

Final Report to the Department of Health and the King's Fund
October 2004

Clinical Governance for Complementary and Alternative Medicine in Primary Care

Jane Wilkinson
Professor David Peters
Julie Donaldson

Contents

Foreword Dr Michael Dixon OBE (Chair, NHS Alliance) & Dr Peter Smith OBE (Chair, NAPC)	2
Executive Summary	3
Acknowledgements	5
Abbreviations	6
Glossary	7
Introduction	9
University of Westminster project overview	10
Section A: Development	
1. Clinical governance	11
1.1 Introduction to clinical governance	11
1.2 Clinical Governance, the thread that integrates	12
1.3 CAM and governance in the context of the new NHS Improvement Plan	15
2. Issues and provisional guidance: CAM and clinical governance	17
2.1 Patient focus: Patient, carer and public involvement – patient experience	18
<i>A1: Issues and provisional guidance: Developing patient, carer and user involvement</i>	19
<i>A2: Issues and provisional guidance for developing a care plan</i>	21
2.2 Clinical Effectiveness, Clinical Audit and Research Governance	23
<i>A3: Provisional guidance for developing Broad Evidence Synthesis Topic Reports</i>	25
<i>A4: Provisional guidance for developing Performance Indicators</i>	28
2.3 Cost effectiveness	31
<i>A5: Developing methods for the economic evaluation of primary care CAM</i>	33
2.4 Intelligent use of information	36
2.5 Risk Management	37
2.6 Continuing Professional Development	38
2.7 Staffing and management	39
<i>A6: Issues in developing interprofessional learning and working for the benefit of patients</i>	41
<i>A7: Developing a Quality Team Development Scheme for CAM</i>	42
2.8 Developing quality assured NHS primary care CAM services	45
2.9 Professional development and change management for complementary practitioners	46
2.10 Making clinical governance work for you	47
3. Toolkits for CAM CG	48
3.1 The Pilot Care Pathway: low back pain	48
3.2 The BESTCAM pilot: low back pain (Broad Evidence Synthesis Topic)	48
3.3 The Integrated Healthcare Network	49
Section B: Research	
4.1 England-wide primary care CAM services: mapping 2003-2004	50
4.2 Clinical governance in a sample of 16 London services	54
Section C: Recommendations	
5. Key recommendations	59
Appendices	
Appendix 1: List of participants in the consensus building (Delphi) process	60
Appendix 2: Methodology for mapping England-wide services	61
Appendix 3: Purposive sample of the London region	62
Appendix 4: The King's Fund seminar series & consensus building	63

Foreword

Britain is witnessing an explosion of interest in complementary medicine both within the NHS and outside. Current developments, particularly patient choice and local empowerment, will further fuel this explosion. Public opinion is moving the argument for integration of complementary medicine towards centre stage.

It is therefore increasingly important that access to complementary medicine and the advice given to patients is both safe and appropriate. This document, based on the work being carried out by the University of Westminster is a timely first attempt to explore how clinical governance – the key to providing safe and accountable services – will apply to complementary and NHS primary care.

Clinical governance is thus an important tool for the integration of complementary and alternative therapies with “orthodox” and NHS health care. Self-regulation with local accountable and professional improvement have been the hallmarks of clinical governance, leading ultimately to higher quality services and greater public confidence. CAM practitioners and their representatives should now urgently work together to integrate these features into their own systems of governance.

Research shows that 50% of patients attending complementary practitioners still do not let their GPs know they are doing so. Other studies tell us that around 50% of GPs encourage their patients to try complementary therapies. Optimising cooperation between orthodox and complementary medicine and subsequent integration of complementary therapies in NHS primary care is more likely to happen if clinical governance is congruent and consistent between them. Its aim must be to improve patient experience and ensure that safety and efficacy are maximised. National bodies and guidelines play their part in this, but the real thrust will need to come from local practitioners with a commitment to establishing high standards within every Primary Care Trust.

Primary Care Trusts, for their part, will need to commission appropriate complementary services in relevant clinical areas. Indeed, a recent Government Command Paper “Building on the Best – choice, responsiveness and equity in the NHS” includes the commitment to develop a framework for access to complementary medicine throughout the NHS. Recent criticisms of CAM miss the point – this is a National Health Service paid for by the electorate who wish to have a say in the services it delivers, which may not be to the liking of all professionals within it.

Recently the Gateway Clinic, a Traditional Chinese Medicine service based at Lambeth Hospital jointly won the Foundation for Integrated Health’s annual prize. Practitioners are employed by the PCT, with most referrals coming from a majority of GP practices in the area. Such developments indicate the emerging landscape of opportunities for practitioners not previously included in the NHS mainstream. This stream is set to widen and CAM practitioners should prepare themselves for new opportunities. The extent to which CAM practitioners are able and willing to embrace the regulation and accountability of clinical governance will become one of the most important determinants of future integration.

This work has been an important starting point for considering the theoretical and practical ramifications of the clinical governance agenda for complementary medicine. This report provides a vision of a better NHS. That is now an achievable vision because the progress of integrated healthcare is now as inevitable as it is desirable. This progression must have clinical governance as its companion. That is what this document is about.

Dr Michael Dixon OBE
Chair, NHS Alliance

Dr Peter Smith OBE
Chair, NAPC

Executive Summary

It would be unequivocally true to say that nothing stands still in the current world of the NHS. In only a short time since we first began to consider the role and remit of Clinical and Corporate Governance, a new and important process of integrated governance emerges in the framework for Healthcare Standards¹.

This latest approach brings together a number of strands of policy development (core and developmental standards) under the umbrella of integrated governance to enable the change agenda to be effectively implemented in terms of a quality output for the end user. It is a process which will form a key part of the performance assessment to be done by the Healthcare Commission and reflects a move to seven domains from the original seven pillars.

All this reshaping evolved during a time when the clinical governance approach to CAM was embryonic in its development, beginning to form through a 'bottom up' approach delivered via a series of workshops during 2003.

The content of this report is reflective of the output of those workshops and can not therefore embrace the onward thinking developing through integrated governance.

This report therefore has to be seen as the beginning of the journey for CAM and the findings must now be built upon to begin to reflect the value of CAM in supporting the challenging new agenda facing Primary Care Trusts in relation to Patient Choice, the management of long term medical conditions and access to treatment. Equally important in the framework to move forward, is the positive role CAM can contribute to an upstream approach to working with clinicians moving from a pure diagnosis and treatment mantra to one of predict and manage.

There is more work to be done to align the initial thinking with the new approach. The value of the workshops as they stand, demonstrates the enthusiasm and drive that exists across CAM practitioners to embrace the new NHS agenda. The next stage can only serve to build on this important first step and begin to reflect the integrated governance approach via the seven domains; this being a true demonstration of the CAM practitioner's desire to be a positive contributor to the new and dynamic NHS of the future.

This report provides a background to the recommendations and toolkits that the University of Westminster project developed through consultation with stakeholders. It provides provisional guidance to support good CG practice for CAM practitioners and service providers as well as recommending developments within the CAM (academic and regulatory) field that will support CG. It also indicates the potential contribution CAM might make to a modernising NHS and the resources needed to facilitate that role.

The integration of CAM into mainstream NHS services should aim to increase patients' choice of cost-beneficial treatment options. Patient-centredness is a core value for CAM practitioners, so they are likely to participate enthusiastically in clinical governance projects focussing on patient choice and satisfaction.

Key elements of clinical governance (CG) addressed in the report

The main focus of the developmental work has been on CG issues prioritised by stakeholders – more than 200 representatives of organisations including; PCTs, service users, CAM professional bodies and training organisations – who attended a series of consensus development seminars in 2003. They highlighted CG issues at the operational / service level and included; patient and public involvement, evaluation of CAM including clinical audit, clinical effectiveness (and cost effectiveness) Continuing Professional Development (CPD), and inter-professional learning and working.

How does this relate to CG as it is developing in the NHS?

These areas match the priorities and activities of mainstream CG and the overall recommendation is for a convergence of CAM and mainstream CG and the inclusion of CAM practitioners in existing quality improvement initiatives (e.g. RCGP's QTD Scheme, Improving Working Lives, local postgraduate education) and governance schemes.

¹ Department of Health (2004) National Standards, Local Action: Health and Social Care Standards and Planning Framework 2005/06–2007/08, Department of Health, July 2004.

Executive Summary

How do these relate to the developing provision of CAM in the NHS?

The consensus is that CAM CG will be crucial to the integration of CAM in the NHS. Stakeholder feedback from the consultation process shows that the CAM field is willing to explore a governance-based integration framework. PCTs commissioning CAM services through APMS contracts (as with PMS and GMS) will expect adequate CG and the report suggests how CAM providers can ensure they meet PCT requirements. The recent survey conducted as part of this project suggests that London CAM units that serve PCTs are developing a range of CG activities. The project also surveyed all England PCTs to establish access to primary care CAM services and their development.

Practical guidance provided in the report

The report reflects the priorities of stakeholders: how to increase patient, carer and user involvement; the need for CAM practitioners to engage with PCTs in service re-design; involving service users in local service development; guidance on developing a broad evidence base for CAM services; examples of inter-professional learning and working as a basis for integrating CAM. Guidance is directed primarily at therapists and professionals providing CAM services or who are developing integrated services, and further work will be needed to address the needs of lone practitioners. The report encourages care teams to create a culture of patient-centred quality development. Qualitative research with experienced providers has produced a simple checklist for embarking on CG development and the thrust of the report is that CAM services should make manageable improvements, prioritising them in consultation with commissioning PCTs.

Additional tools linked to the guidance

The recommendations are intended as a guide to quality development; the associated *on-line toolkits* are designed to support its progress: the BESTCAM pilot is a tool for practitioners developing Evidence Based Practice; the pilot care pathway makes explicit the CG processes of an established integrated service, and links to the care plan guidance; the Integrated Health Network is an online knowledge transfer community supporting all the work undertaken in this project. The provisional guidance contained in this report relates to the operational (service) levels of clinical governance and the overall advice is to develop CAM services and CG activities in parallel, and in negotiation with PCTs. This development should involve a relevant, methodical and step-wise progression, and be related to personal and practice development planning.

Immediate priorities for developing CAM CG:

1. Maintaining the practitioner-focussed CG work
2. Conducting a scoping exercise for developing a framework for access to CAM in the NHS with regards to the patient choice initiative
3. Developing guidance and training in CG for CAM practitioners in collaboration with the CAM regulatory and accrediting bodies and teaching institutions
4. Producing guidance for PCTs commissioning CAM
5. Conducting a programme of work on CAM cost and clinical effectiveness
 - a. To develop practical advice to service providers on relevant data collection
 - b. To explore how current conventional methods of economic evaluation can be harnessed and developed to demonstrate wider and more long-term benefits of healthcare interventions
6. Developing a Quality and Outcomes Framework for CAM in relation to competencies and skills.
7. Extending the Quality Team Development Scheme to incorporate CAM

Acknowledgements

This R&D project was funded by the Department of Health and King's Fund. The input of both organisations beyond the provision of finances - especially with the seminar series and the development of our work - has been invaluable. In particular we would like to thank Gordon Brown and Steve Gillam. We are very appreciative of the continued interest from advisors who have helped shape this project and help build a consensus on key issues relating to CG for CAM in primary care.

Our special thanks to the following people for their continued support and input into the project: Kate Thomas, Deputy Director, MCRU, University of Sheffield, who has provided advice throughout and given substantial input all the way through the seminar series, in the consensus building and in developing the pilot Broad Evidence Synthesis Topic (BEST) CAM report. Dione Hills, Research Consultant, Tavistock Institute, has been a continuous source of advice and encouragement. Thanks also to Michael Dixon and Peter Smith for their support and for giving time to speak at most of the seminars we ran. Christine O'Connor (Catch-on consulting) gave invaluable help in thinking through and facilitating the series itself and bringing an innovative approach to service redesign into the online care pathway pilot. We would also like to thank many of the staff at the Prince of Wales's Foundation for Integrated Health, in particular: Tricia Darnell and Hazel Russo, especially in facilitating the group work during the seminar series. We are grateful for the support given and the collaboration with PoWFIH made possible by Margot Pinder, Michael Fox and Dione Hills.

We thank everyone who participated in the seminar series, consensus building and consultation. Without them much of this work would not have been possible. A full list of participants in each seminar can be found in the separately published reports and a full list of all participants in the Delphi (action research) process is presented in appendix 4.

Particular thanks go to colleagues who presented on key issues throughout the series: Helen Caton (Director, Forton Bank Consulting), Ray Davies (Project Manager, MIND-CHI collaboration), Jo Dent, (Health Policy Advisor and Quality Review Manager, CHI), Prof. Nancy Devlin (Professor of Health Economics, Dept of Economics, City University), Dr Michael Dixon (Chair, NHS Alliance), Dr Oggy East (Semantise Ltd), Dr Stephen Gillam (Primary Care Advisor, King's Fund), Dione Hills, (Collaborative Project Manager, Prince of Wales's Foundation for Integrated Health), Carol Horner (Non-Executive Director, Wycombe PCT), Roy Jones (Independent consultant in self management), Richard Little (Senior Research Fellow, Centre for Health Planning & Management, University of Keele), Dr Sue Morrison (GP, Marylebone Health Centre, London), Christine O'Connor, (Director, Catch on [consulting]), Bob Sang (Director, Sang Jacobsson Limited), Dawn Solomon (Pharmaceutical Advisor/Primary Care Support Manager, Newcastle PCT), Dr Peter Smith (Chair, National Association of Primary Care), Kate Thomas (Deputy Directory, MCRU, University of Sheffield), Gerry Harris (Associate Dean for CPD, London Deanery for General Practice, acupuncturist), Dr Tony Downes (GP, CAM lead for the Royal College of General Practitioners, member of the National QTD Steering Group).

The regular commitment of Dennis Donnelly, (Collaborative Research Project Co-ordinator, Liverpool Centre for Health), Carol Horner (NED, Wycombe PCT), Mike O'Farrell (Chief Executive Officer, British Acupuncture Council), Dr Mike Cummings (Medical Director, British Acupuncture Society), Eleanor Lines (Freelance Consultant, Healthy Bristol) Prof. Alan Breen, (Member of Council, General Chiropractic Council), and Prof. Nicky Robinson, (Professor of Complementary Therapies, Centre for Complementary Therapies, Thames Valley University) gave an essential cohesion to the seminars' groupwork. We greatly appreciate their contribution. More than two hundred PCTs provided information on local CAM services. We appreciate the trouble that they and the service providers took to give details on their services, in particular the time taken by those supplying detailed information on their CG activities. Our thanks also to CHI for providing a seconded worker and for advice given on developing the seminars and CG questionnaire.

This report has been prepared by Jane Wilkinson, Julie Donaldson and Professor David Peters, the key staff on the Clinical Governance Project at the School of Integrated Health, University of Westminster. The report is also based on work undertaken by; Lina Bakhshi, Juliet Formby, Amanda Nadin (CHI seconded worker) and Sarina Singh. Our gratitude also goes to Lesley Wye, NHS CAM Pre-doctoral Fellow and Dr Linda Gibson, University of Nottingham for sharing research efforts in the South West and the West Midlands. And last but not least, many thanks to the seminar series report writer, Caroline White (Guild of Health Writers) and Toni Morris (IHN/project IT support).

Abbreviations

ALBs	Arm's Length Bodies
APMS	Alternative Primary Medical Services
BEST	Broad Evidence Synthesis Topics
CAM	Complementary and Alternative Medicine
CHD	Coronary Heart Disease
CHI	Commission for Health Improvement (see Healthcare Commission in glossary)
CGCAM	Clinical Governance for Complementary and Alternative Medicine
CGR	Clinical Governance Review (conducted by CHI – see Healthcare Commission)
CPD	Continued Professional Development
CP	Complementary Practitioner
CPPIH	Commission for Public and Patient Involvement in Health
CPR	Cardiopulmonary Resuscitation
DH	Department of Health
EBC	Evidence Based Care
EBM	Evidence Based Medicine
EBP	Evidence Based Practice
GMS	General Medical Services (contract)
HC	Healthcare Commission (see CHI)
HDPs	Health Delivery Plans
HIMPs	Health Improvement Plans
IBS	Irritable Bowel Syndrome
IHCM	Institute of Health Care Managers
IHN	Integrated Healthcare Network
KF	King's Fund
MA	Modernisation Agency
MCRU	Medical Care Research Unit, University of Sheffield
MYCAW	Measure Your Concerns and Wellbeing
MYMOP	Measure Yourself Medical Outcomes Profile
NAPC	National Association for Primary Care
NED	Non Executive Director (of PCT)
NeLH	National electronic Library for Health
NICE	National Institute for Clinical Excellence
NSFs	National Service Frameworks
OT	Occupational Therapy
PACT	Prescribing Analysis and Cost (data)
PALS	Patient Advisory and Liaison Services
PAMs	Professions Allied to Medicines
PBMA	Programme Budgeting and Marginal Analysis
PDSA	Plan, Do, Study, Act
PCT	Primary Care Trust
PCO	Primary Care Organisation
PEC	Professional Executive Committee (of PCT)
PEI	Patient Enablement Instrument
PIs	Performance Indicators
PLC	Practice-Led Commissioning
PLP	Personal Learning Plan
PMS	Personal Medical Services (contract)
PoWFIH	Prince of Wales's Foundation for Integrated Health
PPI	Patient and Public Involvement
QALY	Quality Adjusted Life Year
QOF	Quality Outcomes Framework
QoL	Quality of Life
QTD	Quality Team Development
RCGP	Royal College of General Practitioners
RCN	Royal College of Nursing
RCT	Randomised Controlled Trial
RLHH	Royal London Homeopathic Hospital
SIH	School of Integrated Health, University of Westminster
SLA	Service Level Agreement
StHA	Strategic Health Authority

Glossary

Accreditation: A process, based on a system of external peer review using written standards, designed to assess the quality of an activity, service or organisation.

Accountability: Responsibility for, can be called to account for something.

Adverse incident: An event, out of the ordinary and unintended, which may be harmful to patients.

Alternative Provider Medical Services: A contracting framework to facilitate PCTs in commissioning a wide range of services. *"APMS ... offers substantial opportunities for the restructuring of services to offer greater patient choice, improved access and greater responsiveness to the specific needs of the community. PCTs can enter APMS contracts with any individual or organisation that meets the provider conditions set out in directions. This includes the independent sector, voluntary sector, not-for-profit organisations, NHS Trusts, other PCTs, Foundation Trusts, or even GMS and PMS practices. If PCTs contract with GMS / PMS practices via APMS, the practice would hold a separate APMS contract alongside their GMS / PMS contract."* DH April 2004

http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/PrimaryCare/Commissioning/CommissioningArticle/fs/en?CONTENT_ID=4080251&chk=an7wOf

Agenda for Change: The new pay system for NHS staff http://www.modern.nhs.uk/scripts/default.asp?site_id=48

Appraisal: A review procedure in which staff are invited to comment upon their own work and performance.

Audit: see [Clinical audit](#).

Benchmark: A level of care set as a goal to be attained.

Benchmarking: Finding and implementing better practice by comparing performance and identifying processes that work elsewhere and emulating them. Benchmarking activities allow for comparisons of services to be made and lessons to be learned between organisations.

Cardiopulmonary Resuscitation (CPR): A procedure attempted on any person whose cardiac or respiratory functions cease. The procedure includes mouth to mouth resuscitation and performing chest compressions.

Clinical audit: A systematic review of clinical practice which includes identification of the procedures used for the diagnosis, treatment and care, the associated use of resources and the resulting outcome and quality of life for the patient or client.

Clinical effectiveness: The extent to which treatments achieve their intended purpose for the range of patients who will receive them in practice.

Critical appraisal: The process of assessing and interpreting evidence, by systematically considering its validity, results and relevance to practice.

Clinical governance: A framework through which NHS organisations are accountable for continuously improving the quality of services.

Clinical guidelines: Systematically developed statements to help clinicians and patients in decisions about appropriate and effective treatment for specific conditions. They provide a basis for measuring clinical practice.

Clinical outcome: The impact or effect of a treatment on the health or wellbeing of an individual.

Cochrane Library: A quarterly publication on disk and CD-rom produced by the Cochrane Collaboration. It contains a compilation of systematic reviews of randomised, controlled trials of healthcare. For more information visit their website on www.cochrane.co.uk.

Commissioning: The process of agreeing health services which a service provider will deliver for a specified sum of money. Commissioning also involves monitoring contracts to ensure best value.

Commission for Health Improvement (CHI): A national body set up to monitor the implementation of clinical governance under the terms of the Government's White Paper *The New NHS: Modern, Dependable*. It is now part of the Healthcare Commission.

Compliance: The extent to which patients adhere to the advice given by the healthcare provider (for example, in following medication regimens).

Continuing Professional Development (CPD): A process of life long learning for all individuals and teams, which meets the needs of patients and health priorities and enables professionals to expand and fulfil their potential.

Consensus: General agreement on specific issues, by all or most of those involved. Although unanimous consensus is seldom achieved, continuous coordination throughout the study process is expected to gain support from most stakeholders.

Cost-consequence model: A form of economic analysis that compares the cost impacts of various management strategies.

Cost effectiveness analysis (CEA): A type of economic assessment in which interventions having a common outcome are compared. CEAs are widely used to compare the efficiency of various drug regimens. The results of a CEA can be expressed as a cost effectiveness ratio (for example, cost (£) per life-year saved).

Efficacy: The extent to which a treatment achieves its intended purposes under the strict conditions of randomised, controlled trials, in patients typically recruited to such trials (as distinct from effectiveness, see [Clinical effectiveness](#)).

Effectiveness: see [Clinical effectiveness](#).

Evaluation: A research process which aims to provide the data necessary to judge the merits and shortcomings of the subject under investigation.

Evidence-based medicine (EBM): The systematic, explicit and judicious use of the best available evidence in patient care.

Evidence-based practice (EBP): The best available evidence, moderated by the patient circumstances and preferences is applied to improve the quality of clinical judgments. This includes patient-reported, clinician observed and research evidence in making and carrying out decisions about the care of individual patients.

General Medical Services (GMS): General medical services are services provided by family doctors (GPs) and their staff, as framed in the General Medical Services Regulations 1992.

Healthcare Commission: Independent regulator of healthcare. The newly formed Healthcare Commission incorporates the work of the former organisation, CHI www.healthcarecommission.org.uk

Glossary

Inclusion criteria: The criteria used by authors of a review to decide whether to include studies.

Integrated care pathways (ICPs): Locally agreed, evidence-based standards used to manage and monitor clinical processes. They attach clinical interventions to a timeline. ICPs are intended to reduce variations in patient care.

Intervention: This can refer to a treatment, a change in practice or procedure or the introduction of a screening programme.

Manual handling: The transporting or supporting (including the lifting, putting down, pushing, pulling, carrying or moving) of a load by hand or bodily force. A load in this context includes people.

Meta-analysis: The systematic pooling of evidence from a number of clinical trials which summarises the results of several studies into a single estimate, giving more weight to results from larger studies. A systematic review is not the same as a meta-analysis because a systematic review does not use statistical pooling.

Multi-disciplinary team: A group of health workers from different disciplines or professions.

National Institute for Clinical Excellence (NICE): A national body set up by the Department of Health to promote clinical and cost effectiveness. NICE produces and disseminates clinical guidelines and makes recommendations to the government on whether treatments should be available to NHS patients.

National Service Frameworks (NSFs): A common standard across the country for the treatment of common conditions e.g. coronary heart disease, older people, mental health, cancer.

No blame culture: This is where an organisation creates a learning environment so that staff feel comfortable about saying when things have gone wrong because they know they will not be blamed for their error, but instead will be encouraged.

Outcome: Result of an intervention which can be desirable, e.g. improvement in the patient's condition or quality of life, or undesirable, e.g. side-effects.

PACT data Prescribing Analysis and CoST data provided by the Prescription Pricing Authority. It is collected from the dispensed prescriptions they receive (excluding hospital prescriptions) to price and authorise payment to dispensing contractors. (NHS Information Standards Board http://www.isb.nhs.uk/pages/glossary/detail.asp?gl_id=1089)

Paradigm: A set of concepts, values and practices that is shared by a community and serves as a pattern or a model.

PDSA: The PDSA is a model used for testing ideas for creating improvements in a quick and easy format. The model advocates starting with small changes, which can be built into larger improvements to services through successive quick cycles of change.

Peer-reviewed: With reference to an article published in a journal which has been checked by other experts to ensure that the authors have used sound methods and have described their methods in sufficient detail to allow others to reproduce their results.

Personal Medical Services (PMS): Contracts which were introduced in 1997 and allow for a greater flexibility in providing primary care services to the community.

Primary Care Investment Plan (PCIP): A rolling 3 year document produced by PCTs outlining the priorities for developing and investing in primary care. It covers areas such as Information Management and Technology, the development of surgery premises and staffing development.

Primary Care Trusts (PCTs): Local organisations formed in April 2000 which replaced all Primary Care Groups (PCGs) by 2004. They are responsible for the healthcare of local populations; self-supporting, but accountable to health authorities for the overall performance.

Process redesign: An approach that allows health care workers to map and understand the patient's journey and then analyse whether changes to service structure would benefit patient care.

Professions Allied to Medicine (PAMS): These include; dieticians, speech and language therapists, podiatrists, occupational therapists and physiotherapists.

Protocol: Locally agreed ways of managing and treating patients.

QALY (quality-adjusted life-year): QALYS are used as an outcome measure to recognise that the quality, not just the quantity, of life is relevant to the patient

Quality of life (QoL): A measurement of wellbeing based on both subjective and objective judgement. Various tools are available for measuring health-related QoL.

Qualitative research: An umbrella term to describe the systematic investigation of human affairs through empirical inquiry. The multiple disciplines under the umbrella have their own methods of research and means of validating their findings.

Reliability: This is the process of establishing that data analysis and coding remain constant when reviewed at different times by the same researcher (stability) or another researcher (reproducibility).

Risk: The probability of an event occurring following exposure to a risk factor.

Risk Management: A systematic framework for assessing, managing and reducing the risks connected with providing healthcare.

Service Level Agreements (SLAs): Contracts between PCTs and service providers such as NHS Trusts. They are agreed on an annual basis.

Stakeholder: An individual or organisation with an interest in health and health initiatives. Stakeholders can be organisations such as local authorities or individuals such as residents.

Standards: These involve establishing criterion (a statement that sets out clearly what is being measured), having a yardstick for which to measure against, and a target for the percentage achieved.

Systematic review: An overview of the evidence base in a clinical area that has been systematically identified, appraised, and summarised according to pre-determined criteria. Not to be confused with a meta-analysis.

Validity: This refers to the soundness or rigour of a study. A study is valid if the way it is designed and carried out means that the results are unbiased – that is, it gives you a 'true' estimate of clinical effectiveness.

Whistle blowing: The act of informing a designated person in an organisation that patients are at risk (in the eyes of the person blowing the whistle). This also includes systems and processes that indirectly affect patient care.

Introduction

Doctors are keenly interested in public sector access to CAM² and continuing public use of CAM demonstrates its still growing popularity. CAM services are being increasingly accessed via NHS primary care (according to our surveys - in at least 43% of Primary Care Trusts) a trend that is likely to increase as PCTs proceed to establish NHS services more locally, making them patient-centred, participative and primary care based³.

Access to CAM is an aspect of patient choice and self-management, perhaps especially so in chronic conditions and where lifestyle strategies are part of health promotion^{4,5}. PCTs are now free to explore CAM's potential in re-designed services, within a framework for clinical and integrated governance and within the context of national standards and targets⁶. CAM has come to signify important aspects of patient choice and holistic care. Whether or not this is valid, access to CAM might increase NHS user and staff satisfaction and improve NHS recruitment and retention. GPs recognise primary care effectiveness gaps, especially in chronic disease, and may be using CAM to bridge them. The potential for CAM services to reduce costly hospital referral and its role in promoting a healthy lifestyle will further encourage innovation in this area.

Clearly, NHS modernisation presents new opportunities for developing CAM services. However, PCTs' accountability for commissioned services will depend on their CG; PCTs will have to demonstrate CAM's safety and cost effectiveness if they include CAM in re-designed services. CG, by raising confidence that common standards for quality are shared by CAM practitioners and NHS health professionals, could become a potent driver for integration of CAM into the NHS.

