

The consultation and relational empathy (CARE) measure: development and preliminary validation and reliability of an empathy-based consultation process measure

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Background. Empathy is a key aspect of the clinical encounter but there is a lack of patient-assessed measures suitable for general clinical settings.

Objectives. Our aim was to develop a consultation process measure based on a broad definition of empathy, which is meaningful to patients irrespective of their socio-economic background.

Methods. Qualitative and quantitative approaches were used to develop and validate the new measure, which we have called the consultation and relational empathy (CARE) measure. Concurrent validity was assessed by correlational analysis against other validated measures in a series of three pilot studies in general practice (in areas of high or low socio-economic deprivation). Face and content validity was investigated by 43 interviews with patients from both types of areas, and by feedback from GPs and expert researchers in the field.

Results. The initial version of the new measure (pilot 1; high deprivation practice) correlated strongly ($r = 0.85$) with the Reynolds empathy measure (RES) and the Barrett-Lennard empathy subscale (BLESS) ($r = 0.63$), but had a highly skewed distribution (skew -1.879 , kurtosis 3.563). Statistical analysis, and feedback from the 20 patients interviewed, the GPs and the expert researchers, led to a number of modifications. The revised, second version of the CARE measure, tested in an area of low deprivation (pilot 2) also correlated strongly with the established empathy measures ($r = 0.84$ versus RES and $r = 0.77$ versus BLESS) but had a less skewed distribution (skew -0.634 , kurtosis -0.067). Internal reliability of the revised version was high (Cronbach's alpha 0.92). Patient feedback at interview ($n = 13$) led to only minor modification. The final version of the CARE measure, tested in pilot 3 (high deprivation practice) confirmed the validation with the other empathy measures ($r = 0.85$ versus RES and $r = 0.84$ versus BLESS) and the face validity (feedback from 10 patients).

Conclusions. These preliminary results support the validity and reliability of the CARE measure as a tool for measuring patients' perceptions of relational empathy in the consultation.

Keywords. Consultation, empathy, general practice, primary care.

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Introduction

Clinical encounters between patients and health care professionals are the core activity of medical care. Increasing attention is being paid to patients' views on care and the consultation, and to developing a more holistic, patient-centred approach.^{1,2} Empathy is considered to be a basic component of all therapeutic relationships³ and a key factor in patient's definitions of

quality of care.^{4,5} Empathy has been demonstrated to enhance the doctor–patient relationship and to improve patient enablement,⁶ and patient and doctor satisfaction in clinical encounters.^{7,8}

There is an ongoing academic debate concerning the precise meaning and definition of empathy.^{9,10} However, given that empathy is considered to be essential for the formation, development and continuation of the therapeutic relationship, it has been suggested that empathy in the clinical context involves an ability to (i) understand the patient's situation, perspective and feelings (and their attached meanings); (ii) to communicate that understanding and check its accuracy; and (iii) to act on that understanding with the patient in a helpful (therapeutic) way.^{9,10} The term 'relational empathy' has been used to describe such an approach in other contexts.^{11,12}

The measures that have been developed to assess empathy have been designed principally for use in psychiatric or nursing settings (in secondary care), rather than in more general medical settings or primary care. Additionally, concern has been expressed that these scales have been determined solely by professional opinion, and may fail to reflect patients' own views.^{9,10} Working with patients enabled Reynolds to develop his measure of empathy for use in nursing training that reflects patients' views of the helping relationship.¹⁰ There remains a need, however, for a patient-assessed measure designed for use in clinical settings. In this paper, we describe the development and initial validation of such a measure in general practice, which we have called the consultation and relational empathy (CARE) measure.

Methods

A review was undertaken of the conceptual basis of empathy and the commonly used measures, which we have reported elsewhere.⁹ An initial version of the CARE measure was developed from these theoretical considerations, supported by our previous in-depth qualitative work on patient's views on holistic care.¹³ The initial version of the measure is shown in Box 1. Answers were on a scale from 0 to 10 (0 = completely disagree, 5 = neither agree nor disagree, and 10 = completely agree).

