Research Using Personal Data: Meeting Challenges and Seeking Solutions

VENUE: MELVIN HOUSE HOTEL, EDINBURGH

2 NOVEMBER 2006
Acknowledgements

We would like to thank The Chief Scientist Office, Information Services (ISD) and the Arts and Humanities Research Centre (AHRC) Edinburgh University for helping to plan and convene the meeting.

Thanks also to the speakers for providing thoughts and insights; and to Susan Hewitt, ISD for providing administrative support and organisation.
Programme:

09.30 – 10.00  Coffee and Registration

Setting the scene

10.00- 10.10  Welcome and Introductions  Peter Craig, Chief Scientist Office
10.10 –10.30  Current Challenges  Professor Cairns Smith
                University of Aberdeen
10.30 – 10.50  Data Protection Myths  Ms Sheila Logan,
                Information Commissioners Office
10.50 – 11.10  Database research – current practice  Dr R Muir
                Information Services Division
11.10 – 11.30  Coffee Break
11.30 to 11.50  Regulation in Practice: The Role of PAC  Professor G Laurie
                Privacy Advisory Committee
11.50- 12.10  MRC consent and confidentiality guidelines  Dr Sarah Dickson,
                Medical Research Council
12.10- 12.30  Using Health Information in Medical Research  Professor Graham Watt
                Academy of Medical Services
12.30- 13.30  Lunch

Discussion and feedback

13.30-to 14.15  Exploring current issues facing researchers  Chair - Peter Craig,
                Chief Scientist Office
14.15 – 14.45  Seeking solutions  Chair - Professor G Laurie
                Privacy Advisory Committee
14.45 –15.00  Closing remarks
The Aims of the meeting were to:

- Explore the needs of researchers
- Discuss some of the challenges they currently face in accessing and processing health information
- Assist in the production of guidance for researchers on the safe handling of personal information.
- Make links between Research governance and Information Governance
- Start seeking solutions to some of the problems being experienced

Setting the scene

Introductions, Peter Craig, Chief Scientist Office

Researchers using personal data are aware of a growing burden of regulation, which in many cases appears to be stricter than the law requires and which, in many cases seems uninformed by reality. An appropriate balance between risk and benefit is often not struck. Regulatory practice varies and is often inconsistent creating uncertainty about the application and practice of current law and professional standards. This increases the cost of research and is an important factor in inhibiting research developments.

Solutions are required. Much is already being done but we need a clearer understanding of the problems and how solutions may be applied. This was why the meeting was being held.

(link)

Current Challenges, Professor Cairns Smith, University of Aberdeen

A number of recent publications have highlighted the barriers to researchers created by governance structures that focus on data protection and personal privacy in a way that creates barriers to the conduct of research.

A survey of UK University departments of Epidemiology and Public Health carried out in April 2004 reported in September of that year. The survey questions sought evidence on whether research was being inhibited by data protection considerations. Respondents reported that problems were common and serious. Two major issues were the use of sampling frames and problems in carrying out record linkage. These, and other problems, resulted in significant inhibition of research projects, increased costs and poorer quality of research.

Common issues were: confusion; uncertainty; inconsistency and ignorance. Examples of specific areas of confusion included the use of honorary contracts; consent (for example the role of GP as proxy); the need for numerous submissions to different committees; resources consumed by the burden of administration; variable responses from committees that often appeared overcautious and the lack of any process for appeals.

Many agencies have a potential interest in this field: The General Medical Council, The British Medical Association, Medical Defence Unions, Departments of Health, The Medical Research Council, The Academy of Medical Sciences etc. Despite being a
problem experienced by many no individual or body alone seems capable of finding a solution.

The burden of governance appears to be getting worse (EU trials directive, GCP requirements for example) and more guidance is being issued regularly by different authorities causing confusion and uncertainty among researchers.

Solutions have to be found through education and training; better guidance; and one consistent source of advice if possible. Hopefully discussions at this conference would help point in the right direction since public health research in the public interest is being adversely affected.