If NHS modernisation provides a level playing field for the integration of CAM, then it will bring a new breed of health professionals into the mainstream. In a future 'healthcare service of all the talents'⁷ clinical governance will ensure accountability and lifelong learning, allowing radical innovation - organisationally speaking - to feel safer. So far, the CAM professions have needed little encouragement to take a proactive role^{8,9}. Osteopaths and chiropractors, led the way to State registration in the 1990s, and have become a growing presence in the NHS. Inevitably other CAM professions will follow.

Against this background, a pilot research and development project funded by the Department of Health and the King's Fund, set out in 2001 to map the development of CAM primary care services within PCTs, explore stakeholders' ideas and experiences of CAM in the NHS, and develop consensus on best practice for CAM clinical governance. This report documents the outputs from the consultation process undertaken by the University of Westminster, and embraces issues relevant to developing CAM services in NHS primary care. All parties in this consultation - CAM practitioners and their professional bodies, mainstream healthcare workers, representatives of patient groups, PCTs and government and non-government organisations - expressed a common concern that NHS CAM services be appropriate and effective.

The main focus of our work has been on the *operational* (service level) CG issues which were prioritised by stakeholders and hence coverage is more comprehensive in some areas of CG than others¹⁰. The aim of this report is to present information generated through a series of seminars and other project related activities and to present materials contained in the April 2004 consultation documents that have been adjusted in response to feedback. Although we have provided a glossary of terms, we recommend that readers make reference to the full reports on the 2003 seminar series¹¹ and other key documents and resources where indicated.

*Professor David Peters, Clinical Director and Jane Wilkinson, Senior Research Fellow
School of Integrated Health, University of Westminster*

² Thomas KJ, Coleman P, Nicholl J. (2003) Trends in access to complementary or alternative medicines (CAMs) via primary care in England: 1995-2001. Results from a follow-up national survey. *Family Practice*; 575-577.

³ The discontinuation of a small number of well established services has been reported via the network since the latest survey was conducted. Services were cut by the PCT in relation to issues of equity.

⁴ Education on work-life balance and encouragement of patient responsibility for health and wellbeing were highlighted in consensus and consultation phases as being important aspects of CAM interventions

⁵ Department of Health (2003) Building on the Best: Choice, Responsiveness and Equity in the NHS. 9 December 2003, Department of Health

⁶ Department of Health (2004) National Standards, Local Action: Health and Social Care Standards and Planning Framework 2005/06-2007/08, Department of Health, July 2004.

⁷ Department of Health (2000) A Health Service of all the talents: Consultation document on the Review of Workforce Planning. 20 April 2000

⁸ PoWFIH (2003) The Statutory Regulation of the Acupuncture Profession, the report of the Acupuncture Regulatory Working Group. The Prince of Wales's Foundation for Integrated Health, September 2003.

⁹ PoWFIH (2003) Recommendations on the Regulation of Herbal Practitioners in the UK. A report from the Herbal Medicines Regulatory Working Group. The Prince of Wales's Foundation for Integrated Health, September 2003.

¹⁰ For comprehensive coverage of strategic issues relating to CG from the perspective of PCTs please refer to: Stanton P (2004) 'The Strategic Leadership of Clinical Governance in PCTs' (2nd ed.) NHS Modernisation Agency, Clinical Governance Support Team: National Primary Care Trust Development Programme, March 2004

¹¹ Full reports can be accessed on the Integrated Healthcare Network www.ihn.org.uk or via www.wmin.ac.uk/sih/cgcam

Introduction

University of Westminster CG CAM project overview

The Clinical Governance Project has been running for 3 years. It was jointly funded by the Department of Health (DH) and the King's Fund and further DH funding has supported the development of two pilot toolkits. The initial project set out to map the London-wide provision of CAM services by PCTs. This mapping was extended to incorporate an England-wide survey, and report in depth on services with established clinical governance. In addition a network was established to facilitate good practice in the clinical governance of CAM.

This work has been conducted during a period of rapid change in the NHS. The modernisation process got fully under way and PCGs were either merging or transforming into PCTs. It set out with three aims in view: firstly to clarify the extent of current access to CAM services - initially in London and then England-wide; secondly, to document the processes necessary for clinical governance activities relevant to CAM services and finally to establish a network, (www.ihn.org.uk), providing support to members and to help spread good practice in clinical governance of CAM. The network is a continuing source of information about CAM services evolving in the NHS.

Contact has been established with a wide range of projects where CAM is accessed via primary care. Information on clinical governance aims and activities has been collected from a sample of services in the London Region.

As part of the network's development a series of six seminars was hosted by the King's Fund. The aim was to develop consensus on clinical governance of CAM. Syntheses of key material is summarised throughout **Section A 1&2** of this document. Guidelines drawn from the main outputs of the seminars are also presented in **Section A 2** along with three toolkits: the development of an on-line pilot care pathway and Broad Evidence Synthesis Topic Report focusing on CAM treatments for Low Back Pain. An on-line facility was developed jointly with the Prince of Wales's Foundation for Integrated Health was used to establish a network and facilitate the process of developing good clinical governance of CAM as well as developing primary care CAM services in general. The 'Integrated Healthcare Network' www.ihn.org.uk is also described in **Section A3**.

Mapping England-wide Primary care access to CAM

- Preliminary PCT surveys to identify services (2001/2 , 2002/3 and 2003/4)
- Follow up survey with a sample of London-wide service providers to identify:
 - Service details
 - Funding sources
 - Clinical governance activities
- Depth work to examine the processes for developing clinical governance in practice

Network & Consensus Building

- Series of 6 seminars
 - Focus on key aspects of CG
 - Develop consensus on best practice for CG
 - Facilitate networking
- Online Network
 - Established jointly by the University of Westminster and the Prince of Wales's Foundation for Integrated Health (www.ihn.org.uk)
 - Facilitate joint working with a broad range of stakeholder organisations and individuals
 - Shared learning and knowledge transfer

Innovative developments

- Broad Evidence Synthesis Topic (BEST) CAM Report pilot
 - Initiated by K.J. Thomas and discussed by delegates at seminar 1 on the evaluation of CAM.
 - The function of the reports is to draw together a wide range of local and national data on the evidence base for CAM interventions.
- Care Pathways online
 - Initiated and developed by Catch on [consulting] in collaboration with the University of Westminster – pilot pathway for the treatment of Low Back Pain

A. Development: Clinical governance (1)

1.1 Introduction to clinical governance

In the late 1990s, the government introduced a legal requirement for the NHS to provide a quality assured service that is both equitable and accountable.^{12 13} Clinical governance (CG) was placed at the centre of a 10 year plan for modernising the NHS: the modernisation agenda.

The term 'clinical governance' surfaced in the first white papers on health of the new Labour Government in 1997. The term embraces a range of different activities and was, like the white paper itself (*A first class service: quality in the new NHS*¹⁴), intended to systematise several interlinked activities. Its most prominent organisational precursor was the movement for clinical audit.

CG is a system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating "an environment in which excellence in clinical care will flourish."¹⁵ It is a framework within which NHS organisations and staff can continually improve clinical care, whilst seeking to reduce and eradicate poor clinical care.¹⁶ For practical purposes clinical governance encompasses everything to do with managing the quality and continuous improvement of clinical services, including; professional development, clinical audit, developing care pathways, implementing guidelines and risk management¹⁷.

CG is about giving NHS organisations, and the professionals within it, a framework to build a single coherent local programme for quality care. It defines values, cultures and processes and procedures that need to be put in place to sustain that quality of care¹⁸.

CHI (the former NHS independent regulator for NHS performance – now absorbed as part of the new Healthcare Commission¹⁹) defined clinical governance as "...the system of steps and procedures adopted by the NHS to ensure that patients receive the highest possible quality of care." It includes: a patient centred approach, accountability for quality, ensuring high standards and safety, and improvement in patient services and care.

1.1.1 Clinical governance overview²⁰

The Modernisation Agency's Clinical Governance Support Team describes CG as: "A 'whole systems' process whose features include:

- Patient centred care needs at the heart of every NHS organisation. This means that patients are kept well informed and are given the opportunity to participate in their care
- Good information about the quality of services is available to those providing the services as well as to patients and the public
- Variations in the process, outcomes and in access to health care are greatly reduced
- NHS organisations and partners work together to provide quality assured services and drive forward continuous improvement
- Doctors, nurses and other health professionals work in teams to a consistently high standard and identify ways to provide safer and even better care for their patients
- Risks and hazards to patients are reduced to as low a level as possible, creating a safety culture throughout the NHS
- Good practice based on research evidence is systematically adopted"

Dr Stephen Gillam²¹ warns that such quality improvement will not be achieved without investing time, energy and funding.

"The most prominent organisational precursor of clinical governance was the movement for clinical audit. I learnt at least three things when trying to encourage audit in primary care in the

¹² The 1999 NHS Act placed a legal duty for quality on NHS organisations which included corporate accountability for clinical quality and performance <http://www.hmsa.gov.uk/acts/acts1999/19990008.htm>

¹³ Department of Health (1997) The New NHS: Modern, dependable. Department of Health, London <http://www.dh.gov.uk/>

¹⁴ Department of Health (1998) A First Class Service: quality in the NHS. Department of Health, London

¹⁵ Scally D, Donaldson J. (1998) Clinical Governance and the drive for quality improvement in the new NHS in England BMJ 1998; 317:61-65

¹⁶ Department of Health (1998) A First Class Service: quality in the NHS. Department of Health, London

¹⁷ Holt P R. Strategic Healthcare Solutions

¹⁸ Department of Health (1999) Clinical Governance: quality in the new NHS. Department of Health, London

¹⁹ <http://www.chai.org.uk/Homepage/fs/en>

²⁰ Modernisation Agency, Clinical Governance Support Team <http://www.cgsupport.nhs.uk>

²¹ Former Primary Care Advisor at the King's Fund. Wilkinson J, Peters D, Donaldson J. (2004) Clinical Governance for CAM in Primary Care: Report, April 2004. University of Westminster.

A. Development: Clinical governance (1)

80's and 90's. Firstly, you do not internalise quality assurance by inventing new terms and throwing money at them (though that can help) for there is no avoiding painstaking, educational change and the need to provide protected time. Secondly, "closing the loop" – i.e. actually making measurable improvements is a lot harder than pontificating through the medium of guidelines and protocols about what needs to be done better. Thirdly, clinical audit extended its tentacles least successfully into those parts of the health service that always received less support: obscure community services, overlooked primary care disciplines such as optometry, and allied professions. This message is relevant when thinking about the myriad of providers often working in isolation to deliver complementary therapies.

Seven years after the white paper, much progress has been made in developing the infrastructure and support for clinical governance – the birth of new organisations, systems and processes. Clinical effectiveness and clinical governance are not synonymous but the challenge to produce evidence in support of what they do remains central for practitioners of CAM. The contested meanings of effectiveness and the nature of that evidence let alone how to routinise assessment of quality of care will provide fuel for projects like these in perpetuity.

The ultimate prerequisite for fruitful clinical governance activity is trust – trust in robust processes across a health system, trust in partners in other disciplines to whom you may make referrals, trust in close colleagues with whom you may share details of your own performance. This trust is founded upon personal relationships – the essence, after all, of high quality care in any discipline. Yet, if asked, many health professionals still express uncertainty as to what clinical governance actually means. What does it really mean for you? For me, clinical governance is about making the effective choices easy choices. And that is exactly what this project has been striving to support."

1.1.2 The importance of developing clinical governance for CAM

In the current NHS, services cannot be delivered without clinical governance. Therefore CAM must become familiar with the concept and introduce it in ways that relate practically to the workings of PCTs. PCTs, tasked with devolution and service redesign, cannot achieve the NHS objectives unless the people on the ground are actively involved. These are new concepts and new challenges for the NHS. The quality issue underpins the relationship between providers and the PCT.

The emerging CAM field will need to play into both aspects of clinical governance – transformation as well as assurance. The following section provides the context for this process.

1.2 Clinical Governance, the thread that integrates²²

"Quality must be everybody's business." Department of Health 2000²³

The further integration of CAM will demand some standardisation of the quality of service offered. Governance structures will move the CAM field forward. Clinical governance provides a framework within which to build coherent local programmes for quality care. By its very nature it defines the values, cultures, processes and procedures required to sustain that quality of care. In order to enable change and support development, governance processes must be embedded into the culture of the organisation and the values that underpin how practitioners deliver their service.

As with the modernisation of the NHS, clinical governance is a process and not an event. It cannot be something that just happens every now and again nor can it be regarded as a one off. Clearly as the role of governance is emerging from both corporate and clinical perspectives the concept of integrated governance begins to play a more meaningful role²⁴.

1.2.1 Two aspects of governance: transformation and assurance

While clinical governance is a driver for change and transformation it is also concerned with assuring the safety and quality of current practice. Transformation is about reconfiguring current patterns of care and governance is the process which should guide and inform the development. The emerging CAM field must begin to recognise the twin foci of governance and be prepared to embrace both sides of this important concept. It is not just sufficient to

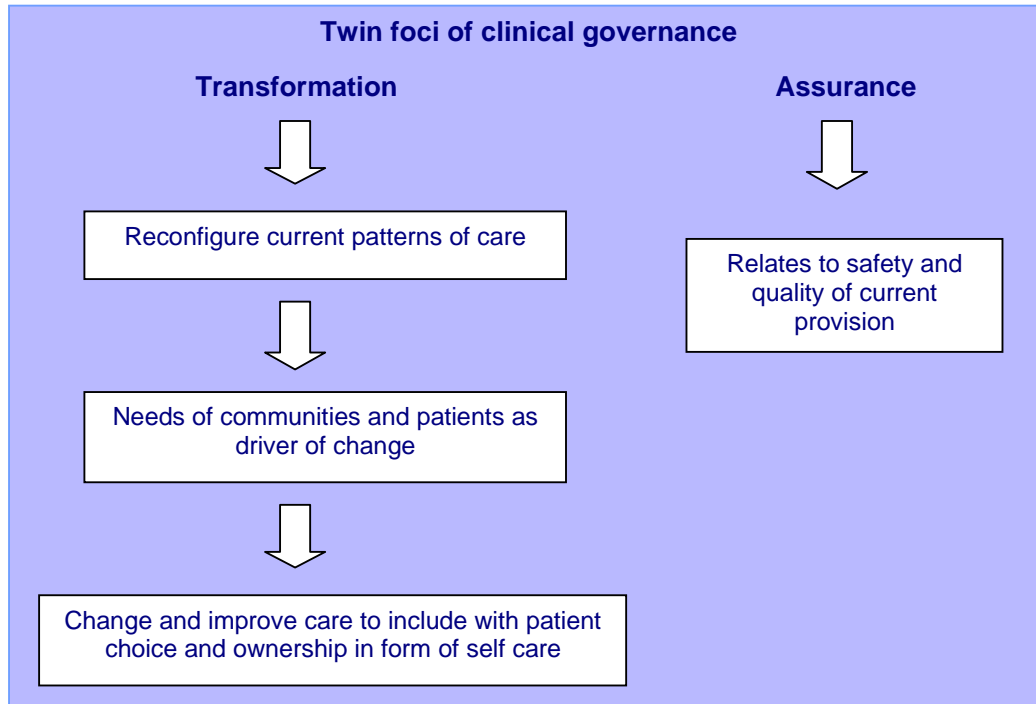
²² The following sections draw on material presented by Christine O'Connor at Seminars 1 & 4 or the King's Fund series. The full reports are available via www.ihn.org.uk or www.wmin.ac.uk/sih/cgcam

²³ Department of Health (2000) *An Organisation with a Memory*. Department of Health, London.

²⁴ Stanton P (2004) *The Strategic Leadership of Clinical Governance in PCTs* (2nd ed.) NHS Modernisation Agency, Clinical Governance Support Team: National Primary Care Trust Development Programme, March 2004

A. Development: Clinical governance (1)

review how current CAM provision may reflect governance requirement but perhaps more importantly CAM practitioners should be concerned with their role in transformation and choice and be clear on what this may mean for the delivery of their services. This requires a proactive approach from the CAM community in not only identifying where they could effectively contribute to a transformed service but also the integrated governance needed to underpin such an approach.



As PCTs have a corporate responsibility for the healthcare they provide, it is crucial that the relationship between the PCT and the services it commissions are transparent. Thus the PCT must be aware of all services that are provided within the PCT community. More specifically this means transparent connections with the PEC i.e. in all cases where CAM practitioners are providing services to NHS primary care patients, contact should be established with the PEC either directly or via the practice to which they are sub-contracted. Furthermore, as the PCT has a clinical responsibility or 'duty of care' for the local population it is essential for all services to provide information and comply with PCT requirements so that the PCT can be assured by the services that it commissions. This includes services delivered via GMS, PMS and APMS contracts.

1.2.2 Clinical Governance is everybody's business

In this brave new world of the NHS it is clear that the PCT has a pivotal role as the cornerstone of the service locally. Along with this comes the budget holding responsibility and the new and challenging approach to commissioning. This revitalised commissioning agenda provides organisations not only with the opportunity to fundamentally transform the way health and healthcare is perceived and delivered but also the responsibility for equally ensuring that clinical governance is a principle which enables and supports whole system change.

Such thinking is not simply within the gift of managers and leaders of these organisations, it must be engaged with and owned by staff, communities, clinicians, health professionals and independent contractors alike to ensure that positive values and the pursuit of excellence are firmly embedded in the heart and soul of the organisation.

Primary Care Organisations must therefore own the responsibility to ensure that:

- All the PCT community - including patients and the public - play an active role in the planning, delivery and evaluation of healthcare
- Staff and all partners in care have clarity of understanding and ownership of CG
- Partnerships reflect the changing face of health and healthcare and incorporate integrated governance principles as new ways of working evolve

A. Development: Clinical governance (1)

1.2.3 Developing accountability strategies for CAM in the NHS

The most developed CAM professions such as osteopathy and chiropractic are already able to demonstrate coherent programmes for quality improvement; their risk management procedures are in place and they have procedures for poorly performing professionals. These elements must be regarded as an inherent part of achieving 'quality standards' which change the way people think about their work and professional development.

Data collection must be done systematically with a clear understanding of what data needs to be collected and for what purpose²⁵. Audit is a central requirement as is research. Research governance is a new field for many PCTs and presents many challenges but challenges which have to be addressed and responded to. Equally clinical accountability, in regard to what practitioners do and say to people, is relevant to all practitioners.

Clinical governance involves proactive workforce planning and development, including recruitment and retention issues. It is uncertain whether the figures from the Wanless Report²⁶, demonstrating the numbers of professionals needed to bring about the modernisation agenda, are achievable. In which case how can that deficit be managed? How do PCTs start to plan more effectively? How can the workforce be utilised effectively within the operating constraints? How can staff get the development they need? Staff development is an essential part of enabling PCTs to deliver services effectively.

CG within CAM must be prepared to embrace education and training strategies. A PCT considering CAM providers should be prepared to include them in the education and training strategy, and ensure this links with the work of the Workforce Confederations. By developing processes that are parallel to those within the NHS the process of integration will be facilitated.

1.2.4 Managing CAM in the NHS

True commissioning requires that organisations effectively audit, manage and evaluate the services they commission. How, for example, might a PCT track and evaluate outcomes of a CAM service? How would the PCT regulate the way it is conducted? This would be impossible without an accountability framework, and unless competencies had been laid down and clinical governance structures put in place, it would be unlikely to happen.

Professional regulation and/or competency frameworks will be needed wherever CAM practitioners enter the NHS. The competency frameworks will have to flow into governance frameworks, so that there is a process in place to help deliver the NHS plan. Workforce planning and development should ensure *all* staff within a PCT are competent and motivated. CAM delivery could make use of a competency framework approach²⁷. Ideally the competencies required in every area of work would be laid down during an initial qualifying training.

Audit must be continuous because neither the work nor the population ever stands still; what is good now may be inferior in ten years time. Process redesign is necessary for the continuous quality improvement required. Clinical audit also involves benchmarking and monitoring improvement as part of an ongoing developmental process.

Quality improvement is key, so it will be essential to measure what is delivered. While clinical effectiveness on the one hand links with the aims of evidence based medicine, on the other, chosen measures of clinical effectiveness must link typical practice with outcomes anticipated. Clinical effectiveness requires the development of templates on IT systems for collecting patient information and data. CAM practitioners must be enabled to do this. Patient data must be dealt with in accordance with all relevant acts and current NHS practice and must not be kept in isolation, for these templates need to reflect the way that data is collected in PCTs and wherever CAM is practised. Systems for call and recall within CAM practitioner services will also be required. Evidence based care (EBC) should ensure that the data collected supports the practices the CAM field introduces into mainstream care.

EBC can also be linked to performance indicators. CAM must negotiate with PCTs to ensure they achieve relevant realistic performance indicators. Clinical effectiveness can be supported by pathways and guidelines that inform working practice.

In part clinical governance is about commissioning services based on best evidence in order to achieve key national and local targets. For example, in redesigning an orthopaedic service,

²⁵ See section on 'Intelligent use of information'

²⁶ Wanless Report (2004) Securing Good Health for the Whole Population. HM Treasury. HMSO London

²⁷ Developed in relation to National Occupational Standards <http://www.skillsforhealth.org.uk>

A. Development: Clinical governance (1)

bearing in mind the existing capacity issues, it will be important to explore available alternatives. For CAM to support what the NHS is trying to achieve it must develop the necessary infrastructures. CAM must be prepared to embrace the new principles being currently implemented by the NHS in order to be recognised as an alternative provider of medical services. Within this will be the need to be able to demonstrate the capacity and capability to deliver an appropriate service which sits within the seamless, integrated service models towards which the NHS is currently striving. Developing links and working with both local PCTs as well as Strategic Health Authorities (responsible for developing capacity and performance monitoring) will be crucial for evolving NHS CAM services.

1.2.5 Clinical accountability and support

As PCTs have a duty of care for their populations and therefore have a duty to develop processes of clinical accountability when contracting a service. This means PCTs also have a duty to their contracted providers to ensure that they have adequate support for quality assurance. As with GPs and the new GMS contract, developing a quality assurance framework for CAM will be a necessary step and one which will need to be supported by PCTs and linked to their duties of accountability and quality. PCTs are required to provide support, leadership and transparent clinical accountability systems for all the services it commissions²⁸.

Ensuring that adequate measures for monitoring the standards and safety of clinical care by a healthcare trust is one of the central elements of clinical governance that has developed particularly in the light of the Bristol²⁹ and Shipman³⁰ enquiries. PCTs must have in place:

“...clear, timely and transparent processes that identify (and differentiate between) safe, sub-optimal and unsafe performance. They must ensure that appropriate steps are taken to deal with each and every instance of unsafe practice that is identified. Boards and PECs must also assure themselves that all reasonable steps have been taken to ensure that staff of organisations providing services to their patients are accountable for their practice and that their practice is appropriately monitored and supported. In doing so they can give a lead to the entire health care community.” (Stanton²⁸)

1.3 CAM and governance in the context of the new NHS Improvement Plan

Much has been done since the inception of the NHS Plan to create an improved NHS in terms of patient experience, quality and investment.

The NHS Improvement Plan³¹ together with Standards for Health³² cover the next 3 years of delivery in term of moving the NHS from a service based on acute response to one which predicts and manages chronic disease, provides access to treatment in a seamless and timely way and focuses on an upstream approach to the public in terms of the personal approach to health and healthcare. In order to fully enable this fundamental change to be delivered the focus of change rests fairly and squarely with the Primary Care Trust/Organisation.

The PCT have been empowered in the following ways:

- Responsible for 80% NHS funding locally
- The commissioner of services for local populations
- Payment by results to enable PCTs to look closely at the way services are delivered locally and delivering care in the least invasive way and the least intensive setting
- New contracts for clinicians to enable changed working processes and a focus on quality outcomes rather than basic bean counting

It is absolutely clear that high quality personalised care will be the way forward in terms of delivery and that this will be done in such a way to reflect:

- Shorter waits and improved access
- Choice at the point of referral for the patient
- Choice for patients supported by information to enable them to make informed choices from a base of knowledge and understanding

²⁸ Stanton P (2004) Executive Summary: The Strategic Leadership of Clinical Governance in PCTs. NHS Modernisation Agency, Clinical Governance Support Team: National Primary Care Trust Development Programme, March 2004

²⁹ <http://www.bristol-inquiry.org.uk>

³⁰ <http://www.the-shipman-inquiry.org.uk>

³¹ Department of Health (2004) The NHS Improvement Plan: Putting people at the heart of public services. June 2004, Department of Health <http://www.dh.gov.uk/assetRoot/04/08/45/22/04084522.pdf>

³² Department of Health (2004) National Standards, Local Action: Health and Social Care Standards and Planning Framework 2005/06–2007/08, Department of Health, July 2004.

A. Development: Clinical governance (1)

- Wider range of services in primary care provided via traditional contracts and alternative provider medical services in order to reflect a move away from the monopoly environment of the past in the NHS
- An environment for staff which will openly encourage a culture which will assure the quality of care provided and demonstrate systems and working practices to enable this
- At the heart of all of this new thinking will be patient safety and encouragement to learn from things that go wrong in order to reduce risks and provide safe experiences within the NHS environment

Whilst the CAM workshops have reflected the operational seven pillars of governance, it is against this new backdrop that CAM comes to the table to embrace a place within the NHS mainstream delivery of care.

Those who have experience of CAM will know that service can be varied and variable. The new approach being embraced by Primary Care Organisations across England will demand that the services they wish to commission are in line with the standards laid down within that specific organisation. This is not aimed at CAM practitioners alone but is already being embraced by general practitioners via the new GMS contract and the Quality and Outcomes Framework, which is within the framework for the new Consultant Contract and also reflected through the 'Agenda for Change'³³ for those employed directly via the service³⁴.

It is critically important that CAM practitioners embrace clinical governance as reflected via the work completed to date, but perhaps the change in the pace of delivery has now opened up an avenue which needs to be pursued in terms of a Quality and Outcomes Framework for CAM. This will require the development of standards in relation to competencies and skills, tools to enable a shared approach to commissioning which is reflective of the quality and safety surrounding the services to be provided for a defined population and evaluation procedures which are able to demonstrate that the investment has delivered its return in terms of patient experience and effect on the system.

The burden of proof rests with CAM practitioners to enable them to take their place as an alternative provider of medical services to the PCT. The provision of this service has to be within the context of change, transformation, safety and need.

Services to be taken on board will have to be able to demonstrate not only that clinical governance underpins the whole proposal but also that:

- The patient is at the centre
- The approach is holistic in nature
- Proactive management is a key part of the delivery
- Individuals delivering are wholly competent and skilled
- Treatment plans are in place and can be integrated into the NHS systems
- Risk is being managed and patient safety is paramount
- The service can deliver outcomes and this is reflected in value for investment
- The service meets the specific needs of the organisation in terms of
 - Population identification
 - Impact on hospitalisation
 - Patient involvement

The work so far has focussed on current patterns of care and the governance structures to enable change within that. CAM must now address the changes in service delivery which PCTs are tasked to manage, embracing the role of the patient and looking more closely at the changes that must be made to the nature of CAM service delivery to fit the need of the commissioner.

This is now truly an agenda for transformation with providers increasingly accountable to the public, patients empowered to take an active role in maintaining their own health and diversity of provider base from which the PCT can commission.

The quality for CAM NHS services has been touched on; now the quality and standards need to be defined.

³³ See http://www.modern.nhs.uk/scripts/default.asp?site_id=48 and <http://www.modern.nhs.uk/agendaforchange/Afcpplain.pdf>

³⁴ The QOF is "a system of standards, incentives and assessment relating mainly to the essential and additional services" provided via both GMS and PMS contracts. <http://www.natpact.nhs.uk/primarycarecontracting/16php>

A. Development: Issues and guidance (2)

2. Issues and provisional guidance: CAM and clinical governance

This section presents the issues concerning clinical governance of CAM in primary care and activities that will underpin good clinical practice that were prioritised³⁵ and discussed throughout the series of seminars, held at the King's Fund in 2003^{36, 37}. Provisional guidance and recommendations on Issues relating to operational aspects of CG which emerged through both the consensus building process and research activities undertaken by the University are also addressed and have been adapted in the light of feedback from the April 2004 consultation document. These issues relate to the service level responsibilities and activities in the CAM field constituting the former seven pillars of CG.³⁸

The report produced alongside the consultation document covered some of the issues addressed in the fourth (learning) seminar which examined the development of the NHS and in particular primary care³⁹. This included factors relating to the development of CAM NHS services e.g. recruitment and retention issues, patient expectation, choice and equity of access, new contracting possibilities (PMS, PMS and GMS), as well as the role of CAM in whole systems planning and service redesign as well as in health promotion, maintenance and self empowerment.

