

## **Title: Findings from a feasibility study to improve GP elicitation of patient concerns in UK General Practice consultations**

### **1. Abstract (200 words)**

**Objectives:** To establish: a) feasibility of training GPs in a communication intervention to solicit additional patient concerns early in the consultation, using specific lexical formulations (“do you have ‘any’ vs. ‘some’ other concerns?”) noting the impact on consultation length, and b) whether patients attend with multiple concerns and whether they voiced them in the consultation.

**Methods:** A mixed-methods three arm RCT feasibility study to assess the feasibility of the communication intervention.

**Results:** Intervention fidelity was high. GPs can be trained to solicit additional concerns early in the consultation (once patients have presented their first concern). Whilst feasible the particular lexical variation of ‘any’ vs ‘some’ seemed to have no bearing on the number of patient concerns elicited, on consultation length or on patient satisfaction. The level of missing questionnaire data was low, suggesting patients found completion of questionnaires acceptable.

**Conclusion:** GPs can solicit for additional concerns without increasing consultation length, but the particular wording, specifically ‘any’ vs. ‘some’ may not be as important as the placement of the GP solicitation.

**Practice Implications:** GPs can solicit early for additional concerns and GPs can establish patients’ additional concerns in the opening of the consultation, which can plan and prioritise patients multiple concerns.

### *2. Introduction*

Previous research has shown that 40% of patients present in primary care consultations with more than one concern (1) and, when free to voice concerns are likely to initiate 2 to 3 per visit (2-4). However, whilst patients may attend with multiple concerns to discuss, questions from the GP such as “How can I help you today?” tend to elicit just a single concern (4,5). This can leave patients with unvoiced concerns (6), which can be a problem for both patients and their health care provider. Research has highlighted how unvoiced concerns can be associated with the worsening of symptoms, increased patient anxiety, the need for additional visits and poor patient satisfaction (1).

Literature on medical interviewing suggests that soliciting early in the consultation can be an effective way to establish all patient concerns early in the consultation (7,8,9). But studies have suggested that this is not routine practice (2,3,10,11,12) and where physicians do ask patients if they have additional concerns, this tends to be at the end of the consultation (10,11). Dealing with additional concerns at the end of a consultation can be problematic for time management and can lead to concerns not being fully elaborated, explored and managed.

The way in which health care practitioners ask patients about additional concerns can also be important. Linguistic studies suggest that small differences in how questions are phrased can have a big impact on the responses received, with certain words noted as being associated with either a positive or negative frame of reference (7,8,9). The word ANY tends to be used in sentences with a negative frame of reference, but not those with a positive frame (1, 13, 14). For example, speakers are likely to say “I don’t have any pain” rather than “I have any pain”. The reverse is true of the word SOME (14) whereby speakers are more likely to say “I have some pain” rather than “I don’t have some pain”. Consequently, negatively polarised words such as ‘any’ may have an increased potential to close down patient responses to questions during the consultation, thereby eliciting fewer concerns. Positively polarised words such as SOME may encourage patients to voice additional concerns in their response (1).

In 2007 Heritage et al. (1) tested whether altering the polarity of doctor enquiries about patient concerns in the US changed the number of patient concerns elicited. Physicians in family practice clinics in Los Angeles and Pennsylvania were randomised to one of two intervention arms. After the patient's initial problem presentation was complete, the physician was instructed to ask, whilst looking directly at the patient, either "Is there Anything else you want to address in your visit today?" (negatively polarized enquiry) or "Is there Something else you want to address in your visit today?" (positively polarized enquiry). The study found that significantly more patients volunteered more than one medical concern in the 'SOME' group (90%) compared with the 'ANY' group (53%). There was no significant increase in consultation length nor was there an effect on patient satisfaction.

The extent to which the findings of this US study translate to UK general practice is unknown. With the exception of Salisbury et al's study of the content of general practice consultations in their cross-sectional study based on video recordings there is minimal information about the proportion of patients in the UK who visit their GP with more than one concern (2). Drawing on Heritage et al.'s study (but not replicating the design), this feasibility study aimed to:

1. Test whether it was feasible to run a similar trial of the brief communication interventions of ANY and SOME formulated enquiries in a UK primary care setting under RCT conditions.
2. Collect information to inform the design of a future fully powered, UK based RCT, if warranted.

