years) need to be considered. Particular situations such as going to university, being homeless, experimenting with illicit drugs should be considered, with a specialist on the group who understands these particular problems.	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline.
SH	Diabetes UK	4	3f	Training implications for prescribers should be considered. Non medical prescribers receive very intensive training and perhaps this should be standard for all prescribers.	Noted. Core skills and training may be considered in general, but detailed recommendations on competencies and training are considered by the Implementation team, and are therefore outside the scope of this guideline. However, where national/professional guidelines on competencies are available, we may refer to these.
SH	Diabetes UK	5	4.3a	Cost of medicines to the patient. For those who are treating their diabetes with diet and physical activity therapy, who are under 60 and are not on any other medication which allows prescription exemption, they will need to pay for their medication. They may need medicines for other conditions related to diabetes and	Noted as an important issue. As for any barrier, we will be guided by the evidence, and specifically, this may be a factor included in the health economic analysis and consideration of cost-effectiveness.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				concordance could be affected by regular prescription costs.	
SH	Diabetes UK	6	General	This is a large area to cover and it seems relevant to split it into different target age groups, as part of the same guideline.	If the evidence is available by age group, we will then synthesise the information in such a way.
SH	Diabetes UK	7	General	This is a very important area to focus on, especially for people with diabetes. We know that concordance is problematic, especially with polypharmacy. Many people with diabetes take a number of different medications, which could be for blood glucose, cholesterol, blood pressure or another condition related to diabetes. Improving concordance to medication is vital to reducing the risk of complications associated with diabetes and improving quality of life.	Noted. Thank you for your comments.
SH	Diabetes UK	8	4.3a	May be worth focussing on factors which affect adherence such as demographic (ethnic group, socioeconomic status, levels of education) psychological (health beliefs, stress and coping, anxiety, depression) and social factors (family relationships etc) as well as healthcare professional, medical system and condition/treatment related factors.	Noted, and we do not intend the barriers as listed in the scope to be comprehensive.
SH	Diabetes UK	9	General	It would be difficult to put forward a healthcare professional for the guideline development group before it has been decided about groups the guidelines will be focussing on eg children and young people will require a different healthcare professional to adults. There will be different issues which will need specialists from different areas.	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline. The GDG may consider that co-opted expert advice should be sought to address the issues of the 16 -18 year olds, but this will depend on the expertise within the GDG.
SH	Diabetes UK	10	4.2	Individuals are often prescribed medicines in hospital and therefore it would seem appropriate for the acute setting to be included as part of the healthcare	We have revised the scope so as not to exclude by setting,Therefore, if a prescription is initiated in hospital, this will be reviewed as appropriate.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				settings.	
SH	Ferring Pharmaceuticals Limited	1	General	The scope says the guidelines will only cover adults, is there a reason why children under 18 years of age are not included. Will there be a separate guideline for children?	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline.
SH	Good Hope Hospitals NHS Trust			This organisation was approached but did not respond.	Noted.
SH	Guys and St Thomas NHS Trust			This organisation was approached but did not respond.	Noted.
SH	Hampshire Partnership NHS Trust			This organisation was approached but did not respond.	Noted.
SH	Health and Safety Executive			This organisation was approached but did not respond.	Noted.
SH	Health Commission Wales			This organisation was approached but did not respond.	Noted.
SH	Healthcare Commission			This organisation was approached but did not respond.	Noted.
SH	Heart of England NHS Foundation Trust			This organisation was approached but did not respond.	Noted.
SH	Heart UK			This organisation was approached but did not respond.	Noted.
SH	Help the Hospices			This organisation was approached but did not respond.	Noted.
SH	Hertfordshire Partnership NHS Trust			This organisation was approached but did not respond.	Noted.
SH	Janssen-Cilag Ltd			This organisation was approached but did not respond.	Noted.
SH	Joint Epilepsy Council (JEC)			This organisation was approached but did not respond.	Noted.
SH	King's College Acute Trust			This organisation was approached but did not respond.	Noted.
SH	Leeds North East Primary Care Trust			This organisation was approached but did not respond.	Noted.
SH	Leukaemia CARE			This organisation was approached but did not	Noted.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				respond.	
SH	Liverpool PCT			This organisation was approached but did not respond.	Noted.
SH	Lundbeck Ltd			This organisation was approached but did not respond.	Noted.
SH	Maidstone and Tunbridge Wells NHS Trust			This organisation was approached but did not respond.	Noted.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	1	General	The MHRA welcomes the proposal to develop a guideline on medicines concordance. The Department of Health highlighted the role of information in its referral, highlighting the importance of "communication with patients around medicine-taking, including the provision and use of medicines information". The MHRA fully supports this initiative and would highlight in particular the importance of good quality, objective and reliable information, including the statutory patient information leaflet, in promoting concordance. This statutory document is an authoritative document reflecting the detail of the licence, it is evidence based, up-to-date in that it reflects current knowledge of safety and will have been subject to testing with patients. It should therefore be the key resource to support interactions between the patient and the healthcare professional.	Noted. Thank you for your comments.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	2	3d	Patients may also have other information needs and lack of available information at the time of medicine taking can also be a barrier to concordance.	Noted, and we do not intend the barriers as listed in the scope to be comprehensive.
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)	3	3f	Although health professionals in the patients' care team are the primary providers of information, patients may choose or need other information and the role of other sources should be considered. Information needs can vary at different times during disease progression and treatment and the timely availability of appropriate information is key.	Noted. We will consider these issues when developing the guidance.
SH	Mental Health Act			This organisation was approached but did not	Noted.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Commission			respond.	
SH	Mental Health Nurses Association			This organisation was approached but did not respond.	Noted.
SH	Merck Pharmaceuticals			This organisation was approached but did not respond.	Noted.
SH	MIND	1	General	Mind welcomes this piece of work - people with mental health problems are very often not involved well in decisions about medicines, and their views on psychiatric drugs not treated with sufficient respect and seriousness. This can mean that a commitment to 'adherence' can result in physical and mental harms from treatments. Guidance to support and improve practice in this area is much needed.	Noted, and we recognise the specific needs of this population. Thank you for your comments.
SH	MTS Medication Technologies Limited	1	4.1.1	We believe the guideline should identify and place appropriate focus on those groups of patients at particularly high risk of non-adherence with multiple drug regimens, eg geriatric groups, dementia patients, mental illness sufferers and addiction sufferers and consider the impact of 'compliance' packaging and/or automation.	Noted, and we recognise the specific needs of these populations. We will guided by the GDG and the evidence on where focused recommendations should be made. Thank you for your comments.
SH	MTS Medication Technologies Limited	2	4.2	We believe the guideline should include specific examination of the extent to which medication used in residential care home environments is used in the manner that accurately reflects the clinical intentions of the prescriber. This should subsequently be extended to examine the implications for training and practice protocols in care homes and pharmacies, together with the role of monitored – dosage systems and automation in this area.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication. However, we recognise the issues specific to this setting, will guided by the GDG and the evidence on where focused recommendations should be made.
SH	MTS Medication Technologies Limited	3	4.3	We believe the guideline should include consideration surrounding improved adherence resulting from Pharmacist interventions that combine patient education, supervision and assessment for deployment of medication organisation in compliance packaging. This is in line with evidence published very recently – Lee JK, Grace KA, Taylor AJ. Effect of a	We will address these issues as possible when undertaking the evidence reviews, and have drafted the scope to include any healthcare professional involved in improving medicines concordance.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				Pharmacy Care Program on Medication Adherence and Persistence, Blood Pressure and Low-Density Lipoprotein Cholesterol. JAMA. Published online Nov 13, 2006.	
SH	Napp Pharmaceuticals			This organisation was approached but did not respond.	Noted.
SH	National Endometriosis Society			This organisation was approached but did not respond.	Noted.
SH	National Institute for Mental Health in England (NIMHE)			This organisation was approached but did not respond.	Noted.
SH	National Osteoporosis Society			This organisation was approached but did not respond.	Noted.
SH	National Patient Safety Agency			This organisation was approached but did not respond.	Noted.
SH	National Prescribing Centre	1	general	NPC and NPC Plus welcome the National Institute for Health and Clinical Excellence's (NICE) decision to produce clinical guidelines on medicines concordance; an aspect of healthcare and treatment that is crucial to the clinical and cost effectiveness of medicines use. We broadly support the proposed scope of the guidelines but do have some specific concerns which we set out below.	Noted. Thank you for your comments.
SH	National Prescribing Centre	2	4.1.1a	The scope is currently limited to prescribed medicines for long-term conditions. We believe that this may restrict the opportunity to learn from the evidence for medicines concordance for short-term treatments. As the scope indicates, the Cochrane review of medication adherence found some evidence of the effectiveness of interventions to improve concordance for long term conditions but the extent of improvement in adherence was small. The Cochrane review found better evidence for improving adherence to short term treatments and with briefer, simpler interventions. It would be useful to consider the reasons for this difference and the extent to which the success with short-term treatment can be applied to adherence with treatments for long-term conditions.	We have revised the scope and will now include prescribed medications for all conditions, regardless of duration.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				In addition, we are concerned that a focus on long-term conditions may give clinicians the impression that concordance is only relevant to the management of long-term conditions and does not relate to treatment of short-term episodes of illness. We appreciate the desire to keep the boundaries of the review work clear and focussed. In our view however, medicines concordance is relevant to all prescribed medications regardless of the nature of the underlying condition that the medication is intended to treat.	
SH	National Prescribing Centre	3	4.2 b	The scope proposes that the medicines concordance guidelines will be focussed on primary care and outpatient healthcare settings. We believe that the guidance should relate to healthcare in whichever setting the care is delivered, including healthcare in inpatient settings and care homes. There is a real possibility that that medicines concordance will be seen as a primary care issue with the current scope, when in fact patient involvement in decisions about medication is also important in inpatient settings to ensure clinical effectiveness of medicines, improve patient safety and address medicines reconciliation across care settings. Considerable effort and resource has been directed towards promoting the use of patients own drugs and self medication in acute settings as a means of facilitating concordance. The extent of utilisation of these schemes has formed part of Department of Health medicines management framework assessments and is currently part of the Health Care Commissions acute hospital portfolio guide to medicines management. A review of the effectiveness of these	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; so any consultation, regardless of setting, resulting in the initiation of prescription (not administration) will be included. In addition, we anticipate that self-management (as related to concordance/adherence) will be included.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				schemes/interventions in facilitating concordance should form part of the clinical guideline.	
SH	National Public Health Service - Wales	1	4.1.1	Agree- review should include adults with long term medical conditions seen commonly in primary and secondary care- also see comments in 4.1.2 re tertiary care	Noted. Thank you for your comments.
SH	National Public Health Service - Wales	2	4.1.2	Children and young adults may be the subject of another review but we agree they should, for pragmatic reasons, not be included in this one	Noted. Thank you for your comments.
