Developing and evaluating interventions for primary care- a focus on consultations in general practice.

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Abstract

The deployment of decision support aids, electronic referral tools or other novel processes to improve diagnostic or therapeutic performance may also disrupt the flow of the consultation in general practice. Therefore 'innovations' or interventions that may result in changes to the structure of the consultation need to be tested in controlled conditions if they are not to harm patient care in practice. We describe a method for conducting 'Phase 1' studies of such interventions illustrated by a consultation from one of four studies using actor-patient consultations. The recording of actor-patient consultations is technically challenging. There are some limitations in using volunteers whose skills may be unknown. However, the method allows lay and professional observation about the performance of doctors using new tools which may help to refine the innovations or offer insights into how and why some clinical scenarios impact on the doctor-patient consultation. This method is not a substitute for adequately powered clinical trials; however, it offers a practical approach to developing a complex intervention for subsequent formal evaluation.

Introduction

As the Australian population ages, more people will be living with chronic conditions and most will be managed in primary care. [1] While consultation based innovations to improve the care given by general practitioners (GPs) are desirable, these innovations must not reduce the performance of the GP in other aspects of the consultations. Examples of such innovations include decision support aids, electronic referral tools other novel processes to improve diagnostic or therapeutic aids. The consultation is a complex activity and the core of general practice, the function of which has remained unchanged over many decades. The description by the UK Royal College of General Practitioners from 1972 still applies today:

"…the ideal consultation. The doctor's attention is devoted exclusively for a short period of time to the life and problems of another human being. He is there to listen and to help. His training will have made him receptive to a wide range of distress signals and given him the means, to answer them. The occasion will be unhurried and something will be gained by both participants; a good consultation brings satisfaction to the doctor as well as to the patient." [2]

There is a risk that well intentioned interventions designed to improve one aspect of a consultation could detract from other aspects and the overall quality of care. Whilst there is a demand for more research in general practice there is an on-going imperative to maintain quality, safety and efficiency whether testing innovations or new ways of working. We argue that any innovation must be tested for safety under controlled conditions before being deployed in the field as a research or clinical tool. In this paper we describe and illustrate a method for doing so. We propose that, before any intervention is introduced in clinical practice, the equivalent of a pharmaceutical phase 1 study is conducted. [3] Phase 1 studies recruit a small number of patients usually not much more than 30 with the aim of investigating:

1. The safe dose range for a drug.
2. The side effects.
3. How the body copes with the drug.
4. If the drug has an effect.

Some patients can have difficulty communicating their concerns and may have multiple GP consultations before the relevant issues are addressed.[4] Communication skills are among the 'core competencies' of general practitioners as outlined by the Royal Australian College of General Practitioners.[5] The competencies include five domains. Two domains have particular relevance; communication skills and doctor patient relationship, and applied professional knowledge and skills. Some well intentioned innovations, as described above, may reduce GPs' attentiveness to important aspects of the clinical presentation and thus reduced the GP's performance in the relevant competencies, resulting in compromised ability to respond to patient need. The relevant theoretical underpinning relates to the fact that patients may present with multiple problems and the GP must address each effectively. Rubinstein et al. describe two processes that help people switch between tasks unconsciously.[6] One is "goal shifting" ("I want to do this now instead of that"), the other is "rule activation" ("I'm turning off the rules for *that* and turning on the rules for *this*"). Problems arise when switching compromises productivity and safety, both of which are required in general practice. Thus, diagnostic and therapeutic errors may occur when either process is compromised. As most interventions in primary care are 'complex interventions'[7] we designed a series of four phase 1 studies. Two of the four tested GP performance with innovations to find out:

1. If the innovation can be delivered within the context of a single GP consultation
2. If the innovation will have an adverse impact on GPs' core competencies
3. If the innovation requires further refinement
4. The likely impact of the innovation on patients.

The other two studies focused on what where conceived as difficult scenarios which we hypothesised would be challenging for practitioners in clinical practice.