The study research objectives (RO) were to establish:

1. Whether UK GPs could be trained to successfully deploy the two intervention questions in a UK primary care context.
2. Whether soliciting for additional concerns increases consultation length.
3. The extent to which patients consult GPs with multiple planned concerns in mind.
4. The extent to which patients multiple planned concerns are voiced within GP consultations.

### 3. *Material and Methods*

#### 3.1 *Design*

A mixed-methods study was conducted to assess the feasibility of the brief communication intervention (Figure 1). First, a three arm RCT was designed to address the study research aims, the results of which are reported in this paper. In contrast to Heritage et al. (1) the study included an independent control arm to allow authors to explore within group differences (before/after the GPs viewed a training video to solicit additional concerns) and between group (intervention vs. control). The team also collected 3 baseline recordings from GPs in the intervention arms (any/some) prior to training to provide the opportunity to compare practice pre- and post-training behaviour. Second, a semi-structured interview study of GP participant views explored perspectives on the acceptability and utility of the communication intervention tested, reported elsewhere (15). Hampshire-B Research Ethics Committee (REC Ref: 12/SC/0678) granted ethics approval and the University of Southampton sponsored the study. Approvals were obtained from Dorset, Hampshire and Wiltshire Primary Care Trusts.

#### 3.2 *Eligibility criteria*

- 3.2.1 GP inclusion/exclusion criteria: To be fully qualified, HCPC registered GPs. For practical reasons of proximity to the researcher base, GPs working outside of Dorset, Hampshire, and Wiltshire were excluded.

3.2.2 Patient inclusion/exclusion criteria: To be over the age of 18, and attending the surgery for a GP consultation (patient or GP initiated). Patients not fluent in English were excluded due to the intervention conditions involving a specific lexical variation.

### *3.3 Recruitment, sampling and sample size<sup>1</sup>*

Two months before the study commenced GP practices were invited via the Primary Care Research Network to participate. 15 practices expressed an interest in participating. Practices were selected to include those with a range of patient list sizes and a mix of urban vs. rural settings. Setup meetings were organized with each practice to discuss the study and assess whether the GPs and practices were willing to participate, to set dates for recruitment and obtain written informed consent. Depending on the practice appointment system and preference, eligible patients on participating GP lists were recruited either by advanced invitation (written or telephone) or on the day of their appointment. Written informed consent was taken on the day of the patient's appointment prior to their participation; all patients were aware of their right to withdraw their data entirely from the study for up to one month after their appointment.

To enable a difference of 30% between the groups to be detected, with 80% power, 21 GPs providing 231 intervention recordings and 63 pre-training recordings (total 294 patients) were required. This was sufficient to allow the assessment of the feasibility, to provide a provisional estimate of effectiveness, and to inform the sample size calculation for a future fully powered trial. Up to 20 recorded consultations per GP were planned in order to account for data loss through technical failure (estimated to be approx. 2 per GP) or failure to recruit (estimated to be approx. 4 patients per GP).

### *3.4 Study procedure*

Figure 1 provides an overview of the study procedure.

#### *3.4.1 Procedure for GPs*

GPs were randomised to one of three groups:

- a. A negatively-polarised solicitation: "Are there ANY other concerns that you'd like to discuss today?"
- b. A positively-polarised solicitation: "Are there SOME other concerns that you'd like to discuss today?"
- c. A control condition, where no intervention was administered and usual care provided.

In the control arm GPs were recorded with an instruction to not alter their usual consulting style. GPs in the two intervention arms of 'any' or 'some' recorded 3 consultations before they were trained to deliver the intervention questions to permit comparative analysis of pre- and post-intervention communication practices for soliciting patient concerns. Intervention arm GPs were asked to watch a training video which mirrored the training used by Heritage et al. (1), with slight adaptations to terminology e.g. General Practice not Family Practice, and actor accents (Appendix A - summary of text and training video). For the recording of the consultations, GPs were instructed to:

- a. Start the video-recorder prior to beginning the consultation.
- b. Check patient awareness of the study and their continued consent to participate.
- c. Continue recording until after the patient had left the consultation room, to ensure that any 'late arising' concerns were captured.