SH	National Public Health Service - Wales	3	4.1.2	Patients being treated in specialist or tertiary centres should be included in the scope if the treatment will require self-administration at any stage (either as an in-patient or on discharge). In saying this we assume that general principles/ guidance for medicines concordance will be recommended in the final guideline. It would seem impractical, within the existing resource and timeframe to explore particular concordance issues associated with every disease state or drug class.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; so any consultation, regardless of setting, resulting in the initiation of prescription (not administration) will be included. We will be guided by the expertise of the Guideline Development Group and co-opted experts on when/how issues can be generalised, but we may need to make some more focused recommendations for specific populations or drug classes as appropriate.
SH	National Public Health Service - Wales	4	4.2	Achieving concordance starts at the point a therapeutic intervention is being considered. All health care workers should be aware of this process and	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				their possible contribution to it. Often the decision to first prescribe is made in tertiary care or secondary care. The factors which at that point are considered and accepted to be part of the therapeutic alliance may not be communicated to those who must subsequently continue to prescribe for the individual or support them in medicine taking eg the pharmacist. Can this be addressed?	medication, excluding administered medication. In addition, the scope is drafted to include any healthcare professional involved in improving medicines concordance.
SH	National Public Health Service - Wales	5	4.3a)	We agree that concordance in prescribing decisions and medicine taking as reported by the patient should be included in the scope. We are particularly interested in why patients stop taking medicines days, weeks or months into the course when they have agreed with the prescriber that they will take the medicine. What influences their decision to stop? In considering communication barriers we would recommend distinguishing between patients who have IT access and are comfortable with the use of IT and those who are not, bearing in mind age and socio-economic factors.	Noted. Thank you for your comments. We will be guided by the evidence, and the list of barriers in the scope is not intended to be comprehensive.
SH	National Public Health Service - Wales	6	4.3 b)	We agree that concordance in prescribing decisions and medicine taking as reported by the healthcare professional should be included in the scope.	Noted. Thank you for your comments.
SH	National Public Health Service - Wales	7	4.3 c) and d)	We agree that the effectiveness and cost effectiveness of interventions to promote concordance/ adherence in prescribing decisions and medicines taking should be included in the scope. We would like to see this expanded to consider the training and other resources that would be required for prescribers and/ or healthcare professionals, to equip them to undertake those interventions considered effective and cost effective. We would like to see a specific comment on the place of monitored dosage units in the final guidance, and therefore would want the scope to encompass this.	Evidence of effectiveness and cost effectiveness of all interventions will be considered. Noted, and core skills may be considered in general, but detailed recommendations on competencies and training are considered by the Implementation team, and are therefore outside the scope of this guideline. However, where national/professional guidelines on competencies are available, we may refer to these. Regarding monitored dosage units, we intend to review evidence and interventions related to all healthcare professionals involved in supporting

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					concordance.
SH	National Public Health Service - Wales	8	4.3 e)	Agree	Noted.
SH	National Public Health Service - Wales	9	General	We would want the guideline to address the issue of concordance in patients receiving many medicines, for different conditions and in situations where there is more than one prescriber initiating treatment.	Noted. The issue of polypharmacy is stated in the remit and we will revise the scope to add more detail about this.
SH	National Public Health Service - Wales	10	General	The guideline should establish if differences in effectiveness and cost effectiveness of concordance interventions exist between conditions with symptoms and those without.	Thank you for your comments, and these will be considered as appropriate when developing the health economics work.
SH	National Public Health Service - Wales	11	General	Concordance may result in a patient deciding to act against what the prescriber considers is best treatment for that patient. The likelihood of this happening and the clinical and cost-consequences should be considered.	Noted as an important issue, and one that we have tried to clarify by using the terms concordance and adherence to distinguish. *Generally, the concept of concordance addresses these patient decisions. By changing communication patterns, patients can speak openly about reasons not to take their medication and the prescriber then has a chance of responding to this. Whereas in other circumstances patients would still decide not to adhere to regimens without telling their doctor.* Health economic consequences will be assessed and addressed further during development of the guideline.
SH	National Public Health Service – Wales	12	General	We welcome a NICE clinical guideline on Medicines Concordance	Noted. Thank you for your comments.
SH	NCRI Consumer Liaison Group			This organisation was approached but did not respond.	Noted.
SH	Neonatal & Paediatric Pharmacists Group (NPPG)			This organisation was approached but did not respond.	Noted.
SH	Newcastle PCT			This organisation was approached but did not respond.	Noted.
SH	Newcastle, North Tyneside & Northumberland Mental			This organisation was approached but did not respond.	Noted.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Health Trust				
SH	NHS Health and Social Care Information Centre			This organisation was approached but did not respond.	Noted.
SH	NHS Plus			This organisation was approached but did not respond.	Noted.
SH	NHS Quality Improvement Scotland			This organisation was approached but did not respond.	Noted.
SH	North Cumbria Acute Hospitals NHS Trust			This organisation was approached but did not respond.	Noted.
SH	North Eastern Derbyshire PCT			This organisation was approached but did not respond.	Noted.
SH	North Staffordshire Combined Healthcare NHS Trust			This organisation was approached but did not respond.	Noted.
SH	Northwest London Hospitals NHS Trust			This organisation was approached but did not respond.	Noted.
SH	Nottingham City PCT			This organisation was approached but did not respond.	Noted.
SH	Nutricia Ltd (UK)			This organisation was approached but did not respond.	Noted.
SH	Orphan Europe (UK) Ltd			This organisation was approached but did not respond.	Noted.
SH	Oxfordshire & Buckinghamshire Mental Health Trust	1	4.2	The scope does not include in-patient care but there is a lot of evidence that discharge planning - including: communication between secondary and primary care about treatment plans, information given to patients in hospital, self administration schemes, use of discharge plans etc have all been shown to have an effect on concordance with medication in primary care	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication. However, communication between healthcare professionals is outside the scope of this guideline.
SH	Oxfordshire & Buckinghamshire Mental Health Trust	2	3c	Definition of concordance should include the idea of 'working together'	We have tried to follow closely the work done by the SDO report. Also please bear in mind that they are working definitions, and as an iterative process they may be subject to change.
SH	Oxfordshire & Buckinghamshire Mental Health Trust	3	4.3a	Patient satisfaction and concordance should be included	Noted and added.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Oxfordshire & Buckinghamshire Mental Health Trust	4	4.3e	Guideline development groups should include a specialist mental health pharmacist(currently: GP/psychiatrist/specialist nurses,1 mental health & 1diabeties/heart disease or asthma specialist nurse, community nurse prescriber, community pharmacist/prescribing advisor, 1 academic researcher, 1 physician for older people). Specialist mh pharmacists can bring expertise to the group on: Medication review, discharge planning, lifestyle and concordance, concordance therapy as an intervention to support service users, medicines information, shared care prescribing and concordance	Noted. Thank you for your suggestions. We will be selecting GDG members in due course. Furthermore, where specific expertise is not represented on the Guideline Development Group, co-opted experts may be approached as appropriate.
SH	Parkinson's Disease Society	1	General	The Parkinson's Disease Society (PDS) welcomes the development of the clinical guideline on medicines concordance by NICE. Active involvement of people with Parkinson's in their treatment has been positively associated to health outcome[1] and treating people as partners rather than passive recipients of their healthcare is an outcome supported wholeheartedly by the PDS. However the Society is concerned that, as is stands, the draft scope of the guideline is too limited and as a result, could have the effect of undermining the principle of concordance. We have indicated in our submission below the areas in which we would like to see the scope extended. Parkinson's is a progressive neurological condition, which occurs when the cells in the part of the brain controlling movement are lost. These cells produce dopamine, a chemical that enables people to perform smooth co-ordinated movements.	Noted. Thank you for your comments and we will address them as appropriate.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				The main treatment for Parkinson's is medication, which works by replacing or mimicking the actions of dopamine. Often people will be on a number of drugs, each of which must be taken at specific times of the day. For people with Parkinson's, concordance, and underlying this, adherence to their medication regimen, including their precise individual timings, is key to the effective management of their condition. If a person with Parkinson's is unable to take their prescribed medication at the right time, the balance of chemicals in their bodies can be severely disrupted – and this will lead to their Parkinson's becoming uncontrolled.	
SH	Parkinson's Disease Society	2	4.1.1/ 4.1.2/ 4.2	The PDS strongly believes that in order to achieve the objective of improved medicines concordance for people with long-term conditions, it is vital that the scope of the clinical guideline is extended to cover inpatient settings. Achieving concordance for people with Parkinson's disease relies upon a partnership approach to decision-making and excellent communication between the healthcare professional and patient, regardless of healthcare setting. Whilst we recognise the importance of improving concordance in outpatient and primary care, because of the impact that poor hospital medicines management policies can have on a patient care, we feel that the omission of inpatient settings from the scope could threaten to undermine the entire principle of concordance. In many ways inpatient care presents an ideal opportunity at which principals of concordance, already established in outpatient and primary care, can be reinforced. For example self-administration policies in hospitals can promote concordance.	Thank you for your comments and views. In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication. Although we recognise the vital importance of administration of medication within an in-patient setting, we consider that the issues are different to those for people when self-administering medication, so have excluded from this guideline.

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				However many hospitals have not adopted this approach and instead insist on taking patients' regular medications off them and locking it away. People with Parkinson's often find that on admission to hospital • they have their anti-parkinsonian medications changed without being consulted for no clinical reason, and that any objections they have to this are dismissed • drug rounds are inflexible, with the onus being on ward staff to tell patients drugs they need to take at what time, leaving little room for patient involvement. Whilst in some circumstances this may be necessary because the patient is too unwell to take responsibility for the timely administration of their medication, the assumption that patients are automatically incapable must be challenged. Lack of awareness about the importance of medication timings in managing Parkinson's and inflexible medication rounds can result in long delays before people receive their medication, by which time they may have developed serious complications. With an uneven release of dopamine, a person may suddenly not be able to move, get out of bed or walk down the corridor. Their ability to feed themselves or communicate may be impaired. Sleep can become disturbed; bowel and kidney function and digestion can be affected. Hallucinations and mood swings can also be triggered and there is an increased risk of accidents and falls. There are additional costs to the patient in terms of a loss of dignity and independence.	

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				(cont'd on following page)	
SH	Parkinson's Disease Society	3	4.1.1/ 4.1.2/ 4.2 (cont'd)	There is also a cost to the provider. People who have developed complications because they have not received their medication on time are very likely to need a higher level of care, requiring more nursing hours. They may require an extended hospital stay and the complications may be so bad that they are unable to have procedure for which they were admitted in the first place. In the words of a man with Parkinson's who was admitted to hospital: " Not only did I not get my pills on time, I was put on a completely different set of Parkinson's drugs than I normally take. It has taken me and my specialist years to find the right drugs and doses for me. I don't see why this has to change when I went into hospital for a leg infection." In April 2006 the PDS launched the 'Get it on time' campaign to ensure that people with Parkinson's get their medication on time – every time in hospitals and care homes.	