Participants at the seminars were in general agreement that NHS modernisation presents opportunities for the expansion of NHS CAM services and that clinical governance is a challenge that CAM will have to address. PCTs are inescapably accountable for commissioning services, so will inevitably be required to demonstrate that the services they deliver are safe, acceptable, effective and represent an efficient use of resources.

Recommendations for developing appropriate tools and approaches for key aspects of CG raised throughout the seminar series are presented within this document⁴⁰. Further work will be needed to develop guidance within the new NHS frameworks (though the content and priorities continue to be relevant). The online toolkits that have been developed to support CG development: the pilot BESTCAM and pilot Care Pathway for the treatment of Low Back Pain in primary care can be accessed via the Integrated Healthcare Network (IHN)⁴¹.

The action research methodology employed to develop consensus on the topics covered is explained in **Appendix 4**. The recommendations are intended to facilitate practitioners and services in the development of their CG activities relevant to the governance of mainstream primary care services. The recommendation is that not all the items would have to be addressed but the comprehensive lists draw out the many tasks which NHS practitioners and service providers are now expected to have considered and that the Healthcare Commission's inspections are likely to look for. There is significant overlap between the results of the consensus process and National Occupational Standards. As already indicated, the development of a competency framework in alignment with current frameworks would progress the integration of CAM further.

Throughout the consultation process to date it is clear that the development of all activities relating to CAM will depend on the resources made available to practitioners, service providers and investments made in providing a framework and supporting activities that will be needed to develop these standards. The type, size, cost and location of CAM service provision are likely to determine to some extent the development of CAM activities. The advice given consistently was to take small steps that relate to the requirements of commissioning Primary Care Organisations so that they can be accountable for the services they provide.

The provisional guidance contained within this report is especially appropriate for teams of practitioners (those providing services under the new APMS contracts or within an integrated primary healthcare setting). Some of the guidance in particular would only be relevant to well established services e.g. developing Performance Indicators.

Most points raised in relation to the guidelines have been incorporated into the text and other elements will hopefully be explored in more detail in future work. Feedback from the consultation documents on the guidance was in general very positive. The two key identified needs were to produce both summarised guidance as well as more detailed and robust guidance in relation to specific CAM interventions.

³⁵ At a stakeholder event held at the King's Fund in 2002

³⁶ See **Appendix 4** for an overview of the seminars and consensus building process

³⁷ For an overview of the seminar series please see **Appendix 4**

³⁸ Wilkinson J, Peters D, Donaldson J. (2004) Clinical Governance for CAM in Primary Care: *Consultation Document*, April 2004. University of Westminster.

³⁹ Wilkinson J, Peters D, Donaldson J. (2004) Clinical Governance for CAM in Primary Care: *Report*, April 2004. University of Westminster.

⁴⁰ An action research methodology - a modified 'Delphi' technique, was applied to summarised feedback from the series. Priority issues from the first round of consensus building (which achieved high consensus on many aspects) have shaped these recommendations and provisional guidance. For an overview of the Delphi technique please see **Appendix 4**

⁴¹ Accessible via www.wmin.ac.uk/sih/cgcam

A. Development: Issues and guidance (2)

2.1 Patient Focus⁴²

Placing patients at the centre of healthcare, from planning through to delivery, is key to the modernisation agenda and pivotal to the development of clinical governance. Patient focus constitutes one of the seven domains of the new National Standards⁴³:

“Health care is provided in partnership with patients, their carers and relatives, respecting their diverse needs, preferences and choices, and in partnership with other organisations (especially social care organisations) whose services impact on patient well-being.”

The notion of patient involvement is essentially about how we see ourselves and our health. That is why effective patient participation in relation to CAM represents the constructive convergence of two social movements, both of them passionate about human welfare. With the integration of CAM we are witnessing more than a clinical/professional/practice movement: the popularity and appeal of CAM has been patient-led; patient centredness and participative intent are inseparable facets of the CAM ethos and they have been powerful factors in its explosive growth.

An older social movement, concerned with democratic deficit, is now active in primary care. It is the political motor driving participation in PCTs and directing the NHS agendas on inclusiveness, involvement and self-management. With 95% of interactions around health happening in primary care, a radical shift is possible, based on a growing confidence in the feasibility of a primary care-led NHS.

2.1.1 Shifting trends in how patients see themselves

A tension at the heart of this growing confidence has to do with how we see ourselves: either as having needs - or - as also being a resource in the process of health creation. Therefore, for the social good, development needs to be equal. For the patient and the professional, this means mutuality at the level of consultation, in processes of decision-making and when re-designing services.

The NHS is now developing some common messages about ways of improving health and self-help, which libraries, chemists and surgeries will all disseminate. Material produced by the Developing Patient Partnership⁴⁴, NHS Direct, and the National Electronic Library (NeLH⁴⁵) could all feed strategically into a message about an integrated model of self-management that draws on both CAM and conventional medicine.

2.1.2 The Patient Experience

Patients' experiences as well as clinical outcomes of care are the focal point for both developing services and how they will be evaluated.

“The values of humanity, respect, justice and empowerment and partnership that underpin clinical governance should be reflected in every aspect of the patient experience. It is the quality of this experience that will lie at the heart of the concerns of the new Commission for Health Audit and Inspection.” (Stanton 2004⁴⁶)

The transformation of the NHS towards patient involvement will mean moving from a “doing to” culture to a “learning with” paradigm:

- Seeing people as both citizens and consumers
- GPs working with other practitioners (often they will be their employees) as partners in the process of developing the system
- Recognising that exercising patient choice means patients taking a share of responsibility
- Looking at the quality of the relationship in order to make it more effective
- Understanding the mutuality needed for an effective and sustainable clinical relationship
- Sharing accountability for the outcomes of these transactions

2.1.3 The way forward

People now have the opportunity to opt in as corporate citizens; partners in decision-making and governance. In future they will participate on the boards of PCTs, or by acting as constructive

⁴² This text draws upon the presentation made by Bob Sang, Director, Sand-Jacobsson Ltd and resulting discussions and consensus building work at Seminar 3, Effective Patient, Care and Public Participation. Thursday, March 27, 2003, King's Fund, London. The report is available by direct request cgcam-net@wmin.ac.uk or downloaded from www.ihn.org.uk or www.wmin.ac.uk/sih/cgcam

⁴³ Department of Health (2004) National Standards, Local Action: Health and Social Care Standards and Planning Framework 2005/06–2007/08, Department of Health, July 2004.

⁴⁴ A UK based health education charity that works with PCOs and the public <http://www.dpp.org.uk/>

⁴⁵ www.nelh.nhs.uk

⁴⁶ Stanton P (2004) 'The Strategic Leadership of Clinical Governance in PCTs' (2nd ed.)

NHS Modernisation Agency, Clinical Governance Support Team: National Primary Care Trust Development Programme, March 2004

A. Development: Issues and guidance (2)

sounding boards and as “critical friends”, and by joining in the design, planning and commissioning of services. All these roles will require training and development. The active partnership made possible through self-management and self-care can be both powerful and therapeutic. Including expert patients⁴⁷ and service users in the monitoring and evaluation of NHS CAM services will be an effective and important aspect of their clinical governance.

“The role of self-care, the development of ‘the expert patient’, possibly playing a much greater role in assisting other patients, and the role of community pharmacists will also need to be developed to expand overall capacity in the increasingly important management of chronic conditions and take pressure off traditionally skilled people.” Wanless 2004⁴⁸

2.1.4 A1: Developing patient, carer and user involvement: Issues and provisional guidance:

The following points result directly from the work undertaken during seminar 3 and related action research (Delphi). The points provide an overview of the types of activities and approaches appropriate for increasing public carer and patient involvement relevant to CAM in primary care. It is recommended that no ‘one fixed approach’ is adopted and that there should be flexibility in the range and style of approaches taken at a local level. The feasibility of each point will ultimately rest on the size of service being delivered and the available resources for involvement strategies.

A1: Developing patient, carer and user involvement: Issues and provisional guidance

1. Practice (service or operational) level guidance

1.1 Working within existing NHS frameworks

- 1.1.1 CAM patient involvement policies should work within the existing NHS involvement structures (national and local initiatives e.g. PALS, Patient Fora, NEDs)⁴⁹
- 1.1.2 Involve patients in service (re-) design and improvement e.g. ‘Critical Friends Groups’ at GP surgeries or primary care service based forums
- 1.1.3 Involve patients in all aspects of clinical governance e.g. audit and research, surveys, user groups, feedback processes
- 1.1.4 Develop an educational process that involves patients
- 1.1.5 ‘Citizen’ involvement e.g. ad hoc meetings for specific purpose—similar to the way a jury service operates⁵⁰

1.2 Improving access and quality of information on CAM and the NHS

- 1.2.1 Improve the quality and quantity of information and communication with the public, patients and carers to ensure that there is an understanding of how and where they can become involved
- 1.2.2 Provide quality information on CAM and the NHS
- 1.2.3 Provide information and advice on consultation and negotiation skills so that patients can fully participate in the decision making process
- 1.2.4 Present information in a range of formats and languages where appropriate
- 1.2.5 Provide information on the evidence base for both orthodox and CAM treatment options
- 1.2.6 Use plain language and not ‘jargon’

1.3 Encouraging and promoting public, patient and carer involvement

- 1.3.1 Provide basic expenses to cover the cost of involvement e.g. travel expenses, reimbursement for loss of earnings, child care, free meals
- 1.3.2 Active involvement: ensure that a real ‘partnership’ with the public, patients and carers is achieved, not just ‘tokenism’
- 1.3.3 Recognise the importance of stakeholder diversity e.g. involving a broad range of patients, carers or the public depending on activity
- 1.3.4 Support patient representatives by providing ‘briefs’ and ‘debriefs’ before and after meetings

1.4 Staff development

- 1.4.1 Provide training in inclusive consultation skills for practitioners and managers

The development of ‘CAM health panels’ was also suggested (one example given was Somerset PCT which has groups of 8-10 lay people with a wide range of backgrounds forming Health panels to advise and inform developments within the PCT). Caution was advised in use of the terms and meaning of ‘representation’ and ‘consultation’ with patients which could potentially negate active and inclusive involvement. Involving CAM patients in all NHS policy frameworks was called for.

⁴⁷ See **Seminar report 3** for an introduction to the expert patient programme

⁴⁸ Wanless Report (2004) Securing Good Health for the Whole Population. HM Treasury. HMSO London

⁴⁹ These initiatives will be useful for smaller service providers and lone practitioners as they are likely to have fewer resources for involvement

⁵⁰ See **Seminar report 3** for further details on involvement strategies

A. Development: Issues and guidance (2)

The issue of facilitating patients/citizens involvement by providing advice on information on negotiation skills was highlighted as being essential to maintaining involvement. Providing information and advice on health service structures and processes (e.g. how a PCT works, and how to participate) was prioritised by all but one participant in the expert consensus building process. Developing local 'learning groups' within an established educational process and involving patients and practitioners was also suggested as a means of facilitating patient involvement as well as developing local resources for patients, such as access to the internet, reading materials on CAM and health related topics, and informal educational events.

Current strategies for involving the public, carers and service users at all levels include:

- **National** - patient representative groups, public consultation strategies and patient participation initiatives, Patient and Advisory Liaison Services (PALS);
- **Strategic** - public/patient Non Executive Directors (NEDs), Patient forums;
- **Service level** - critical friends groups, patient feedback.

Forging closer links and working with such groups will be important in marrying shared objectives between the public, patients, practitioners and the CAM wider field⁵¹.

CAM patient experts and voluntary organisations can act as sponsors/champions and help inform conventional practitioners, patients and PCTs about CAM and its potential use within the NHS. This would have implications for developing local 'CAM strategy groups'. Information for patients, health professionals and PCTs on local registered CAM practitioners would be a way of guiding patients toward appropriate independent sector resources and encourage participation in NHS policy frameworks⁵².

2.1.5 Care Plans and Pathways

Another central aspect of improving patient experience is the development of seamless care and services that are suited to the needs of individual patients. The development of care plans and pathways can encourage ownership and empowerment. Provisional guidance on developing individual care plans, delivered in the context of teamwork were developed through seminar groupwork and subsequent action research and is presented below.

A description of the pilot online care pathway that is being developed as a 'tool' to help design integrated pathways is also presented at the end of **section A3**. Relevant training and supervision for these innovations would be required. The feasibility of including CAM in care planning would depend on its contribution to self-care and empowerment, and its potential effectiveness. This approach should be further investigated⁵³.

2.1.6 A2: Issues and provisional guidance for developing a care plan⁵⁴

The elements listed overleaf are an overview of the appropriate types of activities and approaches for developing care plans. Not all the items would have to be included but those agreed as part of a care plan, within the context of the service, could for instance be presented as a checklist and used to track progress⁵⁵.

Most participants in the expert action research phase favoured an 'Agreement' drawn up between practitioners and patient (i.e. within the context of NHS Plan objectives for shared referral letters – rather than just copying referral letters to patients). However, absolute consensus was not reached on this point. Similarly courses of action advised and refused by the patient were thought by most as a necessary inclusion in the agreement.

One participant recommended the need for a more 'open ended' approach to the consultation process with reference to points **A2:1.1-1.4** below. Another recommended that there needs to be recognition of the communication and understanding limitations of the patient – with these addressed both in the presentation of treatment options and in the extent to which the patient is held to have signed up to what is proposed.

⁵¹ Patients and local populations are now empowered to have a 'real' input into the design and development of local services. Any significant change or service redesign made by PCTs require consultation. Further details can be found in the recent Health and Social Care Act (Section 11) <http://www.legislation.hmso.gov.uk/acts/acts2001/20010015.htm>

⁵² Feedback from the April 2004 consultation highlighted the need for increased information on CAM interventions and treatment options for patients and professionals as well as commissioning primary care organisations. The following patient information guide has been produced recently by The Prince of Wales's Foundation for Integrated Health. (2004) Complementary Healthcare: a guide for patients, The Prince of Wales's Foundation for Integrated Health, London.

⁵³ Priorities from the groupwork feedback and Delphi outputs relating to 'Patient ownership and concordance care plans' can be found in the full **Seminar 3** report. The report is available by direct request cqcam-net@wmin.ac.uk or downloaded from www.ihn.org.uk or www.wmin.ac.uk/sih/cqcam

⁵⁴ These points are based on the issues prioritised from the groupwork and for which a high degree of consensus has been gained. Please refer to discussion areas within the IHN for aspects for which little or no consensus has been reached

⁵⁵ The most highly regulated CAM professions already incorporate these processes into practice

A. Development: Issues and guidance (2)

A related issue was the danger of imposing an old 'medical paradigm' to the expansion of health promotion and care. Instead a new paradigm which takes account of the complexities of reality, involving multiple relationships / sources of support / information / advice, could enhance better health understanding, activities and medicine-treatment, for both patients and practitioners. The tensions between the systems of commissioning / contracting, accountability / governance, and involvement / negotiation were also mentioned as a topic for further discussion. Concern was expressed that the 'health' (literal and metaphorical) of relationships is not lost in the need to accommodate NHS governance requirements.

A2: Issues and provisional guidance for developing a care plan

1. Assessment and referral process

- 1.1 Advice and Information for patient relevant to condition and treatment options (range of formats)
- 1.2 Discussion with the patient might include
 - 1.2.1 Suitability of treatment options (including 'watchful waiting', lifestyle changes, CAM interventions, referrals for further investigations, medication etc)
 - 1.2.2 Patient preferences
 - 1.2.3 Patient expectations regarding treatment and outcomes
 - 1.2.4 Expected outcomes
 - 1.2.5 Ensure the patient is able to discuss personal and/or medical circumstances⁵⁶
 - 1.2.6 Ensure there is a clear understanding of what the treatment entails (including benefits and drawbacks e.g. outcomes, side effects)
 - 1.2.7 What level of engagement is feasible (including whether they are able to engage with the treatment)
- 1.3 Tailor the individual care package appropriate to the condition and situation
 - 1.3.1 Take account of the 'whole person'
- 1.4 Record diagnosis (examination details)

2. Building in a monitoring and review process, some examples are

- 2.1 Treatment reassessed and negotiated with the patient⁵⁷
- 2.2 Record any changes in use of medication
- 2.3 Feedback from patients
- 2.4 Review and evaluation of progress (change, timescales, lifestyle changes, referrals to other treatments & investigations)

3. Care plan: discharge procedure

- 3.1 Clear discharge policy and procedures (available to patient)
- 3.2 Advice on aftercare
 - 3.2.1 Support for aftercare including; networks, self-help groups, expert patient programmes, other means for support in the community

4. 'Agreement' between patient and service that explains:

- 4.1 Safety aspects (including how that is guaranteed for patient and therapist)
- 4.2 A clear accountability framework for the service
- 4.3 Patients' rights (including the right to decline treatment)
- 4.4 Confidentiality policy and procedures
- 4.5 Explanation of the process for referral and treatment (including number of sessions, time required)
- 4.6 Level of engagement expected from the patient (e.g. Weekly appointments)
- 4.7 Clear 'milestones' along the way
- 4.8 The agreement should be renegotiated and developed over time

Feedback on the April 2004 consultation document and comments from the consensus building phase made references to increasing co-ordination between local community services. In relation to continuity of care, networks of CAM practitioners working across communities could facilitate the implementation of care pathways between primary, secondary and community care providers.

⁵⁶ Protocols were recommended in consultation on the appropriate scope and depth of patient/practitioner discussions relating to medical/counselling advice

⁵⁷ This could also incorporate self help care plans e.g. incorporating diet and exercise

A. Development: Issues and guidance (2)

2.1.7 Emerging priorities for patient involvement and experience

1. A CAM focused 'self-managing' programme along similar lines to the 'expert patient' programme⁵⁸
 - Training provided by GPs, PAMs, NHS Managers, expert patient trainers and expert patients
2. A 'CAM strategy' group for increasing public, patient and carer understanding and involvement
 - Provide information to patients, CAM practitioners and NHS staff on:
 - Local access to CAM services
 - The CAM evidence base (including cost effectiveness)
 - Clinical governance of CAM
 - Address issues of equity of access to service provision e.g. all patients have equal access to NHS CAM services regardless of who they are or where they live
 - Co-ordinate feedback from patients on CAM (feedback would need to be anonymised and be congruent with research governance and Caldicott guidelines)
 - CAM 'strategy group' roles and activities:
 - Help move the focus away from disease to a more holistic health maintenance approach
 - Be able to understand and relate within the language and framework of NHS CG and management
 - Establish links with patient involvement initiatives and other existing social networks, community, NGOs and voluntary initiatives
 - Help patients 'get their voices heard'
 - Have local influence e.g. with the PEC, NEDs, patient forums, PALs
 - Attend PCT meetings
 - Help the process of increasing CAM acceptability within the NHS⁵⁹
 - Help promote the benefits of CAM primary care provision
 - Encourage interest, enthusiasm and 'buy in' for CAM NHS services
3. Education programmes in schools on involvement initiatives
4. Developments in primary care for integrating CAM services
 - Improve access to information on CAM for the public, patients and carers e.g. information on regulation available via the *NHS Direct*
 - Discuss establishing a special interest group for CAM within DH Involvement Initiatives⁶⁰
 - Provide training for practitioners and managers in inclusive consultation skills
 - PCTs inform patients about local NHS CAM resources and provide information about the role of CAM and how to access regulated practitioners⁶¹
 - Community pharmacists supported in developing their role as an information resource on CAM
 - Expert patients and service users should be involved in the broad range of clinical governance activities, especially in establishing, monitoring and evaluating new CAM services at the PCT level.

Developing CAM champions and sponsors to take on specific objectives and addressing local issues was also suggested within the groupwork but not developed as part of the CG work as it is beyond the scope of the project. Information relating to champions and sponsors can be found on www.ihn.org.uk and from December 2004 www.wmin.ac.uk/sih/cgcam.

A working outline of the type of appropriate service (operational) level activities relating to involvement strategies is also accessible via the web. These are based on the issues raised throughout the seminar series and subsequent action research. Further work will be required to incorporate elements of the recently announced standards and to identify activities appropriate to practitioners and service providers.

⁵⁸ This issue was suggested later in the series and is picked up in the economic evaluation section of this report (Section A 2.3). However this point did not receive full consensus through the Delphi process. The notion of 'expert patient' was raised as an issue for patients who may relate better to the concept of knowledge and experience enabling effective 'self management' of conditions. This concept would need to be explored at a local level if such groups were established.

⁵⁹ Concern about the myths perpetuated within the NHS about CAM was expressed in consultation feedback. This issue will need to be addressed to facilitate wider integration of CAM

⁶⁰ e.g. the current Commission for Patient and Public Involvement in Health www.cppih.org

⁶¹ One suggestion from the consultation process would be to utilise existing routes of information dissemination present in the PCT to ensure area wide coverage. Incorporating all involvement strategies within NHS frameworks is an approach likely to facilitate further CAM integration

A. Development: Issues and guidance (2)

2.2 Clinical Effectiveness, Clinical Audit and Research Governance

Quality improvement is central to clinical governance and for this it will be essential to measure what is delivered. While clinical effectiveness on the one hand links with the aims of evidence based practice (EBP) - providing interventions that are known to be effective - on the other, it must link typical practice with anticipated outcomes through well-chosen measures of clinical effectiveness. Clinical effectiveness has been defined as:

"The extent to which specific clinical interventions, when deployed in the field for a particular patient or population, do what they are intended to do - i.e. maintain and improve health and secure the greatest possible health gain from the available resources". NHSE, 1996⁶²

Clinical effectiveness also forms one of the domains of the new standards alongside cost effectiveness (see **Section A point 2.3**). Clinical effectiveness is broader than EBP. It is about doing the right thing, to the right person, at the right time and is concerned with demonstrating improvements in quality and performance; effectiveness and cost effectiveness. As with all aspects of CG clinical effectiveness is about improving patients' *'total experience'* of their healthcare⁶³.

The steps for improving effectiveness involve:

- **Producing and accessing evidence** (evidence from research, patterns of care, population needs, availability of resources etc)
- **Reviewing and changing practice** (clinical audit, guidelines and care pathways, benchmarking, research and continued education and training);
- **Monitoring and evaluation** (developing PIs, demonstrating improvements in quality effectiveness and cost effectiveness via measuring health benefits and health improvement, patient and carer experience, clinical outcomes, and wider issues of appropriateness, accessibility and efficiency).

A number of priorities for developing clinical effectiveness were addressed throughout the seminar series; widening the evidence base for CAM to inform practice and service development, the development of PIs, and use of relevant outcome measures. Demonstrating cost effectiveness is increasingly important as a factor for ensuring that services provide value for money as well as producing maximum health gain.

In a perfect world all practice would be based on evidence. As this is not yet the case for many primary care interventions, it is important to look at what is appropriate evidence and from where it can be derived. It is not about taking on the wider research agenda for CAM. It is about harnessing the existing evidence and developing new evidence to make the business case for CAM, to set guidelines, to develop appropriate PIs and facilitate clinical audit.

2.2.1 Broadening out the evidence base⁶⁴

Certain widely cited sources of evidence, such as Cochrane, York University and Bandolier, which pull together the available evidence, focus exclusively on randomised controlled trials (RCTs) and frequently conclude that there is "no good evidence" relating to CAM. Meta-analysis has been criticised and the problems of pooling RCT evidence are well known⁶⁵.

There is a good case for broadening the evidence base. Research from the July 2002 issue of the *Journal of Health Service Research Policy*⁶⁶, looked at the RCT evidence base for 124 clinical decisions taken in PCTs. The results showed that in: 1.6% the RCT evidence did not support the decision, 34% there was RCT evidence to support the decision, 51.6% there was no relevant RCT evidence and in 12.9% the RCT evidence was equivocal. Forty-one other studies suggested that 5 in every 10 decisions are not based on clinical evidence.

Moreover, the original intention of Evidence Based Medicine (EBM) was to integrate the best research evidence with clinical experience and patient values. The true intention of EBM will be lost if decision-makers focus exclusively on RCTs as the only definitive source of evidence. There is a good opportunity to correct this approach by using a broader evidence base for integrating CAM. The pooled RCT evidence is patchy, making it hard to draw definitive conclusions. Yet decisions are usually made about the relevance of CAM on this basis. A different paradigm is therefore required. Tudor Hart (1997):⁶⁷

⁶² NHS Executive (1996) Promoting Clinical Effectiveness: a framework for action in and through the NHS. Leeds, Department of Health.

⁶³ "Effectiveness matters" York Centre for Review and Dissemination <http://www.york.ac.uk/inst/crd/pdf/em51.pdf>

⁶⁴ The following sections draw directly from the presentations made by Kate Thomas, Deputy Director, MCRU, University of Sheffield and Dr Michael Dixon, Chair, NHS Alliance at **Seminar 1**, Building consensus on the evaluation of CAM in primary care

⁶⁵ Feinstein AR. (1995) Meta-analysis: Statistical alchemy for the 21st century. *Journal of Clinical Epidemiology* 1995; 48(1): 71-79.

⁶⁶ Johnstone P, Lacey P. (2002) Are decisions by purchasers in an English health district evidence-based? *Journal of Health Services Research and Policy* 2002 Vol: 7 No: 3 p166 – 169

⁶⁷ Tudor Hart J (1997) What evidence do we need for EBM Cochrane lecture 1997 *Journal of Epidemiology and Community Health* 1997 51. p623-629

A. Development: Issues and guidance (2)

"We need to work within a different paradigm based on development of patients as co-producers rather than consumers, promoting continuing output of health gain through shared decisions using all relevant evidence, within a broader, socialised definition of science."

By requiring the highest level of proof of effectiveness for every therapy in relation to every patient condition, we may be denying patients the benefit of many potentially valuable and cost-effective treatments. Sir John Pattison (Head of NHS R&D) has pushed CAM further up the research agenda, by stating that the NHS would welcome proposals for CAM within the context of the government's challenging NSF priorities. Research conducted by the University of Sheffield's Medical Care Research Unit in 2001 on GP practices in England showed that 5 to 10% of practices provided CAM as part of their delivery on an NSF⁶⁸. When asked about the potential of CAM for use among elderly patients, or those with cancer or mental health problems, half the GPs surveyed said they would consider it. See also **section B** for results of the London-wide sample, which found that all but one service targeted NSFs⁶⁹.

2.2.2 Developing a resource for wide-ranging evidence on CAM treatment options Broad Evidence Synthesis Topic (BEST) CAM reports^{70 71}

The development of Broad Evidence Synthesis Topics (BEST) reports was proposed and accepted by stakeholders as an appropriate means to evolve EBP for CAM in a pragmatic way. It will be important to develop BEST for CAM, above and beyond the RCT. A BEST "starter pack" of all the different sources could provide a rationale for CAM and link to some relevant PIs.

2.2.3 A3: Provisional guidance for developing Broad Evidence Synthesis Topic Reports⁷²

Two different types of tools for developing BESTCAM topic reports have emerged from the consultation process. The first is one that would help individuals and organisations produce local reports through access to relevant on-line resources for searching the Evidence Base which could usefully be made available to all NHS staff. Themed support groups at a local level could build on centrally generated 'core findings' to produce locally relevant 'BESTCAM in practice' information in a co-ordinated series prioritising CAM interventions for specific conditions/patient groups. If a practical framework were adopted to assess relatively easily accessible information (i.e. web based research), this would help reduce duplication of effort and produce reports in a relatively short period of time. This would require academic support and ideally involve training and/or guidelines on developing such reports.

The second type of tool is one that would require more significant resources for researchers to produce more in-depth reports⁷³. The guidance below relate to the first tool which has now been piloted with regards to the treatment of Low Back Pain as an online toolkit⁷⁴. See **section A3 point 3.2**.