For the intervention arm GPs a visible sticker was placed within the GP's room for them to see to remind them of their question. GPs were asked to deploy the intervention question as soon the patient had given their presenting concern(s) and before the GP explored the concern.

### 3.4.2 Procedure for patients

Prior to entering their GP consultation patients completed pre-consultation questionnaire data with RS, the Research Fellow. On entering their consultation patients were asked to give GPs a small recording reminder card to signal their willingness to participate. RS collected post-consultation questionnaire data immediately after the consultation.

[FIGURE 1]

### 3.5 Data collection

Data were collected via video-recorder and questionnaires. Video-recordings enabled fidelity of the intervention delivery to be assessed in relation to whether the GP's timing, wording and eye contact were congruent with training instructions (RO1) (see Appendix B), as well as the consultation length (RO2).

Patients completed a pre-consultation questionnaire to establish the number and nature of concerns for discussion within the consultation (RO3). Immediately following the consultation, patients completed a post-consultation questionnaire which collected socio-demographic data, information on how many concerns they discussed with the GP (RO3/4) and the MISS 21 to measure patient satisfaction (16), the patient enablement inventory (PEI) (17) to measure patient enablement, a single item patient satisfaction question and a single item health literacy question (see Appendix C).

### 3.6 Data Analysis

Table 1 summarises how the data were collected and analysed for each research objective (ROAs this was a feasibility study, we only present descriptive statistics in this paper. A detailed fidelity check compared intervention videos to the intervention instructions provided to GPs during training, focusing in particular on the timing of the solicitation, accuracy of the wording and GP eye contact during the solicitation (GPs were taught to look at the patient whilst soliciting for additional concerns). Control videos were coded all the way through to check whether additional concerns were solicited at any point in the consultation.

[TABLE 1]

## 4 Results

### 4.1 Feasibility of recruitment and randomisation

The study recruited 321 patients. One patient withdrew leaving 320 patients. At an individual level, 4/21 GPs did not recruit the target 14 patients, whilst 12/21 GPs exceeded the minimum number of 14 patients (Appendix D). The overall minimum recruitment target required 294 patients, suggesting recruitment to a definitive RCT would be feasible. Appendix D shows a breakdown of recruitment by GP and Figure 2 summarises the participant identification and recruitment process.

[FIGURE 2]

There were no reported issues in relation to GP willingness to be randomised and no cases whereby the GP refused to deploy the intervention question. No objective data for reasons for non-response

or non-participation are available. However, researcher field notes suggest the sensitivity of the presenting complaint(s), the time taken to complete questionnaires and practice staff support for the study influenced uptake.

Table 2 shows that patient characteristics between groups were well balanced, with the exception of booking type and reason for attending. Following discussion with the full trial steering group study inclusion were expanded to include advanced bookings. The decision was made after randomization based on initial recruitment rates that suggested restricting inclusion to acute visits was likely to result in a failure to recruit the target sample. Given the feasibility nature of the study such flexibility of design was appropriate, but it did represent an important departure from the original Heritage study (1) that provided the impetus for the current study.

[TABLE 2]

#### *4.2 Feasibility of delivering the intervention*

For most GPs the key concern was not being able access to an appropriate computer to allow them to listen to the 5 minute training video. The speakers or volume on some practice computers made it difficult to hear the video. This was resolved by giving GPs access to the study laptop. Viewing the video recorded consultations confirmed that adherence to the intervention was good with 86% (75/87) of the “Some” group and 88% (70/80) of the “Any” group delivering the intervention as instructed.

The level of missing questionnaire data was low, suggesting that patients found the questionnaires acceptable. Nineteen participants did not report the number of their planned concerns in the pre-consultation questionnaire and 7 participants did not provide the number of concerns discussed during their consultation in the post-consultation questionnaire. Hence, the number of planned concerns that were not raised and the number of unplanned concerns that were discussed (i.e. not mentioned in the pre-consultation questionnaire) could be calculated for 252/278 participants (91%).