SH	PERIGON (formerly The NHS Modernisation Agency)			This organisation was approached but did not respond.	Noted.
SH	Pfizer Limited	1	Page 4: section 4.1.2 b	Please could this be more clearly defined. Treatments may be initiated in specialist or tertiary centres, but then either implemented in primary care, or maintained (repeat prescriptions) in primary care. This exclusion needs to be clarified and justified in the scope. A possible example of this is where a Specialist Pain	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication. Any consultation, regardless of setting, resulting in the initiation of prescription (not administration) will be included.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				Consultant may suggest a number of different treatment options that a General Practitioner may wish to prescribe – and may not see that patient for 3 months or so, expecting the treatment to be initiated and titrated by the general practitioner – for example with gabapentin–would this be included? Another example is where an oncologist may prescribe a hormonal treatment for breast cancer, tamoxifen or an aromatase inhibitor, the intial prescription may be prescribed by the specialist, but repeat prescriptions dealt with in primary care	
SH	Pfizer Limited	2	Page 6 Areas that will not be covered	Why are short courses of antibiotics not going to be included- this is an important area for the NHS to address – if only because of the problem of increasing resistance, which has considerable public health and cost implications. Please justify this decision	We have revised the scope and will now include prescribed medications for all conditions, regardless of duration.
SH	Pfizer Limited	3	General	Medicines have the potential to deliver significant health improvements as evidenced through the results of randomised controlled trials. However, the efficacy of medicines in actual clinical practice can be reduced through a variety of factors not least of which is poor concordance with medicine taking. Poor concordance has several important impacts on healthcare systems – financially from the cost of the medicines and missed improvement in health outcomes with subsequent additional financial costs. If medicine usage is to be optimised then consideration of issues around concordance are vital. However, the guideline will only improve patient care if its recommendations are implemented within the NHS, it is important that the scope recognises this and particular attention is paid to how the guideline will be implemented and monitored.	Noted. Thank you for your comments. We will consider these issues as possible during the development of the guideline, and within the remits of NICE guidance.
SH	Pfizer Limited	4	4.3 (c)	Poor concordance is suspected to have significant cost implications for the NHS, attention towards improving concordance may therefore release significant resources as well as improving health	Noted. Thank you for your comments. We will consider these issues as possible during the development of the guideline, and within the remits of NICE guidance.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				outcomes. Attention should therefore be paid during the economic modelling towards estimating the wasted resources and the sub-optimal clinical outcomes resulting from poor concordance. Consideration of these factors may have important implications on the cost-effectiveness of interventions aimed at helping achieve a greater degree of concordance in medicine taking.	
SH	Pfizer Limited	5	3 (f)	Adherence with medicine taking should not be considered a binary function. Patients may be fully adherent or fully non-adherent but the majority have varying levels of adherence possibly at different times and depending on changing circumstances. The guideline must be able to provide advice to healthcare professionals within this complex scenario. Perhaps providing advice to patients about the minimum level of adherence which will still generate a positive benefit could provide them with the knowledge to balance the risks and benefits of medicines better and optimise health outcomes for the nation as a whole.	Noted. Thank you for your comments. We will consider these issues as possible during the development of the guideline, and extract as much information as possible from the available evidence.
SH	Pfizer Limited	6	General	The time frame over which concordance and adherence is to be considered requires definition. The needs of patients and therefore the support required are likely to change with time following treatment initiation. We know from many sources that adherence decreases quite sharply in the first few months the rate of decline slowing thereafter. This may suggest that interventions directed towards patients will need to change at different stages of their journey through medicine taking. Linked to this is consideration of how to maintain concordance over the potentially very long term, should the approaches and methods change with time, how and should concordance be ensured at regular intervals?	Noted and thank you for highlighting all these points. The issues of timeframe and changes in adherence over time is recognised as an important issue and has been added to the scope.
SH	Pfizer Limited	7	4.1.1	The impact of socioeconomic deprivation on concordance and adherence should be considered as this group is associated with higher levels of morbidity	Noted, and we agree that these are important issues to be tackled. We will try to extract as much detail as possible from the evidence on

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				and often poorer healthcare interventions (the "inverse care law"), therefore they may be at particular risk of poor health outcomes from poor concordance, understanding the impact of potential gain in this group may affect the cost-effectiveness of interventions.	these particular issues.
SH	Pfizer Limited	8	4.3	It is important to consider the impact of concordance in prescribing decisions for both acute and chronic conditions. Poor concordance in acute illnesses can result in treatment failure resulting in additional consultations with healthcare professionals as well as the possibility that acute conditions may become chronic adding to the health burden within the population. In addition, specifically excluding consideration of data relating to antibiotic use will exclude many well conducted studies regarding differences in patient and physician expectations and beliefs regarding consultations. Many of these learnings could be equally important and relevant to consultations in other disease areas and could therefore have important impacts on concordance.	We have revised the scope and will now include prescribed medications for all conditions, regardless of duration.
SH	Pfizer Limited	9	4.1.1	The guideline should consider whether concordance is easier to attain within symptomatic as opposed to asymptomatic conditions. In many asymptomatic conditions concordance and adherence is known to be poor reducing the potential health benefit which can be accrued from use of medicines. It may be that resources are better directed towards supporting patients with asymptomatic conditions rather than those with obvious symptomatology e.g. pain.	This is recognised as an important factor, and we will be guided by the evidence and the Guideline Development Group where this is relevant.
SH	Pfizer Limited	10	4.2 (b)	At present it is not intended to consider issues around concordance within specialist areas. Whilst specific disease related information may be more difficult to attain in these rarer conditions, it could be useful to consider if there are any general principles which can be applied as failure to reach concordance in these situations can have significant negative health impacts	Noted (see revisions on settings) and will be considered when drafting recommendations based on the evidence.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				and may be more challenging for other healthcare professionals to address outside the specialist setting.	
SH	Pfizer Limited	11	4.2 (b)	Within hospital based care attaining concordance in the in-patient setting is equally important as in out-patients. Patients may be more receptive to health messages and decision making about their future health following an acute episode of illness severe enough to warrant admission, this may be an opportune moment to intervene with health behaviour change messages and to reinforce the importance of medicine taking.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	Pfizer Limited	12	4.2	Transfer of patient care from a hospital to primary care setting has long been recognised as an area of risk due to poor communication. Evidence in certain conditions would also suggest that this time is associated with a significant drop in adherence with medicine taking. The guideline should consider this time of especial vulnerability and consider strategies which could address problems.	Noted. However, communication between healthcare professionals is outside the scope of this guideline.
SH	Pfizer Limited	13	4.3 (c)	It is important that all activities are assessed rigorously for both efficacy within a trial setting and effectiveness within actual healthcare delivery. Particular attention should be paid to schemes involving healthcare professionals directly delivering interventions as these are time consuming, expensive and represent an opportunity loss from the professionals time.	Noted, and we will use the NICE methodology to ensure rigour, and use health economics to assess cost effectiveness.
SH	Pfizer Limited	14	4.3 (b)	It is important to consider how the benefits and risks of medicines should best be communicated to patients. It is essential for a patient to be able to consider the potential for benefit against the potential for risk within any concordance based interaction with a health care professional. Whilst attempts have been made to better quantify risks e.g. use of terms such as common, rare, very rare; less attention has been paid to offsetting this with a similarly familiar estimate of the likelihood of a patients to benefit from treatment,	Noted, and the importance of communication of risk and how risk is considered when making decisions is recognised.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				this may be especially relevant in asymptomatic conditions where benefit cannot be judged from obvious clinical improvement.	
SH	Pfizer Limited	15	4.3	Changes to patients' medication can occur for a range of reasons, some of these changes will be made following a face-to-face consultation others, increasingly, are being made without this personal contact. In these circumstances letters are often sent to patients or a note attached to their next repeat medication slip informing them of the change, an assumption being made that if the patient does not raise an objection then the patient is in concordance with the change in medication. As this activity is becoming increasingly frequent it is important to understand the impact of this on concordance and subsequent adherence to medication. The guideline scope should specifically include consideration of this growing activity and ways to ensure that concordance is not compromised.	Noted, and we will be guided by the evidence and the experience of the GDG as to the extent to which we can make recommendations in this area.
SH	Pfizer Limited	16	General	The potential impact of the patient choice agenda within the NHS should be considered. At present patient choice is principally limited to the place of an intervention e.g. the hospital in which an operation will be carried out, and is supported by information about the performance and facilities at that site. Expansion of patient choice to the specific treatment provided would necessitate greater involvement of patients in consideration of questions core to concordance such as "do I want treatment for this condition or not?", "Do I want a drug treatment or a non-drug treatment?", "Do I want treatment with medicine A or medicine B?" Such policy development could naturally lead to more concordant decision making and behaviours between physicians and patients.	We agree that these are important issues to be tackled. We will try to extract as much detail as possible from the evidence on these particular issues. We will also liaise as much as possible with the patient representatives nominated for this guideline.
SH	Pfizer Limited	17	4.3	An important area not presently within the scope is the impact of the actual choice of medicine on subsequent concordance and adherence. For many conditions	We agree that these are important issues to be tackled. We will try to extract as much detail as possible from the evidence on these particular

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				there are several different medicines which could be prescribed, whilst some of these medicines may have similar pharmacological actions they often have differences in their pharmacokinetic and pharmacodynamic properties altering their effect on individual patients potentially impacting concordance and adherence. Such impacts are most commonly observed with frequency of dosing e.g. four times a day versus once daily dosing, but may also alter the need for dose titration, or adverse event profiles and frequency, routes and methods of administration etc. Evidence suggests that at least several of these factors can impact on adherence, it may be worth including an evaluation of these within the scope of the proposed guideline.	issues. The issue of choice based on factors such as these will be considered in the guideline, and is recognised as an important issue.
SH	Pharmaceutical Services Negotiating Committee	1	general	PSNC welcomes the proposal to produce NICE guidance on medicines concordance. The proposed scope seems generally appropriate.	Noted. Thank you for your comments.
SH	Pharmaceutical Services Negotiating Committee	2	general	We note the scope regularly refers to prescribers; we would wish to highlight that many health care professionals such as pharmacists and nurses, not operating in a prescribing role, do nonetheless have an involvement in supporting concordant decision making and medicines adherence.	We have drafted the scope to include any healthcare professional involved in improving medicines concordance, not prescribers alone.
SH	Pharmaceutical Services Negotiating Committee	3	4.2	Whilst we understand the need to maintain a scope that allows the guidance to be produced in a reasonable time span we do believe that the extension of the scope to cover the inpatient secondary care setting would be appropriate. We believe this is important because many medicines which are prescribed in primary care are initiated during inpatient stays in hospitals.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	Powys Local Health Board			This organisation was approached but did not respond.	Noted.