Data Protection Myths, Ms Sheila Logan, Information Commissioners Office

The Data Protection Act 1998 does not define the term “research purposes” apart from clarifying that it includes statistical or historical purposes. (Those familiar with this field will recognise the difficulty in distinguishing between Research, Audit, Service evaluation etc). Section 33 of the DPA 1998 contains exemptions for research and is there to allow researchers to comply with the legislation. There is, in fact, very little ‘no’ in the 1998Act. Notably, data processing for research should be ‘compatible’ with the purpose for which the data were originally obtained; and research data may be kept indefinitely (this is not generally appreciated by researchers, despite its importance in view of the need to hold data in case re-analysis is required or research findings are challenged).

The data subjects should be aware that their personal information will be used for research purposes and this can be achieved by using processing information (they must know their data are being processed, by whom and for what purpose). Personal information used for research purposes are not to be processed to support measures or decisions with respect to particular individuals and in a way that substantial damage or substantial distress is, or may, be caused to an individual.

Researchers need to consider whether it is necessary to process personal data or whether “anonymisation” is possible. It is also important (although not always easy) to ascertain who is the data controller. Personal data should not be transferred out with the EEA without adequate safeguards to protect the data subject being in place. Some countries do have robust data protection and privacy legislation. Please contact the Information Commissioner’s Office if you have any questions regarding a transfer of a particular set of personal data outside the EEA.

Researchers should consider the Human Rights Act, article 8 and also the common law duty of confidentiality (lack of clarity about the public interest in carrying out research is a major source of confusion for data controllers).

The Information Commissioner cannot order disclosure of personal data for research purposes, only a court can do this.
We need to distinguish between the primary (clinical) and secondary (research epidemiology etc) uses of health data. The importance of secondary uses lies in its potential for unlocking the store of knowledge held in clinical and historical databases – the challenge is to find ways of doing it that do not compromise personal privacy. Although this conference focuses on research, all secondary users of health data face similar challenges.

Information systems are becoming more complex; demands for data are rising; tools and techniques for analysis are expanding, as are the possibilities of linking databases together. Crucially, this is expanding the numbers of people with potential access to the data.

The Confidentiality and Security Advisory Group for Scotland (CSAGS)\(^1\) reported in April 2002 on patient data processing in NHS Scotland. It drew attention to the public’s low awareness of the uses of health data and recommended a national awareness campaign to address this. It also advised the setting up of an independent body to advise on the public interest and that there should be a central ‘anonymisation service’ for national information flows. Implementation of its recommendations has been relatively slow. However, ISD has provided an anonymisation service for those requiring access to NHSScotland data for some years and is currently extending the scope and functionality of this service – which includes an advice service for researchers. Also it seems likely that a new national body to provide advice and oversight of patient privacy may be established shortly in Scotland.

A wide range of privacy safeguards has been developed in the NHS in Scotland. This includes: notification with the Information Commissioner, the establishment of Caldicott Guardians, Data Protection Officers and IT Security Officers. There has also been progress with staff training, new governance boards (e.g. for the NHS Central Register and for the Community Health Index - two large health-related databases; and the establishment of national standards for Information Governance to which all NHS Scotland bodies must comply.

ISD’s established a Privacy Advisory Committee fifteen years ago, which advises ISD (and The General register Office for Scotland (GROS) on the processing of personal data in national datasets. This committee has discussed a number of emerging problems in recent years e.g. whether we can improve on the current “consent on anonymise” approach; what criteria to apply when releasing potentially identifiable data; just where the “public interest” lies in relation to processing personal data and its attendant risks to privacy and how they should be judged and reconciled.

It is clear that there are many potential problems with consent as a concept and many cases where identifying data fields are needed for effective research. In practice data systems are complex and the law can difficult to interpret. Despite the existence of a lot of “guidance” there is still uncertainty, lack of consistency and an inhibiting effect on secondary data uses.

Secondary uses of data raises a wide range of ethical, legal, policy and social issues, all of which need addressed. For example, should data-base research that involves no contact with data subjects require ethical approval; what constitutes ‘acceptable’

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\(^1\) Confidentiality and Security Advisory Group for Scotland 2002
http://www.show.scot.nhs.uk/sehd/publications/ppcr/ppcr-00.htm
anonymisation'; should we use administrative or clinical databases as sampling frames for research?