#### *4.3 Pre- and post-consultation questionnaires: planned concerns vs. discussed concerns*

Pre-consultation participants reported an average of 1.67 (s.d. 0.90) concerns to discuss with their GP (range 1 to 6). Table 3 shows the distribution of planned concerns set out in the pre-consultation questionnaire compared to concerns that were reported as voiced in the consultation in the post-consultation questionnaire. Seventy six per cent of patients (192/252) voiced all of their planned concerns (shown in yellow) and 20% (51/252) discussed all their planned concerns as well as additional unplanned concerns not mentioned in the pre-consultation questionnaire (shown in purple). Nine participants reported leaving the consultation without voicing all of the concerns they had planned to discuss (shown in green). For instance, there was 1 patient who planned to discuss 3 concerns but only discussed 1.

[TABLE 3]

The number of concerns discussed in the consultation was very similar across groups. The majority of patients discussed one or two concerns. Findings suggest unvoiced concerns were not a large problem in the study population, regardless of the study arm. [Table 4]

A more detailed examination of the non-intervention video recordings (i.e. the control and the baseline consultations that were recorded in the intervention arms, prior to intervention GPs viewing the training video) showed that part of the reason for this may be that within the study population, GPs were already pursuing and / or patients were volunteering additional concerns. Figure 3 shows how and when additional concerns were raised during the consultation in the non-intervention data.

[FIGURE 3]

GPs did not tend to enquire about additional concerns at the start of the consultation. Instead, when they did enquire about additional concerns they tended to do so later in the consultation. Still, by the end of the consultation just 12.5% of participants (18/144) had not discussed an additional concern(s) with the GP in some way. GPs often asked about a specific issue either because of their knowledge of a patient's medical history or whilst examining the patients' notes. In 51% of cases, patients voiced a particular issue or mentioned that they had a list of concerns they wanted to address without being asked to do so by their GP.

#### *4.4 Consultation length, patient satisfaction and patient enablement*

The average consultation was 1.4 minutes longer in the "Some" group (mean 11.6, SD = 4.4) when compared to both the Control group (mean 10.2, SD = 3.7) the "Any" group and the control group had almost identical consultation lengths ("Any" group mean 10.2, SD = 4.0). The method used to solicit for additional concerns did not appear to impact on the consultation length relative to the non-intervention consultations (control group and baseline data).

There were only very small differences in the levels of patient satisfaction as measured by the MISS-21 scores, with less than 2 points separating the mean scores of the three groups. Overall, 258/271 (95.2%) of patients reported being very satisfied with the consultation in the single item satisfaction questionnaire. Patient enablement as captured by the PEI, was 1 point higher in the "Some" group than "Control" group and 2 points higher in the "Some" group than the "Any" group (Table 5).

[TABLE 5]

## **5. Discussion and conclusion**

### **5.1. Discussion**

This feasibility study aimed to establish whether it was feasible to run a brief communication intervention incorporating ANY and SOME formulated enquiries to solicit additional patient concerns in a UK primary care setting, under RCT conditions. Patients and GPs consented to have their consultations video-recorded, the recruitment target was exceeded and questionnaire completion rates were high. Our results suggest that recruiting UK GPs and patients to a video-recorded communication intervention study is feasible. Fidelity checks showed that a majority of GPs could be trained to successfully deploy the two intervention questions in a UK primary care context. Early solicitation of additional concerns did not appear to increase consultation length. Findings suggest few patients left their consultation without voicing their planned concerns. Patient satisfaction and patient enablement were high, particularly in the SOME group, and whether this difference is meaningful could be explored further in a larger study.. This study raises the question of whether patients may play a more active role in consultations than has been previously observed in some of the literature, with 50% voluntarily voicing their additional concern(s) within consultations. However, caution is required due to the lack of diversity in our self-selecting sample (see limitations).

