NHS SERVICE DELIVERY AND ORGANISATION R&D PROGRAMME

Programme of research on patient and carer centred services

Tender documents for

CONCORDANCE, ADHERENCE AND COMPLIANCE IN MEDICINE TAKING: SCOPING EXERCISE

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Concordance, adherence and compliance in medicine taking scoping exercise

This proposal outlines a plan of work to carry out a scoping exercise in concordance, adherence and compliance with medication for the NHS Service Delivery and Organisation (SDO) National Programme

(A) Aims

1. Summarise current knowledge about the determinants of medication taking
2. Construct a conceptual map of the area of compliance, adherence and concordance
3. Identify priorities for future research of relevance to the NHS, with particular emphasis on identifying what new knowledge is needed to be able to develop effective, realisable, efficient and equitable interventions to promote the appropriate use of medicines for the benefit of patients and the NHS.

(B) Background

The prescription of a medicine is one of the most frequent and costly interventions in health care and the appropriate use of medicines is key to the self-management of most chronic illnesses. However, it is estimated that over a third of all prescriptions for chronic illness are not taken as advised and this is thought to represent a significant loss to both the patients and health care system. Due to variations in the definition and measurement of medication taking behaviour across studies it is difficult to gain a definitive picture scale of the problem and so far we know very little about its economic consequences. A plethora of research studies have identified many of the reasons for nonadherence (noncompliance) yet effective methods for improving medicines usage have proved elusive(Haynes et al.) and the issue remains complex and fraught with controversy. The proposed scoping exercise will focus on issues at 3 levels – 1) patients' behaviours; 2) interactions between patients and providers; 3) societal policies and practices.

B1) Patients medication behaviours - Intentional and unintentional nonadherence

At the root of the problem is the fact that nonadherence results from two quite different types of behaviour: *unintentional* and *intentional* (Horne 285-310). Unintentional nonadherence occurs when patients' intentions to take prescribed medication are thwarted by barriers such as forgetting, poor comprehension, or difficulties in opening the packaging. Intentional nonadherence is the result of a decision by the patient not to take the medication or to take less or more than recommended. This distinction has profound implications for how the problem of sub-optimal use of medicines is conceptualised and dealt with, as these different causes would demand different solutions. There is little literature on the extent to which each of these types of nonadherence contributes to the overall picture, however in a recent study of 239 patients starting new medication for a chronic condition found that of the 67 non-adherent patients, 55% were unintentionally nonadherent.(Barber et al.)

Unintentional nonadherence can be addressed by a number of conceptual models. These include the provision, understanding and recall of instructions (Ley 241-54) , approaches based on an understanding of the barriers between intention and action(Horne and Weinman 25-50) and the effects of local circumstances and system errors in health care organisations (Barber 81-84).

Intentional nonadherence is best understood in terms of patient and practitioner beliefs attitudes and expectations influencing the motivation to take (or not to take) medicines. Here, research conducted across a range of illness groups and between different cultural and institutional contexts confirms that patients beliefs about their illness often differ from the medical view, yet have their own internal logical and influence how information (e.g. recommendations to take medication) are interpreted and acted upon(Horne and Weinman 17-32;Horne and Weinman 555-67;Morgan M 95-116). The question of how to manage intentional nonadherence raises issues of patient-provider relationships as well as broader questions, at a societal level, regarding the right of the patient to refuse treatment and the degree of uncertainty about the risks and benefits of the treatment for the individual. Recent reviews (World Health Organisation;Myers and Midence) have summarised literature relating to intentional and unintentional non-adherence, and aimed to contrast patient and professional perspectives or to explain non-adherence with prescribed medication in relation to particular conditions. However there is a need to identify what is known in relation to a) different groups in the population, particularly in terms of social disadvantage and ethnic minority groups, children and adults and b) different broad groups of conditions and related treatment strategies e.g. minor acute vs. severely disabling/life-threatening, preventive vs. symptomatic treatment.

