A MINIMAL SET OF OUTCOME INSTRUMENTS FOR CLINICAL AUDITS

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For the National Musculoskeletal Medicine Initiative I devised a set of audit forms based on what I considered natural practice. The idea was to avoid introducing questions and devices that practitioners would not normally use, and which therefore would be considered an intrusion, with which they would not comply in the conduct of a study. I have since used these instruments in several research studies.

The instruments do not cover every domain of a patient or their problem. They are not intended to do so. Nor do they reflect what so-called experts currently recommend. Those experts recommend a battery of tests, but that recommendation ignores the imposition on patients. It can take up to an hour to administer the instruments conventional required of research studies. No-one in conventional practice is able to conform to such a demand on their time. Furthermore, some ethicists question the burden placed on patients to spend so much time being "assessed".

The rationale behind my instruments is that any caring and responsible doctor would normally ask certain colloquial and clinical questions, in the course of their normal interaction with the patient. My instruments do little more than record the responses to those routine questions. In most instances, to record a response amounts to no more than placing a mark in a box. So, the demand on the practitioner is only seconds worth of effort, to record what they normally do. In only some instances is the actual writing of words required.

LOGIC

The rationale of the instruments can be understood by comparing them to the chronological course of a consultation.

Surely one of the earliest questions that a doctor asks of their patient is "how are you?". The typical responses range through: worse, no better or no change, better, to cured or an equivalent. So, since you would normally ask this question, participating in an audit simply requires that you tick the appropriate box.

The patient's principal complaint, and their presenting feature is pain. Therefore, it is essential that their pain score be recorded. Unless you do so, you cannot establish empirically if their pain subsequently gets better. Two instruments can be used for pain scores: the Visual Analogue Scale or the Numerical Pain Rating Scale. Both are the same conceptually. They require the patient to rate the severity of their pain on a 0-10 scale. They differ only in the manner of recording. For the VAS, the patient places a mark on a 10 cm line. For the NPRS, the patient (or the assessor) ticks the box that corresponds to the patient's rating. The VAS requires face-to-face assessment. The NPRS can be administered over the telephone for patients who have

had the instrument explained to them, and have previously reported their baseline score. Both the VAS and NPRS have been validated [1,2].

Surely, soon thereafter in a consultation the doctor would make some sort of enquiry about "how are you going" or "what are you doing". These questions pertain to physical function. There are instruments that can measure this, such as the SF-36 or the ODI. However, those instruments require specially prepared forms, and extra time to complete. The issue, here, is not to conform obsessively to some sort of "approved" instruments, but to obtain information about physical function. That can be done by using the Patient Specified Functional Outcome Scale. The virtue of this instrument is that it does not ask stupid or irrelevant questions, such as "how fast can you walk up ten steps" (to a patient who lives in flat house), or "are you working" (to a patient who has retired). The instrument is normalized specifically for each individual. They compare themselves not to some external and imposed standard, but to the needs and desires of their own life. The instrument has been validated [3,4,5]. Two burdens are required of the assessing physician. The second is that they must write down four words, which record the patient's response. This should not be viewed as a burden. The instrument can be adapted to include the most common responses, which can be ticked, in order to save writing. The first burden is that the assessor must ask a long question. It is: "I want you to tell me, four things in your life, which you can't do because of your pain, or are restricted in doing, AND (this is the critical bit) which MOST DEARLY you would want restored by a successful treatment." Responses are not ranked. They are only written down in the order that the patient thinks of them. Typical responses, encountered in research studies, are: "can't work", "can't have sex", "can't play with the kids", and "can't [recreate = play golf, go fishing, sit in the cinema]". Others include "walk to the shops", "drive the car". The response must be ones of a physical nature, i.e. one that, in principle, can be demonstrated and witnessed by others (although in the case of "sex", we have to take the patient's word). Responses cannot be metaphysical, such as "be whole again", or "have no pain". The responses must be physical disabilities, of value to the patient, that result from their pain and which successful treatment should restore. For an audit all that is required is to write down: work, sex, kids, golf. Later, in the follow-up, the assessor asks: which of your activities have you regained. These can be scored in a binary fashion: yes or no; or in a graded fashion: not at all, a bit, quit a bit, or completely. Which of these options is used is a matter of choice for the research team. This instrument is brutal. It is not designed to pick up partial scores. But it is very specific. If a patient restores all their desired activities there can be no doubt that the treatment was successful. You will have given the patient their life back. However, if you cannot restore their physical life, we have grounds to question the effectiveness of your treatment, regardless of what the patient says their pain score is. In order to avoid confounding effects, the four activities offered by the patient must be ones that are reasonably attributable to their back pain. "Breathe again" (by an asthmatic) is not a legitimate response, for it is not affected by back surgery.