SH	Prodigy			This organisation was approached but did not respond.	Noted.
SH	Regional Public Health Group			This organisation was approached but did not	Noted.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	- London			respond.	
SH	Roche Products Limited	1	General (including section 1 and Appendix)	The initial Department of Health (DH) referral of this guideline appears quite broad and therefore the task of developing an appropriate scope for this guideline is therefore challenging. The following general points may warrant consideration in order to develop a scope that properly reflects the DH remit and is sufficiently specific to allow a practical guideline to be developed: • The DH remit refers to '…involving patients in decisions…'. Concordance is a poorly defined 'umbrella' term (see further comments below) and incorporates elements other than patients' involvement in decisions per se, also covering the extent to which and reasons why patients adhere/comply with prescribing decisions. It is therefore important to ensure that the general direction of this guideline reflects the DH remit, defines terms clearly and delineates between the multiple (and often inter-related) aspects of prescribing decision models and medication taking behaviour. • For example, will the guideline address interventions that improve adherence/compliance but which do not directly relate to patients' involvement in prescribing decisions per se, ie; non-concordance solutions to 'concordance' issues?	We recognise the importance of these issues and will be guided by the evidence and the experience of the GDG to address them. Regarding definitions, we have used the SDO report definitions as working definitions, which may be adapted during the guideline development. Regarding non-concordance, we have been given the remit of addressing the involvement in decisions, not improving adherence without involvement of the patient.
SH	Roche Products Limited	2	3	The items covered in the current draft of this section all relate specifically to non-adherence/compliance, as justifying the clinical need for this guidance. The need for '…involving patients in decisions…' is not yet	Noted, and we have revised the scope to reflect this.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				clearly justified. This comment illuminates the general concerns raised above, ie; is this guideline just about involving patients, or is it more widely about finding solutions to non-adherence/compliance as identified?	
SH	Roche Products Limited	3	3	There may be a 'clinical need' for a guideline on involving patients in decisions that does not relate specifically to improving adherence/compliance, ie; the broader policy drive towards patient empowerment exemplified by 'Patient Choice' and implemented via elements of the Quality Outcomes Framework (QOF) for general practices.	Noted, and we have revised the scope to reflect this.
SH	Roche Products Limited	4	3.b	The clinical need to address non-adherence/compliance could be usefully further elaborated by describing the potential consequences of this, ie; worsened health outcomes in terms of morbidity/mortality and increased economic burden on the healthcare system.	Noted, and these issues are highlighted in the scope.
SH	Roche Products Limited	5	3.c	The scope rightly highlights the complex terminology involved. We suggest that definition sets other that those in Horne's paper are highlighted, since there are alternative views on this subject. For example, The ISPOR Special Interest Group (SIG) on Medication Compliance has developed work specifically on this subject. http://www.ispor.org/sigs/MCP_accomplishments.asp#definition 'Persistence' is another widely used term and addresses the issue of patients continuing on prescribed medication over time and should therefore be included.	Noted. Many thanks for your comments and suggestions. We will revise the scope as appropriate, in light of this and other stakeholder comments.
SH	Roche Products Limited	6	3.d	Another reason for non-adherence is *difficult* (as distinct from poor) dosing instructions; it is well known and documented that inconvenient or unpleasant medication administration requirements undermine	Noted. We agree that these are important issues to be tackled. We will try to extract as much detail as possible from the evidence on these particular issues.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				adherence/compliance.	
SH	Roche Products Limited	7	3.e	The conclusions from Cochrane and the NCC indicated here suggest that attempting to develop this Guideline might be futile, in terms of available evidence. Perhaps some further rationale for commissioning this research in light of existing work is therefore warranted.	We have been given this remit (which therefore satisfies the criteria needed for the commissioning of a clinical guideline) and we accept that while there may be some areas where there is a lack of RCT evidence, the NICE methodology allows for consideration of other evidence to underpin recommendations. Guidelines are also able to include recommendations to stop doing things, so such recommendations may well be made. In addition, we will be making research recommendations in the final guideline.
SH	Roche Products Limited	8	4.1	The scope of this guidance as it stands at the moment is potentially huge. We therefore support the specification outlined in 4.1.1.a and further suggest that it may be worth considering whether the guideline could usefully focus on specific 'case-study' conditions and/or therapeutic areas / diseases in which concordance or non-adherence/compliance have been identified as a particular issue, in terms of health/economic consequences or government policy (eg; chronic asymptomatic conditions such as - osteoporosis, hypertension, hyperlipidaemia and obesity). The literature on non-adherence to therapies in these conditions is extensive, and includes investigations of both the impact of non-adherence and possible ways of improving non-adherence.	We are aware of these concerns and we will be guided by the expertise of the Guideline Development Group and co-opted experts on when/how issues can be generalised.
SH	Roche Products Limited	9	4.3	It is clearly imperative that this section of the scope reflects a reasoned interpretation of the DH remit, as indicated in our initial comments on the overall strategic direction of this guideline above.	Noted and revised.
SH	Roche Products Limited	10	4.3.d (Areas that will	We find the caveat about including interventions to improve adherence without achieving concordance, *only if they address identified barriers* somewhat	This section has been revised.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
			be covered)	confusing. The reason is that it seems illogical to conceive of interventions being effective, exactly *unless they do* address some underlying factor causing non-adherence. This again relates to our first comment on section 3 above.	
SH	Roche Products Limited	11	4.3.d (Areas that will be covered)	It is also unclear how the guideline would deal with novel medicines that can address non-adherence, for example by nature of their improved tolerability profiles or easier administration and dosing requirements. Even if such cases are deemed outside of scope for not achieving concordance themselves, sharing information on their existence and discussion of these merits between doctors and patients clearly falls within scope. For example, dosing frequency is often a major factor in non-adherence as has been documented in the literature. In addition, we are aware of a validated questionnaire developed to explore patients' attitudes and beliefs in relation to medicines (called the PHIT). The guideline should cover discussion between patients and doctors of such factors and tools when selecting an appropriate regimen. This will simultaneously address both non-adherence specifically plus the more general principles of good concordance.	The issue of choice of medication based on factors such as these will be considered in the guideline, and is recognised as an important issue.
SH	Roche Products Limited	12	4.3 (Areas that will be covered)	Patient Support Programmes are often funded by industry and in some cases these are designed to improve concordance as well as persistence – Two programmes that currently improve concordance in osteoporosis and obesity are supported by Roche and Roche/GSK respectively. Other companies also support similar initiatives. However in most cases these are designed as services for patients and as such are not the subject of publications (although we are looking to support the publication of these	As described in the NICE methodology, we now request specific evidence, as agreed with the Guideline Development Group, and therefore we will consider this when developing the evidence base.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				services in the future). It is critical that the guideline development group (GDG) should be able to draw upon the learnings and benefits of these programmes and therefore we would recommend that the GDG specifically request information from industry in relation to these programmes, to form part of the guideline evidence base.	
SH	Rotherham General Hospitals NHS Trust			This organisation was approached but did not respond.	Noted.
SH	Royal Brompton and Harefield NHS Trust	1	4.1.2 b)	Patients treated in specialist or tertiary centres should be included because of the following: - If we want to promote and improve concordance, then surely everyone should be included and be doing the same thing regardless of where the patient is being seen. - Concordance involves all areas where medicines are prescribed. Our concordance issues are the same and as important as experienced in 1° & 2° care, and if not dealt with at the time of prescribing then will only have to be dealt with when the patient is seen in 1° or 2° care - Specialist and tertiary centres do also treat patients with common diseases and do prescribe and recommend the initiation of common therapies that are seen and prescribed in 1° and 2° care, such as inhalers for asthmatics, aspirin and statins for MI patients and immunosuppressants for transplant patients. Therefore a lot of patients are treated with	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				the same regimes used in 1° and 2° care. - Some of the treatments we initiate are admittedly more complicated, therefore I do feel that concordance is even more important in these groups of patients	
SH	Royal Brompton and Harefield NHS Trust	2	4.2 b)	Inpatients should be included in the healthcare setting - Inpatients should also be included in both 2°, 3° and specialist centres, as medicines do get stopped and changed during inpatient stays and new medicines quite often prescribed. - The patient's inpatient stay provides a great opportunity to educuate and discuss the patient's treatment plan with them and to assess whether or not they are actually able and understand how to take their medication, especially as a lot of Trusts do have a Patients own drug and Self administration scheme. An Inpatient setting also provides patients with the time to think about the consultation they have had with the prescriber and the plan that has been agreed on. Therefore if the patient decides that they actually would like to change or re-discuss anything with regards to their treatment then this can be done	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				and any concerns resolved prior to them being discharged. Where as in a 15min outpatient consultation the patient may forget to ask or highlight any concerns.	
SH	Royal College of General Practitioners	1	3	There is a need for complete clarity about whether the guideline will offer guidance on achieving medication concordance (a shared decision about prescribing which may or may not agree with the clinician's preferences) or medication adherence. The DoH referral relates specifically to issues concerned with concordance, not adherence. But the Scope document in section 3 begins to conflate the two. This conflation commonly occurs, as medication adherence is necessary to achieve optimal biomedical outcomes (assuming prescribing is evidence-based in the first place) and is a therefore a very important "so what " factor". However, there are 2 problems with this conflation. 1. The first is that it assumes that improved concordance (at the time of prescription) leads to improved adherence (later on, when medicines are taken). I do not think that this causal link, though plausible, is yet clearly proven (recent literature would need review to confirm this). 2. The second problem with conflating concordance with adherence is an ethical one. Seeking concordance aims to reach prescribing decisions taking patients' views into account. Seeking adherence aims to get patients to take medicines as prescribed. If	Noted and revised.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				the seeking concordance is seen solely as a method of achieving adherence, it can be criticised as being coercive – see a thoughtful critique by Iona Heath in the BMJ: BMJ 2003;327:856-858 (11 October), doi:10.1136/bmj.327.7419.856. Suggestion: 1. focus on concordance as per the DoH brief – but take care about its definition – see the discussion in Horne et al's SDO publication, p27-37. 2. Identify that there is a patient-centred, ethical rational for concordant prescribing (defined as prescribing after shared decision-making with the patient contributing as they wish) of itself, irrespective of its clinical outcome, which is itself sufficient to justify the guideline 3. identify the current evidence of the extent to which concordance is likely to lead to improved adherence in those who do receive a prescription 4. Avoid describing methods for improving adherence per se – the literature is huge and reviews e.g. Cochrane exist already.	
SH	Royal College of General Practitioners	2	4.1.1	Young people are able to consult alone from the age of 16 yrs onwards. The Children's' Act requires clinicians to take into account the views of patients younger than 16 where they seem competent to contribute and those under 16 can be allowed to make autonomous decisions providing they are seen as "Gillick competent" For these reasons, it seems artificial to draw a line at 18 years for the guideline. Suggestion: the guideline is written for those aged over 16 and should be taken into consideration for anyone younger	Noted.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				than that who is deemed to be competent to express a view on their prescription	
SH	Royal College of General Practitioners	3	4.1.1	There is a need to define what is meant by a "long-term condition" if the guideline continues to exclude acute prescribing	Noted and have revised the scope.
