BLUE SKY RESEARCH FOR PRIMARY CARE

Is there a category of 'basic research' for primary care, which would parallel the basic translational experimental research programme currently funded by the MRC and which would underpin the development of more applied work?

This paper is based on answers to this question by senior UK principal investigators and heads of university departments of general practice and primary care. The paper has two objectives:

1. To establish identity, recognition and support for basic research, underpinning generalist clinical practice in the NHS.

2. To stimulate discussion about whether research funding agencies could be more supportive of such research, including support for future principal investigators in this area.

The paper has been prepared on behalf of the UK Society of Academic Primary Care and the UK Heads of Departments Group, drawing on comments and suggestions from many colleagues, especially Ann-Louise Kinmonth, and Peter Croft, Danielle van der Windt and George Peat, Chris Dowrick, George Freeman, Roger Jones, Helen Lester, Paul Little, Stewart Mercer, Irwin Nazareth, Sarah Purdy, Joanne Reeve, Martin Roland, Debbie Sharp, Frank Sullivan and Brian Willis. Graham Watt is responsible for the final version.

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Background

We define 'basic research for primary care' as research which increases conceptual understanding of the content, processes, organisation and outcomes of primary care. Its purpose is to inform the design and development of new approaches to clinical practice, health service organisation and health policy, through developments in research methods, theory, modelling and exploratory studies.

The MRC Topic Review in 1997 set out a trajectory for General Practice research in the late 20th century. It was followed by MRC investment of over £10 million, mainly in clinical trials with a substantial development component and with significant outputs in the areas of acute illness and chronic disease

Subsequently, general practitioners contributed to serial versions of the MRC guidelines for the development of complex interventions for trial evaluation. The MRC also paid for a peer learning group of young academic GPs to take such work forward within an MRC cooperative grant.

Campbell M Fitzpatrick R Haines A Kinmonth AL Sandercock P Spiegelhalter D Tyrer P. ***Framework for design and evaluation of complex interventions to improve health.*** *BMJ 2000; 321:694-696*

Campbell NC, Murray E Darbyshire J Emery J Farmer A Griffiths F Guthrie B Lester H Wilson P Kinmonth AL. ***Designing and evaluating complex interventions to improve health care****. BMJ 2007;334:445-459*

Craig P Dieppe P Macintyre S Michie S Nazareth I Petticrew M ***Developing and evaluating complex interventions: the new Medical Research Council guidance****. BMJ 2008;337:a1655*

Application of the guidelines led to greater use of the full range of research methods in primary care, avoiding the 'rush to randomise' and increasing understanding of the mechanisms of interventions and the use of new techniques for intervention delivery and fidelity assessment. A more flexible view of outcomes, spanning the disease, the patient, the community and costs, helped to highlight the need to define and measure harm, especially in primary care where illnesses may be less severe but side effects, although rare, can kill.

Woolf SH Kuzel AJ Dovey SM Philips RL. ***A string of mistakes: the importance of cascade analysis in describing, counting and preventing medical errors****. Annals of Family Medicine 2004;2:317-326*

Other pioneering researchers have shown what is possible, often developing new methods in the process.

Hardeman W Michie S Fanshawe T Prevost AT Mcloughlin K Kinmonth AL. ***Fidelity of delivery of a physical activity intervention: Predictors and consequences.*** *Psychological Health 2008;23:11-24*

Farmer AJ Wade A French D Simon J Yudkin P Gray A Craven A Goyder L Holman RR Mant D Kinmonth AL Neil HAW. ***Blood glucose self-monitoring in type 2 diabetes: a randomised controlled trial.*** *Health Technology Assessment. 2009;13:1-72*

Moher D Schulz KF Altman DG. ***The CONSORT statement: revised recommendations for improving the quality of reports of parallel group randomised trials.*** *BMC Medical research Methodology 2001;1:2 doi:10.1186/1471-2288-1-2*

This stream of work is consistent with the recent MRC translational research programme (2008). However, the new programme is defined in terms of support for

preclinical development of novel therapies, interventions and diagnostics, and any necessary research tools for development of therapeutics … and development of exploratory clinical research as far as phase I and II trials.

There is no recognition in the statement of the work which the MRC supported on the development of complex behavioural interventions. With the division of funding responsibilities between the MRC and UKCRN, the move to define and promote basic research in General Practice seems to have stalled. There have been important reviews of General Practice Research by the Academy of Medical Sciences, with a focus on more applied 'translational' research in general practice, and of the UKCRN primary care portfolio, but neither of these reviews appears reflected in recent actions by the MRC.

*Academy of Medical Sciences.****Research in general practice: bringing innovation into patient care. Workshop report.*** *Academy of Medical Sciences, October 2009*

Sullivan F Hinds A Wallace P. ***UK Primary Care Research Portfolio Review. Final Report*** *2009. http://www.sspc.ac.uk/sspc_docs.htm*

There is perhaps a view that primary care research should be funded by NIHR, but while the NIHR primary care portfolio has been strong in informing practice, it has been less strong in informing innovative thought.

The most recent MRC Pipeline publication (2010) refers to

"our mission of improving the health and wealth of the UK by supporting our world class researchers at an early stage in the process, helping them to identify opportunities for turning scientific knowledge into new treatments or diagnostics'.