A crucial legal issue in the UK is the nature of the “public interest”. The common law duty of confidentiality requires that confidential data can only be processed with the consent of the data subjects; or if there is a statutory requirement to process it; or if it is in the public interest. Lack of precedent means that there is no clarity about what tests can be applied to determine whether data processing is or is not in the public interest.

There is also lack of clear policy on a number of key issues e.g. whether patients should be able to “opt-out” of having their data processed (and if so in what circumstances); what “models” of consent should be applied to processing patient data; whether we provide adequate fair processing information to the public; what do the public think about secondary uses of health data and associated issues of trust.

The Lowrance report ‘Learning from Experience’ had suggested that there are three possible approaches when processing personal data for research: get consent; anonymise, or establish a “public interest mandate” for processing the data. (There is another possibility and that is a change in the law, although this will always be difficult in an environment where levels of trust in government are low). Perhaps exploring how such a “public interest mandate” could be established would be a useful route to pursue.

Some training is already available for researchers and links to that can be found on the full presentation.

Conclusions

“E-Health” is expanding the volume and potential of database research. Although systems for managing the information are evolving alongside with governance arrangements there is still confusion and new issues (technical, legal, ethical and social) have emerged that urgently require solutions. Solutions will need to come through: education (of researchers, the public and policy makers); engineering (building privacy into database systems); enforcement (clear standards and firm policing); and more research in the field.

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Regulation in Practice: The Role of Privacy Advisory Committee, Wendy Nganasurian – A lay member's perspective

Advising on the processing of personal health data should be easy – after all there are laws governing what you can and can’t do. However, in practice, there are many shades of grey.

People expect what they say to a health care professional to be kept confidential but they also expect their information to be shared appropriately and used effectively e.g. to ensure safety, counter fraud and improve performance in the health service.

Most people probably think very little about how their information is used to protect people or about how researchers might use their information to increase our knowledge of health related issues. Most people want to help. Information provided to the health service is a bit like giving blood – sharing a little can help a lot.
Both CSAGS and the NHSCR review recommended a public information campaign in recognition that the public understand little about how their health information is used or what the benefits of this are. We need an informed public debate about the value of health information. Some group capable of taking an oversight of how health information is used will be necessary to balance personal privacy against the need to benefit from the knowledge locked up in health information systems.

Both researchers and the public need more information about each other's perspective if they are to work productively together.

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**Rustam Al-Shahi Salman: The Researchers Perspective**

The work of The Privacy Advisory Committee and the evolving regulatory and technical environment are throwing up new questions for regulators. What e.g. is audit what research; should they be separated and if so how; when should researchers be allowed access to datasets that include personal data; can we improve on the “consent or anonymise” default that is current elsewhere?

Researchers have genuine needs to obtain access to data that are classed as personal for technical reasons and in many cases total anonymisation is impossible. It is not always possible to gain consent when carrying out database research because of e.g. the large numbers of data subjects; the capacity of some data subjects to understand and consent; the need to include vulnerable groups; the difficulty of contacting distressed relatives or those with whom contact might be unethical (e.g. people in remission from cancer). Contacting people to gain consent may be intrusive and upsetting.

For these and other reasons it is important that we have clear criteria to guide researchers and decision making processes that are transparent and as objective as possible. This is something towards which the Privacy Advisory Committee is working.

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**MRC Consent and Confidentiality Guidelines, Dr Sarah Dickson, Medical Research Council**

The Medical Research Council (MRC) Regulatory Support Centre is funded directly from MRC head office and based in Queens Medical Research Institute, Little France, Edinburgh. This ensures exposure to the needs of researchers and research managers and close contact with clinicians. The focus is on research involving people as participants; their tissue or data. The centre is a co-ordination centre for the UK CRC regulatory and governance advice service in conjunction with UK CRN in Leeds. The centre will be establishing an advisory group, including directors of MRC units, to help guide the strategic direction of the Regulatory Support Centre.

More information is available on the MRC regulatory support centre website.

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3 [www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/RegulatorySupportCentre/index.htm](http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/RegulatorySupportCentre/index.htm)
Currently this initiative has mainly an English focus and needs to develop a Scottish dimension. However, the website aims to provide practical web-based resources for researchers and is modelled on the clinical trials toolkit, previously developed for researchers. It provides guidance on anonymisation and on consent; on overcoming barriers to recruitment and balancing risks and benefits. It also provides a route map for researchers through the issues surrounding consent and confidentiality in researchers.