SH	Royal College of General Practitioners	4	4.1.2	Much prescribing is initiated in specialist and tertiary care. As currently configured, the guideline would need to make distinctions between these environments which might seem arbitrary and artificial. I appreciate that there is a need to focus efforts in the face of a large literature. Nevertheless, a guideline focusing on primary and outpatient secondary care will still face the need to look at literature across a wide variety of clinical diseases. The only way to cope would be to look for generalised themes that relate to prescribing in general. Focusing on concordance rather than adherence (see comments on section 3 above) will help in limiting the literature to review. Suggestion Write the guideline for any clinician initiating or reviewing medication, accepting that the guideline will only offer guidance and information generalised across different diseases and situations. If there are significant differences in guidance in different settings, attention could be drawn to these.	Noted and have revised the scope.
SH	Royal College of General Practitioners	5	4.3	The guideline should comment so far as possible on the time likely to be needed to achieve concordance Suggestion Include time in the list of possible barriers	Noted and revised.
SH	Royal College of General Practitioners	6	4.3 a and b	It is good that sections a and b include perspectives of both patient and healthcare professional (not just a doctor)	Noted and thank you.
SH	Royal College of General Practitioners	7	4.3 c	It is good that section c recognises that a part of the picture is a healthcare professional providing support after prescribing has taken place	Noted and thank you.
SH	Royal College of General	8	General	It is good that the guideline is in preparation. The	Noted.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Practitioners			literature will be extensive, difficult to define and vary in rigour making the task hard. Nevertheless, communication around prescribing is important for the practice of relationship-centred medicine and this will raise the profile of the issue	
SH	Royal College of Midwives			This organisation was approached but did not respond.	Noted.
SH	Royal College of Nursing	1	General	The RCN welcomes the opportunity to review this draft scope.	Noted. Thank you for your comments.
SH	Royal College of Nursing	2	General	There seems to be something missing regarding the social context of concordance, even though this may be included in looking at barriers -and is well documented elsewhere. It could be difficult to create a guideline to meet all elements of the population.	The list of barriers is not intended to be exhaustive, and we anticipate that social context and influence may well be an issue described in the literature.
SH	Royal College of Nursing	3	general	This is an extremely important issue, particularly in Type 2 diabetes which is a complex condition requiring poly-pharmacy treatment. The DARTS study demonstrated most patients do not take medications as prescribed.	Noted. Thank you for highlighting this issue.
SH	Royal College of Nursing	4	general	Need to include the extent that visual/manual dexterity plays in non-compliance (e.g. difficulty with opening bottles, use of insulin pens)	The list of barriers is not intended to be exhaustive, and we anticipate that this may well be an issue described in the literature.
SH	Royal College of Nursing	5	general	Will this also look at compliance with blood testing too - strips are huge prescribing cost	The remit is to improve decision making around prescribed medications – this therefore would not be covered in this guideline specifically, but the issue is recognised as being important, and some recommendations may well be applicable to the use of healthcare technologies, other than drugs.
SH	Royal College of Nursing	6	general	Presume this guidance will look at cost-effectiveness of poly pills/once daily pills?	This is a factor that is anticipated will be an influence on adherence, so will be considered as appropriate in the health economic work.
SH	Royal College of Nursing	7	general	We presume the role of pharmacists will be included in this guidance too	We have drafted the scope to include any healthcare professional involved in improving medicines concordance, not prescribers alone.
SH	Royal College of Nursing	8	3a	Every prescriber has a duty of care to - assess the	Noted and thank you for your comments.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				patient, do a medication review and achieve concordance this might help to reduce the percentage of patients not taking medicines. This practice might enable the prescriber to identify patients who have not been taking all the other medications before a new medication is prescribed. 1. Identification of the problem is critical, hopefully the guideline will help to achieve this. 2. Following identification, there has to be a mechanism to refer patients to GP highlighting the problem.	We will guide the work on the basis of the available evidence and have not excluded any intervention so far. However, the importance of review and referral is recognised.
SH	Royal College of Nursing	9	3b	Consequence of 3b) Ill-health and reduced quality of life Reduced life expectancy Avoidable healthcare cost Economic loss to society	Noted, and revised. Inclusion of cost and effectiveness data and consequences for the health economic work will be guided by the available evidence and the experience of the Guideline Development Group during development of the guideline.
SH	Royal College of Nursing	10	3 b	Need for the guideline – The statistics re: non concordance of medicines should be widely publicised to the general public. In a world of deficits in the NHS – everyone has a responsibility for effectively utilisation of the NHS resources. If everyone knew, including patients what effect their poor medicine concordance has financially – it may become less socially acceptable to waste medicines.	Noted, and a version of the final recommendations for patients and the public 'Understanding NICE Guidance' will be produced.
SH	Royal College of Nursing	11	Section 3.d	We do not feel that the inability to fund the medication is the issue here, as the patient has no influence over this variable, unless of course this refers to the patient's inability to buy the prescribed medication. If this is what is meant, we suggest rephrasing to be clear.	Noted and revised.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Royal College of Nursing	12	Section 4.1.2	Although under-18 year olds are excluded from the scope, the Children's NSF Medicines chapter might be a useful document to consider as it does give suggestions for competencies for prescribers etc.	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline. In addition, we will consider the NSF chapter as appropriate – thank you.
SH	Royal College of Nursing	13	Section 4.1.2	Is NICE going to consider the needs of 12-18yrs as teenagers are a particularly at risk group re medicines and chronic illness?	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline.
SH	Royal College of Nursing	14	Section 4.3	The statement about inclusion of adherence only if concordance is influenced may be very individual and difficult to define specifically – does this mean that the future guidance would have to justify inclusion of adherence interventions? Where would it justify exclusions as these may be controversial?	Noted, and this section has been revised.
SH	Royal College of Nursing	15	4.3 (b) areas not covered	Why not antibiotics? There are real issues with antimicrobial resistance when people do not finish courses.	We have revised the scope and will now include prescribed medications for all conditions, regardless of duration.
SH	Royal College of Nursing	16	Section 4.4.2	At the stakeholders' information meeting, we were advised of the proposed composition of the guideline development group and welcome the proposal to include a physician specialising in care of the elderly on the guideline development group (quite rightly). Will there also be someone on the group who understands the particular problems of the young adults, aged 18-25 years age group whether they are going to university, homeless, experimenting with illicit drugs etc? No matter what their chronic condition, this is a dangerous time as they leave home, (for example,	Thank you for comment. This is recognised as an important issue, and we will consider your suggestion when we have agreed the Guideline Development Group membership and the expertise represented on that group. If any specific expertise is required, we will seek expert advice from a co-optee.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				dead in bed syndrome etc). We believe that the needs of this age group should be taken into consideration.	
SH	Royal College of Nursing	17	Section 4.4.2	We welcome proposals to include several nurses on the guideline development group.	Noted. Thank you for your comments.
SH	Royal College of Nursing	18	General	Will the guideline developers be able to suggest training implications for prescribers? Non-medical prescribers have a very intensive training that other health care professionals may from example, junior doctor colleagues could benefit from to prevent some of the prescribing errors that occur in secondary care when patients would be continuing the drugs prescribed in primary care.	Noted, and core skills may be considered in general, but detailed recommendations on competencies and training are considered by the Implementation team, and are therefore outside the scope of this guideline. However, where national/professional guidelines on competencies are available, we may refer to these.
SH	Royal College of Nursing	19	General	One issue to bear in mind about concordance and adherence is cost to the patient. Some chronic conditions are exempt from prescription charges. Others are not and this can be very expensive, even with prepaid prescription cards. Those on benefits will be exempt, and the well-off will be able to afford them, but the middle range is the biggest group and may often have to consider whether they can afford the prescription or not especially for "hidden" conditions such as hypertension. We are aware that several patient charities are trying to highlight this at present.	Noted. Thanks for your comment. We will consider the impact of paying for prescriptions as appropriate in the guideline.
SH	Royal College of Nursing	20	General	Prescription cost – impacts concordance and adherence Breast Care Cancer has recently published a survey which found that 45% of cancer sufferers found the cost of prescription caused some financial hardship and 11% actually did not use their prescriptions to get the necessary medication as they could not afford it.	Noted. Thank you for your comment. We will consider the impact of paying for prescriptions as appropriate in the guideline.
SH	Royal College of Nursing	21	Appendix – referral	Competencies required by Prescribers – The National Prescribing Centre has produced a draft document re:	Thank you for bringing this to our attention.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
			from the DH	Concordant Consultations – it would be helpful to include this piece of work.	
SH	Royal College of Nursing	22	General	Interventions and communication should be the main focus of this document with particular attention on who would be the main person involved in these areas, i.e. senior nurses etc.	Noted. Thank you for your comment.
SH	Royal College of Nursing	23	General	Part of the developing the guideline is about addressing issues like education and training for prescribers, especially for medics.	Thank you for your comment.. Noted, and core skills may be considered in general, but detailed recommendations on competencies and training are considered by the Implementation team, and are therefore outside the scope of this guideline. However, where national/professional guidelines on competencies are available, we may refer to these.
SH	Royal College of Paediatrics and Child Health	1	General	The scope addresses only patients aged 18 years and over. We have the following comments to make regarding possible explanations for poor concordance/adherence/compliance with prescribed medication. a) Poor communication - on behalf of the doctor (or nurse practitioner who could prescribe some drugs) who does not explain why the drug is being prescribed, how long it needs to be taken or its potential side-effects b) Poor communication - on behalf of the patient who perhaps does not fully explain his or her symptoms. c) The patient only wanting to be listened to by the doctor - and not prescribed a drug as an alternative to 'quality' listening time in the surgery d) The patient, perceiving that he or she has improved, not feeling the need to continue taking the prescribed medication. Furthermore:	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				It is a very important area in children and adolescents and well worthy of looking at; it is especially worth emphasising that concordance issues are particularly important in children and young people and also involve families and carers. Indeed, difficulties with concordance within the family sometimes lead to child protection concerns. With the extra tier of involvement of the parent/carer in the process it is likely to be a much more complicated exercise. We strongly recommend that NICE addresses medicines concordance in children and young people; this would be most suitably undertaken as an entirely separate study/piece of guidance. We would expect NICE to address the same issues in relation to adolescents, perhaps in particular those with chronic disease, who have very specific needs and who are a group well recognised as having compliance/concordance issues.	