The focus appears to be on medicines and trials of medicines and devices. Potential GP applicants to MRC research training schemes report being daunted by advice that their proposed topics of research are unsuitable.

The aim of this paper, therefore, is to stimulate a review by both MRC and NIHR of the content and balance of their current primary care research portfolios.

The paper also briefly addresses clinical research career opportunities for future general practitioner principal investigators wishing to carry out such research

Context

There have been recent large increases in the quality and volume of primary care research in the UK, as shown by serial results in University Research Assessment Exercises (RAE) and also international comparisons.

Glanville J, Kendrick A, McNally R, Campbell J, Hobbs FDR. ***Research output on primary care in Australia, Canada, Germany, the Netherlands, the United Kingdom, and the United States: bibliometric analysis.*** *BMJ. 2011; 342: d1028.*

These comprise a wide range of types of research, each of which has its own particular value. It is hard to say that one type of research has been more valuable than another.

A consistent comment by principal investigators in primary care is that the dominant "vertical" research paradigm, of disease-specific enquiries, eliciting biomedical mechanisms and evaluating treatments using randomised controlled trials, as evident both in the MRC research strategy and its current research portfolio, can be difficult to apply to many of the problems encountered in primary care.

A particular example is the narrow recruitment criteria for many clinical trials, enabling internal validity at the expense of external generalisation. The highly conditional nature of most such research contrasts with the largely unconditional nature of generalist clinical practice. Patients who are hard to recruit to research studies, or who are excluded on grounds of multiple morbidity or social complexity, account for a substantial proportion of NHS workload and resource use.

To improve this position, epidemiological method must be linked to new approaches to characterisation of patients in trials. Complementary use of cohort studies, anthropological and sociological enquiry and randomisation are required. Pragmatism and good conscience have served generalists and the NHS well, but increasingly this needs to be complemented by evidence-based policy and practice.

An important 'horizontal' task of primary care, and the key role of general practitioners, is to integrate 'vertical science' (i.e. disease specific approaches) in the context of consultations, clinical services and local communities. The Quality and Outcomes Framework (QOF) and most NICE guidelines exemplify

the vertical approach. However, while the mass delivery of evidence-based medicine is important for improving population health, it can have the effect of compartmentalising and fragmenting the care and services that patients receive. Many patients have more than one condition and need an integrated approach.

Interdisciplinary work is needed both to characterise the ways in which different conditions and their treatments interact physiologically and to understand the effects of social and mental context on an individual's coping response to multiple health challenges. A broader range of outcomes needs to be considered that relates to these domains and not simply to disease progression. The system itself must be studied, as exemplified by the new methods developed in primary care for the characterisation of medical errors.

An analogy may be drawn with psychiatric research, which in the 1950s was poorly developed, and thought by some to be 'unresearchable'. Within a couple of decades, psychiatric research was transformed. The challenge in primary care is to build on the work of Starfield, Howie, Freeman and others, whose research on consultations, systems, continuity and multiple morbidity has shown the way.

Several colleagues highlight the lack of attention paid to combining clinical, psychological and social variables in diagnosis, prognosis and treatment in primary care. On the one hand, better explanatory evidence is needed on delays in the presentation and recognition of serious conditions. On the other, better evidence is needed to inform the care of substantial numbers of patients with 'medically undefined problems'.

The MRC states that it will "pick research that delivers" and move towards setting research priorities which are most likely to deliver improved health outcomes. The challenge for researchers wishing to work in these areas is to communicate more effectively not only the distinctive research needs of general practice and primary care, but also why such research is important, not only to individual patients but also in improving population health.

Unlike public health policies not involving contact with the public, or involving single contacts for screening or specific procedures such as immunisation, the contribution of primary care to improving population health is largely based on the sum of serial contacts with individual patients, whereby cumulative contact provides both the coverage and continuity needed for the mass delivery of evidence-based medicine, preventive advice and personalised care. The heterogeneity and long term nature of such activity is a substantial research challenge, and seems to fall outside what is generally understood by "population research".

The nature of generalist clinical practice

Key elements of generalist clinical practice include

- The unconditional nature of most clinical encounters, responding to whatever problems patients present.

- Many conditions are seen at an early stage, when the probabilities are very different from those encountered in specialist settings, and early management decisions are taken in situations of greater uncertainty, presenting research challenges with respect to making early diagnoses.

- Multiple morbidity is common, both in elderly populations and in socio-economically deprived populations, and is not well served by research studies in which multiple morbidity is an exclusion criterion. Multiple morbidity presents a huge new research agenda.

- About 70% of patients consult every year and about 90% over three years, which provides a large measure of sustainable population contact, without recourse to special measures, such as screening or outreach, except for hard to reach groups.

- The contribution of general practice to population health improvement is not only via the mass delivery of evidence-based medicine (as incentivised by the QOF and encouraged by NICE) but also via the sum of long term productive relationships with individual patients, whatever their problems are. The heterogeneity of such activity, its incorporation within routine daily practice and its engagement via case-finding with "hard to reach" patients are all challenges for research.

- Such individual outcomes are generally achieved over the long term via serial encounters, rather than via single transformative encounters. "Co-production" is a very different model from "providers and consumers" and needs its own evidence base.