Other suggested resources which had high consensus but not total agreement in the expert action research phase were the development of an online network with details of research forums to limit duplication and protocols aimed at practitioners to help with statistical evaluation. Use of existing resources that could be used to develop both types of report was also proposed through the consultation phase⁷⁵.

Training on critical appraisal/systematic reviews of the evidence was also mentioned as essential for those producing reports. Some disagreement remained however on how much of a priority central co-ordination for assessing the quality of evidence used in reports was essential for credibility. One concern expressed through the consensus building phase was the potential downgrading of the importance of more general CAM services, which may have 'suffered from a lack of 'identity' in conventional (i.e. condition specific) terms. This was in direct reference to the priorities selected for BESTCAM reports (points 3.1-3.6 overleaf) which are predominantly disease/condition specific. Practical guidance on drafting PEC board papers and other relevant documents was also suggested through the consultation phase.

⁶⁸ Thomas K. (2001) Access to complementary medicine via general practice. British Journal of General Practice 2001; 51; 25-30

⁶⁹ Further points raised in relation to research and published articles on CAM interventions are detailed in the report on **Seminar 1**

⁷⁰ Proposed in **Seminar 1** by Kate Thomas, Deputy Director, MCRU, University of Sheffield. The report is available by direct request cgcarnet@wmin.ac.uk or downloaded from www.ihn.org.uk or www.wmin.ac.uk/sih/cgcarnet

⁷¹ Priorities from the groupwork feedback and Delphi outputs relating to 'Broad Evidence Synthesis Topic reports' can be found in the full report on **Seminar 5**.

⁷² These points are based on the issues prioritised from the group work and for which a high degree of consensus has been gained. Please refer to discussion areas within the IHN for aspects for which little or no consensus has been reached

⁷³ The School of Integrated Health, University of Westminster in collaboration with the RCCM is also developing evidence based reports along similar lines with regards to NSFs

⁷⁴ Accessible via www.ihn.org.uk or www.wmin.ac.uk/sih/cgcarnet

⁷⁵ e.g. guidance from the Agree collaboration <http://www.agreecollaboration.org/>

A. Development: Issues and guidance (2)

A3: Provisional guidance for developing Broad Evidence Synthesis Topic Reports

1. Structure and format for BESTCAM reports

- 1.1 Rigorous (clear methodology for evaluating the evidence)
- 1.2 The basis for evidence collection kept simple, accessible and practical for users
- 1.3 Summary and conclusions easily available to patients, practitioners and physician
- 1.4 The context/ rationale should be stated from the outset (see point 4 'Drivers for CAM' ⁷⁶)

2. Contents

- 2.1 Introduction
- 2.2 Reference section
- 2.3 Summary of findings
- 2.4 Conclusion section
- 2.5 Evidence tables ⁷⁷

3. Priorities for reports

- 3.1 Conditions/conventional treatments with high cost implications in terms of NHS healthcare and other (e.g. social care) resources and absenteeism
- 3.2 Conditions that relate to the drivers for CAM (e.g. Local and National priorities – e.g. NSF's, waiting lists)
- 3.3 Conditions with high prevalence rates
- 3.4 Conditions/orthodox treatments that cost the NHS in terms of finances and resources
- 3.5 Conditions that in part relate to the drivers for CAM, as well as an existing evidence base for the effectiveness of specific interventions
- 3.6 Single conditions linked to National Service Frameworks (NSFs)

4. Drivers for greater access to CAM considered as priorities

- 4.1 Local priorities (Local waiting list priorities, prevalence of conditions etc)
- 4.2 National priorities ⁷⁸ (Health promotion targets/NSFs e.g. smoking cessation)
- 4.3 Perceived effectiveness gaps within orthodox medicine
- 4.4 Cost effectiveness
- 4.5 Patient choice/access
- 4.6 Patient safety
- 4.7 Unmet or poorly met patient needs

5. Priority issues to address in the reports

- 5.1 Potential for cost effective CAM interventions
- 5.2 Equity of care
- 5.3 Care pathways (possibly too specific to be applicable across all PCTs)
- 5.4 The drivers for CAM
- 5.5 Service redesign/shift of resources
- 5.6 Training and education for practitioners (including CPD)

6. The type evidence collated should include

- 6.1 Impact on prescribing rate
- 6.2 Impact on secondary care referrals
- 6.3 Impact on GP consultation rates, workload and accessibility
- 6.4 Cost effectiveness, cost benefits and cost neutrality
- 6.5 Safety (Adverse events/incidents)
- 6.6 Health outcomes (including efficacy)
- 6.7 Wider Health outcomes such as quality of life, wellbeing etc
- 6.8 Patient experience
- 6.9 Patient satisfaction
- 6.10 Acceptability to patients and GPs
- 6.11 Risk benefits (i.e. low risks associated with CAM)

⁷⁶ Drivers for CAM are considered to be local and national priorities, such as NSF's, waiting lists for conditions with a high local prevalence rate, Demand management, perceived effectiveness gap within conventional medicine, cost effectiveness, patient choice/access, patient safety, unmet or poorly met patient needs, service redesign or shift of resources etc

⁷⁷ Including evidence on safety

⁷⁸ Obviously these will change according to recent policy e.g. Standards for Better Health

A. Development: Issues and guidance (2)

A3: Provisional guidance for developing Broad Evidence Synthesis Topic Reports (contd.)

7. The range of research methodologies from which evidence might be derived⁷⁹

- 7.1 Randomised Controlled Trials⁸⁰
- 7.2 Pragmatic Trials
- 7.3 Indicative pilot studies and service reviews
- 7.4 Qualitative studies
- 7.5 Risk-benefit analysis
- 7.6 Cost-effectiveness studies

8. Sources of evidence for the reports

- 8.1 Practice based qualitative and quantitative studies
- 8.2 Cochrane Collaboration systematic reviews
- 8.3 National Electronic Library for Health (NeLH)
- 8.4 On-line resources
- 8.5 Patient groups
- 8.6 Published Journals (including electronic versions) e.g. BMJ
- 8.7 National research networks

9. Resources required to collect evidence for the reports in the short-medium term

- 9.1 Finances
- 9.2 Funded researchers
- 9.3 A steering group
- 9.4 Access to a wide range of evidence
- 9.5 Training in use of research tools
- 9.6 Access to journals (including online access)
- 9.7 Supervisory support for producing reports
- 9.8 A centralised database of evidence with free public online access for patients, practitioners and clinicians⁸¹
- 9.9 Access to research/audit tools for practitioners (e.g. MYMOP)
- 9.10 A network of 'consultants' (to provide advice on preparing BESTCAMs)

10. Future input and actions required

- 10.1 Practitioner organisations representing all the different CAM disciplines should encourage members to audit their results within a shared format
- 10.2 Multidisciplinary communication and feedback

Issues surrounding accessibility and quality of information by practitioners/researchers were identified as a potential problems (i.e. relating to the fact that not all areas have well developed IT). The value of the type of evidence included was rated differently throughout the consultation process with differing opinions on the prominence of RCT type data as compared with e.g. pragmatic trials or the relevance of a hierarchy of evidence – based on the argument that research is either rigorous and valid or not.

Two issues of bias were raised in relation to published research evidence. The first was that some of the sources of evidence show bias towards conventional medicine and secondly there are examples of publication bias where negative (findings) trials are not published.

2.2.4 Priorities for developing BESTCAM reports

Although some issues were raised during the consultation phase about the value of pursuing an evidence base for the purpose of commissioning CAM services (i.e. a key driver), PCTs are required to ensure that all the services they commission are appropriately research based⁸². It is thus crucial that the CAM field develops a coherent approach to evolving a research base for specific interventions and patient/condition groups. In the short to medium term the BESTCAM⁸³ reporting system could be taken up by a consortium of universities (as a broad range of academic expertise, including economic evaluation, will be needed) to produce documents which assess and report upon a range of outcomes. This will however require a substantial resource input.

⁷⁹ Including a range of outcome measures as discussed in Seminar 1

⁸⁰ Evidence for 'effectiveness' can only be derived from RCTs

⁸¹ Recommended through the consultation process that this should be the NeLH

⁸² Stanton P (2004) 'The Strategic Leadership of Clinical Governance in PCTs' (2nd ed.)

NHS Modernisation Agency, Clinical Governance Support Team: National Primary Care Trust Development Programme, March 2004

⁸³ Accessible via www.jhn.org.uk and www.wmin.ac.uk/sih/cgcam

A. Development: Issues and guidance (2)

2.2.5 Emerging priorities

Developments in primary care for integrating CAM services

PCTs need to know which CAM treatments are likely to be effective in addressing their local population's health needs. Furthermore, PCTs will need to be assured that the services they commission are of good quality and delivered in a safe and accountable way.

- Increased and better quality primary care CAM service based research and evaluation
- Increased funding directed towards research into CAM effectiveness
- Courses for implementing research tools developed at a local and national level

Measures of clinical effectiveness should aim to link typical practice with the anticipated outcomes. There is now a growing research capacity within the CAM field and access to mainstream funding is opening up^{84 85}. As CAM treatment options become more popular and NHS access increases, and as CAM becomes more credible within the research community, more funding should be directed towards this field⁸⁶.

Developments in the CAM field

- Address key concerns of commissioning PCTs e.g. evidence of efficacy and effectiveness – including value for money
- Education and training for practitioners in the theory and practice of clinical effectiveness
- Increased reporting and publishing in peer reviewed journals
- BESTCAM reporting system taken up by a consortium of universities
- Themed support groups for production of local development of practical 'BESTCAM in practice'

It is crucial that a pragmatic and unified approach within the field is taken to address some of the key concerns of commissioning PCTs i.e. evidence of efficacy and effectiveness – including value for money. There was a general recognition throughout the series that there is a lack of good evidence published in peer reviewed journals on all types of research – especially relating to primary care provision of CAM, and therefore more service based research will need to be undertaken which employs standardised formats for data collection and analysis⁸⁷. This would help generate consistent data sets that in some cases would allow for comparative analysis with conventional care for the treatment of similar conditions⁸⁸.

2.2.6 Clinical Audit

Clinical audit tends to be used as an all encompassing term for any audit conducted by healthcare professionals:

*"Clinical audits monitor the use of particular interventions, or the care received by patients, against agreed standards. Any departures from 'best practices' can then be examined in order to understand and act upon the causes."*⁸⁹

Audit enables practitioners to; set standards of service, facilitate the development of guidelines, measure actual practice against current practice, make improvements where necessary, identify needs, collect baseline data, monitor key aspects of service on an ongoing basis, incorporate patient and carer views, evaluate their service, and collect data about processes and assess outcomes.⁹⁰ Guidance on best practice in clinical audit has been published by NICE and is available via the NeLH⁹¹. The aims of clinical audit as defined by NICE⁹² are to produce an improvement in the quality of service leading to: improved care of patients, enhanced professionalism of staff, efficient use of resources, aid to continuing education, aid to administration, and accountability to those outside the profession.

2.2.7 Monitoring and evaluating effectiveness: The audit cycle⁹³

The process of clinical audit is the 'audit cycle' and through it, an evidence for CAM can be built. Evidence based CAM in the NHS is a circular process. A case can be made for a service using existing evidence and best practice standards. Once implemented, it is assessed, and adjusted

⁸⁴ With specific reference to the recent awards by the DH to develop University research capacity for CAM

⁸⁵ The Medical Research Council (MRC) is developing a research agenda in CAM. High quality applications are welcomed by the MRC

⁸⁶ Harrison, A and New B. (2002) Public Interests, Private Decisions: Health-related research in the UK, King's Fund, London.

⁸⁷ The issue that PCTs would rather have evidence that CAM services can help them meet targets rather than clinical evidence was raised during the consultation phase with reference to BESTCAM reports

⁸⁸ See references to Research Governance Section A point 2.2.11 and Intelligent Information point 2.4

⁸⁹ <http://www.mharris.eurobell.co.uk/resource/audit/intro.htm>

⁹⁰ <http://www.slam.nhs.uk/about/cg/ca.asp>

⁹¹ National Institute for Clinical Excellence: Principles for best practice in clinical audit. Oxford: Radcliffe Medical Press, 2002.

⁹² www.nice.org.uk/pdf/BestPracticeClinicalAudit.pdf or www.nelh.nhs.uk/BestPracticeClinicalAudit.pdf

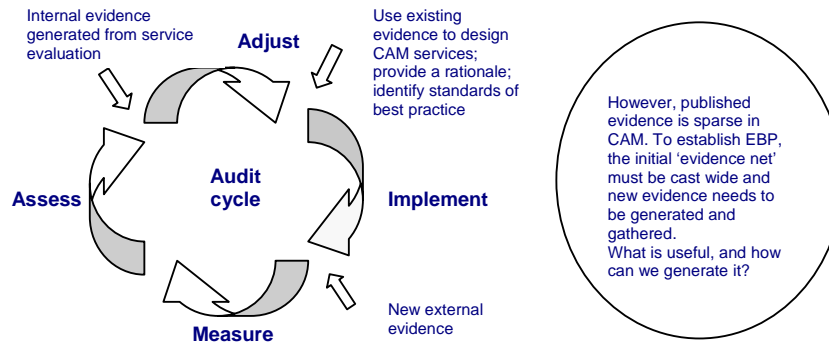
⁹³ <http://www.nice.org.uk/article.asp?a=953>

⁹³ The following sections draw directly from the presentations made by Kate Thomas, Deputy Director, MCRU, University of Sheffield at Seminar 1. The report is available by request cqcam-net@wmin.ac.uk or can be downloaded from www.wmin.ac.uk/sih/cqcam

A. Development: Issues and guidance (2)

according to performance and internal and external feedback to evaluate the service. This means, in effect, that nothing is fixed. Flexibility and continual assessment are givens.

In order to audit health care it is necessary to first have a standard or guidelines for intended care to audit against. Clinical guidelines are statements designed to help practitioner in decisions on the appropriate management of specific conditions and to improve the effectiveness and efficiency of clinical care through the identification of both good clinical practice and desired clinical outcomes. CAM in common with many areas of primary care practice has a lack of reliable research data and thus generating guidelines on 'best current practice' (as is occurring within the conventional field) will be essential for the CAM field.



2.2.8 Developing Performance Indicators (PIs)

PIs use information to identify standards for the delivery of services. They are accepted indices of good practice and allow services to be benchmarked and to measure performance. PIs are a way of monitoring and improving performance as well as enabling PCTs to account for the quality of care. It will be important to get PIs right for CAM, because services will not be funded without them. Therefore, PIs need to be realistic and have a clear rationale. Take for example, a PI that a certain service delivered to x number of patients should reduce secondary referrals by y. Identified PIs need to be backed up by BESTCAM reports and the existing broad evidence base. A range of stakeholders would need to be involved in developing appropriate PIs for CAM and consensus on how services can be appraised.

PIs need to feed into care plans, PCT strategies, NSFs, care pathways and Standards that will be evaluated by the Healthcare Commission. Practitioners need to think about what they can provide and patients about what they need and want. Everyone, including the clinical governance team in the PCT, non-executive directors (NEDs) and the Professional Executive Committee (PEC), needs to be able to sign up to them. As the Healthcare Commission moves the agenda in that direction, there will be many opportunities to decide on new PIs. The possibility of including markers of more integrated care in the new national indicators is a realistic objective.

2.2.9 A4: Provisional guidance for developing Performance Indicators (PIs)

The consensus building and consultation process established that guidance for developing PIs was most appropriate for well established, multi-disciplinary service providers working in collaboration with relevant academic units. However, the early involvement of emergent services and individual practitioners was also advocated.

1. Recommended areas for PI development

1.1 Safety

- 1.1.1 Adverse Events
- 1.1.2 Risk Assessment
- 1.1.3 Health and safety procedures

1.2 Effectiveness

- 1.2.1 Health outcomes for specific conditions
- 1.2.2 Health outcomes for non-specific conditions
- 1.2.3 Functional Improvement
- 1.2.4 Wellbeing
- 1.2.5 Patient enablement in chronic disease
- 1.2.6 Patient feedback and satisfaction
- 1.2.7 Patients ability to cope
- 1.2.8 Impact on patient's family life
- 1.2.9 Patient expectation versus outcome
- 1.2.10 Symptomatic relief
- 1.2.11 Patients' personal productivity

A. Development: Issues and guidance (2)

A4: Provisional guidance for developing Performance Indicators (continued)

1.3 Delivery⁹⁴

- 1.3.1 Closing the gap between patient need and access
- 1.3.2 Access (focus on equity and equality)
- 1.3.3 Acceptability
- 1.3.4 Patient choice
- 1.3.5 Patient feedback and satisfaction
- 1.3.6 Demand management and capacity issues (from the PCTs perspective)
- 1.3.7 Referral rates to primary and secondary care services (including impact on GP referral rates)
- 1.3.8 How well patient care was liaised, co-ordinated and communicated
- 1.3.9 GP satisfaction
- 1.3.10 Availability
- 1.3.11 Appropriateness
- 1.3.12 Impact on conventional services – pressure/demand
- 1.3.13 Waiting times

1.4 Value for money

- 1.4.1 Reduction of primary and secondary care referrals
- 1.4.2 Population health gain or individual QALYs gained
- 1.4.3 Prescribing costs
- 1.4.4 'Knock on costs' such as number of days patients take off work due to illness

1.5 Target particular NHS problem areas within orthodox care e.g. long waiting times, effectiveness gaps, expensive surgery

2. Factors that need to be taken account of in developing PIs

2.1 PIs should be relevant and useful to patients

- 2.1.1 Impact on GP consultation rates
- 2.1.2 Time lost from work
- 2.1.3 Cost of treatments
- 2.1.4 Complaints

2.2 PIs should take account of local patient demographics

2.3 PIs should take account of local prevalence rates for specific conditions

2.4 PIs should relate to national targets/initiatives (e.g. NSFs)

2.5 PIs should also be developed around the 'process' and not just outcomes

3. Individuals/organisations that need to be involved in deciding PIs:

3.1 Complementary Practitioners (CPs)⁹⁵

3.2 PCT /StHA representatives

3.3 Patients

3.4 Expert patients and patient representatives/advocacy groups

3.5 GPs

3.6 Community nurses

3.7 Educationalists (in the fields of CAM and research/evaluation)

3.8 Public health representatives

3.9 Regulatory bodies

4. Individuals/organisations to sign up to the PIs

4.1 Clinical governance teams (PCTs)

4.2 Complementary Practitioners

4.3 General Practitioners

4.4 Members of the PCT Professional Executive Committee (PEC)

4.5 Regulatory bodies

5. Implementation and development

5.1 Conduct a pilot project to develop a range of PIs

5.2 Circulate suggested PIs to all relevant stakeholders to ensure buy-in

5.3 Regular reviews of progress and relevance of PIs

5.4 Develop a standardised questionnaire to help establish benchmarks

5.5 Establish local PI working groups (*online*)

5.6 Local PI groups should work with interested PCTs

5.7 Local PI groups should develop partnerships with other PI groups nationally

5.8 Audit used to measure if PIs are being achieved and sustained

⁹⁴ Inclusion of attendance and did not arrive (DNA) rates was suggested through consultation as this can be an important issue in primary care

⁹⁵ Issue raised in consultation: Only CPs with statutory regulation and appropriate training should be involved in PI development

A. Development: Issues and guidance (2)

Feedback from the consensus building phase highlighted the need for a broader range of qualitative outcomes to evaluate effect and efficacy as the 'best' are unclear and thus an evaluation of these measures would be beneficial to the field. Similarly a need was identified for appropriate methods for measuring 'hard to demonstrate' outcomes such as population health gain or softer impact measures that are assessed by the Healthcare Commission e.g. how well patient care is coordinated, liaised and communicated or, patient choice. The need for the CAM field to engage with the Healthcare Commission in exploring what 'meaningful performance' means was flagged and how CAM services will be evaluated within their inspections.

The difficulty in demonstrating cost effectiveness in the context of service audit was highlighted and the increasing importance of demonstrating cost benefits was identified as a strong driver in the light of recent PCT budget constraints. Pragmatic CAM research initiatives are however beginning to emerge in primary care.

Although all the PIs identified were considered important, participants in the action research phase prioritised outcomes which relate to the aims (defined goals) of the service being delivered and the explicit objectives that the CAM service has agreed with the PCT to meet. Examples are; NSF targets, closing the gap between patient need and access, prescribing costs and referrals to other primary and secondary care services. Effective 'self-care' or 'self-management' as an outcome could also be considered. The development of a nation-wide 'core' set of PIs as well as advice for evolving locally relevant/service specific PIs was suggested through the consensus building phase. As mentioned in relation to outcome measures, patient-specific PIs (i.e. in addressing patients' priorities) could be developed to meet the patient focus agenda. PIs relating to delivery are likely to change as policies and structures within the NHS shift e.g. incorporating elements of the new standards would be appropriate.

Generic PIs could focus on wellbeing, patient satisfaction, patient expectation versus outcome and GP satisfaction. PIs would also need to take into consideration DH guidance as well as local issues identified by PCTs and StHAs and these organisations should be involved in PI development. Above all, it was advised that 'clear goals with simple measures, applied to all patients' are more likely to lead to 'good' information. A discussion to establish 'criteria for evaluating the quality of a service' (particularly in relation to 'acceptability' and 'appropriateness'), was proposed in the consultation process⁹⁶. An online facility was suggested as being most effective for developing local support groups. Most participants in the consensus building process also agreed that for larger services new posts could be created to help develop PIs as well as develop integrated services⁹⁷.

2.2.10 Building service based research into the audit cycle: using specific and generic outcome measures to evaluate CAM

Audit means measuring performance against prior standards; research means providing evidence for creating new standards (filling in the gaps). The advantage of doing both of them is that they provide added value. With the results fed back into a main data source, such as BESTCAM reports, the evidence base can grow. Bearing in mind that research is very time consuming it will be important to ask research questions to which PCTs want the answers. It is easy to make the mistake of asking a confusing mixture of questions at once. Less is often more in research, because asking a simple question and really answering it will be much more effective than skimming the surface of several.

Outcome measures are methodologies used in research that allow us to detect if there has been a change or shift in condition and/or state of wellbeing, and how much benefit the intervention has been. Standardised specific disease outcomes are measures that relate particularly to conditions e.g. asthma. Standardised refers to the fact that they have been used before and are reliable. Both specific and generic outcomes will be necessary.

If CAM can use the same outcome measures as those in conventional medicine, it will be easier to communicate the results. *SF-36*, *SF-12*, and *EQ-5D* are used to look at broad areas of health, such as physical and mental functioning, and vitality—measures that transfer among diseases. There are also ways of measuring patient-specific outcomes relating to their particular needs. *MYMOP* (Measure Your Medical Outcome Profile⁹⁸) is one of the most well known. The *Picker* approach looks at the various things people want and asks whether they got them. *The Patient Enablement Instrument*, known as the *PEI*, focuses on whether patients manage their health with more confidence as a result of the treatment they have received. A whole range of outcome measures address cost/resource use such as; the reduction in prescribed medication or referrals, or the cost of a particular intervention.

⁹⁶ See 1.3 re Quality and Outcomes framework and recommendation 4

⁹⁷ E.g. complementary care coordinators who work within multidisciplinary palliative care teams – see palliative care guidelines www.fihealth.org.uk

⁹⁸ <http://www.hsnc.ac.uk/mymop/main.htm>

A. Development: Issues and guidance (2)

2.2.11 Research governance

The role of research in CG is; providing existing evidence to set up services, setting guidelines and PIs for ongoing monitoring, and auditing services. There is an overlap between monitoring and undertaking research primarily for CG and activities that are undertaken for the purposes of research. The seminars concentrated on the role of research and evaluation within CG. The 'Research Governance Framework' applies to all those participating in research including those who host, fund and manage research within their organisation⁹⁹. The framework sets out the standards and mechanisms for conducting good quality research which safeguards the public in specific ways. Any service conducting research upon their service and involving their patients will need to adhere to these standards.

PCT commissioned CAM services which are considering research will need to develop plans within the context of other research priorities that are being addressed by the PCT and permission sought to conduct any research activity¹⁰⁰.

2.2.12 Emerging priorities

Research and evaluation (including economic evaluation) will require substantial and sustained resources, especially with regard to funded projects and researchers. Pilot services with in-built (and costed-in) research and evaluation may provide greater leverage for PCT uptake¹⁰¹. Services piloted within teaching PCTs may also have greater access to research expertise and input. All research will need to be conducted in line with the new research governance guidelines (April 2004¹⁰²). In light of the revised guidelines¹⁰³ and implementation plan, services will need to forge links with local Universities and independent research units and inform PCTs of any research activity.

Developments in primary care for integrating CAM services

Facilitate CAM practitioners in learning and developing audit skills

Developments in the CAM field¹⁰⁴

Developing practical, specific and generic ways of auditing and evaluating CAM services and opportunities for piloting them should be a priority¹⁰⁵. This could be co-ordinated between regulatory bodies and key CAM academic units. It is impossible to set PIs without first defining best practice. Whether clinical governance can contribute to the evidence base when gaps are uncovered will depend on whether audit or research is conducted. A toolkit for generating PIs could also be usefully developed and piloted in well developed services. Establishing standards of care and PIs within a quality assurance/outcomes framework and developing guidelines in line with other professions will be crucial to moving CAM forward. Utilising the existing evidence base and developing evidence in practice would be part of this. A '*rapid guidelines development scheme*' which could mirror the approach taken by NICE when creating guidelines for treatments on which there is a limited RCT type evidence base, would advance audit processes for CAM.

2.3 Cost effectiveness

2.3.1 Economic evaluation and CAM¹⁰⁶

As a utilitarian system, (i.e. aiming to do the most good for the greatest number of people), the NHS has to consider cost effectiveness very carefully. Although the economics of healthcare are never simple, the widespread integration of CAM will have to be demonstrably cost-effective.

*"Interventions with good evidence of clinical and cost effectiveness will be actively promoted so that patients have faster access to treatments known to work."*¹⁰⁷

⁹⁹ Department of Health (2001) Research Governance Framework for Health and Social care. Department of Health March 2001 [www.doh.gov.uk http://www.ucl.ac.uk/primcare-popsci/nocten/res_gov/research_governance.pdf](http://www.doh.gov.uk/http://www.ucl.ac.uk/primcare-popsci/nocten/res_gov/research_governance.pdf)

¹⁰⁰ Stanton P (2004) 'The Strategic Leadership of Clinical Governance in PCTs' (2nd ed.)

NHS Modernisation Agency, Clinical Governance Support Team: National Primary Care Trust Development Programme, March 2004

¹⁰¹ Training to develop staff competencies in engaging with research and reporting skills to enable CAM practitioners to publish their work could also be costed in

¹⁰² Related to this is the need for increased awareness of ethics in both research and practice, relevant to primary care. Implementation of Caldicott Guardianship is central to research and clinical governance and thus compliance to guidance on ethics will be required of all CAM practitioners and service providers

¹⁰³ Department of Health (2003) Research Governance Framework for Health and Social care. Second ed. Department of Health March 2003

¹⁰⁴ This will involve collaboration between service providers, CPs, researchers, patients and experts within the orthodox field

¹⁰⁵ An example of this has already been produced by the Institute for Musculoskeletal Research and Clinical Implementation (IMRCI): The Audit Tool for the RCGP Acute Back Pain Guidelines can be accessed via http://www.imrci.ac.uk/Back_Pain_Audit_Toolkit/BackPain/backpain.html

¹⁰⁶ The following sections are summarised directly from the presentation given by Dr Michael Dixon, Chair, NHS Alliance. **Seminar 5:** The costs and benefits of CAM in primary care, Thursday June 19, 2003 - King's Fund, London

¹⁰⁷ Department of Health (1998) A First Class Service: quality in the NHS. Department of Health, London

A. Development: Issues and guidance (2)

At the moment there is very little information about the economic effectiveness of CAM within the NHS. But many other things are known about the perceived benefits of CAM. CAM is very popular which says something about the benefits that people perceive they get. The techniques of economic evaluation were presented and discussed in the fifth seminar of the series¹⁰⁸.