SH	Royal College of Physicians of Edinburgh	1	Section 2 a)	The Department of Health has asked for a guideline on medicines concordance without restriction on patient group or condition, and the College considers the proposed restrictions to adult long-term conditions will miss valuable opportunities to address known problem areas eg adherence to short term antibiotic courses. Also, the scope does appear to include poly-pharmacy or medication reviews.	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline. We have also revised the scope and will now include prescribed medications for all conditions, regardless of duration, and will give more detail on poly-pharmacy and medication review in the body of the scope.
SH	Royal College of Physicians of Edinburgh	2	Section 4.1.1 a)	There is no definition of adults with 'long-term medical conditions seen commonly in primary and secondary care'. How long is a long-term condition? However, NICE is specifically requested to deal with	We have revised the scope and will now include prescribed medications for all conditions, regardless of duration.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				poly-pharmacy and co-morbidity, both of which can apply to short-term as well as long-term conditions. The College recommends that the guidance covers all prescribing.	
SH	Royal College of Physicians of Edinburgh	3	Section 4.1.2 a)	The proposed exclusions of children and people being treated in specialist centres are illogical and not supported by any presented evidence. Again, the College recommends that the guidance covers all prescribing, including children. The economic consequences and lack of effectiveness of unused medicines apply whatever the age of the patient. Poor concordance also leads to risks associated with storage of medicines in homes - particularly accidental or deliberate ingestion by children.	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline. In addition, we have revised the scope so as not to exclude by setting.
SH	Royal College of Physicians of Edinburgh	4	Section 4.1.2 b)	As above, the exclusion of tertiary care would be illogical and a missed opportunity. Concordance to medicines prescribed in tertiary care is a problem, just as it is in primary and secondary care. It is complicated by a number of factors including the variable quality of communication between primary and tertiary care, lack of generalist input into treatment decisions and confusion caused by specialist outreach into the community. Healthcare professionals do not always understand co-morbidity and poly-pharmacy outside their specialist fields.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	Royal College of Physicians of Edinburgh	5	Section 4.2	The College suggests that the guideline specifically addresses the specific complementary roles of roles of different groups of (non- medical) health professionals, including: ▪ Pharmacists ▪ Nurse prescribers ▪ Emergency Care Practitioners (including paramedics)	The scope includes interventions by any healthcare professional involved in concordance, not only prescribers. We have revised the scope to include carers. Information and other factors will be included as appropriate. We have also revised the scope to include prescribing for all conditions, regardless of duration.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				Also, the guideline should consider the role of carers for those patients requiring significant support to comply with treatment regimes. The guideline should address the question of written information associated with medicines, including: ▪ Packaging ▪ Labelling ▪ Package inserts ▪ Patient leaflets The guideline should address factors known to affect concordance, including: ▪ Convenient *v* difficult dosages ▪ Avoidance of drug interactions and side-effects The guideline should also aim to help doctors to interpret the new GMC guidance in *Good Medical Practice* about working in partnership with patients - as it applies to prescribing and concordance. The College is concerned that the guideline will miss a valuable opportunity to address a significant problem area if the scope excludes emergency treatment, particularly prescribing for acute conditions in the presence of co-morbidity and poly-pharmacy.	
SH	Royal College of Physicians of London	1	General	Need to include inpatient aspects; indeed preferably the initiation of prescribing regardless of health setting, as that is when opportunities are greatest for discussions with patients.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	Royal College of Physicians of London	2	General	Need to include carers as well as patients, especially with the focus on long term medical conditions.	Noted. Have revised.
SH	Royal College of Physicians of London	3	General	How will the Guideline address service users who are unable to understand instructions or unable to carry out drug self administration i.e. those with dementia	We will be guided by the relevant and available evidence and the expertise of the Guideline Development Group on these and other specific

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				and advanced conditions such as Parkinson's disease and Stroke?	issues.
SH	Royal College of Physicians of London	4	Section 3 Clinical need	General support for the terminology definitions. Important to keep concordance as the outcome. We believe the term 'prescribing communication' within the definition of concordance requires explanation also.	'Prescribing communication' is as quoted in the SDO definition, but we anticipate that if appropriate, we may adapt these definitions as part of the development process.
SH	Royal College of Physicians of London	5		Is there a need to address a potential tension between the desire of doctors to achieve adherence (as that is how they will be measured/assessed) and the over riding importance of concordance?	Noted, and this issue will be considered by the Guideline Development Group when reviewing the evidence and drafting recommendations.
SH	Royal College of Physicians of London	6	Section 4.3.a	Communication issues should cover the explanation of risk. Work done by the RCP Patient & Carer Steering Group indicates that doctors find this difficult (and physicians receive no training, apart from geneticists and oncologists) as do patients. Understanding of the risks and benefits is fundamental to achieving concordance	Noted, and risk (and its communication) is recognised as an important factor in decisions around prescribed medicines.
SH	Royal College of Physicians of London	7	Section 4.3 general	The hospital inpatient setting should be included. One of the key times in the care pathway relating to medicine concordance is discharge from hospital. ➢ Treatment regimes have often been adjusted, changed or initiated. ➢ There is a high incidence of co-morbidities and co-prescribing making prescribing more challenging ➢ Reliable transfer of information to patients is often lacking ➢ Reliable agreement with patients over treatment regimes may not have occurred – patients may concur in the hospital setting but may change their view once at home and self administering ➢ Reliable transfer of information to primary care is challenging – e.g. computer systems are often not adjusted to changes established	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				in hospital If the issue of inpatient care has been deliberately omitted to make development more manageable then this should be proposed as a separate guideline.	
SH	Royal College of Psychiatrists			This organisation was approached but did not respond.	Noted.
SH	Royal College of Speech and Language Therapists			This organisation was approached but did not respond.	Noted.
SH	Royal Pharmaceutical Society of Great Britain	1	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.	Noted. Thank you for your comments.
SH	Royal Pharmaceutical Society of Great Britain	2	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.	Noted and we have revised the scope to reflect this distinction. Furthermore, this is a distinction that will need to be considered by the Guideline Development Group when reviewing the evidence and drafting recommendations.
SH	Royal Pharmaceutical Society of Great Britain	3	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.	Noted. We will consider your suggestion.
SH	Royal Pharmaceutical Society of Great Britain	4	1 Guideline title	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	Noted. Thank you for your comments.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
			and General COMMENT 3	appropriate outcome and terminology is crucial.	
SH	Royal Pharmaceutical Society of Great Britain	5	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.	Noted. Thank you for your comments.
SH	Royal Pharmaceutical Society of Great Britain	6	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	Noted and we have revised the scope to reflect this distinction. Furthermore, this is a distinction that will need to be considered by the Guideline Development Group when reviewing the evidence and drafting recommendations.
SH	Royal Pharmaceutical Society of Great Britain	7	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	Noted. Need to consider revision.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Royal Pharmaceutical Society of Great Britain	8	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	Thank you and we will use the SDO definitions as a key starting point for discussion.
SH	Royal Pharmaceutical Society of Great Britain	9	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.	Noted, and we will consider your proposal – thank you
SH	Royal Pharmaceutical Society of Great Britain	10	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.	Noted. Thank you for your comments.
SH	Royal Pharmaceutical Society of Great Britain	11	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-	Noted and revised.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				adherence is in avoidable healthcare cost and ill-health.	
SH	Royal Pharmaceutical Society of Great Britain	12	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.	Noted, and communication will be considered by the Guideline Development Group when drafting the key clinical questions.
SH	Royal Pharmaceutical Society of Great Britain	13	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)'.	Have revised and included this part of the definition.
SH	Sankyo Pharma UK			This organisation was approached but did not respond.	Noted.
SH	Sarcoma UK			This organisation was approached but did not respond.	Noted.
SH	Schering-Plough Ltd	1	General	The guideline covers a worthwhile topic and should improve NHS service delivery in primary and secondary care.	Noted. Thank you for your comments.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Schering-Plough Ltd	2	4.1.1.a	Limiting scope to patients with "long-term conditions" means the guideline's utility in many therapy areas is unknown. It would be useful if the Final Scope clearly set out what constitutes a long-term condition.	We have revised the scope and will now include prescribed medications for all conditions, regardless of duration.
SH	Schering-Plough Ltd	3	General	Further to this, the guideline would benefit from a sensitivity analysis which compares the overall findings to findings from a small random sample of the evidence which was excluded. By indicating the intention to conduct such an analysis in the Final Scope, NICE would give assurance that its limitation of the evidence base shall have robust justification. A sensitivity analysis would also help to illustrate how and when the guideline should be followed.	We will be using the NICE methodology as described in the Guidelines Manual. Please note, we are no longer excluding conditions by duration.
SH	Schering-Plough Ltd	4	4.2.b	Secondary care inpatients are not currently included. However, prescriptions made for secondary care inpatients have the potential to significantly confound observations made in primary care and in secondary outpatient settings. This is because a secondary care inpatient's existing medication regimen is often discarded upon admission and replaced by a new regimen determined by the physician. The Final Scope should identify this potential source for confounding.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	Schering-Plough Ltd	5	4.1.2.b 4.2.b	The draft scope intends to cover patients in Primary and Secondary care settings but mentions that it will exclude patients from these settings who are receiving "specialist treatment", or treatment regimes "not normally delivered in a generalist primary or secondary care setting". The criteria here are not very clear and create a risk that the evidence search is limited for convenience. Without going into too much detail, the Final Scope	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				could benefit from a one-page tabular summary of the most common Primary and Secondary Care settings which are expected to be included. Also, can you clarify whether you would expect the following secondary care settings to be included: infusion clinics, day chemotherapy clinics?	
SH	Scottish Intercollegiate Guidelines Network (SIGN)			This organisation was approached but did not respond.	Noted.
SH	Sedgefield PCT			This organisation was approached but did not respond.	Noted.
SH	Servier Laboratories Ltd	1	4.2	It is essential that this research and guideline consider the experience of patients upon discharge after an inpatient stay. This is a major point of drug initiation and critical area of concern for concordance	Noted. We will have 3 patient representatives on the guideline.
SH	Servier Laboratories Ltd	2	4.3	There is need for this guideline to consider the cost effectiveness of the actions of Prescribing Advisers who switch a patient's medication to reduce cost where a patient is stable and compliant with that medication. This is potentially a major source of non-compliance and not a cost effective activity where costs and health benefit impact of non-compliance are accounted for.	Noted. Thank you for your comments.
SH	Servier Laboratories Ltd	3	4.3	This section could direct the research to consider the impact of the removal of a doctor's freedom to prescribe on a cost basis and the resulting impact on rates of compliance of the reduced ability of a doctor to tailor therapy specifically to patient needs. It would be interesting to consider if rates of compliance differ in areas where prescribing is tightly controlled (to limit cost) compared to areas where this was not the case (where other factors are held constant).	This is outside the remit of the guideline, however, if there is evidence that cost is a factor that influences the choice of prescriber, this may be considered as appropriate by the Guideline Development Group.