- The contact, coverage and continuity that are intrinsic to general practice provide important opportunities to prevent, delay or reduce the severity of health problems and their complications. Such opportunities for prevention are very different in nature from the "cold calling" approach of screening.

- Consultations on their own are frequently insufficient to address a patient's problems, but provide opportunities to instigate referral to other professions and services, raising issues of continuity, coordination, communication and joint working within the community or across primary and secondary care.

- With intrinsic features of contact, coverage, continuity, flexibility, long term relationships and trust, general practices are the natural hubs around which local health systems can be developed, co-ordinating care and avoiding fragmentation. General practice does not have a monopoly of these features of care, but is the principal source of such care for most patients. Better evidence is needed on how fragmentation of care is best avoided.

- Each general practice is a complicated micro-economy in which the mix of activity reflects a wide range of factors, including needs, demands, incentives, obligations, habits, aspirations and values, within constraints of time, space, staff and links to other services. Studies of the economic impact of additional activities in primary care seldom take account of opportunity costs within this wider framework. Rather, primary care often appears to be considered as a sink, into which additional activity can be poured.

Research agenda

There is general agreement among senior GP researchers that there is a gap to fill, involving basic research on behaviour, consultations and systems, prior to the development of the types of applied study which are usually supported by NIHR. Areas for research enquiry include (examples in Annex A):-

- What can basic sciences (e.g. psychology, social sciences, economics) contribute towards our understanding of individual responses to illness (including resilience, creative capacity, self-agency etc)?
- How does biographical understanding of patients help the management of illness experience?
- What is the impact of multiple morbidity on an individual's quality of life, and how can this be improved?
- Does better "relationship continuity" accelerate or delay the diagnosis of serious conditions?
- Why do some patients become 'chronic patients', and heavy users of services, while others with the same diagnosis do not?

- What clinical symptoms and signs in primary care predict the development and allow earlier diagnosis of serious illness?

- What methods of practitioner/patient communication make best use of serial consultations in primary care, especially for patients with multiple morbidity?
- What are the essential ingredients of integrated (i.e. 'non-fragmented') care (including shared care between specialists and generalists)?

- What systems of care promote personal continuity of care?
- Does continuity of care prevent unplanned admissions?
- What is the epidemiology of unscheduled care e.g. emergency admissions, use of out of hours services, walk-in centres?
- What are the barriers to better joint working between primary and secondary care, with respect to referral, emergency admission, hospital discharge and the management of long term conditions?

- What are the 'active ingredients' of primary care that result in strong primary care systems delivering better outcomes at lower cost?
- What has been the effect of the UK moving to larger primary care teams, with internal specialisation by GPs and changing professional skill-mix and roles?
- What has been the effect of incentivising managed/directed care via QOF and NICE guidelines and the parallel lack of investment in other areas of generalist clinical practice?
- How do we best identify and address variation in GP care?

- How do we improve care for hard to reach groups?
- What are the benefits and costs of helping patients with poor English, and/or who are immigrants unfamiliar with the NHS, to consult with the same clinician for most consultations?
- What are the opportunity costs of adding new activities and services to primary care?

Research development

Work is needed to establish new research methods that are fit for purpose for primary care research

- Early development work leading to the creation of complex interventions (e.g. identifying/developing theory and modelling processes and outcomes) prior to feasibility and pilot testing (which is the role of NIHR).
- Development of new measurement tools (e.g. the CARE measure of patient assessment of practitioner empathy) to capture the 'active ingredients' of effective clinical care.
- Desk-based epidemiology, to capitalise on the increasing availability of large clinical primary care datasets and to set exploratory and intervention studies in context (what part of the overall picture is being studied?)
- Making best use of case-note review to describe the reality of 'continuity' and 'coordination' as experienced by patients
- Qualitative work to describe and explain problems faced by GPs and patients

- Developments in economic assessment to reflect the complicated micro-economy in which primary care is delivered.

Interfaces

Many colleagues comment on the importance of interfaces.

Links with clinical practice are crucial, so that investigators have relevant experience, insights and contacts. It is increasingly difficult for academic GPs to acquire substantial, long term, clinical experience in general practice as part of their academic training. A key attribute of GP researchers, therefore, is the ability to engage with experienced service practitioners.

Several colleagues argue for closer links between academic and service general practice, including the promotion of scholarly approaches, whereby practitioners reflect on their clinical experience as a basis for identifying important research questions and opportunities.

Colleagues also mention the importance of interdisciplinary work, where researchers straddle the boundaries between disciplines. Several internationally well known GP and primary care researchers display such breadth. There is a need to value and support training which breeds interdisciplinary collaboration and the ability to work across interfaces.

Such interdisciplinary experience should include not only the well recognised multi-faceted nature of health services research (encompassing epidemiology, statistics, economics, social sciences) but also collaboration with basic scientists (e.g. the impact of trust on non-specific immune defence; the impact of supported mothering on infant development etc) and secondary care colleagues (e.g. joint working of specialist and generalists in the management of patients with long term conditions)

Training issues

Comments on GP research careers are included in Annex B

Conclusions

The principal objective of this paper is to establish ***identity, recognition and support*** for the basic research needs of generalist clinical practice in the NHS.