B2) Interactions between patients and providers

Concordance : limitations and outstanding questions

The concordance concept(Royal Pharmaceutical Society of Great Britain) attempts to knit together two issues relating to the use of medicines. First it responds to recent evidence for the importance of patients' beliefs (conceptual models) about illness and medication as determinant of medication taking behaviour. Second, it attempts to embody principles of individual rights and issues of the power differentials within prescribing-related consultations to describe the creation of an agreement that respects the wishes and beliefs of the patient(Horne 165-84). Few would disagree with the underlying principles of concordance: respect for patient autonomy and the need to take account of the beliefs and preferences of individual patients in the provision of healthcare. However, the concept has not been fully defined and there is confusion about how it should be operationalised in research and practice (Dieppe and Horne 605;Heath 856-58).

Beyond the consultation

This scoping exercise will consider the prescribing-related consultation but also go beyond it to address *unintentional* nonadherence and other issues outlined in the SDO Briefing document including access to and interpretation of information about medicines. It will also consider broader issues relating societal policies and practice.

B3) Societal policies and practice

It may be too simplistic to consider the consultation in isolation. It is more than a meeting between patient and clinician. The core decision involves at least three parties: the patient, the prescriber and the payer. A philosophy of prescribing which ignores the latter may be noble but ultimately limited in its capacity to foster pragmatic solutions to questions of how best to use medicines. Within the UK NHS, the prescriber is responsible for allocating resources on behalf of 'society' and the needs of the individual must be viewed in the context of the needs of others. What happens when the patient's preferences conflict with the 'greater good' (Horne and Weinman) A closer examination of the balance between individual wants and greater good is essential because of the high costs of medicines. The economic stakes are high. The NHS spent £6.8 billion on medicines in 2002(National Statistics). Despite the high costs of medicines we know little about the costs of nonadherence (Howard et al. 280-85). These will need to be considered beyond the cost of wasted (unused) medicines to include the knock on costs including additional demands on services from under treated illness and failures of preventive strategies.

Concordance is both a philosophy of ends and a philosophy of means – it defines both the desired outcome and the means by which it will be reached. However, this concept is neither related to the other literature on the ends of health care and prescribing, nor the literature on the ways to achieve them. Important elements in the complex balancing act of prescribing are not recognised in the definition of concordance. For example, Cribb and Barber (292-98) have argued that good prescribing needs to balance the technical, evidence based properties of the drug, with the patient's wants, and with issues of the greater good. Buetow et al (261-71) carefully reviewed the literature on prescribing appropriateness and came to a similar conclusion. Concordance needs to be related to the wider literatures on ethics and philosophies of healthcare delivery that address these difficult issues. It needs to be examined to establish whether its statements about ends and means have either supporting arguments or supporting evidence.

Concordance, and other concepts for achieving better use of medicines, need to be examined under difficult prescribing decisions. What should be done if a fully informed patient chooses not to take her TB therapy? What if a patient rejects a potentially life-saving treatment (such as immunosuppresant therapy following renal transplantation) due to erroneous interpretations of the likely risks vs benefits or because of beliefs that are factually incorrect? How should a doctor with prescribing targets and Evidence Based Medicine guidelines balance these against a patient's wishes?

B4) Focus on interventions to promote the optimum use of medicines in chronic illness

The conceptual map produced within this scoping exercise will summarise our current knowledge and outstanding questions at the patient, patient-provider interactions and societal policies and practice levels. In doing this our priority will be the identification of effective equitable, realisable interventions to promote the optimum use of medicines. We will focus on chronic illness, as here there is the greatest potential to enhance the quantity and quality of life

(C) Methods

C1) Strategy for the scoping exercise– literature review, expert panel and stakeholder workshop

Literature review

A comprehensive review of all of the relevant primary literature is beyond the scope of this exercise and is rendered unnecessary by the recent secondary research contributions. A literature search, using systematic search techniques will be undertaken to identify papers (primary papers, secondary research and opinion papers dealing with theory, philosophy and policy) that present new evidence or perspectives that have not been adequately covered in these reviews and the advisory panel will be asked about recent and ongoing work in the field. The review will include literature that extends beyond traditional boundaries of the individual and the prescribing consultation to examine broader issues at the societal level. Key stages of the literature review and development of the conceptual map are shown below (stages 1-6).