Ethical approval was obtained for the pilot studies and interviews. The initial version of the CARE measure was piloted (pilot 1) in general practice, in a five partner (two female and three male) practice in an area of high socio-economic deprivation in Glasgow (a practice receiving maximum deprivation payment) serving a predominantly white population whose first language is English. All the GPs participated in the pilot. In this first pilot, we compared the CARE measure with the Barret-Lennard empathy subscale

Box 1 Initial version of the CARE measure (pilot 1)

1. The doctor's manner made me feel completely at ease
2. I felt the doctor was a bit abrupt
3. The doctor listened to everything I had to say with his/her full attention
4. The doctor seemed genuinely interested in me as a person
5. I felt the doctor slightly 'talked down' to me at times
6. The doctor was very sympathetic about my problems
7. The doctor seemed to understand exactly the way I've been feeling
8. I feel the doctor really respects me as a person
9. The doctor explained things in a way I could fully understand
10. The doctor had a positive attitude
11. The doctor was very thorough
12. I feel I can totally trust the doctor
13. Seeing the doctor has made me feel more hopeful about things

(BLESS)¹⁴ which is a very widely used measure in empathy research in psychiatry and nursing, and could be considered as a 'gold standard' in these settings. Consecutive patients were asked by reception staff on arrival for their consultation if they would be willing to complete the questionnaire after seeing the doctor, and asked on the questionnaire if they would be willing to take part in a follow-up interview.

We conducted 20 interviews with patients from the practice 2–3 weeks after the questionnaire, in order to assess further the face and content validity. Patients were sampled purposively in order to represent a range of characteristics and a range of empathy scores (Table 1). One to one interviews took place in a setting of the patient's choice; most preferred to be seen at the practice. Interviews were taped, and lasted between 10 and 30 min. A semi-structured format was followed in which patients were asked their overall views on the empathy measure, and then asked to comment on each item in detail. In these interviews, we also compared the CARE measure with the Reynolds empathy scale (RES)¹⁰, which is designed for use in face to face interviews.

The analysis of the transcripts of the interviews broadly reflected a grounded theory approach,¹⁵ in which comment and views on the measure and the individual items were grouped according to emerging themes, and the analysis was continuous and iterative.¹⁶

We also sought the views of 20 colleagues associated with the Departments of General Practice and Primary Care in Glasgow and Edinburgh, and the views of UK experts in research on consultation measures at a 2 day meeting in Edinburgh in July 2001, a few of whom provided ongoing advice concerning the development of the measure. An expert in research on empathy in

TABLE 1 Characteristics of patients interviewed in the first pilot study

Age (years)	Sex	Empathy score (possible range 0–130)	Marital status	Age at leaving full-time education (years)
19	F	102	Single	19
27	F	74	Single	17
28	F	55	Co-habiting	16
37	F	109	Married	18
38	M	66	Co-habiting	25
39	F	66	Divorced	16
45	F	110	Single	17
46	F	99	Married	15
46	M	107	Co-habiting	16
55	M	81	Married	15
60	F	106	Married	21
62	M	90	Married	15
65	M	104	Married	15
68	F	100	Widowed	15
68	M	106	Married	15
69	F	110	Married	15
74	F	110	Married	14
77	M	104	Married	15
77	F	110	Divorced	14
78	F	91	Widowed	14

nursing also gave ongoing advice and feedback. The aim of this was to support the face and content validation of the measure. These views were collected from free text comments invited at the end of sample CARE measure questionnaires, and followed-up where appropriate by ongoing Email correspondence.