The contribution of such care to health improvement is via the sum of care provided for all patients. The purpose of primary care, therefore, is to provide high quality care, whatever condition or combination of conditions a patient may have, and to do this effectively and efficiently for all patients.

The MRC and the NIHR have a joint interest in considering their respective roles in supporting such research. Joint ESRC funding might suit some research topics. Explicit recognition and support could help to make existing MRC schemes more accepting of basic research for primary care. However, committees, panels and peer reviewers assessing such research would need appropriate expertise concerning the primary care context.

ANNEX A

EXAMPLES OF BASIC RESEARCH FOR PRIMARY CARE

The examples chosen are neither systematic nor comprehensive in their coverage of primary care research, but are illustrative of research studies which have made important contributions to the evidence base underlying clinical, managerial and policy decisions in primary care.

PROGNOSIS AND PREDICTION OF MAJOR ILLNESS

Many conditions are seen at an early stage, when the probabilities are very different from those encountered in specialist settings, and decisions are taken in situations of uncertainty.

Buckley BS Simpson CR Mclernon DJ Murphy AW Hannaford PC. ***Five year prognosis in patients with angina identified in primary care: incident cohort study.*** *BMJ 2009;339:b3058 doi:1010.1136/bmj.b3058*

This paper described the clinical course of 1785 patients in 40 general practices with a diagnosis of angina as their first manifestation of ischaemic heart disease. Such patients differ from patients with angina who are seen in hospital clinics and who are more likely to be entered into clinical trials, with respect to complication rates and outcomes of surgical interventions.

Henriksson M, Palmer S, Chen R, Damant J, Fitzpatrick NK, Abrams K,Hingorani AD, Stenestrand U, Janzon M, Feder G, Keogh B, Shipley MJ, Kaski JC, Timmis A, Sculpher M, Hemingway H. ***Assessing the cost effectiveness of using prognostic biomarkers with decision models: case study in prioritising patients waiting for coronary artery surgery.*** *BMJ. 2010 Jan19;340:b5606*

This secondary care study, involving a primary care investigator, provides evidence of the use of prognostic biomarkers in assessing patients waiting for coronary artery surgery. Following the paper by Buckley et al (above), further research is needed to assess the usefulness of prognostic biomarkers in primary care.

Prediction of major illnesses prior to their onset can allow for early interventions to prevent incident illness and this lead to reduction in morbidity and health and social care cost

King M, Walker C, Levy G, Bottomley C, Royston P, Weich S, Bellón-Saameño J, Moreno, B, Švab I, Rotar D , Rifel J, Maaroos H, Aluoja A, Kalda R, Neeleman J, Geerlings M, Xavier Mi, Carraça I, Gonçalves-Pereira M, Benjamin V, Saldivia S, Melipillan R, Torres-Gonzalez F, Nazareth I. ***Development and validation of an international risk prediction algorithm for episodes of major depression in general practice attendees: the PREDICT study*** *Archives of General Psychiatry 2008;65(12):1368-1376*

This paper describes the development of a risk algorithm for the prediction of major depression in people attending general practice. The study recruited

10,045 people across seven countries and followed them up over 12 months. These data were used to develop the first risk algorithm for onset of major depression. This algorithm functions as well as similar risk algorithms for cardiovascular events and will be useful in prevention of depression.

This study is an example an international research effort in primary care. It also highlight how one may apply basic epidemiological and statistical modelling approaches to primary care data in order to create an instrument that can be used in daily general practice to predict risk of depression over the next 12 months.

PREVENTION – FIRST DO NO HARM

Cost-effectiveness of screening depends on a balance between harms to the many who screen negative and the benefits to the few who screen positive

Eborall HC Griffin SJ Prevost AT Kinmonth AL French DP Sutton S ***Psychological Impact of Screening for Type 2 Diabetes: Controlled Trial and Comparative Study Embedded in the ADDITION (Cambridge) Randomised Controlled Trial*** *British Medical Journal, 335 (7618): 486*

Eborall HC Davies RG Kinmonth AL Griffin SJ Lawton J Patients' ***Experiences of Screening for Type II Diabetes: A Prospective Qualitative Study Embedded in the ADDITION (Cambridge) Randomised Controlled Trial****. British Medical Journal, 335 (7618): 490*

These studies, using quantitative randomised outcomes and augmented by individual interviews, provide a robust answer to the question of psychological harms of screening for type 2 diabetes. They illustrate a theoretical framing of an important primary care problem with a sophisticated study design enabled by interdisciplinary working across general practice, epidemiology, psychology, sociology and statistics

EARLY DIAGNOSIS

Longitudinal clinical datasets in primary care have the potential to provide important diagnostic and prognostic information

Tabak AG Jokela M Akbaraly TN Brunner E Kivimaki M Witte DR. ***Trajectories in glycaemia, insulin sensitivity, and insulin secretion before diagnosis of type 2 diabetes: an analysis from the Whitehall Study.*** *Lancet 2009;373:2215-21.*

This analysis from the Whitehall cohort study shows that changes in glucose concentrations, insulin sensitivity and insulin secretion were observed as much as 3-6 years before the diagnoses of diabetes. The findings from this classical epidemiological study illustrate what might be possible in primary care terms of using longitudinal clinical information to make early diagnoses.