2.3.2 Challenges in the economic evaluation of CAM¹⁰⁹

The lack of evidence on effectiveness: A key issue for CAM is that you cannot perform an economic evaluation unless reliable effectiveness evidence is available to facilitate the measurement of benefit. Effectiveness evidence is a precursor to, and a prerequisite for, performing economic evaluation and therefore represents the priority for professionals working in this area. Only once we have demonstrated that a particular CAM is effective does performing an economic evaluation become feasible.

Standardisation of 'treatment' (care) protocols & generalisability of cost and benefit data: A further challenge for economic evaluation of CAM is the lack of standardised treatment protocols, or some way to regularise what a particular treatment therapy package comprises and how it is delivered.

Generalisability from one particular service delivery context is a problem when interpreting CAM research, because one practitioner or one particular service will operate differently from another and a characteristic of CAM is its practitioners' respect for individuality and their adoption of a more holistic view of individuals than conventional medicine. Nevertheless, if we lack a clear idea of what a particular series of CAM services and treatment entail it becomes very difficult to say anything generalisable about the value for money of that service outside the specific context in which its costs or benefits have been observed.

'Conventional' measures of health-related outcome (QALYs) may be too restrictive: An issue relating to the economic evaluation of CAM is that the conventional measures of health-related outcomes used to estimate QALYs may be too restrictive in their view of what constitutes 'health' and 'quality of life'. There have been few studies that have applied these sorts of measures to CAM.

Patients have preferences regarding the process of care (not just health-related outcomes): Recognising patients' preferences and respecting patients' choices is, of course, becoming an increasingly important policy theme in the NHS. However, patients' preferences about where, when and what care is delivered, and how it is delivered, are not taken into account by Cost Utility Analysis.

2.3.3 Exploring alternative methods of economic evaluation

Economists have developed increasingly sophisticated techniques for identifying the aspects of services relevant to patients' preferences and for assessing willingness to pay in relation to these (for example, Conjoint Analysis¹¹⁰). The fact that most CAMs have tended to be provided in the private sector means that 'willingness to pay' approaches to researching benefit may be more readily applicable here than for most other public sector health services.

2.3.4 Practical frameworks for PCTs – estimating costs and benefits: Programme Budgeting and Marginal Analysis (PBMA)¹¹¹

PBMA use in the NHS has steadily increased over the last 25 years. It supports a systematic approach to decision making, by addressing both marginal costs and marginal benefits. It could provide a framework for a PCT to determine how much and what types of CAM it could introduce by comparing cost-benefits of delivering CAM with those of existing treatments.

However, given the new participatory agenda these perspectives and holistic benefits may have to be taken into account. They might for instance include CAM service spin-off effects like patient empowerment or staff job satisfaction. An economic tool that related the cost of CAM service benefits could be used in tandem with a means of measuring clinical and other benefits so as to allow comparisons to be made with mainstream treatments. It is impossible to make PBMA comparisons if different tools are employed to measure the benefits. The need for unbiased comparisons between the outcomes of CAM treatments and conventional interventions was highlighted through the seminars and consultation.

¹⁰⁸ For more detailed coverage of these techniques please refer to the report on **Seminar 5** available by direct request cgcarnet@wmin.ac.uk or downloaded from www.ihn.org.uk and www.wmin.ac.uk/sih/cgcarnet

¹⁰⁹ The following sections are summarised directly from the presentation given by Professor Nancy Devlin, Professor of Health Economics, Department of Economics, City University. **Seminar 5:** The costs and benefits of CAM

¹¹⁰ Please refer to the full Seminar 5 report for an explanation of different methods of economic evaluation

¹¹¹ The following text draws directly from the presentation made by Richard Little, Senior Research Fellow and Health Economist in the Centre for Health Planning and Management, Keele University. **Seminar 5:** The costs and benefits of CAM in primary care, Thursday June 19 2003 - King's Fund, London

A. Development: Issues and guidance (2)

2.3.5 What is so different about economic evaluation of CAM?¹¹²

Valid economic evaluations of all interventions, including CAM, are absolutely essential. In many ways economic evaluation of CAM is no different from the economic evaluation of conventional medicine and the same could be argued for CAM's clinical evaluation. Yet the challenges involved raise questions about how best to evaluate not only CAM but conventional medicine too.

The imperative of the 'single metric' in economic evaluation is at the heart of the problem. Economists would like to produce generalisable outcomes, so they can assess whether CAM is doing something different when compared to other treatments and provides value for money. More feedback is needed from economists, on how to move forward on these issues by separating some of the empirical evidence from speculation.

There is a lot of intuitive understanding about 'expanded benefits' from CAM but ways need to be found to bring in patients' perspectives on the benefits they would like to receive. This raises the issue of whether the NHS ought to be providing those kinds of benefits and what an NHS-appropriate definition of health might be; this question is perhaps the most central.

The widening scope of evaluation, will in turn lead to the development of more appropriate and relevant methodologies e.g. tools to capture patient experience and their own evaluations of effectiveness and adverse effects of treatment. Whilst recognising a need to incorporate current practice in the evaluation of CAM (in particular innovative models such as PBMA), any research should ask a question that is both relevant to CAM (need to know) and congruent with the sorts of outcomes commonly associated with CAM.¹¹³

2.3.6 A5: Developing methods for the economic evaluation of primary care CAM¹¹⁴

It is recommended that further work is focused on the area of economic evaluation - undertaken by experts from a range of disciplines. A wide range of possible benefits could be promoted, when developing a business case for a CAM service. Basic evaluation of a CAM service is an important first CG step, and there is an inevitable cost implication to even a basic evaluation. However, evaluating an economic benefit or demonstrating wider economic or social outcomes calls for even more resources, so any business plan would have to take that into account.

One or more of the items below could be included as a service outcome (even a performance indicator) *providing the service had the means to deliver and evaluate them*. But any complex or in depth research involving multiple outcomes would certainly entail not only financial costs, but also require research support. This might be available if grant funding can be mobilised, and/or strong links can be made with the appropriate local research networks or university department.

A5: Developing methods for the economic evaluation of primary care CAM

1. Measuring patient related outcomes

- 1.1 Health states; symptom relief and dis-benefits of side effects
- 1.2 Wellbeing; empowerment, emotional wellbeing, coping strategies and patients feeling good about themselves (despite some impairment)¹¹⁵
- 1.3 Process utilities i.e. what patients value; empathy, the pleasure of receiving treatment, touch, & the time that is taken
- 1.4 Health behaviours i.e. changes in patient knowledge, behaviour and understanding of their health e.g. changing attitude to health, taking greater responsibility, healthy eating & exercise
- 1.5 Patient identified outcomes commonly associated with CAM interventions (modality specific and condition / symptom specific – including levels of pain and mobility/disability) as well as more general gains e.g. satisfaction, perceived value of safe, non-invasive modalities, and of the personal locus of control remaining with the patient etc
- 1.6 Patient satisfaction
- 1.7 Cost to the individual e.g. loss of earnings, cost of medical equipment and interventions
- 1.8 Wellbeing, empowerment, emotional wellbeing coping strategies and patients feeling good about themselves (despite having some impairment)
- 1.9 Patient choice evaluated as an outcome / benefit

¹¹² The following sections are summarised from the presentation made by Kate Thomas, Deputy Director, MCRU, University of Sheffield. **Seminar 5**. For full coverage of these issues from **Seminar 5** please refer to the report which is available by direct request cgcam-net@wmin.ac.uk or can be downloaded from www.ihi.org.uk and www.wmin.ac.uk/sih/cgcam

¹¹³ Priorities from the groupwork feedback and Delphi outputs relating to 'Developing economic evaluation of CAM in primary care' can be found in the full report on **Seminar 5** available directly from the IHI-N or www.wmin.ac.uk/sih/cgcam or direct e-mail request cgcam-net@wmin.ac.uk

¹¹⁴ These points are based on the issues prioritised from the groupwork and for which a high degree of consensus has been gained. Please refer to discussion areas within the IHI-N for aspects for which little or no consensus has been reached

¹¹⁵ These elements would be captured by point 1.1. These are compatible with QoL, QALYs and Cost Utility Analysis

A. Development: Issues and guidance (2)

A5: Developing methods for the economic evaluation of primary care CAM (continued)

2. Measuring PCT/NHS related outcomes

- 2.1 Impact on PCT's ability to address local targets (e.g. access, waiting lists)
- 2.2 Impact on demand (and cost) for other services e.g. primary and secondary referrals (using study group data as well as PACT data)
- 2.3 Impact on PCT drugs bill (reduced prescribing)
- 2.4 Impact on national clinical priorities (e.g. NSFs)
- 2.5 The health promotion and preventative impact of CAM interventions (as this is part of the PCT remit)
- 2.6 Impact on conditions for which there are gaps in provision and demand within the PCT
- 2.7 Impact on related PCT employment issues e.g. absenteeism and workforce efficiency, GP stress and recruitment and retention issues

3. Measuring wider social outcomes¹¹⁶

- 3.1 Social services, welfare and business related costs e.g. early return to work, claims for sickness and mobility benefits, welfare benefits to support individuals separated due to impact of ill health, need for social services involvement and care, disability services, occupational health. (N.B. Incorporate the concerns of the new Care Trusts as they have unified budgets and will become increasingly relevant)
- 3.2 Long-term community health gains – (when health becomes a driver for change & there is continuity and cohesion over generations)
- 3.3 Wider benefits to the patient, their carer(s), family and family life (including family cohesiveness and related costs e.g. need for carer to stop work to provide care, separation)

4. Costs and other related outcomes and considerations

- 4.1 Related cost implications of side effects of conventional option.
- 4.2 An assessment of the whole service as well as different aspects of the service (i.e. not just comparing different types of therapeutic intervention and not just focusing on individual patient outcomes) i.e. Calculate total cost savings (may be cost neutral)
- 4.3 A breakdown of the costs for treatment of individual patients (CAM and orthodox pathways)
- 4.4 Calculate the whole set-up costs for services including; overheads, salaries, training, informing referrers to the service, time for meeting and resources for communication, provision of patient information, systems for regulation, supervision, audit and other clinical governance activities¹¹⁷

5. Appropriate methodologies (see also pilot studies suggested below)¹¹⁸

- 5.1 Conventional outcome measures relative to health states; general health (EQ5D, SF36) or specific condition related scales
- 5.2 Cost utility analysis (orthodox i.e. QALYs)
- 5.3 Develop a new model for evaluating effectiveness based on the example of NICE guidelines on infection control. As RCT evidence wasn't available NICE based the guidelines on best practice and expert opinion. A CAM version could incorporate both these aspects as well as the holistic care angle
- 5.4 Cost Benefit analysis (conventional methodology)
- 5.5 Cohort studies: contemporary care control groups versus CAM integrated intervention group
- 5.6 Cost effectiveness analysis (e.g. conjoint analysis)
- 5.7 Cost minimisation (conventional methodology)
- 5.8 Longitudinal studies (e.g. including comparative studies)
- 5.9 Early intervention studies e.g. delayed use of medication
- 5.10 Develop 'tools' to measure the four domains of benefit: health states, wellbeing, process utilities and health behaviours
- 5.11 Programme Budgeting and Marginal Analysis
- 5.12 Gap analyses - local orthodox services to identify provision and demand
- 5.13 Measures used in the field of occupational health and employment e.g. workforce efficiency measures

¹¹⁶ There was general acknowledgement through the consensus building process that these points would be difficult to measure

¹¹⁷ A cautionary point from the consultation process was to be consistent with the costs evaluated in conventional care and to set such a detailed standard may be counterproductive when comparing costs

¹¹⁸ One of the main difficulties highlighted here through consensus building was to bridge the gap between what is desirable and what is feasible

A. Development: Issues and guidance (2)

A5: Developing methods for the economic evaluation of primary care CAM (continued)

6. Research considerations¹¹⁹

- 6.1 Make sure that any evaluation fulfils the information requirements of the PCT (especially those specified by a commissioning panel)
- 6.2 Ensure evaluations incorporate PCT and patient expectations and requirements
- 6.3 Define measures of analysis very clearly e.g. measuring outcomes for complex conditions; costs of maintenance, support, remedial care
- 6.4 Consider whether the focus should be on an individual therapy or package model of delivery (i.e. assessing the overall model of delivery or the individual therapies within it)
- 6.5 Consider whether to measure individual gain to individual patients, or system gains to the whole PCT
- 6.6 Consider where economic analysis fits with patient choice and factors that determine their decisions to chose CAM as treatment option
- 6.7 Consider which aspects of economic analysis determine commissioning decisions.
- 6.8 Be creative and think about outcomes of the service in new and expansive ways

Suggested Pilot cost effectiveness studies

PILOT STUDY 1:

- PS1.1 Conduct a gap analysis of local conventional services: to identify gaps in provision and demand within the PCT e.g. stress and low back pain
- PS1.2 Conduct an analysis of employment issues for the PCT e.g. absenteeism and workforce efficiency: in relation to the target condition / patient group e.g. stress and low back pain
- PS1.3 Develop a symbiotic relationship with services that overlap e.g. occupation health and primary care
- PS1.4 Establish links with services that may need to be redesigned or be impacted upon if CAM pathways are introduced and discuss how to best increase the efficiency of the referral pathways (e.g. with psychiatrists, orthopaedic and rheumatology consultants and physiotherapy teams.)
- PS1.5 Cohort study: A contemporary control group that receives standard contemporary care. The study group receive the CAM intervention (translated into an IHCP-Integrated Holistic Care Policy)
- PS1.6 GP assess the cohort groups and assigns to interventions
- PS1.7 Measure impact on referrals to primary and secondary care on the cohort as well as PACT data

PILOT STUDY 2:

- PS2.1 Tailor a service to meet PCT needs e.g. reductions in GP consultations and secondary care referrals
- PS2.2 Also/or tailor the service to meet patient needs and preferences (expressed through patient pressure within the PCT and championing of CAM from outside the PCT)
- PS2.3 Measurement has to be simple, appropriate and sensitive to the outcomes required
- PS2.4 Include data on safety (e.g. side effects and related costs)
- PS2.5 Filter access to the service via a gatekeeper (criteria based on symptoms, condition, complexity of problem or income?)
- PS2.6 Examine the whole programme of CAM
- PS2.7 Monitoring and evaluation conducted by a nationally funded framework or through academic links
- PS2.8 Monitoring and evaluation should include quality assurance (including performance indicators), risk management and the accountability framework i.e. CG
- PS2.9 Conduct PBMA (assuming that there is a level playing field between CAM and orthodox services)

2.3.7 Emerging priorities

As well as more direct health gain, measured outcomes might include longer-term effects on individuals and their immediate families, and wider costs to the social system as a whole. This also relates to long-term prevention of clinical sequelae and the possibility that CAM consultations can contribute to health promotion and self-management.

However, although it may be ideal in the long-term to incorporate the wider, holistic benefits of CAM in the evaluation of services, this is not essential in the short-term. The emerging advice to service providers is to assess the priorities for evaluation in the light of the PCTs requirements and set realistic targets for audit and evaluation. Developing standardised treatment packages for providing equitable service provision will facilitate evaluation of cost and clinical effectiveness. One of the main issues for the application of a framework such as PBMA will be obtaining cost information on CAM services. Established CAM services are well positioned to provide data on costs and benefits and there could be a potential for large scale pragmatic studies based on typical practice.

¹¹⁹ See earlier section on research governance. <http://www.uoi.chi.nhs.uk/>

A. Development: Issues and guidance (2)

Developments in primary care for integrating CAM services

- Further exploration of the economic evaluation of CAM is essential. A focused expert consultation process could advance this area and potentially lead to learning materials that could be disseminated through seminars and the web.

Developments in the CAM field

- Develop a flexible system for taking new ideas on board in relation to economic evaluation (from both the CAM and patient agenda)
- Amalgamate units of analysis (wider benefits and outcomes) with conventional health research and economic evaluation (rather than their being add-ons - even if conventional medicine does not normally take those outcomes into account, perhaps CAM evaluation can undertake a unified approach to evaluation)
- Monitoring and evaluation conducted by a nationally funded framework or through academic links¹²⁰
- Big numbers are required for convincing evidence at the decision making level, this is dependent on adequate resources, which individual practitioners do not have i.e. thus large scale research (e.g. see pilot 2) for evidence aimed at the DH and Government decision making level: multi-site trials could be appropriate
- Develop evidence based regulation – as is important for acceptability

2.4 Intelligent use of information

The development of information systems and appropriate use of information underpins all clinical governance activity. Information management systems which provide links for sharing information across disciplines and organisations is seen as central to clinical effectiveness. A key issue for PCTs is that accurate and relevant information is provided by all services they commission so that they are able to meet their responsibilities for assuring the safety and quality of those services as well as informing decisions on developmental or 'transformational' needs. CHI found that use of information was the least developed area of CG in NHS organisations and subsequently produced a web-based self-assessment tool. The concept of '*intelligent*' information was introduced by CHI to emphasise the need for more useful and appropriate data collection.

"Their expectation is that 'intelligent information' (that is, robust data that has been analysed and made comprehensible and fit for purpose in relation to the audience and the use to which is to be put) should underpin all decisions made by the Boards of NHS organisations and thus provide the foundation for 'integrated governance'". Stanton 2004¹²¹

It is important that systems are in place for information management to ensure reliable and accurate (quality) data. Information can be used to; inform clinical governance activities including monitoring performance and outcomes, review and improve clinical practice e.g. clinical and performance indicators, supporting performance reviews and improvement to services and the implementation of policies and guidelines.

There are several implications for CAM practitioners and service providers; an understanding of the new NHS IT developments, a willingness to keep accurate records in accordance with the policies and guidelines adhered to by PCTs, i.e. an understanding and adherence to the policies and guidelines relating to use of information and informed consent, specifically relating to the implementation of the recommendations from the Caldicott Report¹²² and the Data Protection Act¹²³. Processes to ensure confidentiality and adherence to Caldicott guidance and the Data Protection Act are essential. The DH has also published a code of practice on confidentiality, these can be accessed via their website¹²⁴. Information provided to patients, their carers as well as other professionals and the wider local community on CAM interventions will also be a crucial development within the field¹²⁵.

2.4.1 Emerging priorities

Standardised data collection in audit and evaluation (including costs) could provide a greater body of consistent evidence on CAM primary care interventions in a way that allows comparisons to be made to conventional treatments. The CAM community could contribute much by encouraging their members to collate more data at practice level; for example through the development, piloting and widespread use of generic audit tools relevant to CAM services. Such tools might be endorsed by

¹²⁰ See section on research governance.

¹²¹ Stanton P (2004) Executive Summary: The Strategic Leadership of Clinical Governance in PCTs. NHS Modernisation Agency, Clinical Governance Support Team: National Primary Care Trust Development Programme, March 2004

¹²² Department of Health, (1997) The Caldicott Committee: Report on the review of Patient Identifiable Information, Department of Health, London. <http://static.oxfordradcliffe.net/confidential/gems/caldrep.pdf>

¹²³ The Data Protection Act, (1998) HMSO, London

¹²⁴ <http://www.legislation.hmso.gov.uk/acts/acts1998/19980029.htm#aofs>

¹²⁵ Department of Health. Confidentiality: Code of Practice. 2003 <http://www.dh.gov.uk>

¹²⁶ This would in part address concerns raised during the consensus and consultation phases on the myths and views held on CAM by conventional medicine that continue to hamper service development

A. Development: Issues and guidance (2)

regulatory bodies, and practitioner-researcher activities should be accredited by professional bodies as relevant to CPD requirements.

PCTs will need to be assured that CAM practitioners implement the guidelines on issues of confidentiality and use of patient information. This learning could be delivered and assured through the accrediting and regulatory CAM bodies. Clinical effectiveness requires the development of templates on IT systems for collecting patient information and data which can evolve alongside NHS data collection systems will be necessary to facilitate research and evaluation processes.

The issue of whether enhanced patient records or parallel notes for CAM practitioners are appropriate will need to be explored further with reference to Caldicott guidance on management of data. The transition of information and how well it is managed are key issues that will be reviewed by the Healthcare Commission. Balancing confidentiality and information transfer (to and from PCTs and providers) will be essential and processes for information transfer will need to be transparent.

Developments in the CAM field ¹²⁶

- Centralised point for data collection on audit and evaluation outcomes
- Education on issues of confidentiality, collection, recording and use of patient information
- Adherence to guidelines on use of information could be delivered and assured through the accrediting and regulatory CAM bodies
- Relevant information on CAM interventions (including safety and efficacy)

Developments in primary care for integrating CAM services

- Development of templates on IT systems for collecting patient information and data.
- IT systems flexible enough to collate patient data developed alongside NHS data collection systems will be necessary to facilitate research and evaluation processes
- Ways of supporting evaluation through the application of appropriate information technology should be explored
- PCTs are responsible for providing training and support to staff in use and interpretation of data

2.5 Risk Management

Risk management is an important aspect of quality improvement and is central to the one of the seven new domains - for standards on safety. The development of risk management policies is crucial to ensuring that treatments are safe as well as effective. The 1999 NHS Act¹²⁷ stipulated that risks and hazards to patients were to be reduced to as low a level as possible, and a culture of safety should be encouraged throughout the NHS. PCTs have a legal duty of care for their local population which means that the services they commission provide safe as well as effective care.

Throughout the seminar series risk management activities were highlighted as central to service delivery and monitoring¹²⁸. CHI has produced clear guidance and a framework for clinical risk management and has developed a self-assessment tool for PCTs.

*"Effective risk management in an organisation needs leadership, clarity of roles, strategic direction and a firm understanding of engagement and communication."*¹²⁹

The Department of Health provides resources for policies and guidance on health and safety on their website¹³⁰. In November 2003 (reprinted in April 2004), the National Patient Safety Agency (NPSA) published an overview of the "Seven Steps to Patient Safety" for NHS staff¹³¹

The steps are summarised as follows:

"Step 1: Build a safety culture - Create a culture that is open and fair; Step 2: Lead and support your staff - Establish a clear and strong focus on patient safety throughout your organization; Step 3: Integrate your risk management activity - Develop systems and processes to manage your risks and identify and assess things that could go wrong; Step 4: Promote reporting - Ensure your staff can easily report incidents locally and nationally; Step 5: Involve and communicate with patients and the public - Develop ways to communicate openly with and listen to patients; Step 6: Learn and share safety lessons - Encourage staff to use root cause analysis to learn how and why incidents happen Step 7: Implement solutions to prevent harm - Embed lessons through changes to practice, processes or systems"

¹²⁶ This will involve collaboration between service providers, complementary practitioners, researchers, patients and conventional practitioners

¹²⁷ The NHS Health Act (1999), HMSO, London <http://www.hmso.gov.uk/acts/acts1999/19990008.htm>

¹²⁸ An online information resource on risk management will be accessible via www.wmin.ac.uk/sih/cgcam

¹²⁹ http://www.chi.nhs.uk/eng/about/publications/risk_mgmt/acute_trusts.pdf

¹³⁰ <http://www.dh.gov.uk/PolicyAndGuidance/fs/en>

¹³¹ [http://81.144.177.110/site/media/documents/499_sevensteps_overview\(2\).pdf](http://81.144.177.110/site/media/documents/499_sevensteps_overview(2).pdf)

A. Development: Issues and guidance (2)

2.5.1 Emerging priorities

Coherent risk policies and procedures for all services will need to be developed and disseminated to all staff and systems for call and recall¹³² within CAM practitioner services will also be required. Staff education or training events on risk management will be an important area for CPD especially in learning lessons from practice e.g. near misses. Services need to develop systems to collate and monitor incidents and trends as well as protocols and trigger events for CAM interventions, especially for the prevention and control of specific risks e.g. counting in and out of needles in acupuncture, or the safe storage of aromatherapy oils. Patient complaints information should also be incorporated into any risk assessment and improvements to services made as a result of risk management activities should be documented.

As the new core and developmental standards will apply to all NHS commissioned services it will be essential for CAM services to be able to demonstrate their safety to PCTs.¹³³ Issues relating to pharmaceutical and pharmacovigilance were identified, in consultation phase, as areas for further work. The assessment of the suitability, quality, safety and interactions of medicinal products used by CAM practitioners; development of CAM formularies, adverse events reporting systems and prescribing policies were all highlighted as essential processes – especially where herbal medicines were concerned.

Developments in primary care for integrating CAM services

- Generic red flag criteria for CAM interventions made available to all CAM practitioners

Developments in the CAM field

- Accrediting organisations all include training on risk as part of qualification training and CPD
- Education on risk management in the NHS for all NHS CAM practitioners

2.6 Continuing Professional Development¹³⁴

A *First Class Service* laid out the framework for Continuing Professional Development (CPD) for all primary care practitioners¹³⁵. Continuing (or continuous) professional development has been described as:

“The maintenance and enhancement of the knowledge, expertise, and competence of professionals throughout their careers, according to a plan formulated with regard to the needs of the professional, the employer and society.” (Madden & Mitchell 1993¹³⁶).

CPD involves having a plan for learning based on the reflective learning cycle, which is agreed between individual practitioners and managers (Kolb, 1984¹³⁷). Personal Development Plans (PLPs) acknowledge the ways in which adults learn and the variety of opportunities available for learning¹³⁸. Within primary care CPD is set by annual appraisal. The primary aim of a PLP is to identify a practitioner's educational/professional needs, within the context of the needs of service users and the organisation within which they work. The practitioner must identify them him/herself and must own them.

PCTs must involve CAM staff as mainstream educational events as part of their obligations set out in *Working together, learning together*¹³⁹. This stipulated that by 2003 PCTs must: “So far as is practicable, ensure that learning opportunities comparable to those for its own staff are available to contract and agency staff.” PCTs will also need to work with professional societies:

“Employers should ensure that their local CPD programmes are underpinned by the standards set by the relevant professional and regulatory bodies. Partnership between employers and the professional and regulatory bodies will be essential for promoting and monitoring effective CPD frameworks.” Department of Health (2001)

CPD is also used as a means of demonstrating competence¹⁴⁰. The DH see the move amongst regulatory bodies to develop CPD strategies for revalidation or re-certification of members as key to

¹³² Administrative system for ensuring appointments and follow-ups with patients run efficiently

¹³³ Department of Health (2004) National Standards, Local Action: Health and Social Care Standards and Planning Framework 2005/06–2007/08, Department of Health, July 2004.

¹³⁴ Elements of this section draw on the presentation given by Gerry Harris, Associate Dean for CPD, London Deanery for General Practice, Acupuncturist and discussions at the final **Seminar 6**, for a full copy of the report please visit the IHN or contact the clinical governance project directly cgcarnet@wmin.ac.uk

¹³⁵ Department of Health (1998) *A First Class Service: quality in the NHS*. Department of Health, London

¹³⁶ Madden, C.A. and Mitchell, V.A. (1993) *Professions, Standards and Competence: A*

Survey of Continuing Education for the Professions, Bristol: University of Bristol

¹³⁷ Kolb D (1984) *Experiential Learning: experiences as the source of learning and development*. E Englewood Cliffs, NJ: Prentice-Hall

¹³⁸ See also the following section on staffing and management regarding PDPs and interprofessional working

¹³⁹ Department of Health (2001) *Working together, learning together: A framework for lifelong learning in the NHS*.

¹⁴⁰ Allied Health Professions Project: *Demonstrating competence through continuing professional development*. 2003

<http://www.dh.gov.uk/assetRoot/04/07/14/62/04071462.pdf>

A. Development: Issues and guidance (2)

ensuring that health professionals maintain appropriate levels of competence. *Quality in the new NHS* provides guidance on the principles and criteria for establishing local systems of CPD¹⁴¹.

CAM practitioners ideally should aim to develop good practice in a range of clinical governance activities e.g. clinical audit, the use of clear referral protocols, effective use of team meetings and issues relating to accountability e.g. delegation. By encouraging clear communication in these ways a firm basis for team processes and decision making about the use of CAM could be founded. The development of knowledge and skills will call for targeted education as well as work-based learning and documented CPD portfolio entries. Exploring developments within conventional NHS professions will be of benefit to the CAM professions¹⁴².