Method

The research was conducted at the Curtin Health Innovation Research Institute (CHIRI) in Western Australia over a period of eighteen months. In each study six actor-patients portraying people with a chronic or complex illness consulted each of six general practitioners. Each study included challenges and or innovations which might impair the performance of the practitioner's core competencies. The four innovations / challenges were: An interactive referral pro forma for use with patients presenting symptoms which require specialist investigation; interruptions to GP consultations in which 'patients' presented with high risk cancer symptoms; psychosexual problems presented within the context of a cancer diagnosis; and a care needs assessment tool for use with caregivers of cancer patients. Each consultation was audio or video recorded. As a part of each study, actors and doctors were invited to view the recordings during a 'stimulated recall' session. The session focused on how the innovation could be refined and how the quality of the consultation could be maintained or improved by tailoring the innovation or designing a practical solution to the challenges presented during the consultation .[8] Core

competencies were measured using a validated schedule namely the Leicester assessment package (LAP). Scoring for core competencies was done by two independent researchers who were trained in using the LAP.[9,10] The final scores reflect a consensus view on the consultation following discussion about differences in scores by the assessors.

The video shown with this report demonstrates an example of a consultation in which an innovation was introduced. In the consultation the actor presents as the caregiver to a cancer patient. The innovation is a 'Needs Assessment Tool for Caregivers' or NAT-C. The NAT-C was designed in response to data which suggests that many caregivers develop physical and psychological conditions as a consequence of procrastinating with their own needs. The tool was intended to help practitioners proactively address the needs of such caregivers. [1-13] The background to the case presented is shown in Box 1. In a subsequent stimulated recall session the practitioner and actor-patient were invited to view the consultation and comment on how the NAT-C could be refined and or tailored for use in 'real' consultations. The results of this study are reported elsewhere.

31yr old married man, son has leukemia. Patient abusing alcohol. Not clinically depressed. Consultation with young male patient unable to cope with son's diagnosis.

Potential outcomes:
- Screen for depression and alcohol abuse.
- Refer to support group.
- Offer support and close follow up.

Box 1. Case presenting to a General practitioner

Summary of Results and Discussion

The results of two of the four workshops have now been published in peer reviewed open access journals.[9,10] The majority of consultations were recorded with sufficient technical clarity to allow analysis. In both published studies GPs differed in core competencies as measured by the Leicester Assessment Package (LAP), and demonstrated variable differences in performance according to the case presented. The GEE model identified an improved LAP score in consultations in which experimental innovations were used after controlling for the different GPs and scenarios, but in all cases this improvement was not significant. We present one of the consultations as a video with this report. The consultation was scored as illustrated in Table 1. The scoring of individual components on the schedule is outlined on Table 2. The participants made observations which helped to refine the innovations or offered insights into how and why challenges presented in practice might impact on doctor-patient consultations.