Following statistical analysis of data from the pilot study, feedback from qualitative interviews with patients and feedback from the GPs and expert advisors, we substantially revised the CARE measure. The revised version was then piloted in a low deprivation practice (receiving no deprivation payments) of five GP partners (two female and three male) in Glasgow, again serving a predominantly white population whose first language is English. The revised CARE measure was compared with the RES and the BLESS. Thirteen individual qualitative interviews were then carried out with patients from this low deprivation practice, again purposively sampled to give a range of individual patient characteristics (Table 2).

Based on the patient feedback in pilot 2, only minor wording modifications were made. However, to re-check the validity of these changes, a third and final pilot was carried out. This took place in a four partner practice (two female, two male) in an area of high deprivation (as in pilot 1, and again serving a

TABLE 2 Characteristics of patients interviewed in the second pilot study

Age (years)	Sex	Empathy score (possible range 10–50)	Marital status	Age at leaving full-time education (years)
34	F	50	Married	16
39	F	38	Married	17
47	F	50	Married	15
52	F	50	Married	16
52	M	12	Married	16
53	M	31	Married	16
56	M	41	Married	24
60	M	50	Single	18
61	F	38	Single	22
64	M	50	Single	15
67	F	39	Married	17
71	M	50	Married	18
74	F	50	Married	15

predominantly white population whose first language is English), but the patients interviewed had a wider range of educational level (based on age at leaving full-time education). The final version of the CARE measure was again tested against the RES and the BLESS.

Statistical tests of validity and reliability were based on correlational analysis (Pearson's coefficient). Internal reliability was assessed by Cronbach's alpha. Factor analysis was used on the final version by means of SPSS.

Results

Initial version of the CARE measure

Concurrent validity. The first pilot study in primary care showed high correlations with the RES ($r = 0.85$, $n = 20$, $P < 0.001$) and the BLESS ($r = 0.63$, $n = 41$, $P < 0.001$). Thus, at an early stage in the development of the CARE measure, we were reassured by evidence of the concurrent validity of the new measure.

Face and content validity—patient's views. The 20 patients interviewed from the 'high deprivation practice' consisted of seven men and 13 women, with a mean age of 54 years (range 19–78) and a mean age of leaving full-time education of 16.3 years (range 14–25). They were chosen to reflect not only a mix of gender, ages and educational level, but also a range of empathy scores on the questionnaire (see Table 1). Irrespective of their ratings of the GP's empathy at the consultation, patients consistently endorsed the importance of the majority of the items in the CARE measure. They generally found the wording easy to understand, but the two negatively

phrased items (Box 1, items 2 and 5) were confusing. In addition, items 4 and 8, with the terms ‘as an individual’ and ‘as a person’ were picked out by some of the younger patients (who consulted less frequently) as they felt that the doctor would not get to know them as a person or an individual, and that this was not necessarily important to them at every consultation. Further exploration, however, revealed that they were equally wary of being treated as ‘just a case’ or ‘just a number’.

Face, content and construct validity—GPs and expert researchers view’s. Comments and suggestions on the initial version of the CARE measure were also received from 20 GP colleagues and the UK expert researchers on consultations in general practice. Most of the GPs’ comments were positive, in that they felt the items were easily understood and highly relevant to everyday consultations. Some of the experts pointed out that that initial version of the measure related to both the process and the outcome of the consultation, and that there could be confusion as to whether it was a ‘process measure’, as intended, or an ‘outcome measure’. In particular, items 8, 11 and 13 were felt to be ambiguous in this respect. Item 12 was felt to be too vague and not necessarily linked to empathy.

Internal reliability and distribution. The Cronbach’s alpha (the test of internal reliability) revealed that the two negatively phrased items (items 2 and 5) weakened the Cronbach’s alpha when included. A further consideration was the distribution of the responses. The initial version of CARE measure utilized a 10-point rating scale for each item (ranging from ‘completely disagree’ to ‘completely agree’). However, analysis of the initial pilots showed this produced highly skewed responses; 42% of respondents scored the maximum possible score (summing all scores of all the individual items), and the mean score was 89% of the maximum possible score (skew -1.879 , kurtosis 3.563) with a coefficient of variation of only 17%.

