What is general practice research?

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Abstract

Given the eclectic nature of general practice and the combination of scientific and communicative practices, there is both place and need for practice-based research, as well as drawing on the wealth of findings available from studies undertaken within other disciplines. GP research should utilise and adapt methods from many sources, including biomedical and social science fields, as well as developing new task-specific tools. The RCT, with appropriate blinding and intention to treat analysis, remains the method of choice for determining whether an intervention is efficacious and effective. Other methodologies may be more appropriate in addressing other types of questions. Individual GPs' involvement in research ranges from active consumer through participant, collaborator to primary investigator. Evidence-based care is an amalgamation of clinical judgement and research-based knowledge. The one common denominator is endeavouring to provide the best possible health care for our patients, and continuing to monitor that our performance is as optimally safe and effective as current state of knowledge will allow.

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Research can be viewed as 'organised curiosity' – investigation into how and what we do, whether it works, whether we can do it better; effectively an extension of human curiosity. As general practitioners (GPs) it can be argued that in one sense we do 'research' every day. A patient presents with a problem, we gather information (usually by taking a history), formulate hypotheses regarding likely differential diagnoses, and then test these out with further information-gathering – additional history, medical examination, investigations. We might try a treatment and assess its effect, and then revise the management plan based on patient feedback about the positive results and side-effects of the intervention.

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GP research therefore might be considered as a more formalised systematic approach to this established process, using established scientific methodologies. One formalised strategy to the information-gathering GPs do every day is the n-of-1 trial.[1,2] These are single-patient randomised controlled trials with multiple crossovers, developed for the management of chronic conditions (particularly where some treatments have higher risks than others), and are a prescribed extension of the strategy *'Let's try this treatment for a while and see if it works.'*

General practice is the medical discipline with the broadest base and the least defined boundaries. GPs are *'personal doctors, primarily responsible for the provision of comprehensive and continuing care to every individual seeking medical care irrespective of age, sex and illness. They care for individuals in the context of their family, their community, and their culture, always respecting the autonomy of their patients. GPs deal with health problems in their physical, psychological, social, cultural and existential dimensions.'*[3]

What constitutes 'GP research' similarly is difficult to circumscribe. Research conducted by GPs ourselves within our own practice settings clearly can be labelled GP research. However, any study could be considered general practice-relevant research if its findings potentially af-

fect a GP's practice, whether it is conducted by specialist medical disciplines, our primary health care colleagues (such as practice nurses and pharmacists) or other professional groups. For example, a sociologist might survey community attitudes with regard to specific health issues, or a pharmacist researcher assess how many patients actually present prescriptions to their chemist. Primary health care can also be evaluated by a non-professional group, for example from the patient's perspective.

Much medical research evidence is biomedical data (especially randomised controlled trial [RCT] findings) derived from secondary and tertiary health care settings. While such evidence aids clinical decision-making in primary health care, it also has considerable limitations.[4] GP researcher Barbara Starfield describes primary care as *'first-contact, continuous, comprehensive, and coordinated care provided to populations undifferentiated by gender, disease, or organ system'*.[5] General practice has a different patient population and deals with different conditions in comparison to hospital-based practice. Practices vary widely in nature according to location, ethnic and socio-economic factors. The greater the choice patients have regarding the practice they attend, the more a particular practice will be tailored to a doctor's own style of practice, personality, manner of relating to patients, and reputation. It is difficult to make inferences from the specific to the general,[6] and this lack of generalisability means findings in one practice may have limited application in another. Ultimately, each doctor reviewing study findings must answer the question: *'What are the implications of these results in my own practice and will they alter what I do?'*

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There is an ongoing dilemma about the degree to which findings relating to individual patients with their unique histories, can be extrapolated to other patients with similar conditions, and how much we should change our patient management strategies on that basis. Our patients often have complex multi-faceted problems with both biological and psychosocial components. It may not be possible to eliminate biases and confounders. There are often not simple cause-effect relationships to be demonstrated, for example between treatment and outcome. What will be frequently found will be associations or correlations rather than causal relationships.