Table 1. *LAP scores for illustrated consultation.*

	Score	Competencies	Weighted scores for each section
A	**B**	**Interviewing/history taking** (Relative weighting 20%)	Sum of rows 1-14B divided by (10 x 5) multiplied by 20. = 18.8
1	(*)	Introduces self to patients	
2	5	Puts patients at ease	
3	5	Allows patients to elaborate presenting problem fully	
4	5	Listens attentively	
5	(*)	Seeks clarification of words used by patients as appropriate	
6	4	Phrases questions simply and clearly	
7	5	Uses silence appropriately	
8	4	Recognises patients' verbal cues	
9	(*)	Recognises patients' non-verbal cues	
10	5	Identifies patients reasons for consultation	
11	5	Considers physical, social and psychological factors as appropriate	
12	(*)	Elicits relevant and specific information from patient's records to help distinguish between working diagnoses	
13	4	Elicits relevant and specific information from patient to help distinguish between working diagnoses	
14	5	Exhibits well organised approach to information-gathering	
		Patient management (Relative weighting 20%)	Sum of rows 15-25B divided by (7 x 5) multiplied by 20. = 18.3
15	4	Formulates management plans appropriate to findings and circumstances	
16	4	Formulates management in collaboration with patients	
17	5	Demonstrates understanding of importance of reassurance and explanation	
18	5	Uses clear and understandable language	
19	(*)	Makes discriminating use of drug therapy	
20	(*)	Makes discriminating use of referral	
21	(*)	Makes discriminating use of investigations	
22	5	Is prepared to use time appropriately	
23	5	Checks patients' level of understanding	
24	4	Arranges appropriate follow-up	
25	(*)	Attempts to modify help-seeking behaviour of patients as appropriate	
		Problem solving (Relative weighting 20%)	Sum of rows 26-31B divided by (3 x 5) multiplied by 20. = 18.7
26	4	Generates appropriate working diagnoses or identifies problem(s) depending on circumstances	
27	(*)	Seeks relevant and discriminating physical signs to help confirm or refute working diagnoses	
28	5	Correctly interprets and applies information obtained from patient records, history, physical examination and investigations	
29	5	Is capable of applying knowledge of basic, behavioural and clinical sciences to the identification, management and solution of patients' problems	
30	(*)	Is capable of recognising the limits of personal competence	
31	(*)	Acts appropriately at limits of competence	
		Behaviour/relationship with patients (Relative weighting 10%)	Sum of rows 32-34B divided by (2 x 5) multiplied by 10. = 9
32	4	Maintains friendly but professional relationship, with due regard to the ethics of medical practice	
33	5	Conveys sensitivity to the needs of patients	
34	(*)	Demonstrates an awareness that the patient's attitude to the doctor (and vice-versa) affects management and achievement of levels of cooperation and compliance	
		Anticipatory care (Relative weighting 10%)	Sum of rows 35-37B divided by (3 x 5) multiplied by 10. = 8
35	5	Acts on appropriate opportunities for health promotion and disease prevention	
36	4	Provides sufficient explanation for preventive initiatives taken	
37	4	Sensitively attempt to enlist patients' cooperation to promote change to healthier lifestyle	

Table 2. *Scoring competencies using the LAP.*

Either

(*) (missing data)	Competence not challenged
0	Challenged but not addressed
1	Addressed but to a lesser standard then minimal competence
2	Minimal competence expected of a GP
3	Addressed to the standard of the typical GP
4	Addressed to the standard of a good GP
5	Mastery

We report a method to develop or refine interventions to be deployed within the context of the consultation in general practice. They offer the prospect of testing such innovations within controlled conditions and assessing their likely impact in actual clinical practice. The design of such so-called Phase 1 studies has several strengths; they replicate conditions which may be difficult to observe in clinical practice. Many of the conditions which were tested in our studies present infrequently in general practice. The practitioners all consulted the same patients and in the same sequence. In many ways the methodology mimics the formal assessment or examinations of candidates seeking membership to many professional colleges. However, the method presents a number of technical challenges and limitations.

We would recommend that investigators invest in technical support for the recording of consultations to guarantee high quality footage and to minimise disruption or inconvenience to participants. Unfortunately a variable proportion of consultations in our studies were not video recorded due to technical failures and so could not be analysed. While audio recording of consultation would have been technically easier and much less disruptive and only one LAP competence is completely dependent on visual inspection, we found that observation of participants is critical to the evaluating the impact of some innovations.

While agreement by assessors on LAP scores was generally good with no systematic variation in the difference in LAP scores over the range of LAP scores, we recommend cross-training and calibration of assessors. This was the approach we adopted for the scoring of the consultation reported with this report. The assessors were also investigators in the studies and could not be blinded to aims of the study. While we do not believe this had an impact on their scores, it would be prudent to blind assessors to the aims of studies in the future.

Participating GPs in these studies will always be volunteers and therefore potentially unrepresentative. Nor did we have any measures of how the volunteer practitioners perform in routine practice using the LAP or any other consultation competence measure. We are therefore unable to report how well their performance reflected that when consulting with 'real' patients. We therefore recommend either a preview of practitioner performance in routine practice or the development of a pool of 'characterised' volunteer practitioners who are prepared to test innovations in controlled conditions in order to provide a practitioner performance baseline. We were also unable to assess the impact of video recording on the GPs' performance although the literature on recording for the purposes of assessment suggests that it has no significant adverse effect.[14]

Conclusions

These studies were designed to investigate the practicalities of establishing the methodology rather than obtain conclusive results in relation to a hypothesis. These methods are no substitute to adequately powered Phase 2 and 3 studies, however they offer a practical approach to developing an innovation for subsequent formal evaluation.

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