Better explanatory evidence is needed on delays in the presentation and recognition of serious conditions

Hamilton W, Peters TJ, Bankhead C, Sharp D. ***Risk of ovarian cancer in women with symptoms in primary care: population based case-control study.*** *BMJ. 2009; 339: b2998.Published online 2009 August 25. doi: 10.1136/bmj.b2998*

This case-control study compared the pre-diagnosis symptoms of 212 women with ovarian cancer with 1060 matched controls in 39 general practices. The importance of this paper is that it starts to provide GPs with an algorithm for considering a cancer diagnosis at an earlier stage. More work is also needed on informing the public of the need to present potentially sinister symptoms earlier and to encourage them to use the C word in front of the doctor.

The necessity of making early and accurate diagnoses of serious disease in primary care, rather than 'using time a as diagnostic tool' is now much more widely recognised as a clinical and research priority.

Thompson, MJ, Ninis N, Perera, R, Mayon-White R, Phillips C, Bailey L, Harnden A, Mant D, Levin M. ***Clinical recognition of meningococcal disease in children and adolescents.*** *Lancet 2006; 367 (9508): 397-403*

Haj-Hassan TA; Thompson MJ; Mayon-White RT; Ninis N; Harnden A; Smith LFP; Perera R; Mant, DC. ***Which early `red flag' symptoms identify children with meningococcal disease in primary care?*** *British Journal of General Practice* ***61*** *(584) . e97-e104(8) 2011 March*

The need and scope for early diagnosis is well exemplified by research into childhood meningitis by Mant's group in Oxford. The study recruited 1212 children aged under 16 years presenting to their GP with an acute illness. The study confirms the diagnostic value of classic "red flag" symptoms of neck stiffness, rash and photophobia but also suggests that the presence of confusion or leg pain in a child with unexplained acute febrile illness should also usually prompt a face to face assessment to exclude meningococcal disease.

As well as bringing methodological rigour and inventiveness to a diagnostic problem that has long defied solution, these studies emphasise how effectively NHS databases and clinical records can be used in high quality research.

CLINICAL TRIALS IN THE COMMUNITY

Health problems requiring professional intervention usually present in primary care and many conditions are best studied in

Little P, Gould C, Williamson I, Moore M, Warner G, Dunleavey J. *Pragmatic randomised controlled trial of two prescribing strategies for childhood acute otitis media.* BMJ 2001;322: 336-41

Sullivan FM, Swan IRC, Donnan PT, Morrison JMM, Smith BM, McKinstry B, Davenport RJ, Vale LD, Clarkson JE, Hammersley V, Hayavi S, Daly FD. *Early Treatment with Prednisolone or Acyclovir and Recovery in Bell's Palsy*. New England Journal of Medicine 2007; 357:1598-607.

Appropriate management in primary care can improve outcomes for patients with problems which may not be sufficiently serious to refer to secondary care. Treatments are often offered without an adequate evidence base. This is true in other disciplines; however most hospital specialties have some centres of excellence to develop the basic science in their discipline. Primary care still needs too develop an adequate capability.

COMPLEX INTERVENTIONS

Early development work leads to the creation of complex interventions (e.g. identifying/developing theory and modelling processes and outcomes)

*Kinmonth AL Wareham N Hardeman W Sutton S prevost A fanshawe T Williams K Ekelund U Spiegelhalter D Griffin S(**The ProActive (UK) Trial: no evidence of efficacy of a theory-ased behavioural intervention to increase physical activity in an at-risk group in primary care.** Lancet,;2008: 371: 41-48*

Development work for this explanatory trial included attention to defining the behaviour, the appropriate population, the cognitive determinants of behaviour, techniques to alter them, and measurement of processes including fidelity of intervention delivery and of objective outcomes. The care taken in the early theoretical, modelling and acceptability phases of this study meant that a negative result has led to a review of the sufficiency of the theory of planned behaviour to enable behaviour change and to new thinking about the kinds of control groups needed in complex intervention trials

*Hardeman W Michie S Fanshawe T Prevost AT Mcloughlin K Kinmonth AL. **Fidelity of delivery of a physical activity intervention: Predictors and consequences.** Psychological Health 2008;23:11-24.*

*Michie S Hardeman W Fanshawe T Prevost AT Taylor L Kinmonth AL **Investigating theoretical explanations for behaviour change: the Case Study of ProActive** .Psychology and Health 2008; 23: 25-39*

*Hardeman W Kinmonth AL Michie S Sutton S **Impact of a physical activity intervention programme on cognitive predictors of behaviour among adults at risk of Type 2 diabetes (ProActive randomised controlled trial).** International Journal of Behavioural and Nutritional Physiology Act 2009 6: 16*

MODELLING OUTCOMES

Pragmatic randomised controlled trials are an expensive and lengthy way of assessing interventions effects in primary care. As large clinical data sets have become available, it is possible to model outcomes based on observational data as long as confounding and biases are allowed for.

van Staa TP, Leufkens HG, Zhang B, Smeeth L. ***A comparison of cost effectiveness using data from randomized trials or actual clinical practice: selective cox-2 inhibitors as an example.*** *PLoS Med 2009 Dec;6(12):e1000194.*

This paper used the UK General Practice Database (GPRD) to estimate the exposure characteristics and individual probabilities of upper gastro-intestinal events during current exposure to non-steroidal anti-inflammatory drugs (NSAIDs) or coxibs. The study was based on 971,426 patients who had been prescribed a NSAID and 148,592 who had been prescribed a coxib. Such modelling of outcomes is likely to become a growth area for primary care science, as a complement or practical alternative to pragmatic RCTs. Great caution is required because of the dangers of bias and confounding

UNDERSTANDING THE PATIENT ENCOUNTER

Patients with medically unexplained symptoms are often subject to multiple, serial, specialist investigation, at great cost to the NHS and with little benefit to themselves.