Using Health Information in Medical Research, Professor Graham Watt

The report of the Academy of Medical Sciences “Personal Data for Public Good: Using health Information in Medical Research” addresses in detail: types of research; the associated public benefit; the current legal and regulatory framework; the difficulties that “anonymisation” and “informed consent” impose on the conduct of research and its subsequent value; the need for demonstrable standards; and the importance of public engagement.

The report was produced by a working party set up in 2004 to enquire into the present position. A wide range of written and oral evidence was taken from researchers, patients, regulatory bodies and others concerned with aspects of health care including expert legal opinion.

The report draws attention to the importance of the NHS information systems as a source of knowledge for improved health and the exceptional value of research when effectively and responsibly carried out. Effective research may require the use of data without informed consent and may require access to personal data. Many regulatory agencies are currently involved in assessing research proposals and researchers encounter problems with conflicting opinions; lack of expertise; bureaucracy and defensive attitudes. However, it is lawful to use identifiable data for medical research without consent, provided such use is proportionate with respect to privacy and public interest benefits.

There will be a continued need for a body with statutory authority such as PIAG or PAC, but these need to modify their approaches. It will be essential to engage widespread public support and guarantees given to the public about their electronic health records and to recognise society’s legitimate requirements for secondary data use, including research.

Agreed frameworks for NHS data use are required that encompass consent for data storage, research, sampling frames, and participation in record linkage. Failure to improve on the current situation risks, amongst other things, adverse effects on marginalised and hard to reach groups.

Recruiting patients for studies is a crucial issue and policy decisions and public agreement are needed on whether “opt-in” or “opt-out” solutions are adopted. There are particular problems with opt-in models that may act against the public interest. More research is required on public attitudes to inform policy - research to date has often been too general and under-informed. Findings to date suggest that there is general support.

4 http://www.acmedsci.ac.uk/index.php?pid=48&prid=5

5 Patient Information Advisory Group http://www.advisorybodies.doh.gov.uk/piag/About.htm
but poor awareness of research and there is fear of unauthorised access to databanks by external agencies.

There is a need for more investment in public engagement, for more transparency and for better definitions of good practice. A body is needed to ensure good practice is followed. Potential data subjects need to be able to opt out of research and of being samples without detriment. More research is needed into public awareness; and public engagement programmes are needed if high quality database research is to continue

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Discussion and feedback

A number of recurrent issues had emerged from the morning’s presentations. These included:

Complexity - of IT systems and of regulations. Researchers and regulators often fail to understand them sufficiently. Also, IT developments, governance structures and user requirements often appear disconnected. It is the responsibility of those guiding “eHealth” to address this.

We are talking here about secondary uses of health data. Research is only one of a number of “Secondary Uses” currently experiencing difficulty. Similar problems affect the uses of health data for surveillance, planning and service. The importance of distinguishing between primary and secondary uses of data was emphasised. There are real issues about who needs to have access to health information for primary (clinical) purposes – and this will take time and technology to resolve. The debate is clouded by suspicions linked to identity cards and identity theft – this should not be allowed to prevent sensible steps being taken to address current difficulties in access to data for secondary uses

Confusion and uncertainty are common and a lack of consistency in decisions about the limits of data protection and confidentiality guidance in practice is the rule rather than the exception – amongst both researchers and regulators.

Perceived bureaucracy, and a growing burden of regulation is inhibiting research and innovation in the use of health data. This threatens to deprive us of the valuable information locked up in health data sets. Researchers want things made simpler and clearer.

Lack of awareness – amongst the public of the uses of their data persists – five years after CSAGS recommended an information campaign to address this problem.

The framework of safeguards that has grown up (in a rather ad hoc way) and is already in place is also poorly understood – by researchers and policy makers. Most researchers know little about the current routes through the regulatory process and have little understanding of the real nature of the data protection act.

Multiple committees exist and are often seen as taking defensive attitudes and of being over cautious in their approaches by data users.

The public interest is an important concept in data use but there is no guidance as to what constitutes an acceptable test that could be applied in practice. It has been suggested that we try to establish a “public interest mandate” – how might this be done – who could take the lead?