2.6.1 Emerging priorities

Developments in primary care for integrating CAM services

- Involve contracted CAM practitioners in mainstream educational events

Developments in the CAM field

- Regulatory bodies develop CPD strategies for the revalidation (or re-certification) of members in relation to NHS frameworks and establish mechanisms for liaising with PCTs and service providers on CPD (i.e. co-ordinating CPD requirements)
- Establish dialogue between interested CAM professional bodies and a representative group from the most CAM-active PCTs, to explore ways of implementing clinical governance and supporting it. Possibly as a 'national forum for integrated healthcare'.¹⁴³

2.7 Staffing and management

2.7.1 Developing accountability

The most developed CAM professions can already demonstrate coherent programmes for quality improvement. Increasing professionalism within the CAM field will influence decisions on which interventions are taken up and offered as treatment options within primary care¹⁴⁴. The classification of CAM therapies into three separate groupings by the House of Lords Select Committee on Science and Technology in 2000¹⁴⁵ was based in part on levels of regulation and influenced the conclusions on the suitability of CAM NHS provision¹⁴⁶.

CG involves proactive workforce planning and development, including recruitment and retention. Clear lines of supervision and accountability for all staff are also required. Staff development is an essential part of enabling PCTs to deliver services effectively. A PCT contracting CAM providers should include them in its education and training strategy (e.g. educational half-days), provide educational funding (which is generally not the case at the moment) and ensure links are made with the Workforce Confederations.

Professional regulation and/or competency frameworks will be needed and competency frameworks will have to feed into governance frameworks, so that there are processes in place that can help deliver the NHS plan. Developing National Occupational Standards within the CAM professions will also be an important next step in developing staff competencies. Some elements of the standards have emerged through the consensus building phase; these would ideally be developed through the national framework with the involvement of relevant CAM accrediting/regulatory bodies¹⁴⁷.

2.7.2 Contracting Complementary Practitioners¹⁴⁸

The NHS has been a monopoly provider of services, accountable to the Department of Health. However, now the NHS is moving towards a greater diversity and plurality of services that will be more responsive to patient needs. It will be managed according to transparent, common standards, inspected and regulated by an independent body that reports nationally and locally, (Healthcare Commission). GPs can use their new contracts as a tool for change as it provides different mechanisms to extend the range and quality of services offered in primary care, rewarding practices for doing this, in a bid to shift care from the acute sector to primary care.

¹⁴¹ Department of Health (1999) *Quality in the new NHS*. Health service circular, Department of Health

¹⁴² e.g. consultation on post registration development for nurses and midwives <http://www.dh.gov.uk/consultations/Liveconsultations/fs/en>

¹⁴³ A 'development pathway' for CAM graduates was suggested through the consultation phase. The aim would be to develop 'professionalism' through structured practical experience over a number of years

¹⁴⁴ Whilst acknowledging that that doctors can advise that patients seek care from any practitioner (where the doctor believes it will be in the patient's interests), the GMC regards statutory regulation as providing an assured level of competence and accountability of practitioners that systems of voluntary regulation cannot provide

¹⁴⁵ HL Paper 123. (2000) House of Lords Select Committee on Science and Technology. 6th Report, Complementary and Alternative Medicine. HMSO, London

¹⁴⁶ The University's mapping exercises found that predominantly group one therapies were being accessed via primary care

¹⁴⁷ National Occupational Standards are available for adoption and adaptation by professions which have not yet developed standards <http://skillsforhealth.org.uk>

¹⁴⁸ This section draws on the presentation given by Christine O'Connor, Director, Catch On [Consulting] at **Seminar 6**.

A. Development: Issues and guidance (2)

Importantly for CAM, Primary Care Organisations can provide services themselves or commission them from other providers (e.g. via APMS)¹⁴⁹. Practice-Led Commissioning (PLC), intended to come into place from April 2005, is also likely to represent a major opportunity for CAM and patients and practices may choose to use budget underspends for CAM therapies. In time the local sensitivity that PLM allows could lead to a more radical overhaul of local services depending upon the wishes of local practices and their patients (often working together for their localities) and this could lead to the sustainable provision of a wide range of complementary therapies within local agreement as to when, where and how they might be provided¹⁵⁰.

2.7.3 Integrating CAM in primary care: a professional development process¹⁵¹

A challenge for CAM practitioners will be to move away from the purely self-directed style that independent, privately-funded practitioners are used to, towards a multidisciplinary approach. The integration exercise demands personal and professional growth of doctors too; in fact, one of the most critical factor for co-workers hoping to integrate their practice will be the time available for group reflection, where team members can examine their own strongly held beliefs and attitudes, and explore the potential of joint working.

Whether CAM is provided by conventional or by non-medically qualified practitioners, the imperatives are the same: to plan, manage and evaluate the service, with the twin aims of professional development and quality improvement always in view. The decision - be it for a practice or a PCT- to bring CAM into a mainstream medical service is a developmental challenge; something to be taken thoughtfully into account during long-term planning. Personal learning plans that reflect these organisational aims will encourage the integration process.

2.7.4 Using personal development plans to encourage inter-professional working¹⁵²

Teamwork should become a training option for GPs because they will need to work in teams to fulfil the new contract. Also, because many GPs now refer to CAM practitioners, knowledge of CAM should become a higher priority in more GP Personal Learning Plans (PLPs). Similarly other relevant health professionals would benefit from education on CAM. Appropriate programme development will need to follow. Each PCT has at least one primary care tutor (not all of whom are doctors) who runs self-directed learning groups which are potentially a good opportunity for team building and for promoting practice-based learning.

Personal development plans can help promote team-building and inter-professional learning, if there is the will for this. Staff appraisal linked to adequately resourced staff development for the appraisee helps ensure that a practitioner's PLP relates to a service's development plan. It is important to maintain the broader picture of more holistic co-working and not just fix on targets. The strategic need is to play into PCT priorities. Reflection on outcomes can be an important bridge to team working. It will be important to develop integrated teams' key objectives and aims and to promote holistic quality markers. Such activities will need to be adequately resourced.

2.7.5 Emerging priorities

Developments in primary care for integrating CAM services

- Developing contracts and commissioning guidance for CAM practitioners
- Facilitating interprofessional working knowledge of CAM should become a higher priority in GPs Personal Learning Plans (PLPs)¹⁵³

Developments in the CAM field

- Aspects of NHS employment covered within practitioner training programmes

2.7.6 A6: Issues in developing interprofessional learning and working for the benefit of patients¹⁵⁴

The following issues are relevant to practitioners working within multidisciplinary teams. They are not intended, as with other recommendations and provisional guidance, to be a check list of activities but rather wider themes and issues for team development to be prioritised within the context and tasks being undertaken. The priorities for individual groups would necessarily depend on the team concerned, its objectives and developmental needs. Team working was identified in the consensus building phase as an essential component of education and training for CPs.

¹⁴⁹ See earlier reference to APMS: **Section A**

¹⁵⁰ E-mail correspondence with Dr Michael Dixon (September 2004)

¹⁵¹ Professor David Peters, Clinical Director, School of Integrated Health, University of Westminster

¹⁵² This section draws on the presentation given by Gerry Harris, Associate Dean for CPD, London Deanery for General Practice, Acupuncturist, and groupwork feedback at **Seminar 6**.

¹⁵³ An issue raised in the seminars and consultation phase was the need for increased CAM familiarisation courses for conventional medical practitioners

¹⁵⁴ These points are based on the issues prioritised from the groupwork and for which a high degree of consensus has been gained.

A. Development: Issues and guidance (2)

A6: Issues in developing interprofessional learning and working for the benefit of patients

1. Laying the foundations for integrated teamwork

- 1.1 Understand (and obtain) appropriate accreditation / regulation
- 1.2 Learn about the context of primary care practice e.g. be familiar with the NHS structure
- 1.3 Document Continuing Professional Development (CPD)
- 1.4 Identify what the benefits are for CAM practitioners working in primary care
- 1.5 Identify potential difficulties that may arise between CAM and NHS team members
- 1.6 Encourage communication between GPs and CAM practitioners at local practice and PCT level
- 1.7 Formalise and make explicit the process of decision making for different CAM approaches¹⁵⁵
- 1.8 Form a CAM team in the local PCT area (as CAM professionals often work in isolation)

2. Establishing the structure and process for meeting

- 2.1 Develop clear referral protocols for the service
- 2.2 Establish shared values e.g. inclusion, good boundaries, safety for all, mutual respect, and being patient centred (i.e. taking the focus away from personal agendas and professional difference)
- 2.3 Define roles and responsibilities
- 2.4 Mutual recognition of differences and problems between professions (e.g. that CAM private practitioners may not easily understand the mindset, working environment and culture of NHS staff, and that GPs lack a grasp of the work CPs do)
- 2.5 Establish regular meeting times
- 2.6 Develop key objectives (aims/mission)
- 2.7 Create a common mission based on patient care
- 2.8 If possible build meetings around data e.g. case-mix, critical events, process difficulties, as well as critical events and problem based case study (joint working builds bridges)
- 2.9 Identify who could be included in the interdisciplinary team
- 2.10 Involve patients
- 2.11 When creating a team from scratch - start at a very simple level

3. Working as a team: education and practice

- 3.1 Meet on a regular basis
- 3.2 Set clear agendas for meetings with dedicated time for each issue
- 3.3 Develop realistic targets
- 3.4 Record agreements and the process for reaching them
- 3.5 Build rapport and relationships between team members (needs time)
- 3.6 Make meetings worthwhile (compelling, rewarding, empowering and constructive)
- 3.7 Keep a record of the meetings and ensure they form part of PLPs and CPD work
- 3.8 Make meetings worthwhile (compelling, rewarding, empowering and constructive)
- 3.9 Good 'Followership' is important (as much as good leadership)
- 3.10 Hold joint training sessions
- 3.11 Note achievements (as motivation)

4. Working as a team : Research

- 4.1 Gather evidence on effectiveness, cost benefits, good practice, critical events, inter-professional learning
- 4.2 Monitor patient demand for the service
- 4.3 Discuss and aim to conduct research into relevant aspects of delivery of the service
- 4.4 Develop and promote holistic quality markers

5. Developing an integrated approach within the team

- 5.1 Facilitate communication between disciplines
- 5.2 Play into the PCTs priorities e.g. the need to balance the books re overspend on drugs
- 5.3 Explore the use of CAM to address local and national priorities e.g. demand management, preventative healthcare
- 5.4 Emphasise the potential contributions of CAM in managing chronic conditions

¹⁵⁵ Note from consensus building: Formalising the process of decision making for different CAM approaches should be carried out jointly with patient, GP and practitioner, and as such this may be difficult to orchestrate. However the use of guidelines and agreed outcomes would allow teams to clarify their decision making processes.

A. Development: Issues and guidance (2)

A6: Issues in developing interprofessional learning & working for the benefit of patients (continued)

6. Personal discipline and skills needed

- 6.1 Emphasis on professional issues (not personal)
- 6.2 Actively participate and strive to take into account the challenges faced by NHS workers
- 6.3 Acknowledge and understand other people's point of view
- 6.4 Develop team working skills: understand team dynamics
- 6.5 Give encouragement to other team members
- 6.6 Promote open communication and mutuality
- 6.7 Use supervision to reflect on experiences of working in the NHS
- 6.8 Acknowledge and understand other people's point of view

The IHN (www.ihn.org.uk) provides access to some learning and CPD resources including PDSA frameworks that can be applied to team development. These will also be made accessible from December 2004 via www.wmin.ac.uk/sih/cgcam.

2.7.7 Developing a 'Quality Team Development Scheme' for CAM¹⁵⁶

Participants in the final seminar of the series and the subsequent consultation phase (which focused on interprofessional learning and working) were very much in favour of a Quality Team Development (QTD) Scheme for CAM. QTD is a necessary driver for high quality care (Campbell *et al*, 2001¹⁵⁷). Developed by the Royal College of General Practitioners, this scheme is supported by the Department of Health, the Institute of Healthcare Managers (IHCM) and the Royal College of Nursing (RCN). QTD provides a comprehensive approach to clinical governance and it enables Primary Care Organisations to gather the evidence required for CHI (now Healthcare Commission) inspections. QTD is also a method for managing and monitoring practices in line with the new GMS and PMS contracts.

The next step is to develop QTD for CAM alongside a Quality Outcomes Framework, with criteria adapted for CAM. Practitioners in the primary health care team can become QTD assessors, and this could include complementary practitioners.

The key elements prioritised during consensus for CAM QTD mirror those aspects identified in the existing RCGP scheme: developing individual and team professional development plans, accurate record keeping systems and protocols and guidelines based on evidence; all of which could feed into care pathways. Protocols could be established for assessing quality assurance, performance improvement, practitioner qualities, teamwork and professionalism. Criteria for assessment would include measures of patient satisfaction, patient and public participation as a quality marker, as well as other measurable outcomes already identified in previous workshops¹⁵⁸.

2.7.8 A7: Developing a 'Quality Team Development Scheme' for CAM¹⁵⁹

The following standards and criteria relate to multidisciplinary team working and integrated service provision. They form the basis for developing an extended Quality team development scheme that incorporates CAM. The themes that were prioritised through the consensus building process thus closely resemble those aspects developed by the RCGP for conventional practitioners.

A7: Developing a 'Quality Team Development Scheme' for CAM

1. Setting standards and criteria for services

- 1.1 Demand management:
 - 1.1.1 Managing access: assessment and monitoring demand for service, set criteria for how patients access services
 - 1.1.2 Length of consultation with practitioner
 - 1.1.3 Appointment times and booking procedures
 - 1.1.4 Standards for waiting room times
 - 1.1.5 Policy on continuity of care

¹⁵⁶ This scheme was introduced by Dr Tony Downes, GP, CAM lead for the Royal College of General Practitioners, member of the National QTD Steering Group at the 6th seminar in the series.

¹⁵⁷ Campbell S.M. (2003) Identifying predictors of high quality care in English general practice: observational study. *BMJ*. Vol.323

¹⁵⁸ Priorities from the groupwork feedback and Delphi outputs relating to 'Developing a QTD scheme for CAM' can be found in the full report on Seminar 6 which can be accessed via the IHN or www.wmin.ac.uk/sih/cgcam or requested directly cgcam-net@wmin.ac.uk

¹⁵⁹ These points are based on the issues prioritised from the groupwork and for which a high degree of consensus has been gained. Please refer to discussion areas within the IHN for aspects for which little or no consensus has been reached

A. Development: Issues and guidance (2)

A7: Developing a 'Quality Team Development Scheme' for CAM contd.

1. Setting standards and criteria for services

- 1.2 Safety
 - 1.2.1 Develop protocols on health and safety
 - 1.2.2 Red flag criteria for conditions to refer directly to GP
 - 1.2.3 Clearly identified lines of responsibility for risk management
- 1.3 Referral guidelines and protocols:
 - 1.3.1 Availability of service
 - 1.3.2 Appropriate referrals
 - 1.3.3 Referral letters / forms
 - 1.3.4 Monitoring
- 1.4 Develop protocols for the treatment of specific conditions and patient groups
 - 1.4.1 Management of chronic illness,
 - 1.4.2 Management of patients with multiple health problems
 - 1.4.3 Treatment of children
 - 1.4.4 Treatment of elderly people
 - 1.4.5 Conditions or patient groups relevant to local needs
- 1.5 Shared care and care pathway guidelines and protocols
- 1.6 Patient information
 - 1.6.1 Appointment times and days
 - 1.6.2 System for making appointments
 - 1.6.3 Treatment options
 - 1.6.4 How patients can feedback on services
 - 1.6.5 Leaflets available on self help
- 1.7 Preventative care and health promotion
 - 1.7.1 Lifestyle advice
 - 1.7.2 Addressing local health needs and inequalities
- 1.8 Identified gaps in service provision for specific conditions

2. Standards and criteria for the interprofessional team

- 2.1 Non-professional representation
 - 2.1.1 Lay or user participation as a quality marker
- 2.2 Appropriate professional training and accreditation / qualifications
- 2.3 Appropriate registration and regulation
- 2.4 Continuing Professional Development (CPD)
- 2.5 Individual and team professional development plans
- 2.6 Adequate ongoing supervision
- 2.7 Practitioner qualities
 - 2.7.1 Personal approach
 - 2.7.2 Team-working
 - 2.7.3 Understanding of quality improvement and task/methods of CG
- 2.8 Shared team values
 - 2.8.1 Patient centred care and informed partnership
 - 2.8.2 Holism
 - 2.8.3 Provision of a quality service
 - 2.8.4 Teamwork
 - 2.8.5 Discrimination policies
 - 2.8.6 Probity
- 2.9 Effective teamwork between therapist and wider primary healthcare team
 - 2.9.1 Effective means of communication
 - 2.9.2 Meetings
 - 2.9.3 Team development and support
 - 2.9.4 Teambuilding processes

A. Development: Issues and guidance (2)

A7: Developing a 'Quality Team Development Scheme' for CAM (continued)

3. Patient and public involvement¹⁶⁰

- 3.1 Involvement in care
 - 3.1.1 Shared information
 - 3.1.2 Shared decisions and responsibilities with patients
 - 3.1.3 Support for patients and carers
- 3.2 Patient surveys
- 3.3 Involvement in planning and development of services
- 3.4 Involvement in evaluation of the service
- 3.5 Community development
 - 3.5.1 Work with other agencies re local health promotion and improvement

4. Contribution to the work of the PCT

- 4.1 Education on how PCTs work
- 4.2 Participation and communication with the PCT
 - 4.2.1 Identification of potential local service improvements
 - 4.2.2 Involvement with PCT meetings / events

5. Clinical governance

- 5.1 Identify a CG lead within the team
- 5.2 Ensure resources for CG and staff development are available
- 5.3 Established mechanisms for the continual monitoring and improvement of services
- 5.4 Participate in CG activities of PCT (share data)
- 5.5 Regular audits covering a range of topics
 - 5.5.1 Clinical care
 - 5.5.2 Communication with patients
 - 5.5.3 Service organisation

6. Risk management policies¹⁶¹

- 6.1 Adverse events recording and improvements to service as a result
- 6.2 Complaints policies and procedures

7. Managing underperformance

- 7.1 A 'no blame' approach taken to appraisal and supervision

8. Research and effectiveness

- 8.1 Evidence based guidelines and protocols for treatment and standards of care
- 8.2 Evaluate measurable outcomes
- 8.3 Evaluate costs and savings
- 8.4 Evaluate patient wellbeing
- 8.5 Evaluate demand
- 8.6 Develop a suitable evidence base for CAM (in addition to RCTs)

9. Practice management¹⁶²

- 9.1 Clearly identified roles and responsibilities
- 9.2 Personnel management processes
- 9.3 All statutory regulations adhered to e.g. equal opportunities, harassment, disciplinary and grievance
- 9.4 Efficient record keeping policies and procedures
- 9.5 Health and safety at work
- 9.6 Infection control
- 9.7 Policies and procedures regularly reviewed and agreed by all staff
- 9.8 Service planning
 - 9.8.1 Production of development plans
- 9.9 Information management
 - 9.9.1 Access to information to support CPD and clinical care
 - 9.9.2 Premises and equipment policies
 - 9.9.3 Procurement
 - 9.9.4 Maintenance
 - 9.9.5 Safety
- 9.10 Financial management
 - 9.10.1 Monitor income and expenditure, performance against plans

¹⁶⁰ Other suggestions arising from the consultation process included; participation in practice patient satisfaction surveys; involvement in expert patient programmes and involvement with PALs and practice/patient partnerships/user groups.

¹⁶¹ Significant event audit was also suggested through the consultation process

¹⁶² Participation in annual appraisal and revalidation processes (including CAM consultation reviews by video assessment) was also suggested

A. Development: Issues and guidance (2)

Other aspects that were highlighted through the consultation phase included the provision of choice and diversity to health promotion and management of disease e.g. smoking cessation, supporting the management of illness and developing CAM for public health related issues. Developing standards and criteria for other aspects of integrated governance such as research and corporate governance frameworks for CAM was also recommended. Incorporating these elements alongside the new standards in tandem with a Quality Outcomes Framework would enhance a QTD for CAM. It was recommended that separate guidance for practitioners, multidisciplinary teams and managers is developed so as to clarify roles and responsibilities.

2.8 Developing quality assured NHS primary care CAM services ¹⁶³

For CAM to support what the NHS is trying to achieve it must develop the necessary structures. Only if CAM can deliver appropriate services in ways that commissioning primary care organisations feel comfortable with, will the integration of CAM become feasible. CAM providers might for instance find they have to justify a different way of working within the NHS¹⁶⁴. This would mean negotiating operational change in the NHS, and demonstrating that it represents good use of resources. All this change will require motivation and willingness to explore different approaches.

Primary care is inherently holistic, patient-centred and multi-professional. Health creation and empowerment are essential principles it shares with CAM, and the fact that CAM is low-tech probably appeals to primary care practitioners. For all these reasons CAM also resonates with central themes in Government health policy with its primary care centred NHS.

The modernisation agenda has opened up new contracting possibilities and existing examples of these and other pilot services can inform of the various models that could be appropriately adopted via PMS flexibilities, GMS enhanced services and the independent service contracts (APMS). Primary Care Organisations can provide services themselves or commission them from other providers. CAM could also feature in initiatives for improving admission and discharge planning and redesign; intermediate care; enhanced services in primary care; choice, plurality, and diversity agendas.

The inherent opportunities for service re-design have yet to be explored. Therefore the field of CAM will need to comprehend fully the potential of the new NHS with its frameworks of accountability, professional development and quality improvement.

Resources are limited and clinical governance must ensure resources are used effectively. CAM practitioners who become part of the NHS development process will be expected to engage with its clinical governance processes, and PCTs will rightly expect new providers to give a transparent account of their services. Resources for governance activities themselves will also need to be utilised from within the CAM professions and the NHS¹⁶⁵.

The governance structures themselves will move the CAM field forward because they provide a framework for building coherent local healthcare delivery by defining the values, cultures, processes and procedures required to sustain and improve that quality of care. CAM professional bodies have an interest in NHS service re-design and CG is part of a process that could open up NHS career pathways to properly qualified and regulated CAM practitioners.

2.8.1 Understanding the local primary care environment ¹⁶⁶

Having an understanding of the local primary care environment is essential to understanding clinical governance and this was prioritised throughout the seminar series. This includes: the relevance of CAM and potential benefits to PCTs in terms of costs and workload priorities; identifying the necessary actions to further integration; mapping local health needs; identifying key decision-makers within the PCT as well as local partners such as other NHS Trusts, healthcare professionals and expert patients.

NHS CAM practitioners and service providers will need to learn about the structures, priorities and pressure points around service delivery and commissioning plans of the PCTs. Understanding and being able to relate within the language and frameworks of NHS governance and management will be crucial.

¹⁶³ This text draws directly from the presentations made by Christine O'Connor, Director, Catch On [Consulting] throughout the seminar series.

¹⁶⁴ One of the key concerns expressed throughout the consultation and consensus building phases was that the ethos of CAM (i.e. holistic approaches to healthcare and disease management) would be lost to practitioners working within NHS infrastructures. In general participants felt that CAM has much to contribute to the development and management of NHS services. Similarly, concern about practitioners being able to maintain a balance between clinical practice and governance activities was recurrent throughout the consensus and consultation building phases.

¹⁶⁵ A central concern in the April consultation document was how governance activities would be resourced. The issue of costing-in governance activities and whether this may make CAM options less financially appealing to primary care commissioning organisations was also raised.

¹⁶⁶ Information and advice 'Understanding the local primary care environment' and to 'Building a comprehensive business case' – resulting from the consensus building process – can be accessed via the IHN www.ihn.org.uk or the University website www.wmin.ac.uk/sih/cqcam

A. Development: Issues and guidance (2)

2.9 Integrated NHS practice: Professional development and change management for complementary practitioners¹⁶⁷

There are a number of ways in which individuals can respond to change:

- Reactively by acting only when one is forced to
- Adopting the ostrich stance and putting one's head in the sand in the hope the ensuing change will disappear
- Proactively by planning for change and trying to keep ahead of the game

The new NHS is a minefield of change. Many on the frontline feel challenged in trying to link what appear to be hard nationally driven targets with a change mentality and with a direct relationship to the reality of patient need. How then can a clinician sustain a satisfying professional life whilst embracing changes which often seem alien to the end point concept of the patient at the centre?

2.9.1 The return of holism

This new approach to the NHS is perhaps the lever to give holism a second chance. The challenge is to ensure that the holistic baby is not thrown out with the assessment competency-based bathwater. The ideals of holistic practice need to be revisited in their widest sense. As well as looking at the whole patient and whole practitioner, we need to look at the whole working team and environment and this is the next loop in the spiral. Working and learning together enables practitioners to work collaboratively and effectively to produce clinical outcomes sought and the data capture required to demonstrate the quality of work. The new GMS contract with quality at the centre is designed to be one method of harnessing change and facilitating team development and learning.

2.9.2 Collaborative partnership

Ideas about team working and learning are embodied in the theme of partnership that is key in current health and social care policy. Collaborative partnership is *the* theme for this decade: partnership with colleagues, patients, local communities and with government. However, working together does not just happen and many practitioners have experience of dysfunctional 'teams'. Practitioners need to learn *how* to work collaboratively in multidisciplinary and multiprofessional groups and to capture the new learning that emerges (i.e. interprofessionally).

2.9.3 Marylebone Health Centre: Collaborative partnership

The Marylebone practice focuses on inter-(between) and intra-(within) professional collaboration. This professional linking is between all practitioners working in the extended team, both within and outside the health centre (e.g. community and practice nurses, colleagues from local community health teams, social services, counsellors). The principles of working and learning together are generic and the generalisability of this approach is what is so exciting about this way of working. It is time and labour intensive to work together and requires a strong commitment, but there is value added for both patients and workers. Working partnerships begin with patients and extend beyond the health centre team colleagues to the local community and to government.

2.9.4 Quality assurance / governance

The strongest link to government comes through the mechanisms of clinical governance. Working together can provide a means of achieving quality in service delivery outcomes and sustainable practice, satisfied patients and practitioners. Good practice should be reflected in clinical governance and continuing professional development frameworks. However, the practical doing of governance is everything, and if the process is not right, the outcomes are unlikely to be accurate or meaningful. It is difficult and resource heavy to get everyone in a multiprofessional team together. These new ways of working are slow to develop and most of the governance structures are aimed at conventional practice which has tended to focus on uni-professional and traditional medical approaches. Direct links between teamworking and improved patient outcomes are not supported by current literature relating to orthodoxy, despite strong inference in new NHS values. They are potentially even more tenuous in many CAM and holistic settings where patient satisfaction and containment are the aim, but difficult to capture. This relates back to the notion of competencies.

2.9.5 Competencies and Interprofessional learning

NHS targets and standards may be seen as reductionist and one-dimensional: they need to be uni-factorial and reproducible and therefore often derive from the lowest common denominator. This ensures a minimum quality, but restricts the possibility for capture of some qualitative aspects of thinking. In the end, this can stifle creative thinking and professional growth. New learning between

¹⁶⁷ The following sections have been prepared and edited by Dr Sue Morrison, Marylebone Health Centre, Christine O'Connor, Catch On (consulting) and Lesley Wye, University of Bristol for NHS professionals working in integrated settings. Based on and quoting some sections of an article written by Morrison S. (2004) Holism and interprofessional learning: From the whole patient to the whole team. Journal of Holistic Healthcare. Vol 1, Issue 1 May 2004.

A. Development: Issues and guidance (2)

professionals comes through extensive dialogue, and pre-specified competencies ignore these complexities of learning and developing. There is a lack of quality assessment tools for more holistic and multifaceted practice that could enhance the existing taxonomies of competence and this is a priority area for research and development.

2.9.6 The next stage

Working and learning together can be rewarding and fun, but it is also demanding and can be difficult and conflictual along the way. Practitioners need to learn how to collaborate alongside new clinical learning. Interprofessional education is the 'how' and not the 'what' of our endeavours. A holistic approach to education in practice will set the scene for developing more holistic practitioners.

Change can only be achieved by seeing past the early stages of a target driven approach, this is only a step on the ladder and those embracing change will have the vision to see beyond to what really lies ahead. Team work is the vehicle to deliver a new experience in healthcare for patients and the public. Putting the patient at the centre surrounded by expert advisors adds a slightly different dimension and moves us away from a purely 'done to' mentality to one of shared decision making. Practitioners must not only embrace an holistic approach to care but must also embrace the real change which puts choice at the heart of the transaction between patient and practitioner.