Changes made to the initial version of the CARE measure. Based on the statistical analyses detailed above, and the views of the 20 patients interviewed, together with feedback from experts and GP colleagues, the initial version of the CARE measure was substantially revised. As shown in Box 2, it was reduced to 10 items. The 10-point rating scale was changed to a 5-point rating scale from ‘poor’ to ‘excellent’, in an attempt to reduce the skewed distribution of the measure. A short explanatory description of each item was added, based on the comments made by patients in the qualitative interviews (see Appendix for final version). The negatively worded items (2 and 5) were removed on the basis of the weakening influence they had on the internal reliability of the measure, and because several patients found the negative wording

Box 2 Revised version of the CARE measure (pilot 2)

How was the doctor at...

1. Making you feel at ease
2. Letting you tell your story
3. Really listening
4. Being interested in you as a whole person
5. Fully understanding your concerns
6. Showing care and compassion
7. Being positive
8. Explaining things clearly
9. Helping you to take control
10. Making a plan of action with you

confusing (see above). However, the phrases ‘not cold or abrupt’ and ‘not treating you as a number’ were inserted into the explanatory description of items 1 and 4, respectively, thus retaining the concepts (see Appendix 1). Item 4 was re-worded to change the emphasis from ‘genuinely’ and ‘as a person’ to ‘being interested in you as a whole person’ on the basis of the patients’ comments. The importance of the patient’s narrative was apparent from many of the interviews, so a new item ‘letting you tell your story’ was included in the revised measure (item 2). Item 6 was re-worded from ‘sympathetic’ to ‘showing care and compassion’ (item 6) as ‘sympathy’ had connotations that were different from ‘empathy’ for some of the GPs and expert researchers. Item 7 was changed from ‘feelings’ to the more generic term ‘concerns’, as several patients and GPs pointed out that exploring feelings is not necessarily important in every consultation. Item 8 was removed on the basis of patient’s views on the term ‘as a person’, but the concept of the doctor being respectful was incorporated into item 1 of the revised measure (Appendix). Items 11, 12 and 13 were removed on the basis of not being clearly related to the process of an empathetic consultation, as pointed out by the expert group. The important processes in ‘feeling hopeful’ at the end of the consultation seemed to relate to helping the patient ‘take control’ of their illness or problem, and to ‘making a plan of action’ with the patient. Thus these two items were included in the revised measure (Box 2, items 9 and 10). The revised CARE measure was then tested in pilot 2.

Revised version of the CARE measure—pilot 2

Concurrent validity. The revised version of the CARE measure showed strong correlations with the RES ($r = 0.84$, $n = 13$, $P < 0.001$) and the BLESS ($r = 0.77$, $n = 88$, $P < 0.001$) in the second pilot, again supporting its concurrent validity.

Face and content validity. Interviews were conducted with six men and seven women, with a mean age of

54 years (range 34–74) and a mean age of leaving full-time education of 17.3 years (range 15–24). These subjects had recorded a range of empathy scores on the questionnaire (see Table 1) in the second pilot study in general practice. These interviews supported the face and content validity of the revised version, as did further feedback from the expert working group. Minor changes were made to the precise wording of the explanatory stems of each item, but not to the items themselves.

Internal reliability and distribution. The internal reliability of the revised CARE was high, with an overall Cronbach's alpha value of 0.92. Removal of any of the 10 items in the measure had the effect of weakening internal reliability. The revised measure also exhibited less of the 'ceiling effect' seen with the initial version, with reductions in skew and kurtosis (skew -0.634 , kurtosis -0.067), and an increase in the coefficient of variation (35%). Whereas the maximal possible overall score was observed in 42% of respondents in the initial version in primary care, this was reduced to 27% in the revised version in pilot 2.

The final version of the CARE measure (Appendix) was then tested in pilot 3, as a final check of validity.