SH	Servier Laboratories Ltd	4	4.3	The guideline could consider appropriate methods of detecting compliance and the effect of monitoring on patient compliance. The guideline might also consider methods for managing patient non-compliance	Noted, and review and monitoring will be included in the evidence reviews.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				detected through monitoring.	
SH	Servier Laboratories Ltd	5	4.3	The guideline could consider the role of tolerability in conventional health technology appraisal used by NICE and consider the implications of better accounting for tolerability through compliance.	Noted and tolerability and its effect on compliance will be reviewed.
SH	Sheffield Children's Hospital Trust			This organisation was approached but did not respond.	Noted.
SH	Sheffield PCT			This organisation was approached but did not respond.	Noted.
SH	Sheffield Teaching Acute Trust	1	Population 4.1.2	a) children and young adults are excluded from this review. Medicine taking behaviour is often learned in childhood; children with chronic illnesses will continue to take many medicines in their adult life and use substantial healthcare resources. The inclusion of them should be reconsidered. Reference within this document should be made to the NSF for Children and how the principals can be applied. This should include reference to the various stages of responsibility of medicine taking, for example parental administration, child taking some responsibility for medicines under supervision to child taking complete responsibility for medicines. It is important that children are directly involved in decisions about their medicines.	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline.
SH	Sheffield Teaching Acute Trust	2		b) What is the rationale for excluding tertiary care patients? The issues of concordance are even more critical for those at tertiary referral centres than those attending secondary care. They have restricted access to the specialist team, are likely to be prescribed multiple medicines, with possible increased risks of adverse drug reactions and are likely to have high healthcare resource utilisation. A patient with angina attending a tertiary referral centre will have largely the same if not enhanced issues with their medication as those attending secondary care.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Sheffield Teaching Acute Trust	3	General – Healthcare setting	Why are inpatient settings excluded? Patients admitted to hospital often have new treatments initiated. They are in unfamiliar settings with healthcare professionals that they have limited access to. They are less likely to feel empowered and able to contribute to decisions on their care and therefore require more support. They are often followed up as an outpatient and hence would become included in the recommendation later in their care after the initial decisions about treatment have been initiated.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	Sheffield Teaching Acute Trust	4		It is known that discharge from hospital has many risks of patients receiving the wrong medicines that could be reduced by patient empowerment. The improvement of this system is crucial for empowering patients to be responsible for their own medicines and to feel able to contribute to any decision making process. The involvement of the patient and provision of information on their new medicines or changes in their medicines is a crucial task on discharge that is poorly performed. Use of pharmacist prescribers upon discharge could improve the focus on the information given to the patient about their medicines. Support from the beginning is important and the transitions between primary, secondary and tertiary centres of care crucial.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication. Also, we include interventions by all healthcare professionals involved in concordance, not prescribers alone.
SH	Sheffield Teaching Acute Trust	5	Points to be covered 4.3	This should include understanding the motivations to take medicines of the individual patients.	The reviews will include barriers and facilitators to medicines taking.
SH	Skin Care Campaign			This organisation was approached but did not respond.	Noted.
SH	Society and College of Radiographers	1	1.	Guideline title uses the word 'prescribed'. However, what about the supply and administration of medicines? Has this not been added because NICE feels there is not a compliance issue with the supply and administration of medicines?	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication. The issues around administered medications are

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					very different to those for self-administered medications, so have been excluded from this guideline.
SH	Society and College of Radiographers	2	4.2	Does this include radiotherapy radiographers acting as supplementary prescribers when they prescribe for on-treatment review?	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	Society and College of Radiographers	3	4.3	An area that perhaps requires investigation is whether concordance is better if it is a health care professional (i.e. nurse or AHP) rather than a doctor.	We will try to extract as much information as possible for the evidence that is available for the clinical questions.
SH	Society and College of Radiographers	4	4.3 Areas that will not be covered a) and b)	Why is emergency treatment being excluded? This is an area where radiographers can supply and administer drugs. Why are medicines prescribed for acute conditions being excluded? This is potentially one of the areas for biggest waste i.e. many people do not take a whole course of antibiotics or just refuse to take them.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	Society and College of Radiographers	5	General	A flag up type system for either the G.P or the pharmacist would be very useful; to remind patients when to get their repeat prescription. This would improve compliance as currently the system often relies on patients remembering themselves when they need to obtain a new prescription.	Thanks for your suggestion. We will try to extract as much information as possible for the evidence that is available for the clinical questions.
SH	Society and College of Radiographers	6	General	Perhaps there should be guidelines on frequency of patient review by either a G.P or indeed an AHP/Nurse to check that all medications on a repeat prescription are still required. This would improve cost efficiency by removing drugs that are no longer required.	Thanks for your suggestion and review is a key intervention that will be considered in the guideline. We will try to extract as much information as possible for the evidence that is available for the clinical questions.
SH	South Asian Health Foundation			This organisation was approached but did not respond.	Noted.
SH	South East Sheffield Primary Care Trust			This organisation was approached but did not respond.	Noted.
SH	Staffordshire Ambulance HQ			This organisation was approached but did not respond.	Noted.
SH	Staffordshire Ambulance			This organisation was approached but did not	Noted.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Service NHS Trust			respond.	
SH	Staffordshire Moorlands Primary Care Trust			This organisation was approached but did not respond.	Noted.
SH	Stockport PCT			This organisation was approached but did not respond.	Noted.
SH	Takeda UK Limited			This organisation was approached but did not respond.	Noted.
SH	Tameside and Glossop Acute Trust			This organisation was approached but did not respond.	Noted.
SH	The Association of the British Pharmaceutical Industry (ABPI)	1	General	The ABPI welcomes the decision for NICE to develop a guideline on medicines concordance particularly with regard to the data in paragraph 3b	Noted. Thank you for your comments.
SH	The Association of the British Pharmaceutical Industry (ABPI)	2	Paragraph 4.1.2	We believe that children with long term conditions should also be included. Children with diabetes who fail to concord with their medicine taking are more likely to develop the complications of diabetes at an early stage for instance. We believe the scope should be broadened to all people with a long term chronic condition.	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline.
SH	The Association of the British Pharmaceutical Industry (ABPI)	3	Paragraph 4.3(d)	We believe that pill reminder tools should be assessed as there is no good evidence for their use and certainly not for what is the best method. They are being increasingly used in the community with elderly people and could potentially save the NHS/Social Services money by delaying admission to more structured care.	Thanks for your suggestion and such interventions will be considered in the evidence reviews. We will try to extract as much information as possible for the evidence that is available for the clinical questions.
SH	The Association of the British Pharmaceutical Industry (ABPI)	4	Paragraph 4.3 Areas that will not be covered	We agree that in most acute situations concordance is not so relevant but that is certainly not the case with antibiotics. Failure to complete a course is thought to increase resistance particularly if the rest of the course is taken on a future occasion and for a sub-optimal period of time.	We have revised the scope and will now include prescribed medications for all conditions, regardless of duration.
SH	The Association of the British Pharmaceutical Industry (ABPI)	5	General	Items not included in the scope but should be considered: the role of information prescriptions, the design and readability of Patient Information Leaflets, Power Questions.	Noted, and the provision of information will be considered.
SH	The British Psychological			This organisation was approached but did not	Noted.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Society			respond.	
SH	The College of Mental Health Pharmacists	1	General	The special needs of those suffering from mental illness need to addressed perhaps separately. Mental illness has many precipitating as well as perpetuating features with respect to non-concordance not least of which is the lack of insight that is commonly part of a psychotic illness such as schizophrenia or hypomania The guideline group should include a specialist mental health pharmacist. They can bring expertise to the group with respect to mental health re. medication review, discharge planning, care plans, lifestyle and concordance, concordance /compliance therapy as an intervention to support service users, medicines information, shared carets.	We appreciate the importance of your comments and welcome them. We have set out a comprehensive list of professionals that we think should have representation on the GDG group and will be soon making the final decision.
SH	The College of Mental Health Pharmacists	2	2 (a)	In psychiatry there is little good data on cost-effectiveness. This is due to the many variables that can affect outcome and the lack of adequate or appropriate modelling or decision tree analysis in the specialty. A better term here may therefore be "the economic use of medicines"	Noted. Thank your for your comment. However, we are charged with assessing cost effectiveness, and will be guided by the evidence and the GDG to determine the key areas for economic work.
SH	The College of Mental Health Pharmacists	3	3 (c)	There needs to be a clear definition of concordance. The term implies a degree of agreement between the patient, the prescriber and the medicine regimen chosen. If concordance is achieved there will be greater chance of the patient fulfilling the actual requirements of their medication or lifestyle regimen. Compliance and adherence should be seen as part of the process of concordance. Decisions about medicines should be part of the management of health/illness and the treatment as a whole. Healthcare professionals and patients should work together to achieve good concordance, good outcomes and patient satisfaction.	We have followed the work of the SDO in regard to concepts and terminology. However, the definitions may be revised or adapted during the guideline development.
SH	The College of Mental Health Pharmacists	4	3 (d)	Need to include illness effects here such as lack of insight, reduced cognitition, lack of motivation etc	Noted and revised.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	The College of Mental Health Pharmacists	5	4.1.1 (a)	Need to specifically mention here those with enduring/enduring mental illness/SMI	We have not specified defined groups as we are including prescribing for all conditions.
SH	The College of Mental Health Pharmacists	6	4.1.2.(b)	Why are patients treated in specialist or tertiary centres not to be covered. This will exclude some with severe mental illness (SMI)	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	The College of Mental Health Pharmacists	7	4.2.(a)	Need to include here those with severe mental illness being cared for in the community by e.g. home treatment, crisis intervention, assertive outreach and other community mental health teams.	We have specified community care, regardless of condition.
SH	The College of Mental Health Pharmacists	8		Need also to include the inpatient setting here since there is substantial evidence supporting discharge planning, communication between secondary and primary care re. treatment plans, information given to patients prior to discharge, self administration schemes, compliance assessment etc that impact on future concordance in primary care.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	The College of Mental Health Pharmacists	9	Appendix	Dealing with "poly-pharmacy" – the term "poly-prescribing" is more accurate in this context	This is the remit given from the Department of Health and this can not be changed.
SH	The College of Mental Health Pharmacists	10		Need to include the skills and competencies of pharmacists	This is the remit given from the Department of Health and this can not be changed. However, we will be giving guidance for all healthcare professionals involved in concordance, not prescribers alone.
SH	The College of Mental Health Pharmacists	11		Need to define "medication review"	This is the remit given from the Department of Health and can not be changed, but the GDG will define 'medication review' as appropriate when drafting recommendations.
SH	The David Lewis Centre			This organisation was approached but did not respond.	Noted.
SH	The Long-term Medical Conditions Alliance	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.	Noted. Thank you for your comments.
SH	The Long-term Medical Conditions Alliance	2	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-	Noted and revised.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				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.	
SH	The Long-term Medical Conditions Alliance	3	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)'.	Noted and have revised.