Traditionally research conducted by GPs predominantly has been observational studies, such as surveys of GPs' views, rather than experimental interventional studies.[7] In the past, it has been argued that given the nature of our patients (with multiple, multidimensional problems combining biomedical and psychosocial components, or lack of definitive diagnosis), plus the often complex nature of our interventions (involving both drug and non-drug therapies) general practice does not lend itself easily to the use of RCTs.[8] However, the discipline of general practice does not hold a monopoly on complexity, and a recent editorial in the *Lancet* argued strongly for more rigorous research in family medicine.[9] The lack of boundaries to primary care can be viewed as a great strength, offering a perspective which can inform and influence all other specialities.

As GPs our primary aim is to improve our patients' health. There are many gaps in the evidence-base underpinning management decisions in primary care.[10] The chief purpose of conducting general practice research is to answer research questions relevant to everyday practice. Good questions are those that are interesting and important enough to be worth answering, and capable of being answered within a predictable and acceptable timeframe. A question is not worth pursuing if the solution is beyond the resources of the researcher, or will not contribute to improvements in patient care.[11]

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The method used to answer the question should be as rigorous as possible, to minimise the effects of bias. In this regard, the RCT, with appropriate blinding and intention to treat analysis, remains the method of choice for determining whether an intervention is efficacious (produces benefits under ideal circumstances) and effective (performs as expected in practice with a specified population). While research boundaries and settings may be fuzzy and imprecise, robust research is still feasible to conduct within general practice. RCTs are doable. Clinical trial results can be applied to individual patients – risk assessment derived from a meta-analysis of randomised trials where available can help evaluate the potential benefits and harm of a treatment for an individual. In general, patients at greatest risk of a disease will benefit most; the chance of harm (such as treatment discomfort or adverse effects) is relatively fixed.[12]

Techniques have developed to deal with the complications and complexities that might arise in conducting RCTs within primary care. Where patients decline to be randomised, a trial might include an arm of patients given their preferred treatment option and then comparisons made be-

tween the outcomes for randomised patients and those choosing their treatment.[13] Pooling of data from a series n-of-1 trials, adjusting both for within-patient and between-patient differences, may allow generalising treatment effectiveness to the population.[14] Factorial designs can assess the effects of different interventions used both individually and combined. This method is particularly suitable where it can be assumed that the different interventions act independently, although often this assumption cannot be made, and large sample numbers are required to test statistically for any interaction, a major limitation of this design.[10] Crossover trials, where two or more interventions are given in a random sequence to all patients, allows for comparisons made within rather than between individuals. Such studies need smaller sample sizes but do have some disadvantages – for example they only study short-term effects of treatments for stable, chronic diseases, and are unsuitable for treatments aiming for a 'cure'. Further, patients who do not complete the trial will not have been exposed to all the interventions, hence can contribute no data to the analysis. Finally, cluster randomisation (for example, randomising at the level of a general practice rather than individuals) may prevent the contamination between control and intervention groups that can occur if some patients in a practice receive a different treatment than others.[15]

There are always ethical issues to address when randomising patients to receive an intervention. As well as patients giving well-informed, voluntary consent, clinical equipoise is essential. GPs recruiting patients must be genuinely uncertain whether one intervention is more efficacious than another, and hence allocation of a patient to any of the study arms is ethically justified.[16]

While an RCT may be the best method to answer questions on treatment effectiveness, other methods are more appropriate to answer different question types. For example, a study may be based on observations at a single point in time (cross-sectional study); it may involve following a group of individuals over time (cohort study); compare a target sample with matched controls (case control series) or repeat measures before and after an intervention (a before-after study). Once a research question is asked, the next step is to determine the most suitable method to address it.