Expert Panel

The core team of applicants represent the fundamental disciplines for talking the topic (health psychology, health economics, medical sociology, health services research, pharmacy practice and prescribing). This team will work closely with an *expert panel* of advisors with additional areas of expertise (general practice/consultation methods, evidence-based medicine, paediatrics, prescribing policy, health informatics, healthcare philosophy/ethics) Please see Appendix 1 listing the Advisory panel members with expertise and affiliations. This panel will augment and extend the expertise of the applicants. The study researcher (see Costings section below) will collate the literature and work with applicants and advisory panel members who will guide the interpretation and evaluation of the literature. Through their intimate knowledge of the field they will also be able to advise the researcher on unpublished or on-going work of relevance to the scoping exercise. It is expected that the researcher will visit each person two or three times over the course of the project. The applicants will evaluate the literature, derive the conceptual map and write the scoping report.

Workshop

A draft conceptual map and our summary of outstanding questions will presented at a national workshop. This will be a listening exercise in which we invite key stakeholders to comment and identify outstanding questions. We anticipate inviting 30-40 people representing academia, healthcare professions, NHS policy and management, and patient groups. Presentations by member the research group will be used to present the key issues/outstanding questions at each of the three levels of investigation (patient, patient-provider interaction, societal policies and practice). This will be followed by group worships and plenary in which the invited participants will discuss their response and feedback in a plenary session. The results will be written up by the research team and circulated to participants for further comment. This process will inform the final draft of the Conceptual map and research agenda (Stages 7-9). We have used a similar approach to identify the key questions about users' perspectives of complementary and alterative medicine (CAM), in a workshop funded by the MRC and held at the University of Brighton in collaboration with the MRC Health Services Research Unit, University of Bristol.

Key stages and timescale

	Scoping Exercise Stages	Timescales
1.	Review of secondary literature and reviews	
2.	Identify whether significant primary research has been omitted or published since the reviews	
3.	Draft summary of current knowledge and identify outstanding questions	
4.	Advisory panel comment on draft based on their specialist knowledge	
5.	Researcher produces revised summary and key issues	1-5Completed end Month 4
6.	Research team drafts conceptual map and research agenda	Completed by end Month 6
7.	Invited seminar/workshop for key stake-holders. Functions as a listening exercise and opportunity to consult more widely than our advisory panel	Completed by end month 7
8.	Redraft conceptual map and research agenda	
9.	Write up scoping exercise including results of the workshop	Completed end Month 9

C2) The multi-disciplinary team: composition and rationale

The applicants have all contributed to the literature on medication taking and their expertise spans many of the relevant disciplines and approaches. They have published primary and secondary research in the topic. We believe we have the expertise and capacity to successfully complete the project. Professors Horne and Weinman have published extensively on the causes of nonadherence and have developed psychological models and validated tools for assessing practitioner and patient perspectives and use of medication. Dr Morgan is a medical sociologist who has conducted qualitative studies of non-adherence, particularly among ethnic minorities and undertaken research on the medical consultation. She has also successfully undertaken an SDO scoping exercise on Access to Health. Professor Barber has published widely on the philosophy and ethics of prescribing and on the healthcare systems and policy relating to the use of medicines. Dr Elliott is one of the few health economists within the UK specialising on the economic aspects of adherence and adherence interventions. Gaps in expertise are addressed within the advisory group.

(D) Outputs and deliverables

The following outputs will be provided for each of the levels of investigation:

Patient behaviour

1. An evaluation and comparison of theories, philosophies and evidence for the underlying reasons for nonadherence, including both intentional and unintentional reasons. We will also, identify the degree to which explanations for nonadherence and interventions to facilitate adherences are generalisible or need to be situation specific (e.g. across illness and treatment types, across socio-economic groups and ages including children and adolescents).
2. A review of methods for assessing medication-taking behaviour and identify priorities for further developments as well as methods for eliciting and assessing patients beliefs, attitudes, preferences and experiences relative to medication taking. Here we will consider the application of measures in clinical practice as well as research.

