The Task Force on Medicines Partnership

Proposal for a topic to be referred to the National Institute for Clinical Excellence (NICE) for the development of a clinical guideline on concordance (shared decision making with patients on medicine taking)

Overview:

Concordance describes a process of prescribing and medicine taking based on partnership between patients and health professionals.

The concept of concordance first came to prominence through the publication in 1997 of the report of the Enquiry into the Causes and Consequences of Non-compliance in medicine taking based at the Royal Pharmaceutical Society[1]. This enquiry confirmed that around 50% of medicines for long term conditions are not taken as prescribed. Non-compliance imposes a huge burden of avoidable ill-health and premature mortality on patients, as well as significant cost to the NHS through wasted medicines, drug resistance and, more importantly, in dealing with preventable illness and complications. The enquiry concluded that patients are not the passive recipients of prescribing decisions, but have their own views about medicines, how they should be used and how medicine-taking fits in with their daily lives. Numerous studies have shown that patients' attitudes to risk and the extent to which they find side effects tolerable can differ markedly from the assumptions made by health professionals, and that patients' beliefs and views about medicines are a key influence on whether and how they take them[2]. Patients are much more likely to follow treatment if they have been active partners in prescribing decisions and their views and preferences have been recognised and taken into account[3], [4]. This in turn is only possible if they have sufficient information and understanding about the medicines available to them[5].

The research therefore suggests that three essential elements are required to put concordance into practice[6]:

- First, patients must have enough information about their illness and treatment options to take an active role in decision making. This information must be clear, accurate and sufficiently detailed, and tailored to their individual needs,.

- Secondly, prescribing consultations must involve patients as partners, to the extent that they want to be. During the consultation, patients should be asked about their views and beliefs about their illness and treatment, and these must be explored fully before a decision on treatment is reached jointly between the health professional and the patient.

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[1] From Compliance to Concordance, Royal Pharmaceutical Society of Great Britain, 1997

[2] LaRosa JH & LaRosa JC (2000), Enhancing drug compliance in lipid-lowering treatment, *Archives of Family Medicine,* 9:1169-1175

[3] Dayan-Lintzer M and Klein, P (1999), Galenic, concerted choice and compliance with HRT, *Contraception, Fertilite, Sexualite* 27 (4): 318-321

[4] Cassileth BR, Zupkis RV, Sutton-Smith K, March V. (1980) Information and participation preferences among cancer patients. *Annals of Internal Medicine* 92: 832-6

[5] Makoul G, Arntson P, Schofield T. (1995) Health promotion in primary care: physician-patient communication and decision making about prescription medications. *Soc Sci Med* ; 41 (9): 1241-1254.

[6] Concordance evaluation toolkit, Task Force on Medicines Partnership 2003

- Finally, after a medicine has been prescribed, patients should have access to ongoing support so that any problems or questions that may arise can be addressed. Health professionals should use all opportunities to talk with patients about how their treatment is progressing and resolve any practical difficulties, and medicines should be reviewed regularly, with patients.

Since the start of 2001, the Task Force on Medicines Partnership has been supporting and evaluating practical projects to implement concordance within the UK health system. There is now an extensive and persuasive evidence base which supports the view that concordance between patients and health professionals is key to maximising the benefit of prescribed medication. Several more trials and projects are in progress or being planned now. A clinical guideline from NICE detailing the elements of concordance and how they can be achieved would be timely, and would have the potential to improve health outcomes and the cost effectiveness of care.

Evidence base:

There is no single clinical trial or set of trials which proves a definitive link between concordance in prescribing and improved health outcomes through better compliance. Rather, there is a growing and diverse evidence base which collectively supports the elements of concordance as being key to effective use of medicines.

The current evidence base falls into three categories:

Studies of the extent and causes of non compliance	• The extent of non-compliance in different therapeutic areas • Reasons for, or factors associated with non-compliance
The gap between patients' needs/wishes and current prescribing practice	• Patients' preferences for more information about medicines • Patients' preferences for greater involvement in prescribing decisions • What is generally voiced now, by patients and professionals, in prescribing consultations, and how this falls short of patients' and professionals' true 'agendas'
Intervention studies aimed at improving compliance	• Evidence that single-factor interventions that do not involve patients in prescribing decisions are unsuccessful (e.g. providing additional written information alone) • Emerging evidence that interventions which involve patients more are successful in improving both compliance and patient satisfaction

The most significant reviews which draw together this evidence are as follows:

Evidence already published

- Carter S, Taylor D and Levenson R: *A question of choice: compliance in Medicine Taking*; Medicines Partnership 2003
- Coulter A. *The autonomous patient: ending paternalism in medical care*. The Stationery Office. London 2002
- World Health Organisation: *Adherence to long term therapies: evidence for action.* Geneva 2003
- Cox K, Stevenson F, Britten N and Dundar Y. *A systematic review of two-way communication between patients and health professionals about medicines* Medicines Partnership Dec 2002
- Haynes RB, McDonald H, Garg AX, Montague P, *Interventions for helping patients to follow prescriptions for medications* (Cochrane Review) Cochrane Library February 2002, also summarised in the Journal of the American Medical Association JAMA 2002;288:2868-2879
- Royal Pharmaceutical Society of Great Britain *From Compliance to Concordance: achieving shared goals in medicine taking* (1997)

Evidence which will be available by early 2005

- NHS SDO review of research on compliance and concordance and scoping of the future research agenda (to be commissioned in November 2003)
- Publication by Medicines Partnership of the collated results of major surveys of public and professionals' attitudes to medicine taking and medicines information (early 2004)
- Bond Christine (Editor) *Concordance Reader* (in press)
- Results of major Medicines Partnership studies on concordance[7] (throughout 2004 and 2005)

Rationale for referral to NICE:

Prescribed medication remains by far the most common from of therapeutic intervention, and new and more effective medicines are constantly being introduced. Using medicines to best effect is therefore of critical importance in successfully managing many, if not most conditions. In the past, most attention (including that of NICE) has been devoted to guiding prescribers' treatment decisions rather than to ways of involving patients in these decisions and monitoring whether the medicines selected are actually taken as prescribed. However, until issues of medicine *taking* are addressed, as well as questions of what to prescribe, a significant proportion of drugs will be wasted and the potential therapeutic gain will not be realised.

A NICE guideline in this arena would focus health professionals' attention on the significance of this issue to health outcomes. It would offer practical suggestions based on evidence on how to facilitate concordance at an early stage in the treatment process in order to avoid problems later on when medicines are not being taken as intended. Guidance would also help prescribers to respond appropriately and ethically to patients who wish to make an informed choice not to follow "best practice" treatment. All NICE

[7] Details available at www.medicines-partnership.org/ projects

guidelines explicitly state that the treatment pathway recommended in the guideline may not be appropriate to every patient. Guidelines are sometimes resisted because doctors have found it difficult to apply this principle in practice. Meanwhile, the new GP contract (GMS II) includes the concept of informed dissent. A guideline on concordance would very valuable in providing a process that doctors could follow with patients that would enable them *not to prescribe* with confidence, in circumstances where this was the patient's informed choice.

Related guidance:

There is no single source of related guidance on concordance. Elements of concordance are reflected in key policy documents from the Department of Health, for example in the Diabetes[8] and Older People's[9] NSFs, and in the generic Medicines Management guidance supporting all the long term conditions NSFs which is due to be published later this year. However, a single source of guidance on this topic would be very useful to prescribers and other health professionals.

Timing:

There is already sufficient evidence in this area to support the creation of a guideline. By early 2005, there will be significantly more evidence available (see Evidence Base, above), and this would be the ideal time to produce such a guideline.

Potential costs/workforce/management implications:

We envisage that the implementation of NICE guidance in this area will have implications in a number of areas. Overall a guideline on concordance is likely to result in long term savings for the NHS:

(i) Prescribing costs

The impact of concordance on prescribing will vary by therapeutic area and patient group, but there is growing evidence that concordance is likely to reduce prescribing and make it more appropriate to patients' needs. Evaluations of face to face medication review services that take into account patients' preferences and priorities have indicated that the number of medicines prescribed is typically reduced[10]. Other studies have shown that prescribing decisions in general practice are strongly influenced by factors other than clinical ones. These include the expectations that a patient brings to the consultation[11]. GPs probably overestimate patient's expectations of a prescription[12], [13]. The strongest determinant of prescribing is the doctor's opinion about the patient's expectations of a prescription. Patients may be ten times more likely to receive a prescription if the GP thought that the patient expected medication[14]. Hence, by making patients' agendas in consultations more explicit through a concordant approach, inappropriate prescribing is likely to be reduced.

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[8] National Service Framework for Diabetes Services, Department of Health xxxx

[9] Medicines and Older People (Supplement to the National Service Framework for Older People) Department of Health 2001

[10] Room for Review, a guide to Medication Review, Medicines Partnership 2002

[11] Bradley CP Factors which influence the decision whether or not to prescribe: the dilemma facing general practitioners. Br J Gen Pract 1994;42:454-8

[12] Virji A, Britten N A study of the relationship between patients attitudes and doctors prescribing. Family Practice 1991;8:314-9

[13] Webb S Lloyd M. Prescribing and referral in general practice: a study of patients expectations and doctors actions. Br J Gen Pract 1994;44:165-9

[14] Cockburn J, Pit S. Prescribing behaviour in clinical practice: patients expectations and doctors perceptions of patients expectations- a questionnaire study. BMJ 1997;315:520-523.