SH	The Long-term Medical Conditions Alliance	4	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	Thank you for your comments.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				therefore welcome the statement that the guideline development group will take reasonable steps to identify ineffective approaches to care.	
SH	The Long-term Medical Conditions Alliance	5	4.1.2b	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 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.	In light of the stakeholder comments we have revised the scope so as to not exclude by setting; and have chosen to only include prescribed medication, excluding administered medication.
SH	The Long-term Medical Conditions Alliance	6	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). A better approach might be simply to describe it as 'Concordance', as reported by the patient and healthcare professional, but then to ensure that the term is very well defined earlier in the document.	Noted and revised.
SH	The Long-term Medical Conditions Alliance	7	4.3d	We would agree with the exclusion of interventions aimed at improving adherence without achieving concordance. To the example of 'dosette' boxes given we would suggest adding pharmaceutical company sponsored patient compliance programmes (email or telephone based), as there is a similar debate around these as there is around pill reminder boxes.	Noted, and this is a distinction (concordance and adherence) that we need to consider with the Guideline Development Group. We have revised 4.3 to address concerns raised by stakeholders, and have been more general about the type of interventions to be considered.
SH	The Medicines Information Project	1	General	Easy access to helpful, timely, reliable medicines information is a necessary (though not sufficient) condition for concordance in prescribing consultations and effective medicine taking. Unless patients are well informed about the range of treatment options available to them and their likely risks and benefits, it is impossible for them to participate as partners with	We will be looking at all types of interventions available in the evidence and will be guided by the available evidence and the expertise of the Guideline Development Group during the development of the guideline. We have not excluded any type of intervention *a priori*

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				healthcare professionals in prescribing decisions. Furthermore, many questions about medicines arise after the prescribing consultation has taken place, and finding answers to these is an important prerequisite for effective medicine use. It will be important in developing this guideline to a) consider the quality and sources of available patient information to support concordance b) make recommendations as to how existing information can and should be used, and c) point to what more may be needed.	
SH	The Medicines Information Project	2	General	Whilst 'dealing with poly-pharmacy and co-morbidity' appear as issues in the guideline referral from the Department of Health, they are not covered anywhere in the scope, but present major challenges to the achievement of concordance. They could be mentioned within section 4.3c, for example by referring to interventions targeted at single medicines *and* those aimed at helping patients to get the most out of a number of medicines prescribed for them (including medication review).	Noted and revised.
SH	The Medicines Information Project	3	3d	In the list of barriers to adherence here, the rather narrow term 'poor instructions' could be expanded to say 'lack of accessible information on the key features of the medicine and how it should be used'.	Noted and revised.
SH	The Medicines Information Project	4	3f	Whilst this statement is undoubtedly true, it is important to note that the amount and level of written information given to patients by prescribers reflects not only their attitudes and competence, but also whether high quality, timely information is available to them in a form that they can pass on. Furthermore, although healthcare practitioners are a key source of information about medicines, patient knowledge and behaviour is also shaped by what other sources of medicines information are available to them, both before and after consultations, and this should not be overlooked.	We will aim to extract as much information as possible from the available evidence, and have not excluded any type of intervention.
SH	The Medicines Information	5	4.3c	Given the immense importance of patient information	We will aim to extract as much information as

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Project			in enabling concordance, we would like to see the addition here of interventions aimed at improving the quality and accessibility of medicines information available to patients. In line with the existing wording in this section, this may be needed before, during and after the prescribing consultation, and the source and mode of delivery are important factors. The range of information considered by the guideline should include patient decision aids.	possible from the available evidence, and have not excluded any type of intervention. Noted as an important issue with varied influencing factors.
SH	The National Centre for Young People with Epilepsy			This organisation was approached but did not respond.	Noted.
SH	The National Pharmaceutical Association	1	general	The National Pharmacy Association welcomes NICE's intention to produce guidance to improve patient concordance. Whilst we agree with the general aims of the guidelines we believe the range of the scope should be increased Throughout the document reference is made to the role of the prescriber but not to the pharmacist who also has a role to play in improving concordance. Prescribers might only see the patient when the initial prescription is issued and then when the patient's treatment is reviewed, which might only occur annually. Pharmacists have the opportunity to engage with the patient each time a prescription is dispensed. Under the terms of the pharmacy contractual arrangements, pharmacists have to interact with patients give advice and respond to questions, full details available on the PSNC website www.psnc.org.uk/contract The role carers, particularly relatives, have to play when patients are unable to self administer their medication also needs to be taken into account.	Noted and we aim to include all healthcare professionals involved in concordance, not prescribers alone. Carers have now been included in the scope.
SH	The National Pharmaceutical Association	2	3.d	This section lists the reasons why patients may not adhere to medication regimes. It omits the physical ability or dexterity to remove medication from packaging, read instructions or to swallow solid form	We will aim to extract as much information as possible from the available evidence, and have not excluded any type of intervention. However, the list of barriers in the scope is not

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				medication. Pharmacists identify these problems whilst conducting a disability discrimination act assessment under the terms of the essential service 1, dispensing. Some problems will be resolved by the pharmacist and for others e.g. changes in formulation, they can make recommendations to the prescriber. Memory problems will be identified during the assessment and pharmacists will also be able to support some patients, and improve compliance, for whom poor memory is a factor by recommending appropriate strategies. Hudson. Pharmaceutical care of the elderly. PJ 1997 259 686 -688 There could also be religious or dietary reasons as to why particular forms of medication e.g. capsules are unacceptable, pharmacists are able to recommend alternative formulations. Pharmacists can also advise on medication management during periods of fasting e.g. Ramadan.	intended to be comprehensive. We will note your suggestions for consideration during development.
SH	The National Pharmaceutical Association	3	4.3.c	Interventions by pharmacists have been shown to be cost effective. See Community Pharmacy Contractual Framework; How a collaborative approach will benefit patients, GPs and PCTs available at http://www.primarycarecontracting.nhs.uk/uploads/Pharmacy/sepo6uploads/messages_for_gps_september_2006.pdf	Noted and we aim to include all healthcare professionals involved in concordance, not prescribers alone.
SH	The National Pharmaceutical Association	4	Areas that will not be covered b)	We believe that short courses of antibiotics should be included. Short courses of antibiotics are frequently not taken appropriately this can contribute to antibiotic resistance and may lead to the need for subsequent course(s) of second line, more expensive medication. Counselling patients and reinforcing counselling with information leaflets has been shown to reduce the number of patients taking unnecessary antibiotics.	We have revised the scope and will now include prescribed medications for all conditions, regardless of duration.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				http://www.bmj.com/cgi/content/abstract/324/7329/91	
SH	The North West London Hospitals NHS Trust			This organisation was approached but did not respond.	Noted.
SH	The Royal Society of Medicine			This organisation was approached but did not respond.	Noted.
SH	The Stroke Association			This organisation was approached but did not respond.	Noted.
SH	The Survivors Trust			This organisation was approached but did not respond.	Noted.
SH	Trafford Primary Care Trusts			This organisation was approached but did not respond.	Noted.
SH	UK Psychiatric Pharmacy Group	1	General	We would support a broad approach to develop guidance for all people involved in the care of patients – such as the multi-disciplinary team working often see in mental health which often include social care staff and support workers.	Noted and we aim to include all healthcare professionals involved in concordance, not prescribers alone.
SH	UK Psychiatric Pharmacy Group	2	General	We would counsel the guideline group to consider issues faced un the mental health clinical milieu as part of the guideline development. It is often considered that he issue of concordance is particularly difficult to address in this patient group. Clearly co-morbidities may complicate concordance and compliance significantly and should be considered.	We have not excluded any patient groups or settings.
SH	UK Psychiatric Pharmacy Group	3	General	Consent is often an issue in mental health service users such as those with dementia or in acute psychiatric emergencies.	Thank you for your comments.
SH	UK Psychiatric Pharmacy Group	4	4.1.2a	Limiting this scope to patients of 18 or over seems an arbitrary and unhelpful restriction with regard to medicines. Informed consent is often given by patients under the age of 18 and similar issues arise in concordance as with over-18's. Consent is clearly an issue to be considered in all age groups.	We have revised the scope and will now include people aged 16 years and older. However, medication taking in young adults is an important issue, and we consider that due to the complexity and the specific needs of young adults, this should be addressed in a different guideline.
SH	UK Psychiatric Pharmacy Group	5	4.2	Mental health service users are often treated in clinical settings that involve community teams such as assertive outreach teams and home treatment or	We have not excluded any patient groups or settings.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				crisis teams. We would wish to see the guidance apply to all mental health service users particularly those for whom insight may be impaired and engagement with services problematical. Concordance can be significantly influenced during a period of in-patient care. For example in many mental health services self medication schemes are in place as part of the rehabilitation programme after illness.	
SH	UK Psychiatric Pharmacy Group	6	4.3	We would support the broad outline detailed here and additionally comment that the difficulties faced by service users for whom English is not their first language, those with sensory and/or learning disabilities. We also envisage that the use of technology such as access through electronic media to information is likely to be extremely useful.	Noted and thank you for your comments.
SH	UK Psychiatric Pharmacy Group	7	4.3d	The issue of compliance aids is a complex one and it would be regrettable if NICE did not offer guidance on this issue which exercises many pharmacists and other health care practitioners endeavouring to address concordance issues.	Noted and will be covered in the evidence reviews.
SH	University Hospital Birmingham NHS Trust	1	General	The DH referral asks that guideline development should cover the skills and competencies required by prescribers. It is not clear from the scope whether or not this will be included.	Noted, and core skills may be considered in general, but detailed recommendations on competencies and training are considered by the Implementation team, and are therefore outside the scope of this guideline. However, where national/professional guidelines on competencies are available, we may refer to these.
SH	University Hospital Birmingham NHS Trust	2	4.3c	Targets for intervention should include carers as they can often be responsible for medication taking in patients with long term conditions	Noted and have revised.
SH	University Hospital Birmingham NHS Trust	3	4.3d	Targets for intervention should include carers as they can often be responsible for medication taking in patients with long term conditions	Noted and have revised.
SH	Vale of Aylesbury Primary Care Trust			This organisation was approached but did not respond.	Noted.
SH	Walsall PCT			This organisation was approached but did not	Noted.

Key: SH = stakeholder

Type	Stakeholder	No	Section number	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				respond.	
SH	Welsh Assembly Government	1		I think it is important to note that this work not only plays an important part of the NSF's but also on the management of chronic conditions across England and Wales. Wales will shortly be launching the Welsh Model and Framework for Chronic Conditions in which medicines management will be a key theme.	Noted and thank you for your comments. We will consider this document in the development of the guideline.
SH	Welsh Scientific Advisory Committee (WSAC)			This organisation was approached but did not respond.	Noted.
SH	West Lancashire Primary Care Trust			This organisation was approached but did not respond.	Noted.
SH	Withybush Hospital			This organisation was approached but did not respond.	Noted.