Final version of the CARE measure—pilot 3

The final version of the CARE measure again showed strong correlations with the RES ($r = 0.85$, $n = 10$, $P < 0.001$) and the BLESS ($r = 0.84$, $n = 10$, $P < 0.001$) in the third pilot (in the high deprivation area). Interviews were conducted with five men and five women, with a mean age of 45 years (range 22–78), a mean age of leaving full-time education of 17.1 years (range 14–21), and a range of empathy scores. These interviews confirmed the face and content validity of the final version of the CARE measure (Table 3). The internal reliability of the CARE measure remained high, with an overall Cronbach's alpha

value of 0.93. Removal of any of the 10 items in the measure again had the effect of weakening internal reliability. Maximal possible overall score was observed in 26% of respondents in pilot 3.

Discussion

In this paper, we have reported the development and preliminary validation of a new process measure based on a broad definition of clinical empathy, in the context of the clinical encounter. We have called this the CARE measure. The aim of this measure is to provide a tool for the evaluation of the quality of consultations in terms of the 'human' aspects of medical care. By basing the measure on process rather than outcome, it provides doctors with direct feedback of their strengths and weaknesses in terms of relational empathy, as perceived by their patients. For this reason, it has utility not only in research, but also as a tool for self-audit (e.g. in appraisal and revalidation), and recently has been accredited for use in GP appraisal and revalidation in Scotland.¹⁷ It may also be of use in teaching and assessing consultation skills in undergraduate and postgraduate medical education. As a patient-reported measure, it avoids any attempt to judge the quality of technical care (such as clinical examination), which is likely to be best assessed by other (direct) methods.

The theoretical considerations regarding empathy in the clinical context have been discussed previously.⁹ Empathy can have moral, cognitive, emotive and behavioural components, though the importance of each to the clinical encounter is not known. The CARE measure may relate to all components of empathy, although items 1 and 6 (Appendix) may particularly relate to the emotive component, with the other items relating to cognitive and behavioural aspects. However, it should be borne in mind that it is the patient's overall perception of the doctor's empathy that appears to determine beneficial effects.^{9,10}

The wording of the CARE measure reflects a desire to produce a measure that is meaningful to patients across the socio-economic spectrum. In this respect, it may differ to some extent from current measures of patient-centredness, given the evidence that many patients seem generally to prefer a directive style of consultation (especially the elderly and those of lower social class).¹⁸ Thus, although the items in the CARE measure would include the major aspects of patient-centred consulting as commonly defined, the explanatory stems to each item are intended to allow for flexibility in the 'degree' of patient participation, according to the patient's desire for this. Our involvement of patients' 'voices' at all stages in the development of the measure, including patients of low socio-economic status, has helped considerably in achieving this aim.

In conclusion, our aim was to develop a consultation process measure based on a broad definition of

TABLE 3 Characteristics of patients interviewed in the third pilot study

Age (years)	Sex	Empathy score (possible range 10–50)	Marital status	Age at leaving full-time education (years)
22	F	40	Single	16
28	M	37	Single	20
30	M	46	Single	18
35	M	34	Divorced	18
43	F	50	Married	17
47	M	42	Co-habiting	16
47	F	49	Divorced	21
55	F	50	Married	15
63	F	27	Divorced	16
78	M	17	Single	14

empathy, which is meaningful to patients irrespective of their socio-economic level. The preliminary data reported in this current paper seem to support the validity and reliability of the new CARE measure. Work is underway on how the new measure relates to other current measures of consultation quality, including the 'patient enablement instrument'.¹⁹ We have also investigated recently the ability of the CARE measure to discriminate effectively between doctors, in a large study of 3000 patients in general practice, the results of which are currently being prepared for publication. The suitability of the CARE measure as a quality tool in secondary care is also currently being investigated. Further work, however, is required to validate the measure in linguistically and culturally diverse settings.

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Ethical approval: Detailed in Methods.

Conflicts of interest: None.

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