(ii) **Other health service costs**

By achieving better clinical control of key conditions, the implementation of concordance will reduce the preventable costs of ill health across the NHS caused by non-compliance. There is reason to think that the avoidable cost of non-compliance is currently rising, as effective medicines are increasingly available for chronic conditions, particularly those which need to be taken on a preventative basis over a long period of time to be effective, but where the patient may not see or feel an immediate benefit.

In an illustrative example, Medicines Partnership has used the available literature to estimate the cost of non-compliance with statin therapy in the UK in 2003. This suggested that, as a direct consequence of non-compliance, there will be 7,500 heart attacks, 1,200 strokes, 4,900 vascular deaths, 1200 coronary artery by-pass grafts, 1,600 angioplasties; 5,700 cardiac catheterisations and 91,800 acute bed days which would not have occurred if statins were taken as prescribed. The research further showed that a 1 percentage point increase in statin compliance would save 350 lives, 4,500 bed days and £2m from NHS secondary care costs[15].

(iii) Wasted medicines

Medicines wastage is extremely difficult to measure with any degree of accuracy. There are countless anecdotal examples of medicine cupboards being found to hold many years-worth of unused medication and local "dump" campaigns have documented millions of pounds worth of unused medicines returned to pharmacies. These figures are generally agreed to be the tip of the iceberg. Concordance will reduce waste by achieving better compliance, and by reducing prescribing for patients who do not want to take medicine.[16]

(iv) Medication safety / litigation

There is growing evidence that involving patients more in prescribing decisions enables them to use medicines more safely and to play a role themselves in detecting errors in prescribing, dispensing or administration of medicines. Adverse reactions to medicines are implicated in 5-17% of hospital admissions for older people and taking several medicines at once increases the risk of adverse reactions and hospital readmission[17]. A concordant approach to prescribing is likely to reduce NHS litigation costs and reduce the cost of treating the consequences of medication errors by picking up problems with medicines before they reach a critical stage.

(v) Staff time

Implementing guidance on concordance is likely to require more health professional time to be spent with patients at diagnosis and at key decision points during treatment, to ensure that patients are supported in making joint decisions about their treatment. In some cases, this will best be achieved by expanding the roles of nurses and pharmacists, rather than placing an additional burden on medical staff time. This role extension is entirely in line with existing NHS policies for workforce development, and additional time spent at these critical stages should result in a corresponding reduction in

[15] Task Force on Medicines Partnership, unpublished research, 2003

[16] According to the All Party Pharmacy Group report of July 2000, £230 million worth of medicines are returned to pharmacies for disposal each year.

[17] Medicines and Older People (Supplement to the National Service Framework for Older People) Department of Health 2001

time required to deal with continuing ill-health and address medication-related problems later on.

(vi) Training and staff development

Concordance requires a major culture change across the prescribing professions, and this in turn will require investment in training and professional development. This can be achieved within existing frameworks, such as through undergraduate communication skills training, GP's Continuing Professional Development, the supplementary prescribing curricula and through the developing programmes of the NHS University. Much of this work is already under way. The existence of a NICE guideline on concordance would provide additional impetus and focus to existing and developing programmes.

In summary, the implementation of concordance will have implications for the way in which staff work across the NHS, but can be accommodated within existing structures and processes, and without significant reorganisation. It is envisaged that the implementation of concordance has the potential to reduce overall NHS costs, whilst improving health and supporting patient choice.

Proposed remit of the NICE guideline:

The proposed guideline would raise awareness of the need for shared decision making around prescribing and the taking of medicines. It would include practical recommendations for achieving concordance and guidance on communicating with patients around medicine taking.

The guideline would focus on the management of chronic conditions, including mental health problems, as these are the areas where the evidence base is best developed and where concordance is likely to have the greatest impact in terms of improved outcomes and cost-effectiveness. The principles and practices underpinning concordance are the same in all situations so that the guideline would also be more generally applicable including to short-term illness.

The guideline would not specifically address the needs of people with learning disabilities, children, or people with sensory or cognitive impairments such as dementia. Once again, the principles of concordance and the techniques and skills needed to put it into practice would bring benefits to all patients including the groups listed above.

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