Ring A, Dowrick CF, Humphris GM, Davies J, Salmon P. ***The somatising effect of clinical consultation: what patients and doctors say and do not say when patients present medically unexplained physical symptoms.*** *Social Science in Medicine. 2005; 61:1505-15.*

This paper analysed the consultations of 420 consecutive patients identified by British GPs as presenting medical unidentified symptoms (MUS). The findings suggest that the explanation for the high level of physical intervention for MUS lies in GPs' responses rather than patient demands. The authors propose that explanations for "somatisation" should be sought in doctor-patient interaction rather than in patients' psychopathology

With regard to 'chronicity', the findings implicate GP behaviours/responses in the genesis, persistence and even exacerbation of medically unexplained symptoms in primary care, and (with other papers in this series) have been responsible for shifting focus away from the patient as the principal agent in creating demand for medical intervention in the management of MUS.

With regard to the active ingredients of effective primary care systems, the paper offers some intriguing answers to the reverse of this question i.e. suggesting some of the active ingredients that result in primary care providing worse treatment at higher costs.

Methodologically, the paper describes the creation of a new coding scheme which generates quantitative data from transcripts of routine consultations.

Health care may be technically proficient while failing to meet the needs of patients

Reeve J, Lynch T, Lloyd-Williams M, Payne S. ***From personal challenge to technical fix: the risks of depersonalised care.*** *Health and Social Care in the Community. doi: 10.1111/j.1365-2524.2011.01026.x*

This research focuses on the complexity of needs associated with distress in people with advanced cancer. 27 people were interviewed about their personal experiences of living with illness and related distress. Holistic content research revealed two emerging themes: "personal or personalised care" and "expectations of truth and certainty".

This study is an example of 'social science in primary care': using a classic theory (iatrogenesis and Illich's work on Medical Nemesis) to highlight new challenges resulting from the technical organisation of health care. It addresses one of the areas of 'basic science' in primary care, namely understanding the impact of health systems on individual health and wellbeing.

CONTINUITY OF CARE

Continuity of care is an important feature of high quality care, but there is very little research evidence on this topic

Boulton M, Tarrant C, Windridge K, Baker R, Freeman GK. ***How are different types of continuity achieved? A mixed methods longitudinal study.*** *British Journal of General Practice 2006;56:749-755*

Despite the importance of continuity in primary care, studies of serial consultations are difficult to carry out and there have been few such studies. A notable exception was a diary study examining patients' experiences of consultations at their general practice over a period of six months. 31 patients were recruited with records of 151 consultations between them. Four patterns of use of primary care services were identified:

(1) preference for a named provider – successful outcome

(2) preference for a named provider – unsuccessful outcome

(3) priority for swift access – successful outcome

(4) mixed preference for named provider and swift access.

While the study was limited by its small size, possibly unrepresentative respondents and limited follow up period, it opened up the real world of patients' ongoing experience in accessing care and showed contrasting preferences and ways of expressing these. There was a wide range of success for patients' wishes and the persistence and skill sometimes needed in seeing a named practitioner was notable. That this study was part of an ongoing

programme in parallel with other approaches improved awareness of its context and allowed cross-referencing with a cross-sectional survey (Baker et al 2007) and a Discrete Choice Analysis study (Turner et al 2007). The programme is reported as a whole in Baker et al 2006.

Baker R, Boulton M, Windridge K, Tarrant C, Bankart J, Freeman GK. ***Interpersonal continuity of care: A cross-sectional survey of primary care patients' preferences and their experiences.*** *British Journal of General Practice 2007;57:283-290.*

Turner D, Tarrant C, Windridge K, Bryan S, Boulton M, Freeman G, Baker R. ***Do patients value continuity of care in general practice? An investigation using stated preference discrete choice experiments?*** *Journal of Health Services Research and Policy 2007;**12:**132-137.*

Baker R, Freeman G, Boulton M, Windridge K, Preston C, Low J, Turner D, Hutton E, Bryan S. ***Continuity of care: patients' and carers' views and choices in their use of primary care services*** *(SDO/13b/2001) Revised Final Report for NCCSDO 2006. http://www.sdo.lshtm.ac.uk/files/project/13b-final-report.pdf (accessed 8th Aug 11).*

UNDERSTANDING EMERGENCY ADMISSIONS

General practices can vary by as much as fourfold, in the rates at which their patients are admitted to hospital as medical emergencies

Purdy S, Griffin T, Salisbury C, Sharp D. ***Emergency respiratory admissions: influence of practice, population and hospital factors.*** *Journal of Health Services Research and Policy 2011;16:133-140. doi: 10.1258/jhsrp.2010.010013*

This study used linked data from several routine datasets to explore the relationship between population, hospital and general practice characteristics and general practice admission rates for asthma and chronic obstructive pulmonary disease (COPD) in England. During the course of the study a revised method for defining practice level deprivation was devised and subsequently published.