Patient-provider interactions

3. A summary of the evidence for the effects of patient-provider interactions on the use of medicines that identifies key studies that have assessed gaps between patient and provider inputs (e.g. beliefs, attitudes, knowledge, preferences) and methods for addressing gaps within the prescribing-related consultation. This will consider the role of different health professionals (e.g. doctors, nurses and pharmacist) and issues relating to inter-professional communication and the consistency of advice to patients.
4. A list of outstanding questions about how to equip healthcare practitioners with the knowledge, skills and attitudes to elicit and take account of patients' beliefs and preferences and to tailor approaches to the needs of the individual in order to promote the optimal use of medication.

Societal policies and practice

5. A critical appraisal of the concept of concordance and related concepts such as partnership in medicine taking and patient-centred care; a mapping of these onto ethical theory and consideration of application to practice settings.
6. A summary of outstanding questions relating to the economics of nonadherence and the implications for adherence interventions.
7. A summary of outstanding questions about concordance, adherence and compliance and how they relate to healthcare policy.

Synthesis across levels

8. An explanation of why adherence interventions have, in systematic reviews, been shown to be relatively ineffective. This will lead to a critical appraisal of theories and approaches that could improve medicines taking, including concordance, and other related concepts, such as shared decision-making and patient-centred care.
9. A summary of current knowledge and outstanding questions relating to patients' access to and interpretation of information about medicines.
10. A clarification of terminology. We will explore the terms used to explain medicines-taking behaviour, primarily but not exclusively 'compliance', 'adherence' and 'concordance' and if possible propose standardisation of the terminology.

D1) Summary of deliverables

1. A summary of current knowledge about the process of medication taking that identifies outstanding questions at three levels: patient, patient-provider interactions and societal policies and practice..
2. A conceptual map for understanding concordance adherence and compliance. This map will focus on the identification of effective, equitable and realisable interventions to promote the optimum use of medicines, particularly in chronic illness, as here there is the greatest potential to enhance the quantity and quality of life.
3. A research agenda that focuses on the key areas of theory and evidence that are essential to inform future policies and practice around optimising medicines taking. This will include recommendations for the primary research, secondary research and methodology that is necessary to clarify our understanding of the process of medication taking and of developing and evaluating interventions to facilitate the appropriate use of medication.

(E) References

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Appendix 1 Composition of the Advisory Panel

Name and Title	Affiliation	Expertise
Justin Keen Professor of Health Politics and Information Management	Nuffield Institute for Health, University of Leeds.	Health informatics, health policy, access and utilisation of medicines information
Richard Meakin General Practitioner and Senior Lecturer in Primary Care	Royal free and University College School of Medicine	Studies of doctor-patient negotiation in primary care consultations. Assessment of patient expectations and satisfaction
Alan Cribb Professor of Bioethics and Education	Director, Centre for Public Policy Research Department of Education and Professional Studies Kings College London	Links between empirical research on social/ policy analysis and perspectives in applied ethics. Changing models of healthcare
John Geddes Professor of Epidemiological Psychiatry	Centre for Evidence Based Mental Health Department of Psychiatry University of Oxford	Randomised controlled trial and systematic reviews. Evidence-based practice
Richard Vincent Professor of Medical Science Consultant Cardiologist	Associate Dean Brighton and Sussex Medical School	Secondary medical care (cardiology)Medical education, multi-professional working
Martin Anderson Director of Patient Affairs	Association of the British pharmaceutical industries (ABPI)	Pharmaceutical industry perspectives
Paul Seddon Consultant Paediatrician	Brighton and Sussex University Hospitals	Will consider issues relating to children and adolescents
Stephen Firn	Chief Executive Oxleas NHS Trust and Registered Mental Nurse	NHS Policy, NHS Management, Nursing policy and practice