There is also a place for qualitative research within general practice. The primary data obtained by a GP is often patients' testimony, their accounts of personal experience. A history is not only facts and events, but also the meaning of these experiences to patients in their lives. Social sciences tend to focus on meaning and interpretation of narratives, and there may be difficulty in generalising these findings beyond the contexts in which they are obtained. Because qualitative research tries to understand and interpret personal experience to explain social phenomena, it can address questions that quantitative research cannot - for example, why people do not comply with a treatment regimen or why a certain health care intervention is successful.

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The best research project might incorporate a combination of qualitative and quantitative methods and perspectives when evaluating a problem. There is an increasing move towards a multimethod approach involving the collection, analysis and integration of both these types of data.[17] Qualitative research might be used to explore a topic and help inform design of a quantitative component; to explain the quantitative results, or converge both data sets (triangulation) which broadens the perspective, and 'fleshes out' the skeletal outline provided by a statistical numerical analysis.

Conducting rigorous academic research of this calibre generally requires a team approach, and is best conducted within the university environment in collaboration with participating GPs, primary health care organisations, and other key stakeholders. Universities are very keen to work with 'coal face' GPs on research projects.

There are many ways in which the GP in the field can actively participate in research. The primary goal of any general practice research must be to improve patient care.[18] GPs can identify the gaps in our knowledge, and generate the research questions needing answers. For good, relevant GP research to occur, there needs to be strong connections and communication between coal-face GPs and academic departments.

As part of ongoing professional development, Fellows of the Royal New Zealand College of General Practitioners (RNZCGP) are required to perform practice review and quality cycle improvement.[19] This requires choosing a topic where there is evidence that improving practice will make a difference to patient care. Indicators (markers for improvement) are set, questions to ask (criteria) are determined, and expectations of outcomes (standards) are decided. The appropriate data is collected, any gaps from the expected standard are identified, and then actions are taken to close these gaps and improve patient care. Improvements are measured by repeating the cycle.

Such activities are generally deemed audit, not research – they are undertaken by people directly responsible for patient care with a view to informing and improving manage-

ment with the practice. However, differentiation between what constitutes audit and research is tenuous. A practice review may uncover useful information or understanding that is of potential value to other practices. Dissemination of anonymous collated findings beyond the 'in-house' practice boundary is seen to be adding to general knowledge, and once this happens, 'audit' becomes 'research'.[20]

GP involvement in research may range from study participant to active collaborator, or even primary investigator. The latter is more feasible for the GP engaged in higher study, possibly completing a dissertation or thesis, with academic support and supervision.

At the very least, all GPs need to be active consumers of research. GP vocational training should explicitly support the acquisition and maintenance of critical appraisal skills.[21] GPs will continue to face uncertainty and be confronted with problems for which there are no clear-cut solutions. However evidence is accumulating where questions have been answered to a high standard. GPs need the skills to access this accumulated knowledge, assess the quality of the evidence, and ultimately make a judgement regarding the relevance of this knowledge for an individual patient. An evidence-based practice of medicine should reject the use of treatments which have been demonstrated not to be effective and safe, and where claims of benefit rest solely on unsubstantiated pseudoscience. GPs who themselves conduct research, or have training in critical appraisal of research, are best able to assess the validity of therapies and procedures accurately and efficiently. Completing a masters level paper in research methodology is recommended before embarking on independent research. The RNZCGP offers research funding grants to assist GPs, and university departments are generally eager to collaborate with GPs interested in pursuing research.

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Our role as GPs is to provide ongoing health care for our patients. It is important to evaluate whether what we do is safe and effective. To move from opinion-based to evidence-based practice of medicine, GPs need to be able to access and interpret the appropriate research findings and then apply this information to their individual patients.[22] They add the pool of research knowledge to their practical wisdom gained by clinical experience, so that their medical decision-making results from an amalgam of science and art, the cumulative evidence at their disposal.[23]

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