Anonymisation and identifiability. There are no accepted standards and it is not clear how data users should assess risk (although software packages now exist that do this).
How might we simplify regulation and reduce the sources of advice and decision taking? The SE has plans to establish an Information Governance Board and this is a route being taken in England – the proposed remit of this committee should be examined to see if it is likely to be useful in reducing some of the barriers to research. In England there is an intention if necessary to enact legislation to allow the committee to function (Section 60 of the health and Social Care Bill was always intended to be a temporary measure).

Change in the law seems a possibility in England but this does not appear to have been discussed at an official level in Scotland. It would potentially be contentious. This needs to be explored with policy makers.

CSAGS also advised that there should be a “central anonymisation agency” for national datasets. ISD has provided this service until now and has plans to expand its scope and remit – partly because of rising demand for data and partly because of IT driven developments. One important effect of the latter is that data sets are increasingly being joined up – so that e.g. current governance arrangements (both ethical and privacy led) for record linkage are becoming less useful and appropriate. The governance arrangements for this service need to be more transparent.

The current Privacy Advisory Committee will be a key source of advice in setting this up. The research community also needs to be involved – as does the public. This work needs to align with and draw on similar work in England (e.g. because many studies are UK wide)

Solutions

It was proposed that solutions could be sought under the headings of education; engineering; enforcement and research. The meeting had heard about a number of new developments in education and there are already good examples of education and training (need to summarise these and make them available) but more needs done – responsibility for this should be clarified. This could be taken forward by a combination of the MRC and the CSO but would need to be funded. The interface between “research governance” and “information governance” and who should take on the role of ensuring they are co-ordinated also needs to be explored.

There is still a strong feeling that the public information campaign recommended by CSAGS has not been pursued. Many secondary users of health data feel that this has left us exposed and this recommendation needed revisited by the Scottish Executive.

Existing Education resources are not well known to researchers and this should be remedied [action] and better training geared to the needs of researchers should be developed. There is some prospect of this and this should be explored with the Information Governance team at ISD.

The role and makeup of Research Ethics Committees should be reviewed with a view to assessing their ability to adequately address issues of privacy in research involving the use of personal data [action]. The results of the recent review of research ethics should be checked for this.

Whose role is it to enforcement good standards? It is a task that requires resources but without it can the public ever be reassured that standards, where they exist, are being adhered to? Even the Patient Information Advisory Group (PIAG) in England has insufficient funding to follow up all studies and police whether its recommendations are being followed. This needs considered when the National Health Information Governance Board is established in Scotland.
National standards for Statistical Disclosure Control are needed. This is a responsibility of the Chief Statistician. Action is being taken on this at present following the publication of national guidance by the Office of National Statistics (ONS) and this needs to be publicised to researchers.

The Secondary Uses Service provided by ISD is undergoing changes in its national approach to acquiring, storing and providing access to health information. Governance arrangements for this service need to be clear and understood by all with an interest in this area. ISD should review these arrangements. This will be an opportunity to inform and to consult and to improve transparency about who is doing what with patient data and to what standards.

**Concluding remarks (Dr Muir)**

It was agreed that a summary of the meeting would be prepared and circulated to those who had presented and attended for comments and corrections. It was intended that some positive proposals could be drawn from the proceedings and disseminated to those in a position to do something about them. The report on the meeting would be the basis of a working paper to be taken forward at a follow up meeting in 2007.

**Possible actions emerging from the discussions**

In both England and Scotland there are plans to introduce a National Health Information Governance Board, whose role and remit needs to be formulated that may well take these issues into consideration. The role of this body in regulating research uses of health data should be clarified and the possibility of a statutory basis for this in Scotland should be investigated.

[Scottish Executive]

The lack of public information on the uses of health data for research and the ways in which privacy is safeguarded should be addressed

[Scottish Executive]

Publicise what privacy training is currently available for researchers and explore potential for better training geared to needs of researchers; investigate how to provide incentives for researchers to train; explore the interface between research governance and information governance; provide the research community with information on the ‘research passport’ and explore whether this addresses privacy issues

[CSO and ISD]

Develop a Scottish version of MRC guidance

[MRC; CSO and ISD]

Sponsor research into public awareness and attitudes to health data uses

[CSO]

Make current guidance on anonymisation available to researchers

[Chief statistician]
APPENDIX 1

BIOGRAPHICAL DETAILS

Dr. Rustam Al-Shahi

Currently specialist registrar in neurology in Edinburgh, taking up a Medical Research Council clinician scientist post at the University of Edinburgh 2005-2010, during which time he will become an honorary consultant neurologist and continue his work on the population-based clinical epidemiology of vascular malformations of the brain.