2.10 Making clinical governance work for you¹⁶⁸

The first of an online collection of narrative experiences of developing clinical governance in practice is now available on the IHN¹⁶⁹ and will be accessible via the University website from December 2004¹⁷⁰. The aim is to help practitioners, service providers and PCTs share valuable information with colleagues. The document "CG can work for you" points out that all health professionals working for the NHS have to be involved in CG activities (Peters D and Fisher P 2004). Whilst the authors – who both work in NHS CAM services - acknowledge that the element of compulsion and the bureaucratic tone of much of the guidance that has been issued can be intimidating, especially when unfamiliar with the way the NHS works, they reassure practitioners and service providers that they should not to be put off and point out that the purpose of CG, above all, is to improve services.

"The purpose of CG is to improve the service. Despite what you might think from some of the documents on it, you have considerable freedom to set your own agenda. For instance patient-centredness is a core value for CAM practitioners, and CG can be a valuable way of ensuring that your services really are patient-centred, and making them more so."

The authors' experience suggests that quality development begins with 'protected' time to sit down and discuss your work with colleagues. CG is not just a matter of ticking boxes, or obeying directives from on high, but of genuinely looking for ways to improve the service. The whole NHS CG strategy depends on grass roots buy-in. It is service providers who are in the best position to spot problems and set their own quality development agenda. Ultimately practitioners gain by improving their own work; patients by getting better services. The advice is to start small. The following table outlines probable key issues and relevant ways of working on CG proposed by the authors.

Some CG essentials	Possible methods
What does your service set out to achieve?	Stated objectives in service contract? Develop personal mission statement?
Are there any particular or recurrent problems with the service?	Discuss with team, identify problem, audit to define nature and frequency, implement improvements, re-audit
What sort of patients/problems am I treating?	Daily log of age, sex and diagnosis
In daily practice, can I spot learning needs as they arise?	Incident log of significant incidents, patient unmet needs
How do I deal with critical incidents and complaints?	Log any incidents. Link to learning plan. Have a documented complaints procedure.
Am I up-to-date with practice? Am I doing enough of the right sort of CPD?	Annual appraisal with a senior colleague. Personal Development Plan
Do I have a system for evaluating the outcomes of the service I provide, including patient satisfaction?	Consider using a simple patient centred outcome measure. (e.g. MYMOP) to track clinical change. Ask a sample of patients to complete satisfaction questionnaires.

¹⁶⁸ Written by Dr Peter Fisher, Clinical Director, Royal London Homeopathic Hospital and Prof. David Peters, Clinical Director, School of Integrated Health, University of Westminster

¹⁶⁹ www.ihn.org.uk

¹⁷⁰ www.wmin.ac.uk/sih/cqcam

Section A Development: Toolkits (3)

3.1 The Pilot Care Pathway: low back pain

This toolkit - accessed online as a series of interactive web pages - pilots a framework for care pathways with CAM options¹⁷¹. It is based on an existing integrated primary care service where CAM treatment options are available and it makes transparent the clinical governance processes, standards and activities appropriate to each stage of the pathway. The care pathway is being developed primarily for members of the IHN network: PCTs, service providers and practitioners, and those supporting their work - professional bodies, academic groups, and support organisations.

Content includes information on the development of primary care in relation to the 10 year NHS plan; an outline of the current NHS structures and information on key developments such as the GP Quality Outcomes Framework, APMS, NSFs and the new standards. Summaries and links to key documents and resources available on the web include the Department of Health, their ALBs and sources of information on complementary and integrated healthcare.

The pilot online care pathway is available on the Integrated Healthcare Network www.ihn.org.uk and via www.wmin.ac.uk/sih/cgcam.

3.2 The BESTCAM pilot: low back pain (Broad Evidence Synthesis Topic)¹⁷²

CAM CG will encourage evidence based CAM services. The BESTCAM pilot presents the EBM process for CAM practitioners, initially modelled on a search for evidence on low back pain. The generic framework produced - applicable to a range of common conditions - is accessed via a series of web-pages linked to sites providing more detailed information where required.

The need for a source of wide-ranging evidence on CAM options was proposed in the first seminar in the King's Fund series by Kate Thomas, Deputy Director of the Medical Care Research Unit at the University of Sheffield. The development of a BESTCAM pilot provides an ideal opportunity to identify a format for the process of collating a relevant body of evidence to support the pilot integrated care pathway. The output could potentially provide a blueprint for other pathways and support the development of clinical governance activities, specifically clinical effectiveness and audit.

Two types of frameworks were identified for BESTCAM development.

- One, which could be funded and published at a national level, involving academics in producing rigorous, high quality reports, and
- A second, to meet the needs of; practitioners in delivering evidence-based healthcare, those involved in local service improvements/redesign or people working to develop a business case locally.

The 'practical' framework has been developed as a pilot online resource¹⁷³, using the example of low back pain interventions in primary care to support aspects of the related online care pathway¹⁷⁴.

The elements of the framework include: sources for data on health care needs assessment (prevalence, patterns of service, costs); a range of evidence - efficacy, effectiveness, qualitative, audits; research methods and controversies - RCTs and meta-analysis; online sources for research abstracts and papers and advice and links to information on how to assess the quality of studies.

The aim is to develop a framework for bringing together a broad range of evidence about CAM in a way that empowers people to make good decisions about treatment choices.

The BESTCAM toolkit will be of interest to

- Professionals (e.g. doctors considering referral/evidence based practice, CAM practitioners developing EBP)
- Organisations (e.g. PCTs considering developing or commissioning CAM services)

Further work will be required to develop the first model and there would be scope to develop reports for the benefit of service users and patients wishing to make well informed treatment choices, or seeking to participate in CAM service development.

¹⁷¹ The development of care pathways was prioritised in the consensus building phase in the context of increasing patient choice and involvement. Care pathways are one of several best practice methods advocated within the NHS and they are likely to evolve as more sophisticated methodologies develop. Criticism of the pathway approach by conventional practitioners (i.e. that this approach can lead to a 'routinised and restricted view of options' was highlighted in the consultation process

¹⁷² Priorities from the groupwork feedback and Delphi outputs relating to 'Broad Evidence Synthesis Topic reports' can be found on the IHN. For full coverage of **Seminar 5** please refer to the report, which can be requested by e-mail: cgcam-net@wmin.ac.uk or can be downloaded from www.ihn.org.uk and www.wmin.ac.uk/sih/cgcam

¹⁷³ Accessible via www.ihn.org.uk and www.wmin.ac.uk/sih/cgcam

¹⁷⁴ The online BESTCAM resource is intended to facilitate the production of reports and not at this point a synthesised summary of research on LBP

Section A Development: Toolkits (3)

Initiatives involving the NeLH and NHS Direct, funded by the Department of Health are in development. The production of BESTCAM reports requires that the costs of collating, reviewing and maintaining a central base be assured within an organisation with the necessary expertise and rigour. Other resources might include: free access to research/audit/governance tools for practitioners (e.g. questionnaires, outcome measures); training in use of research tools; template research proposals; help with statistical evaluation.

A multi-professional approach will be necessary, involving researchers, a network of consultants, and a steering group to develop the reports; also supervisory support was needed for those producing the reports and a coordinator/monitor to assure quality of evidence.

3.3 The Integrated Healthcare Network www.ihn.org.uk

A website and networking package was launched in September 2002 in partnership with the Prince of Wales's Foundation for Integrated Health to support the work of two related projects. The primary aim was to provide an online platform to support individuals and organisations developing primary care CAM services. Over 400 individuals have registered on the site.

The IHN contains key reference documents and links relevant to developing primary care CAM services; e.g. clinical governance issues (including reports and outputs from the seminar series), gathering the evidence, monitoring and evaluation, how CAM practitioners can work with PCTs and government policy in relation to CAM. The IHN also offers an e-mail and online conference facility, discussion areas and queries facility as well as access to the online pilot care pathway and the BESTCAM report.

The continued development of the site - as a support to individuals and organisations delivering primary care CAM and integrated services - is currently under review.

A PDF of this report and other work produced by the University on the Clinical Governance project can be downloaded from the IHN or via the School of Integrated Health's website www.wmin.ac.uk/sih/cgcam

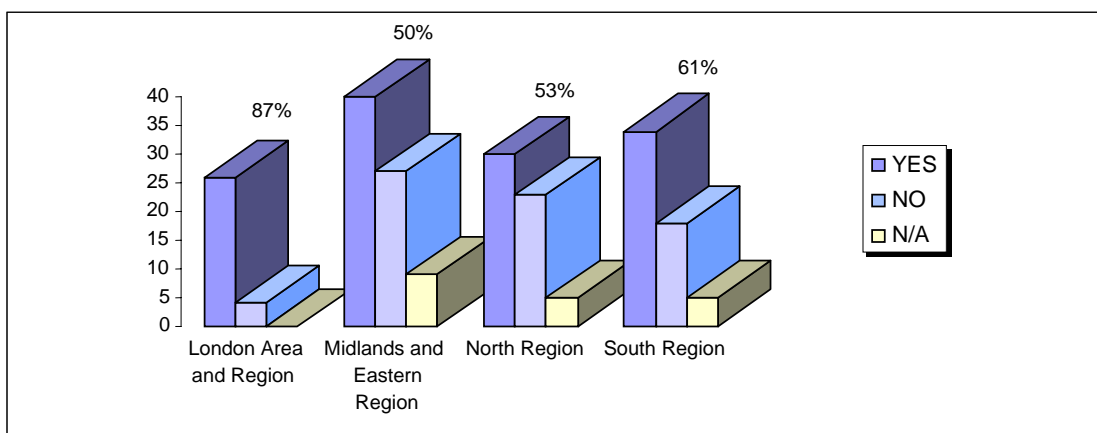
Section B: Research (4)

4.1 England-wide CAM services (2003-2004)¹⁷⁵

At the time of the second mapping exercise (up to April 2004) there were 301 PCTs in England, organised by the NHS into four regions comprised of eight areas. London is both an area and a region. By March 2004 information had been gathered on 73% of PCTs ($n=221$) and 100% follow up had been achieved on the services identified in the PCT survey.

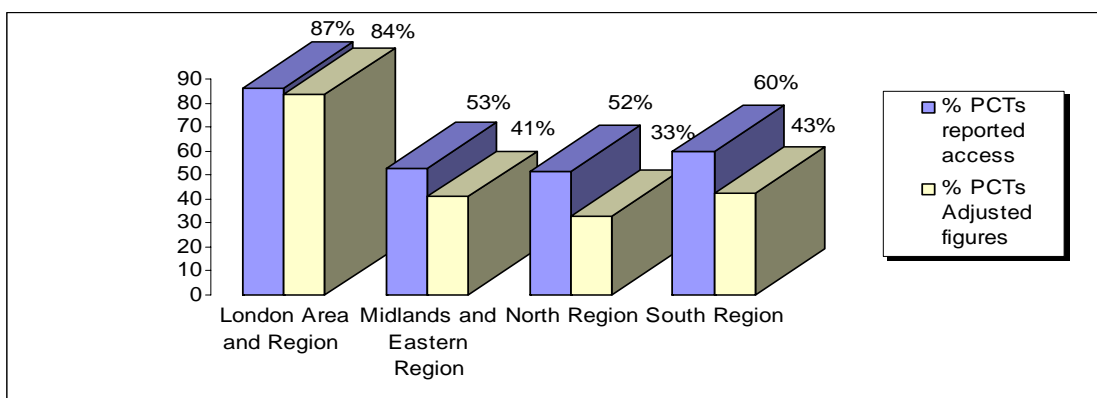
A total of 232¹⁷⁶ services were identified by PCTs and by following up contacts from previous surveys conducted by the University. 59% of PCTs had CAM services in their area which were being accessed via primary care. 9% reported CAM services that did not meet our inclusion criteria (NA)¹⁷⁷. Chart 1 shows the number of PCTs with services that met the inclusion criteria applied in this survey. [i.e. services that were free (or primarily free) at the point of access via primary care and if provided by a GP, were delivered in protected time, separately funded by the PCT.]

Chart 1: Initial England wide PCT survey – Regional primary care access to CAM



If the above figures are then adjusted to assume a 'worse case scenario', whereby all non-responding PCTs did not have CAM primary care accessed services within their locality, an estimated 43% of PCTs do. Chart 2 illustrates significant regional variations in CAM service provision. London had by far the biggest proportion of recorded services per number of PCTs (67 registered services across 31 PCTs.¹⁷⁸) Trent area had the lowest proportion of services per number of responding PCTs (eight services: 21 PCTs).

Chart 2: Adjusted 'worse case scenario' primary care access to CAM by region



¹⁷⁵ Methodology in **Appendix 2**

¹⁷⁶ N.B. Some services are accessed by more than one PCT

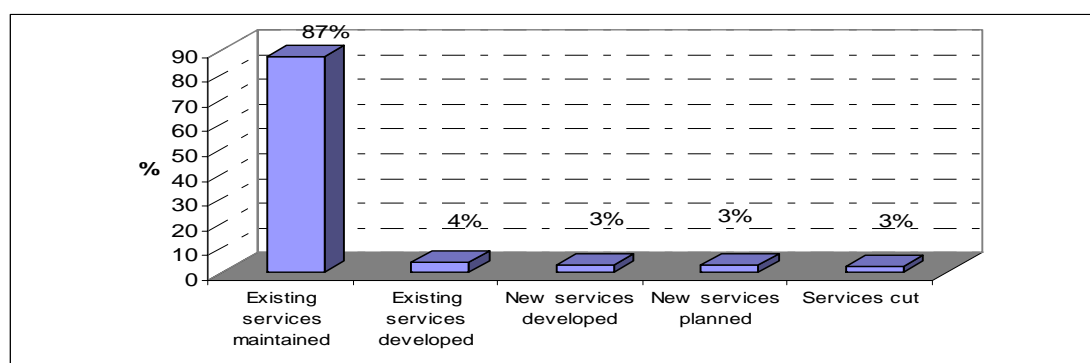
¹⁷⁷ These figures relate primarily to services that are either provided by GPs and nurses as part of routine treatment and primary care referrals to secondary care (hospital) services that may or may not provide CAM as an option, for example physiotherapists practicing CAM as part of their routine treatment.

¹⁷⁸ This figure is significantly increased by the number of individual contracts that PCTs have for primary care direct access to CAM treatments with the RLHH hospital, each SLA with individual PCTs were included as separate services. Given that there are a total of 26 PCT contracts in London region with the RLHH, one has been discontinued. 3 PCTs had services with another service thus the actual figure is - 40 separate services.

Section B: Research (4)

The 2003 survey asked PCTs whether services had been cut, continued or developed since April 2003. This along with the follow up survey of service providers indicate that the great majority of CAM services accessed via primary care have been continued or developed. A small number of new services are being planned or have been established.

Chart 3: Development of primary care accessed CAM services since April 2003

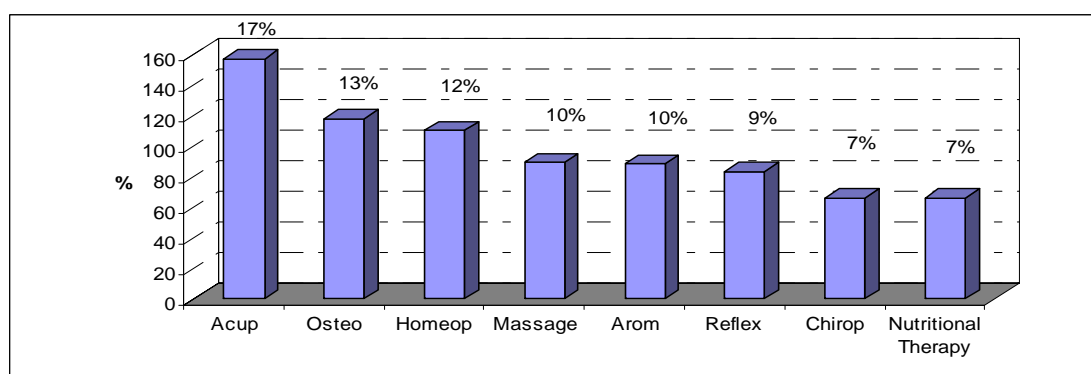


The great majority of services had been maintained or developed ($n = 226/232$) with only a small number of new ones established or being planned. London had the highest percentage of services being maintained 97% ($n = 65/67$). Northern and Yorkshire had the highest number of new and existing services that were being developed 38% ($n = 9/24$). CAM services were accessible to patients area-wide in 45% of PCTs. New and developing services were more likely to be available area wide (60%).

4.1.1 CAM deployment in the England-wide survey

By March 2004 100% of all identified services had been followed up by contacting service providers. The following information was collated from the initial follow up survey conducted between autumn 2003 to spring 2004. Acupuncture, osteopathy, homeopathy, therapeutic massage, chiropractic and nutritional therapy continue to be the main modalities. A further 16% of other therapies were listed; most frequently cranial osteopathy, herbal medicine and yoga. In 44% of services three or more CAM treatment modalities were offered. A higher percentage of multi-therapy services were in the South and London Regions.

Chart 4: Type of therapy for England-wide services

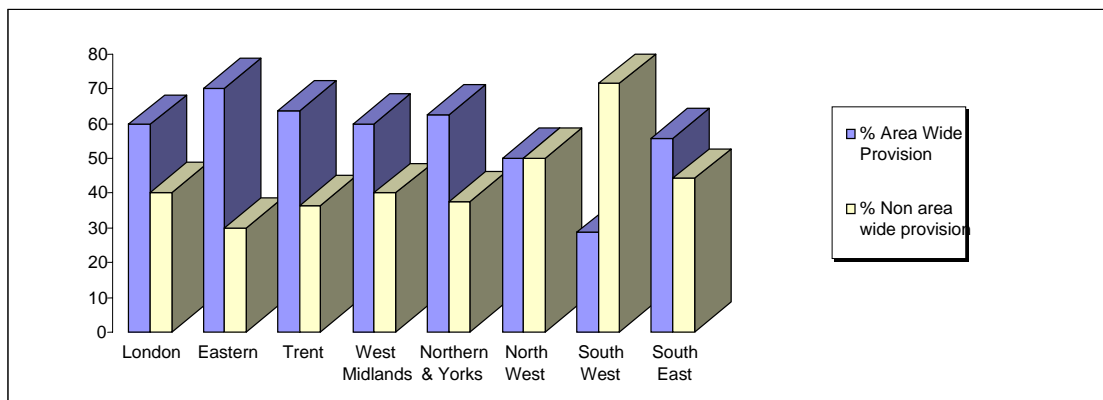


4.1.2 Referrals and equity of access

On average 57% of services are being delivered area-wide ($n = 132/232$). This means that 45% of PCTs with CAM services provide area-wide access to them ($n = 100/221$). Approximately 50% of the services being maintained have area-wide access, a percentage that increases to nearer 60% for new and developing services. Although some of the Eastern area services (e.g. Trent and West Midlands) have a rather higher percentage of PCT-wide services overall, these areas have relatively far fewer CAM services compared with other areas.

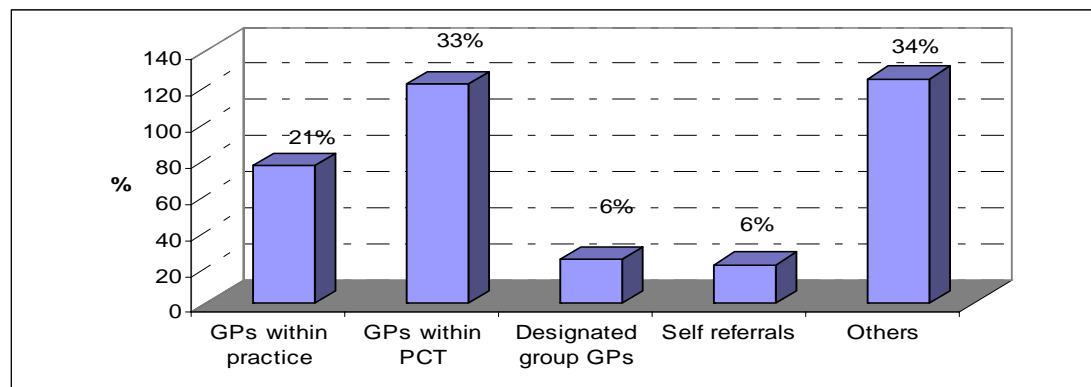
Section B: Research (4)

Chart 5: PCT wide access to CAM services



The majority of referrals to these services were made by GPs to services available area wide (33%). GPs also referred (21%) to services available within their local PCT area. 34% of services accepted referrals from other health professionals, most often from clinical teams (nurses and consultants) and community practitioners, e.g. MH Nurses, Midwives, and Health Visitors.

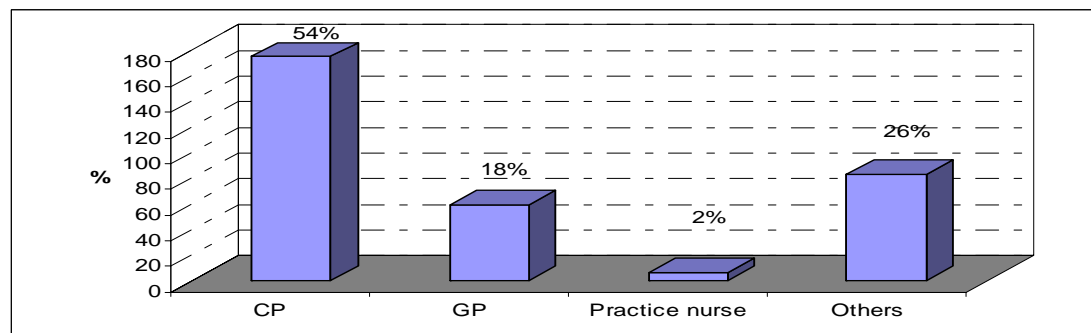
Chart 6: Referrals to services



4.1.3 Providers of CAM treatments: practitioners

CAM treatments identified in this study were more often provided by non-medical complementary practitioners (54%). In fact any services provided as part of 'normal professional practice' for instance by individual GPs as part of general medical services, or by practice nurses, health visitors are not included. Nor have we included services offered in the course of their mainstream work, by primary or secondary care practitioners - such as physiotherapists or practice nurses - unless these practitioners had been *primarily* employed to deliver CAM. It is therefore important to complement this report with the study by Thomas¹⁷⁹ (2003) that focuses on GP provision of CAM.

Chart 7: CAM practitioners



¹⁷⁹ Thomas KJ, Coleman P, Nicholl J. (2003) Trends in access to complementary or alternative medicines (CAMs) via primary care in England: 1995-2001. Results from a follow-up national survey. *Family Practice*; 575-577.

Section B: Research (4)

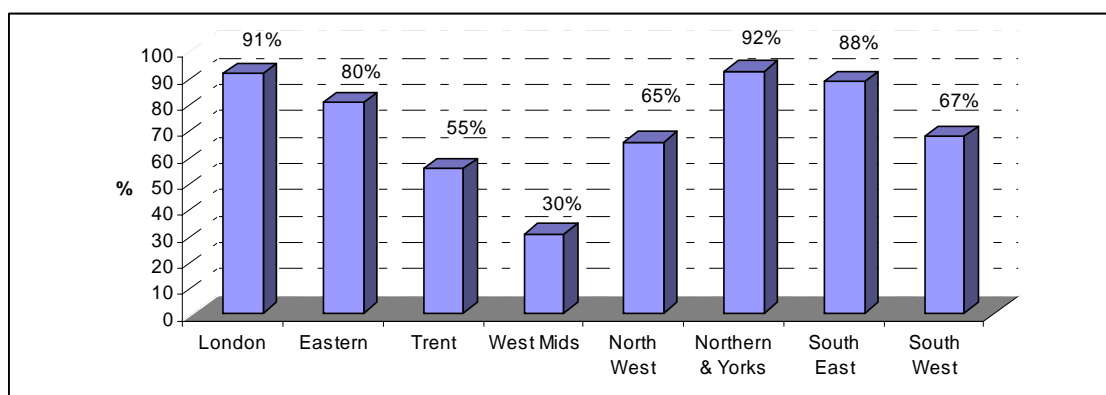
4.1.4 Location of service provision

The majority of services (48%) were provided from primary care settings and 28% at secondary care sites¹⁸⁰. Most other services were provided from a range of community-based settings, including local community hospitals, hospices, training colleges, premises owned by charitable organisations and practitioners' own private practice premises. 59 PCTs had contracts for primary care referrals to the Homeopathic Hospitals in London and Bristol.

4.1.5 Funding and payments for treatment

As in the previous survey of London-wide services, almost all London services received some form of PCT funding ($n=91\%$). In the England-wide survey this figure is 80%. 88% of the services were totally free at the point of delivery for patients. In most of the remaining services patients made small contributions, the highest patient contribution was 50% of the cost. Data from a sample of London-wide services reported in the following section, give some insight into costs. However, these details were the most difficult to obtain as it was in some cases hard to untangle direct costs.

Chart 8: Percentages of services with PCT funding



¹⁸⁰ These figures for secondary care providers are increased due to access to the total number of PCTs that have SLAs with the RLHH, which are counted as separate services. (please see **Appendices 2 and 3**)

Section B: Research (4)

4.2 Clinical governance in a sample of 16 London services

A purposive sample of 20 services from the London region (40% of all London services) was selected from the initial England wide mapping exercise¹⁸¹. 16 services completed the 'service detail' follow up questionnaire which asked for further information on the service and clinical governance activities. This phase, which took place between late 2003 and March 2004, aimed to gather more service details and to provide a 'snap-shot' of clinical governance practice in a range of services.

The sample's selection criteria were based on location (e.g. primary care general practice provision, secondary care, community setting), therapy provision (single and multiple treatment modalities), funding (PCT and non-PCT), and area-wide access (PCT wide or not). A breakdown of the sample is given in **Appendix 3**. Although the figures given reflect the whole sample, they may not be a generalisable reflection of what happens in other services. This comment applies particularly to the cost data¹⁸².

Services were mainly located in primary healthcare settings – 13 were based in GP surgeries or health centres, and had been in operation from between two and 150 years. Over half of the services had been running for eight or more years, one for five years, and the rest between two and four years ($n=6$). One service was a secondary care provider offering access to CAM treatments for patients referred by their GP. Another service was set within a Hospital Trust's separate premises and one provided treatments at the training college from which students were providing supervised treatments.

In the sample it appears that older services, established for eight years or more, were more likely to have stronger links with mainstream healthcare. This relationship varied from highly integrated multidisciplinary care to having joint administration (as was the case in two services). Shared premises were a common feature of the more fully integrated multidisciplinary providers.

4.2.1 Referral procedures, patient populations and monitoring data

All but one service from the sample had some form of referral procedure in place. The only exception to this was where a GP provider accepted direct patient self-referrals from the practice population. Two-thirds of the sample had developed criteria for referrals, and half had a system with referral letters or forms between practitioners. A quarter ran familiarisation courses for referrers, and feedback to the referrer was provided in 11 of the 16 services.

Apart from one service, a defined range of patient/conditions were targeted. Most often these related to National Service Frameworks (NSFs). One service included all current NSF targets. Back and neck pain was highest on the list, targeted by two-thirds of services. Chronic diseases were targeted by almost a half, while a quarter addressed anxiety or focused on children's services. All but two services collated basic data on age, gender and ethnic background. All services, with the exception of the service that only accepted self-referrals, collated data on the numbers of patients using the service. Two-thirds kept data on numbers of CAM sessions received by patients.

4.2.2 Funding

Details on funding were hardest to obtain as it was in some cases difficult to untangle direct from indirect income, thus data was only collated on 11 services. In this sample PCT funding reached the services by way of a range of initiatives including; enhanced services, PMS and waiting list initiatives, though none were part of a prescribing initiative. One service was still running on funds left over from the fund-holding period. The average level of funding for the 11 services on which we managed to get details is £50,820 pa. This figure excludes SLAs with the RLHH¹⁸³. Funding from PCTs for services ranged between £1,500 pa. to £230,300 pa. One service had established a charitable arm which allowed patient contributions to be made.

4.2.3 Clinical governance activities

11 of the 16 services provided annual reviews or evaluations; two others held regular review meetings; one regularly produced statistics that included GP and patient comments. Only two had no review processes - one a very limited service provided within a GMS contract, and the other collated very basic details on an overstretched single treatment service. The focus of this study was to capture the range of service (operational) level activities relating to the 7 pillars of governance that were being reviewed by CHI at the time. The focus was thus on technical aspects of CG.