Griffin T, Peters T, Salisbury C, Sharp D, Purdy S. ***Validation of an improved area-based method of calculating general practice–level deprivation****. Journal of Clinical Epidemiology 2010; 63: 746-751*

The paper on respiratory admissions found that practice population, geographic and hospital supply factors are consistently associated with asthma and COPD admissions. Living closer to a hospital and greater bed availability are both associated with increased rates of admission. Higher smoking rates among patients in a practice are associated with higher admission rates. There is little evidence from this study that other modifiable general practice factors such as care currently incentivised by the quality and outcomes framework are important in influencing admission rates.

This paper was listed as a 'recent highlight' on the website of the Journal of Health Services Research & Policy and is an output from a MRC funded Clinician Scientist Fellowship.

MENTAL HEALTH

Mental health problems are a major cause of morbidity and the most common type co-morbidity in the NHS, especially in deprived areas, but their nature and extent is poorly captured by routine data

Lester HE, Tritter JQ, Sorohan H. ***Providing primary care for people with serious mental illness: a focus group study.*** *British Medical Journal 2005;330:1122-1128.*

This study cost £5,000 (hiring out venues for the focus groups and paying travel expenses). PI time was covered by a DH career scientist post.

"The study was very simple in concept, design and execution: truly basic research for primary care. The previous literature described how GPs found people with serious mental illness feckless and difficult to communicate with and treat and how patients with serious mental illness found primary care difficult to access and GPs hard to communicate with.

A way forward was to bring patients and GPs together in a safe environment to talk through these issues together, via 6 focus groups with GPs alone and 6 with patients alone, first of all, to get them used to the methodology and to talking about issues openly.

Volunteers were then asked to talk to each other in focus group settings. 50% agreed to in 6 combined focus groups with both GP and patients with serious mental illness.

Patients thought primary care was the cornerstone of their health care; sometimes patients had to 'edit' themselves to get all their concerns into 10 minutes; sometimes they DNA'd appointments because they had to leave noisy waiting rooms or had become too unwell in the time between booking and attending; therefore, patients 'acted up' i.e. exaggerated the mental health symptoms to get timely access to primary care".

GPs perceived serious mental illness as a lifelong condition but patients emphasized the importance of hope for recovery. GPs mirrored patients' acting up of symptoms to gain timely access to secondary care. The importance that patients attached to continuity of care and listening skills, compared with specific mental health knowledge, encouraged GPs to see that they had a significant role to play in the care of people with serious mental illness.

The study has been widely cited (including in WHO documents) http://www.euro.who.int/__data/assets/pdf_file/0008/96452/E87301.pdf' and has informed indicators in the mental illness domain of the QOF. The paper demonstrated that GPs can play a significant role in the care of patients with serious mental illness, which is now directly influencing the mental health clinical commissioning agenda through documents prepared by the Joint Commissioning Panel for Mental Health.
http://www.rcpsych.ac.uk/policy/policyandparliamentary/projects/live/commissioning.aspx

UNDERSTANDING CONSULTATIONS

Patient-centredness is a key aspect of NHS policy, but is easier to promote than to define or study

Mead N, Bower P. ***Measuring patient-centredness: a comparison of three observation-based instruments.*** *Patient Education & Counselling 2000; 39:71-80.*

Research on the consultation, and key processes in the consultation, is hampered by narrow (and differing) conceptual frameworks, limited measures, the difficulty of measurement (including reliability and validity), the time needed to perform measurement, and inadequate power. There have been very few large studies of the consultation, therefore, where the myriad aspects of verbal and non verbal behaviour in the consultation have been measured and related to outcomes. An example of the type of work that is needed - but adequately powered and more comprehensive in the methods used - is the small study by Mead and Bower where different aspects of patient centredness were measured and compared with each other and construct and concurrent validity were assessed.

DRUGS MISUSE

Injecting drug misusers are a difficult group to engage with, either for clinical research or for research that informs clinical care and NHS policy

Kimber J Copeland L Hickman M Macleod J McKenzie J De Angelis D Robertson JR. ***Survival and cessation in injecting drug uses: prospective observational study of outcomes and effect of opiate substitution treatment.*** *BMJ 2010;340:c3172 doi:10.1136/bmj.c3712*

This paper describes a long term follow up study of a prospective cohort of injecting drug users - a very difficult group to study. It looks at the impact of opiate substitution on health outcomes. Such a study would not be ethically or scientifically feasible as a randomised controlled trial, yet the long term impacts of opiate substitution were previously unclear. The study showed that opiate substitution treatment in injecting drug users in primary care reduces the risk of mortality, with survival benefits increasing with cumulative exposure to treatment. Opiate substitution treatment does not however reduce the overall

duration of injecting. This information is very important as future debates on the direction of drug policy and benefits of drug treatment need to consider that there is a balance between saving lives and achieving abstinence. Abstinence alone is not a sufficient marker of health benefit in this difficult to treat population.