#### *RO1. Can UK GPs be trained to successfully deploy two intervention questions ('any', 'some')?*

GPs were comfortable soliciting for additional concerns and fidelity checks and interviews as part of a nested qualitative study exploring GP views (15) suggest they were able to do this early in the consultation once the chief concern had been voiced. Most GPs perceived early solicitation to be an efficient way to ensure the elicitation of additional concerns and to aid time management by clarifying patient concerns early in the consultation. This is in line with other literature which

suggests there are significant benefits associated with early solicitation and agenda setting (12, 18), yet these practices are not routinely found in primary care consultations. Indeed, Heritage et al (12) noted that only around 5% of physicians ask about additional concerns at the beginning of the visit.

*RO2. Does soliciting for multiple additional concerns increase consultation length?*

In terms of the consultation length, the consultations were similar to Heritage et al.'s (1) average length of 11.4 and Salisbury et al.'s (2) finding of 11.9 minutes. Analysis suggested that the average consultation was only 1.4 minutes longer in the "Some" group (mean 11.6) compared to both the Control group (mean 10.2) and the "Any" group (mean 10.2). But this did not represent a meaningful increase in length and is, therefore, in line with previous literature that suggests soliciting for additional patient concerns does not appear to increase consultation length (1, 7, 18).

*RO3. To what extent did patients consult with (multiple) planned concerns?*

On average, patients in this study consulted with 1-2 concerns (mean 1.6, range 1-6), with only 20% of patients discussing three or more concerns. This is comparable to the number of concerns reported in Heritage et al.'s study (1) (mean 1.9, range 1-6). In contrast, Salisbury et al.'s (2) findings based on observing 229 consultations, across 22 practices in Bristol and North Somerset in the UK, found patients raised an average of 2.5 (range) concerns per consultation, with 41% of consultations involving at least three problems.

*RO4. To what extent do patients voice their planned concerns within GP consultations?*

Patients generally addressed all of their concerns in the consultation, regardless of the group to which their consulting GP was randomised. This result differs from the effect found in Heritage et al.'s 2007 study (1), which suggested that using the 'SOME' solicitation increased the number of patient concerns elicited and reduced the number of patients leaving the consultation with planned concerns left unvoiced. There may be a number of explanations for this difference. First, whilst the average number of concerns reported in our study is comparable to Heritage et al.'s (1.6 versus 1.9 respectively), in this study nine participants reported leaving the consultation without voicing a planned concern, 3 in the control group, 4 in the "Some" group and 2 in the "Any" group. This suggests that patients and GPs were managing to discuss the 'full' extent of patient's planned concerns without intervention and that our study population were dissimilar to those recruited in Heritage et al.'s study from the outset (1). Future comparative research could therefore investigate whether primary care patients in the UK are more 'active' than their US counterparts. Second, the three-arm RCT feasibility design adopted was different to Heritage et al.'s two-armed pre-test-post-test trial design. Other differences in terms of the design of the two studies make direct comparison inappropriate including: 1) eligibility criteria (this study included both new and long standing health problems and this contrasts with Heritage et al.'s focus on 'acute'/'new' problems); 2) recruitment strategies and 3) the demographic profiles of the participating patient cohorts (UK patients tended to be of white ethnicity and older, when compared to the population participating in Heritage et al.'s study). Finally, the funding and organisation of primary care services between the UK and US are clearly different with the former offering a service that is free at the point of access in contrast to a largely patient funded 'out of pocket' service, and this may influence patient disclosure of additional concerns.

*5.1.1 Comparison with the literature*

Just as Salisbury et al. (2) recently concluded that UK general practice consultations are complex encounters, our work and that of others (1, 2, 6) suggests that many patients have more than one concern and, as Salisbury et al. suggest, additional concerns can be dealt with relatively quickly. Hence, in line with Heritage's original conclusions (1), the fear of opening up Pandora's box is not well founded. Moreover, this feasibility study suggests GPs can be easily trained to solicit additional concerns early in the consultation. Despite differences in the findings regarding the importance of

lexical formulation, both studies clearly show that early solicitation can be accomplished and tends to elicit patient concerns. More recent work continues to indicate the importance of placement (early is best) as well as question phrasing for patient understanding in terms of what type of 'problem' or 'concern' may or may not be raised (e.g. 'new' or 'non-new' / existing problems) (19).