Dr Peter Craig

Peter Craig is responsible for research on public health (and until recently, mental health) at the Chief Scientist Office, Scottish Executive Health Department. He is also the programme manager for the Medical Research Council Population Health Sciences Research Network. Before coming to Scotland he managed research on disability and incapacity benefits at the Department of Social Security in Whitehall. He is a fellow of the School of Community Health Sciences at the University of Edinburgh where he teaches on the MSc in Public Health Research.

Dr Sarah Dickson

Sarah graduated from University of Lancaster in 1996 with BSc (Hons) in Biological Sciences, and was awarded an MSc with Distinction in Reproductive Biology from the University of Edinburgh in 1997. She continued her research in human reproduction at Edinburgh, where she obtained a PhD (ovarian angiogenesis) in 2001. She then held the post of Clinical Studies Manager at the MRC Human Reproductive Sciences Unit.

In 2004, Sarah became MRC's Research Governance Co-ordinator, where she project managed the development of the MRC/DH Clinical Trials Tool Kit to assist researchers with the requirements of the EU Clinical Trials Directive. She has since set up, and Heads, the MRC Regulatory Support Centre, to continue to provide practical help to the academic research community with evolving legislative and good practice requirements.

Dr Graeme Laurie

Graeme Laurie is Professor of Medical Jurisprudence at the University of Edinburgh and co-director of the Arts and Humanities Research Council (AHRC) Research Centre for Studies in Intellectual Property and Technology Law. His research interests include the role of law in promoting and regulating science, medicine and technology. He is currently the Chair of the Privacy Advisory Committee for Scotland, and sits on other bodies such as the Scottish Executive's Generation Scotland Advisory Board and the NHS Central Register Governance Board.
Dr Rod Muir

Dr Muir trained in Edinburgh and graduated in 1972. He worked as a general practitioner and in anaesthetics before leaving clinical practice in 1990 to train in Public Health.

His is currently a Consultant in Public Health with the Information Services Division (ISD) of National Services Scotland (formerly CSA) providing advice on the analysis and exploitation of national data. As Caldicott Guardian for ISD he is responsible for ensuring that this data is held and used according to high standards of Confidentiality and Security whilst, at the same time, being made available for clinical care, public health and research.

Mrs. Wendy Nganasurian

Lay Member of the Scottish Medicines Consortium and Chair of its Patient and Public Involvement Group; Chair of the Highland Formulary Sub-Group; Trustee of Asthma UK; Lay Member of the Scottish Intercollegiate Guidelines Network and Chair of the Health Informatics Centre Confidentiality and Privacy Advisory Committee.

Professor W Cairns S Smith OBE

Professor of Public Health
Head of Department of Public Health,
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School of Medicine,
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Deputy Head of School of Medicine
Honorary Consultant in Public Health, NHS Grampian
Convenor of the Scottish Affair Committee of the Faculty of Public Health
Convenor of the UK Heads of Academic Departments of Public Health

Professor Graham CM Watt,

Professor Watt graduated at Aberdeen University in 1976 and, in a varied career, trained in general practice at Glyncorrwg in South Wales (where he worked with Dr Julian Tudor Hart), Ladywell Medical Centre in Edinburgh and Townhead Health Centre in Glasgow. He is accredited jointly in general practice and public health.

He has longstanding research interests in the epidemiology of health and disease in families (currently chairing the MIDSPAN Study Steering Committee), inequalities in health and health care and the development of academic capacity in primary care.

Elected as a Fellow of the Academy of Medical Sciences In 2000; co-opted as member of Council 2005. Member of the Academy Working Group which produced the report Personal Data for Public Good : using health Information In medical research. Now represents the Academy on the DOH Care Record Development Board Secondary Uses Group.