MULTIPLE MORBIDITY

Multiple morbidity is common, both in elderly populations and in socio-economically deprived populations, and is not well served by research studies in which multiple morbidity is an exclusion criterion.

Salisbury C, Johnson L, Purdy S, Valderas JM, Montgomery AA. ***Epidemiology and impact of multimorbidity in primary care: a retrospective cohort study.*** *British Journal of General Practice 2011;61:18-24*

This paper describes the extent to which multimorbidity is the norm in UK general practice, with patients with multiple long term conditions making up a disproportionate number of those consulting GPs. This situation is likely to increase as the population ages. The paper briefly highlights the fact that this has implications for the production of guidelines, for the training of doctors, and for how care is delivered. This type of research is needed to characterise the nature of the population needing health care in this country (given that most health care is provided in general practice). Increased recognition of the high prevalence of multimorbidity should influence the research agenda (for example, by demonstrating the very limited usefulness of studies that exclude people with comorbidities) as well as influencing the priorities for health care policy and service organisation.

INEQUALITIES IN HEALTH CARE

The inverse care law states that the availability of good medical care tends to vary inversely with the need for it in the population served. Very few studies have described how the inverse care law operates in practice

Mercer SW and Watt GCM. ***The inverse care law: clinical primary care encounters in deprived and affluent areas of Scotland.*** *Annals of Family Medicine 2007, 5: 503-510*

This paper demonstrates the importance of 'basic research' in general practice. It studied 3044 consultations in general practice, including 1804 consultations in the most deprived areas of Scotland. The study shows what is possible to achieve in terms of data collection 'at the coal-face' from patients in high deprivation areas. The response rates were high and the characteristics of the patients who participated were representative of the population sampled. Poorer access, less time, higher GP stress and lower patient enablement are some of the ways that the inverse care law continues to operate within the NHS and confounds attempts to narrow health inequalities.

ANNEX B

BASIC RESEARCH FOR PRIMARY CARE – RESEARCH TRAINING ISSUES CONCERNING ACADEMIC GENERAL PRACTITIONERS

While it is possible for primary care researchers to pursue research careers within the vertical, disease-based paradigm, it is desirable that such careers can also be pursued by addressing the methods required for basic research in general practice and primary care.

This Annex focuses on research careers and training opportunities for general practitioners, on the premise that many types of primary care research are only possible when general practitioners are involved as principal investigators.

Clearly, other health care professions and academic disciplines also have lead roles in primary care research. A full review of research training for primary care research would reflect these multiprofessional and multidisciplinary elements.

All agree that it would be useful to have an overview of the numbers of GPs and other primary care researchers holding career training development posts at all levels, and welcome the MRC's commitment not only to do this but also to amend its recording systems (including drop down menus) to make it easier to conduct such an exercise.

To promote the types of research described above there is a need to build on the pioneering examples of senior researchers, to support young clinical researchers and to provide continuity and security for post-doctoral clinical researchers as they develop their own research programmes and teams.

The NIHR training programmes have been very helpful to general practice and primary care research in England (not matched in the devolved nations), with quality standards which bear comparison with the MRC, while lacking its kudos.

It is certainly possible for academic GPs to obtain MRC research career funding, as several have done so. The small numbers at the CRF stage may be explained by the relatively early stage in their careers that GPs are expected to apply for such schemes. The short clinical training period (three years) means that, even with the additional Academic Clinical Fellowship year, they are preparing an application whilst completing their CCT (MRCGP) if not MRCP and other diplomas and Masters degrees. The emerging ACF cohort is voting with its feet to take a further year or so in service before attempting the CRF hurdle. It remains to be seen if they will return.

In 2006, a review of MRC Support for Clinical Academic Careers, to which several senior GP researchers contributed, proposed that a bursary scheme should be piloted to support training in research methods (underpinning clinical trials, epidemiology and HSR). Whilst this funding is now available for GP ACFs in England, it may be timely to revisit this proposal in relation to the needs of others embarking on a career in general practice research, for example in the devolved nations, and those who are not on Integrated Academic Training (IAT) schemes. Bursaries might support interdisciplinary research and service following registration and before CRF application. Joint ESRC posts might be particularly relevant for the social science research that several of the examples given above describe..

Senior clinical research fellowships are highly valued in providing the continuity and security needed to develop research programmes and teams, but are difficult to obtain. Several leading primary care researchers described ad hominem ways which they had obtained such support.

The MRC and Wellcome schemes are felt to be more restrictive and less accepting of the types of research that more senior academic GPs wish to pursue. The MRC was said to be very keen to encourage Clinical Scientists to apply for Senior Fellowships, but the advice to "get a disease focus for your work, in a more clinical rather than HSR Programme" can be off putting.

There was little support in the correspondence generating this paper for the suggestion that research on challenging general practice and primary care topics is best carried out by more experienced researchers. A more prevalent view is that high calibre junior researchers are capable of carrying out such research, with appropriate preparation and supervision, as is the case in other clinical specialities.

Given the importance of interdisciplinary interfaces in realising the research needs and opportunities of general practice and primary care, the MRC and NIHR might consider ways in which such links could be supported during academic career training.