¹⁸¹ A methodology for selecting samples that reflect key aspects of the whole study sample. Similar to 'maximum variation sampling'. See Patton M.Q. (1990) *Qualitative Evaluation and Research Methods*. London: Sage. Also see **Appendix 3**

¹⁸² Most services completed the survey in full. Some data was missing on funding as it was difficult for some service to extract exact figures.

¹⁸³ As SLAs vary widely and the average figures skew the data

Section B: Research (4)

In most services the *overall* responsibility for clinical governance rested with the providers themselves. Three services indicated that responsibility for CG was with the PCT. All provided one treatment option as part of a multidisciplinary package of care within a general practice setting and were funded by the PCT. Two offered their service area wide. For one PCT-wide and PCT funded service offering a multidisciplinary service, responsibility rested with the PCT steering group overseeing the service.

4.2.4 Patient, carer and service user involvement and experience

All of the services sampled provided some information for patients/service users. Three-quarters of the services provided information on the service and facilities available, description of treatments and medicines, self help information and therapists' qualifications.

Information available to patients/service users and carers	Number of services (n = 16)
Service/facilities available	13
Description of treatments/medicines	12
Self help information	12
Therapist qualifications	11
Waiting times	6
Staff disciplinary/grievance procedures	5
How well the service is doing	4

All services had some form of complaints process, ten services gained informed consent for treatment and two had developed customer care policies. Two services reported that patients, service users or carers did not have a say in treatment options – however in both these cases there was only one treatment option, so choice was limited. Three-quarters of the services have arrangements to meet cultural and disability needs (n=13) and almost a half of the services had facilities for children. Only one of the services (in a GP practice) had no specific arrangements to meet cultural, disability or children's needs, (though this applied to the general practice service as a whole).

4.2.5 Effectiveness and Evidence Based Practice (EBP)

Patient outcome measures were being used in eight services, with team discussions on EBP in seven, and application of EBP reported in six. Guidelines for referral were being implemented in seven services and of these, four were locally established guidelines. Integrated care pathways had been developed in just four services and only three had undertaken audit cycles. One of the more established services had developed Performance Indicators. The general practice services that provided single CAM treatment options were not conducting any activities related to developing effectiveness and implementing EBP for CAM interventions.

Staff providing CAM treatments at all 16 services had access to research and evidence of best practice via the internet. In 14 services staff had access to journals and in nine there was access to library facilities. Other types of access to research evidence and best practice reported included access via professional bodies and NHS databases (such as NeLH), as well as access via Universities and Colleges. Just over half of the services had completed some kind of research project (n = 9). Most projects were conducted in-house although a small number had collaborated with external organisations (universities and research centres) and had published data. Two of the well established services were very research active. Methodologies included; case studies, action research, and an international homeopathic prescribing data collection project, as well as clinical trials.

4.2.6 Audit and Clinical Audit

Thirteen services had undertaken some kind of clinical audit. Three of the sampled services did not conduct any - these were all general practice based services providing single CAM treatment options for the practice population. The types of audits conducted by the remaining services are shown in the table below.

Type of audit	Number of services (n = 16)
Waiting times	10
Patient audit (age, gender etc)	10
Demand on service e.g. no. of refs	9
Clinical Audit	7
Risk assessment audit	7

Section B: Research (4)

4.2.7 Risk Assessment and management activities

All services had some kind of risk management activity, on average six different kinds of risk management activity had been undertaken (see table below). Those services undertaking assessments and actions to prevent and control specific risks mainly focused on infection control ($n=10/16$) and workplace health and safety ($n=9/16$). Only one service had just one risk management strategy in place - adverse event reporting. Seven services had policies on violence and five services offering acupuncture had a policy for counting needles in and out.

Type of risk assessment and management activity	Number of services ($n = 16$)
Assessment, prevention and control of specific risks	13
Significant event audit	10
Protocols/guidelines	9
Adverse incidents and near miss reporting	8
Identified contraindications	8
Red flag criteria	6
Risk management strategy/policy	5
Whistle blowing policy	4
Trigger events	2

4.2.8 Use of information to support clinical governance and delivery

Eight services had hand written CAM patient notes and in six services notes were integrated with general practice hand written notes. Five services had computerised CAM notes and nine had integrated practice computerised notes. Two services did not permit CAM practitioners access to practice based information. In one service, provided for several practices, access to notes depended on the policy of individual practices. All CAM services were covered by the Data Protection Act and in 11 services the Caldicott recommendations had been implemented.

4.2.9 Continuing Professional Development (CPD)

In nine of the services, CAM practitioners were reported as being involved with CPD schemes (though CPs have to undertake CPD activities as part of their own individual registration and continued accreditation). GP CPD is linked to GP appraisal and postgraduate education needs. Eight services ran regular multidisciplinary case meetings for CAM staff. Ten services had peer support groups for practitioners and seven provided protected time and support for educational and CPD activities. Two Services had undertaken action learning cycles.

Training available to staff	Number of services ($n = 16$)
Confidentiality issues	12
Literature/Database and Internet searches	11
Critical appraisal	11
Obtaining patient/service user consent to treatment	9
Communication skills	9
Complaints handling	9
CPR	8
Research Methodologies	6
Audit Skills	6
Manual Handling	6
Risk prevention and management	6
Patient/service user (customer) care	6

4.2.10 Staffing and management

All of the services had employment policies and procedures in place for CAM staff. Some activities were not relevant to services provided by GPs as part of a dedicated service e.g. qualification checks as these are covered via either GMS or PMS contracts with the PCT for other primary care services.

Nine services provided clinical supervision or mentoring schemes; in eight, individual appraisals of therapists were linked to personal development plans. Twelve services held regular multidisciplinary team meetings and seven undertook team building exercises.

Section B: Research (4)

Staffing and management	Number of services (<i>n</i> = 16)
Workplace inductions	14
Qualification/accreditation checks	14
Code of ethics	11
CAM Staff contract	11
Equal opportunities	10
Registration checks	9
Race relations	8
Grievance procedures	8
Disciplinary procedures	8
Indemnity insurance checks	8
Staff feedback (surveys, via appraisal)	7
Minimum post qualification practice period	4
Annual Service Development Review	1

4.2.11 Service development and improvement

Half of the services reported that improvements had been made to the service as a result of; clinical audit (*n* = 10), adverse incidents (*n* = 8), risk management (*n* = 6), research (*n* = 8), and patient/service user complaints or comments (*n* = 3). All services were expected to continue into the next financial year, two were planning to open out their services for PCT area-wide access and almost half were due to expand (*n*=7/16). Some services commented on their wish to expand in response to demand, but said they were restricted by funding which was not set to increase¹⁸⁴.

4.2.12 Conclusions

The results of the follow-up study suggest that CAM services in the London region (being accessed directly via primary care) were already engaged in significant ways, with clinical governance. More established services are conducting substantial levels of CG activity across the seven key technical pillars that formed the original CHI framework for CG (at the operational level) - and apparently successfully - since they continue to survive within the new NHS framework.

It is impossible to say how much this sample typifies CAM primary care service provision in London or the rest of England. Although the figures given illustrate the type of activities undertaken by this sample of services, they cannot reflect the types and levels in all services. The sample was consistent with key characteristics of all services in the London region, but other factors particular to this sample, could influence the findings: for instance the number of years a services has been operating tends to be reflected in higher levels of CG activity, and over a half of the services sampled were eight or more years old, with six of them established for over ten years. Similarly, levels of funding, and organisational support as well as expertise and resources available for developing clinical governance are bound to have an effect.

¹⁸⁴ This was especially the case for a small number of GPs and Practice manager who still had funding from PCG/fundholding day. One service (not included in this sample) commented on providers' frustration at not being able to expand services further by using money saved through reduced GP prescribing costs, which they attributed to the effects of CAM interventions. Instead the savings had been incorporated into the main prescribing budget held by the PCT.

Section C: Recommendations (5)

5. Key recommendations

The following broad ranging recommendations result directly from the R&D work undertaken by the University and are also shaped by the feedback to the April 2004 consultation document.

1. Existing examples of established high quality CAM services provide various models that could be adopted, whether via PMS flexibilities, GMS enhanced services or independent service contracts (APMS). *'Guidelines for integrating CAM into Primary Care'*¹⁸⁵, would discuss the possible models and governance options and the processes required for collaboration. A toolkit which could be supported both online and through seminars, would prepare PCTs, GPs and CAM service providers for integration and CG.
2. Integration with mainstream NHS services has so far depended on PCTs taking the initiative. Future APMS initiatives for CAM service must demonstrate that they are 'fit-for-purpose', have an adequate CG strategy as well as meeting 'core' and 'developmental' standards.
3. Successful services will necessarily accord with NHS standards of professional regulation, be evidence based, encourage a team approach to working, and conform to Healthcare Commission review standards. An action-research/learning model can help focus service development. Also there is a potential to further explore current mainstream programmes for developing primary care services, such as the expansion of the RCGP's *Quality Team Development Scheme*, to incorporate CAM. This particular scheme was very much favoured throughout the consultation process.
4. Development of a *Quality and Outcomes Framework for CAM* would also help align services within the current system. This will require the development of standards in relation to competencies and skills, tools to enable a shared approach to commissioning which is reflective of the quality and safety surrounding the services to be provided for a defined population and evaluation procedures which are able to demonstrate that the investment has delivered its return in terms of patient experience and effect on the system.
5. A (business) case for commissioning CAM services will require an evidence base for effectiveness, costs and acceptability. Identified local service development targets are a likely priority - most particularly the potential for effective CAM interventions in chronic disease management and preventative healthcare/health promotion. *'Guidance for PCTs commissioning CAM'* would provide a framework for structuring the business case, including an evidence base, patients' and GPs' needs and attitudes as well as patterns of service use.
6. A local case for integration should take non-clinical as well as strategic clinical priorities into account. Well presented economic arguments would need to be pitched at an appropriate level. By thus marrying up supply and demand - particularly in the area of referral management, and by having agreed appropriate *Indicators of Effectiveness* – redesigned services could be piloted. *The role of CAM in whole system planning* should be explored where there are capacity problems which CAM addresses by reducing costly investigations and the need for medical time and intervention. A project is needed to pilot ways of including CAM in one or more of the modernisation programmes.
7. CAM professional bodies have an interest in the inclusion of CAM into NHS service re-design and governance and standards. These processes could open up NHS career pathways to properly qualified and regulated CAM practitioners. The CAM professional bodies could be invited into a consultation process to explore a) the implications of the new 'Standards for Better Health' including CG, b) how to develop an explicit relationship to PCTs' long-term strategies and c) and consider what CAM might feasibly deliver, particularly in relation to aspects of healthcare that PCTs are not providing as effectively as they would wish. This project would be best conducted by a small consortium of Universities with established interests in working with CAM practitioners. It would aim to produce a *step-wise programme for developing CG awareness and capacity*, as well as appropriate learning modules for undergraduate and postgraduate degrees.
8. University CAM courses are producing a growing number of educated well-trained practitioners, who might help fill the NHS shortfall in human resources while adding to patient choice and services' cost effectiveness. A *survey of practitioners*, in collaboration with accrediting organisations, would elucidate CAM practitioners' *expectations of working in the NHS and their capacity and willingness to do so*. *Exploring options for state funded placements for training 'NHS ready' professionals* (as with other professions allied to medicine) may help address capacity issues.

¹⁸⁵ NB italics indicate proposed projects

Section C: Recommendations (5)

9. CAM practitioners aiming to work within the NHS should understand how to develop accountable and acceptable CAM services. They must also know about the context of NHS primary care practice – possibly through post-qualifying courses – and understand the new PCT structures, policies, priorities and pressure points around service delivery and commissioning plans of the PCTs. The CAM professions could support this aim by introducing the concept of standards and CG into curricula and CPD. *A standard for CAM practitioners' knowledge about the NHS, standards and CG* could be developed and become a quality mark for practitioners' ability to develop clinical governance.
10. Educators – including University departments and accrediting bodies - should help the mainstream 'familiarise' with CAM and build bridges between disciplines. Knowledge of CAM should become a higher priority in more GP Personal Learning Plans and ways of achieving this aim should be piloted.
11. Developing guidelines in line with other professions will be crucial for future progress, and it is recommended that attention within the field (especially within primary care practice) is paid to the development of guidelines and standards of care. *A 'rapid guidelines development scheme'* perhaps mirroring the approach taken by NICE for creating guidelines for treatments on which there is a limited RCT type evidence base, would be appropriate for CAM. A project focusing on the *development of benchmarks, standards and performance indicators* could contribute to the standardisation and thus measurement of CAM interventions in primary care – working in collaboration with key Arm's Length Bodies (ALBs).
12. Further exploration of the economic evaluation of CAM is essential. This will require sustained resources for funded projects and researchers. As well as more direct health gain, CAM outcomes might include longer-term effects on individuals and their immediate families, and wider systemic benefits. CAM, as part of a health creation strategy might deliver long-term prevention of clinical sequelae and contribute to health promotion and self-management. However, although it may be ideal in the long-term to incorporate the wider, holistic benefits of CAM in the evaluation of services, this is not essential in the short-term. A focused expert consultation process involving health economists with an interest in CAM would advance this area and provide learning materials for dissemination through seminars and the web. *Developing practical advice for CAM service providers on collating and presenting appropriate cost and outcomes data* would be of benefit to service providers, commissioning PCTs and policy makers.
13. Enthusiasm amongst key health economists to *develop conventional approaches to cost effectiveness* could be harnessed to calculate the wider costs and benefits of CAM and conventional care. These are currently intuitively understood but not yet incorporated into mainstream economics.
14. Established CAM services are well positioned to provide data on costs and benefits and there could be a potential for large scale pragmatic studies based on representative CAM practice. *Pilot services with in-built (and costed-in) research and evaluation* may provide greater leverage for PCT uptake. Standardised data collection in audit and evaluation (including costs) could provide a greater body of consistent evidence on CAM primary care interventions in a way that allows comparisons to be made with conventional treatments. Clinical effectiveness research would be progressed by the *development of templates on IT systems for collecting patient information and data* which can evolve alongside NHS data collection systems
15. The CAM community could contribute much by encouraging their members to collate more data at practice level; for example through the *development, piloting and widespread use of generic audit tools relevant to CAM services*. Such tools might be endorsed by regulatory bodies, and practitioner-researcher activities should be accredited by professional bodies as relevant to CPD requirements.
16. It would help reduce duplication of effort and produce reports on evidence of effectiveness in a relatively short period of time if a practical framework was adopted to assess relatively easily the most accessible information (i.e. web based research). In the short to medium term *the BESTCAM reporting system* (which was piloted in the current project) needs to be *evaluated as a decision-making tool*. Academic support and guidelines on how to go about developing the reports would further support evidence based CAM practice.
17. CAM governance is not separate from mainstream NHS governance: the objectives and principles are identical in any other area of medicine and many of the specifics are similar. If CAM CG could link to local mainstream NHS CG arrangements, this sharing of resources would ease the burden of CG implementation. In addition, resources should be allocated to a *CAM support unit*, to further develop the established network of professionals and practitioners working to deliver integrated healthcare, as well as relevant toolkits and provide consultation on service development.

Ms Lina Bakhshi, Community Health Information Officer, Barnet Primary Care Trust
 Mr Ron Bishop, President, British Acupuncture Council
 Dr Matthew Brook, GP, Portland Group Practice
 Ms Stella Carmichael, HAZ Fellowship Researcher, HAZ
 Ms Helen Caton, Director, Consultant in Health and Social Care, Forton Bank Consulting
 Mr Cecil Chen, Ex-council Member & Education Committee Member, British Acupuncture Council
 Mr Mathew Cousins, President, British Osteopathic Association
 Dr Mike Cummings, Medical Director, British Medical Acupuncture Society
 Ms Ranjana Devi, Centre Manager and CM Adviser, Tameside Holistic Therapy Centre
 Professor Nancy Devlin, Professor of Health Economics, Dept of Economics, City University
 Mr Dennis Donnelly, Collaborative research project coordinator, Osteopath, Liverpool Centre for Health
 Dr Tony Downes, Member of the College Council RCGP (CAM), Royal College of General Practitioners
 Professor Gene Feder, Deputy Director, Dept. General Practice and Primary Care, University of London
 Ms Linda Gibson, Lecturer in Public Health, Public Health and Epidemiology
 Ms Dione Hills, Project Manager, Integrated Healthcare, Foundation for Integrated Health
 Dr Judith Howie, Senior Lecturer, Thames Valley University
 Mrs Christina King, Homoeopath and previously Clinical Governance Co-ordinator, Ashford PCT
 Ms Jenny Langworthy, Senior Research Fellow, IMRCI
 Professor George Lewith, Senior Research Fellow (visiting Prof. @ University of Westminster), The Centre for the Study of Complementary Medicine
 Mrs Eleanor Lines, Consultant (Freelance), Healthy Bristol
 Mr Michael Lingard, Professional Healthcare Practitioner (Osteopathy), St Bridget
 Mrs Sato Liu, Executive Director, The Natural Medicines Society
 Mrs Dorothea Magonet, Head of Training, Society of Teachers of the Alexander Technique
 Mrs Ruth McDonald, Research Fellow, NPCRD & Non Executive Director, South Liverpool PCT
 Mr Brian McGinnis, Special Adviser, MENCAP
 Ms Eve Martin, Network Operations Manager, Leukaemia CARE Society
 Dr Sue Morrison, GP, Marylebone Health Centre
 Ms Christine O'Connor, Director, Catch On (Consulting)
 Mr Michael O'Farrell, Chief Executive Officer, British Acupuncture Council
 Ms Josephine O'Gorman, Complementary Therapies Manager, Complementary Health Project, Walthamstow, Leyton and Leytonstone PCT
 Dr Karen Pilkington, Senior Research Fellow, School of Integrated Health, University of Westminster
 Ms Margot Pinder, Development Manager, Information & Delivery, Prince of Wales's Foundation for Integrated Health
 Professor Nick Read, Chair of Trustees, IBS Network
 Ms Iris Renwick, Staff Nurse E Grade, Daventry & South Northants PCT
 Dr Janet Richardson, Research Director, School of Integrated Health, University of Westminster
 Ms Emilie Roberts, Senior Policy Officer, Healthcare Commission
 Prof Nichola Robinson, Head of Centre for Complementary Therapies, Richard Wells Research Centre, Thames Valley University
 Ms Hazel Russo, Project Manager, Prince of Wales's Foundation for Integrated Health
 Mr Bob Sang, Director, Sang-Jacobssen Ltd
 Mr Greg Sharp, Osteopath, General Osteopathic Council
 Mrs Christine Stacey, Senior Lecturer, University of Greenwich
 Mrs Pauline Stuttard, Homeopath, Society of Homeopaths
 Mrs Cristal Sumner, Head of Education and Training, Faculty of Homeopathy
 Ms Sylvina Tate, Principal Lecturer, University of Westminster
 Mrs Nia Taylor, Chief Executive, Backcare
 Ms Kate Thomas, Deputy Director, MCRU, University of Sheffield
 Mr Mike Took, Policy Officer, Rethink
 Ms Sue Ward, Information & Education Manager, National Eczema Society
 Mr Robert Wenlock, Non-Executive Director, Lambeth PCT
 Mrs Lesley Wye, NHS CAM Pre-doctoral Fellow, Division of Primary Care, University of Bristol

The first mapping exercise of London-wide CAM services was undertaken by the University of Westminster in 2001/2002. The exercise entailed four phases of data collection: initial telephone contact with the PCTs, e-mail survey sent to all PCTs, follow up telephone and e-mail contact with PCTs, and an initial telephone survey of identified representatives of services. The methods used were subsequently modified for a 2003/4 review of CAM England-wide services.

Contacts for all PCTs were obtained via the King's Fund. A total of 301 PCTs were identified. These are organised by the NHS into four regions and eight areas. PCTs were initially contacted via telephone to establish key contacts and correct e-mail addresses, for gathering data on four basic facts. 1. Any CAM services being accessed via primary care 2. Service contact details 3. Development of services identified since April 2003 (i.e. continued, developed, new or planned) 4. Services availability for patients across the whole of the PCT.

The inclusion criteria for the search mirrored the list developed during the second phase of work conducted in 2002. Services included were those accessed via primary care, free (or in part) at the point of delivery. As the focus of this project is on the development of clinical governance for CAM, only dedicated CAM services were included. Examples of those services excluded are; where GPs or nurses were offering CAM as part of routine treatment; or for example secondary care referrals to services run by medically trained staff that may or may not incorporate CAM treatments as part of their care e.g. physiotherapists practicing acupuncture on some patients.

As in the previous survey in 2001-2, the task of mapping CAM services in England highlighted significant gaps in the information currently held by PCTs on their provision. The initial response rate by PCTs was again very poor and the high response rate finally achieved at the end of 2003 was due to intensive telephone and e-mail follow up. These difficulties were mainly due to: 1. The lack of information kept centrally by PCTs on CAM services available in their area. 2. Problems in identifying which PCT staff were responsible or would be aware of those services. The continual changes initially within PCGs/PCTs, and the resulting restructuring of staff roles meant contacts gathered in the earlier survey were rarely relevant subsequently. 3. The lack of PCT staff time available to offer information about key personnel and service details. Several PCTs refused information on the grounds that they were "too busy" – understandable given the enormity of the modernisation agenda. PCT responses are shown in the table below:

Region & Area	Number PCTs	Total have data on	% have data on	Y	N	NA	% PCT have CAM
London Area and Region	31	30	97%	26	4	0	87%
Midlands & Eastern Region	98	76	78%	40	27	9	53%
North Region	92	58	63%	30	23	5	52%
South Region	80	57	71%	34	18	5	60%
TOTAL	301	221	73%	130	72	19	59%

At the beginning of 2004¹⁸⁶ all identified services had been followed up with phone calls and questionnaires for service providers. More detailed information was gathered (via e-mail questionnaire and telephone follow up) on service details and clinical governance activities on a purposive selection of London-wide services. The key areas addressed in the follow up survey were service details (including management structures; types of integration; patient groups/conditions targeted by services; referral details; funding and future development of service) and clinical governance activities (including audit and clinical audit policies; clinical effectiveness and evidence based practice policies; risk management policies; staffing and management policies; education, training and CPD policies; use of information to support and deliver CG; patient, carer and service user involvement policies; service development).

The survey had two secondary aims: It was in part designed to inform service providers about the types of activities that will be expected of CAM providers working in NHS primary care. The survey also invited service providers to engage with the information produced by the project. This includes outputs from the seminar series and the Integrated Healthcare Network (IHN). The follow up questionnaire was based on the one originally used in 2002¹⁸⁷ but was substantially modified to take into account work published by CHI¹⁸⁸.

¹⁸⁶ These statistics result from the work conducted by Julie Donaldson, Sarina Singh, Juliet Formby, Lina Bakshi, Amanda Nadin and Jane Wilkinson

¹⁸⁷ Wilkinson J, Peters D. Clinical Governance for Complementary Therapies in Primary Care. Report to the King's Fund and Department of Health. Second Interim Report, October 2002 (www.ihn.org.uk and www.wmin.ac.uk/sih/cgcam)

¹⁸⁸ <http://www.chi.nhs.uk/> From the 31 March 2004 CHI became part of the new Healthcare Commission. www.healthcarecommission.org.uk

Purposive sample selected for the London region follow-up

The purposive sample was designed to capture a range of service types according to features identified in the initial survey of PCTs i.e. whether services were providing single or multiple treatment options, if they had PCT funding or not, whether they were delivering services to the whole of the population and the location from which the service was provided.

A total of 67 contracts for CAM services were identified in total. All SLAs with the RLHH were calculated as just one service to be incorporated into the sample for the London-wide follow-up as the sample would have created duplicate data that would likely skew the information collated. 26 PCTs (27 separately listed services) have SLAs with the Royal London Homeopathic Hospital. One service had been discontinued. Similarly one clinic which provides services to three PCTs was calculated as one service in the total sample. One service had been discontinued and thus this reduced the total number of services -from which the purposive sample was taken - to 40 ($n=68-27$).

Breakdown of 16 London services for sample (figures in brackets reflect all services $n=40$)**Single / multiple modalities**

Single:	10 (21)
Multiple:	6 (19)

PCT Funding

Funded:	14 (34)
Not funded:	2 (6)

PCT Wide

PCT wide:	5 (14)
Not PCT wide:	11 (26)

Where service is provided

Primary care setting (1c):	13 (32)
Secondary care (2c):	2 (4)
Other:	1 (2)

2 services from the whole survey were based in a community setting; unfortunately data had not been collated in time from one service that had been purposively selected for follow-up.

Case mix

Single treatment modality/ PCT Funded / PCT wide / 1c	2
Single treatment modality / PCT Funded / Not PCT wide/ 1c	5
Single treatment modality / PCT Funded / Not PCT wide/ other (training site)	1
Single treatment modality / No PCT Funding / Not PCT wide /1c:	2
Multiple treatment modality / PCT Funded / PCT wide / 1c:	1
Multiple treatment modality / PCT Funded / Not PCT wide / 1c:	3
Multiple treatment modality / PCT Funded / PCT wide / 2c:	2

Type of practitioner (figures in brackets reflect type of practitioners all services $n=40$ ¹⁸⁹)

GP	4 (9)
Complementary Therapist	12 (31)
Supervised students	2 (2)
Medically qualified hospital doctors	1 (1)
Nurses	1 (2)
Allied Health Professionals	1 (2)

¹⁸⁹ The total number exceeds 40 as some services have more than one type of provider

The King's Fund seminar series and consensus building process

A process aimed at building consensus on key operational (service) level aspects of clinical governance for CAM - prioritised by a range of stakeholders in 2002 - began with a series of six seminars held in 2003. The purpose of the seminars was to encourage learning about CG and the NHS modernisation agenda, and to explore the ideas and experience of a diverse interest group. The issues covered were prioritised in 2002 by a range of stakeholders and the seminars were designed to be in part non directive and responsive to the issues raised throughout the series.

In order to prioritise the issues raised during the initial seminar series held at the King's Fund in 2003, a second phase of consensus building was undertaken by participants with experience and expertise in specific areas relating to the seminar outputs. This process is designed to filter out the most important actions required to evolve CAM CG in a way that is relevant to current NHS primary care practice. The guidelines are based points that have been rated as very important and for which high consensus has been achieved. Other elements which were considered to be important or on which little consensus was achieved may be accessed via the IHN along with commentaries on the guidelines that were made during the research and consultation phases.

A good proportion of participants attended the whole series and evaluation of the seminars showed most participants had valued them for both content and the opportunity to network. Each seminar focused on a different topic: evaluating CAM in primary care; the costs and benefits of CAM; effective patient, carer and public involvement; recent NHS and primary care changes; PCTs, clinical governance and the role of CHI (Healthcare Commission); contracts, CPD and inter-professional working. The series reviewed fundamental clinical governance issues, learned how these issues applied to the delivery of NHS services, and identified issues that were particularly relevant to CAM. The presentations and discussions have been written up and can now be accessed on the IHN website.

Consensus building

Delphi Technique

A modified Delphi technique has been applied to the summarised feedback and has been circulated among stakeholders and academics with expertise in the relevant areas. The consensus building work is being continued through the web-based networking facility (the Integrated Health Network - www.ihn.org.uk) and via e-mail.

The Delphi technique has been widely applied in healthcare as a way of developing consensus between experts on issues relating to practice¹⁹⁰. The technique entails 'rounds' of opinion generation and consensus seeking. In this study, themes identified in the seminar series were used to generate a sequence of statements, which were incorporated into questionnaires so that opinions on their level of importance could be scored.

The 'first round Delphi sheets' on each topic area have been completed by e-mail, fax and post by relevant stakeholders including, research academics, health economists, voluntary organisations with specialist knowledge, CAM representative bodies. Results from this round were collated along with suggestions and comments and these were then fed back to participants for a second and final 'Delphi' round. Priorities from the Delphi process were drafted into provisional guidance to help practitioners and service providers develop appropriate clinical governance and were presented in the University's April 2004 consultation document.

¹⁹⁰ Jones J, Hunter D. (1996) Consensus methods for medical and health services research. *BMJ* 1996;311:376-80