### *Limitations*

In this study, GPs included in the study were motivated to participate and had an interest in communication. It is possible that such GPs are different to GPs not willing to take part and other GPs not approached and this may impact the generalisability of our findings. Indeed, the kinds of patients that are comfortable participating in this sort of research could, be different to those who did not participate. That said, this limitation applies to much research, and is difficult to avoid.

The demographic characteristics were not varied. The distribution of HL was very skewed, with 82.5% reporting high health literacy. Patients for whom English is not their first language, and/or who have low(er) health literacy levels are likely to experience greatest difficulty voicing and discussing additional concerns. In addition, patients who attended with concerns that were particularly complex or 'delicate' may not have consented to participate.

### *5.2. Conclusion*

This study demonstrated feasibility and gathered a large corpus of video data, much of which can be used for secondary analysis to further our understanding of how to optimise the effective elicitation of additional patient concerns in the primary care visit. Understanding the nature and number of patient concerns and how best to solicit those concerns is important if we are to optimise the service offered to patients and the comfort of GPs doing their work.

### *5.3 Practice Implications*

In this study, GPs tended to solicit for additional concerns at the end of the consultation rather than early in the consultation. Subsequent work will look at the effectiveness or otherwise of these late arising solicitations in terms of establishing additional patient concerns. We suggest that GPs can solicit early in the consultation in the opening environment and patients can respond with additional concerns in response to such solicitations. This allows GPs to prioritise and manage patient expectations from the outset. Whilst this is an effective practice for establishing the full extent of patient concerns early on in the consultation, many questions exist about the precise timing and phrasing of questions and more research is warranted.

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## **Conflict of interests**

None.

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**i Recruitment**

Initially, only strategy 1 (see below) existed as a recruitment strategy. However, feedback from practices regarding the difficulty of implementing strategy one, along with their recommendations for modifying recruitment, led to revision. All of the practices managed their appointment systems in different ways, with some only using a walk in service (in contrast to others that offered a majority of advanced bookings), thus patient recruitment needed to be flexible and tailored to practice systems. Hence, 4 main strategies of recruitment were used:

*Recruitment strategies for patients who had booked appointments in 'Advance' (1-2 weeks before the appointment)*

All eligible patients with an appointment made  $\geq 1$  week in advance of the recruitment day were mailed an information pack (invitation letter and Patient Information Sheet (PIS)).

*Strategy 1:* A reply slip was included with the invitation letter. Those interested in participating returned a reply slip or telephoned the Research Fellow to express interest. The Research Fellow responded to those who replied to confirm eligibility and to arrange a meeting to discuss the study on the day of recruitment 20 minutes in advance of the individual patient appointment.

*Strategy 2:* A member of the practice team called all invited patients 1-3 days prior to the recruitment day, and using the study telephone recruitment script, confirmed that the information pack had been received, established interest and answered patient questions. Practices were given a summary of frequently asked questions (FAQs) to support the team members who were responsible for calling patients. Interested patients were asked to attend the practice 20 minutes before their appointment on the day of recruitment to speak to the researcher.

*Recruitment strategies for patients who had booked 'On the day' appointments*

'On the day' appointments included those who had booked  $< 1$  week in advance. The two strategies below outline the different practice members who could be involved in this approach. In both of the strategies below, patients who expressed an interest were given a 'Study Summary Sheet', which provided key information from the Patient Information Sheet in order to enable patients to digest information and make an informed decision when recruited on the day. Once interested patients had read the study summary, the Research Fellow confirmed their interest and eligibility, and checked their understanding of the study and what participation would entail. All patients recruited in this way were provided with the Patient Information Sheet to take home.

*Strategy 3:*

Using the 'Telephone and Face to Face Recruitment Script' receptionists asked eligible patients calling and/or booking in at the desk whether they would be interested in speaking to a researcher about the study.

*Strategy 4*

Using the 'Telephone and Face to Face Recruitment Script' GPs asked eligible patients whether they would be interested in speaking to a researcher about the study.