My instruments do not now progress to the usual assessments: of psychology or other social domains. My argument is that these are relevant only for treatments that make modest gains in depression or coping or stress. If a treatment really works, it will be evident in serious reductions in pain scores, accompanied by demonstrable improvements in physical function. If you achieve that, you do not need

supplementary and second-rate evidence from psychosocial assessments. That is for weak treatments only.

However, a critical assessment pertains to use of other health care. If your patient still goes to the chiropractor, and still sucks drugs, you cannot claim to have been successful. You cannot tell if the outcome is due to your ministrations or those of the other therapist. So, success must be accompanied by abandonment of other health care, or a serious reduction in it. A somewhat lower does of opioids, does not count; but no more opioids and using only simple analgesics would be a partial win. No drugs at all would be a complete win. Nor can you claim to have been successful if you patient is on a waiting list for a Pain Clinic.

A final domain of enquiry pertains to return to work. This is pertinent to workers compensation cases. Insurers are not interested in pain scores or ADLs, if they are still paying wages replacement. So, we cannot avoid recording return to work. In my instruments, this is done by tick the box.

INSTRUMENTS

Copies of the instruments follow, for appraisal. They can be printed on a word processor and inserted into any medical record that uses A4 stationery. They can be adopted from their Word form into any electronic medium that a surgeon might prefer to use for their records. In paper form, the inception data are two sides of a single A4 page, as are the follow-up data.

References

1. Farrar JT, Young JP, La Moreaux L, Werth JL, Poole M. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001; 94:149-158.
2. Briggs M, Closs JS. A descriptive study of the use of visual analogue scales and verbal rating scales for the assessment of postoperative pain in orthopedic patients. J Pain Symptom Manage 1999; 18:438-446.
3. Stratford P, Gill C, Westaway M, Binkley J. Assessing disability and change on individual patients: a report of a patient specific measure. Physiother Can 1995; 47:258-263.
4. Westaway MN, Stratford PW, Binkley JM. The patient-specific functional scale: validation of its use in persons with neck dysfunction. J Orthop & Sports Phys Ther 1998; 27:331-338.
5. Chatman AB, Hyams SP, Neel JM, Binkley JM, Stratford PW, Schomberg A, Stabler M. The patient-specific functional scale: measurement properties in patients with knee dysfunction. Phys Ther 1997; 77:82-829.

OUTCOMES AUDIT

[INSERT NAME OF PARTICIPATING SURGEON]

ASSESSMENT FORM - INCEPTION DATA PAGE ONE

Patient ID : ..... ***Date :*** .....

NUMERICAL PAIN SCALE

Pain at present: ……. (0 - 10)

Pain last week: ……(0 - 10)

PATIENT SPECIFIED, FOUR ACTIVITIES OF DAILY LIVING

that the patient feels are impeded by their pain, and which MOST DEARLY they would want restored.

1. …….

2. …….

3. …….

4. …….

STRUCTURED QUESTION TO DETERMINE 4 ADLS.

> **"I am going to ask you a difficult question, … but it is difficult only because it is a long question. So, please bear with me.**
>
> **I want you to tell me… FOUR things in your life, that you can't do, or have difficulty doing, because of your back pain, … and WHICH MOST DEARLY you would want restored.**
>
> **These four things can't general or vague, such as 'to be free of pain', or 'to be whole again'. They have to be activities - something that you do, and which someone else could see you doing."**

DO NOT offer suggestions or prompts. Be patient even if the patient has difficulty thinking of activities.

If patients remain confused, or offer responses that do not constitute ADLs, offer:

> **"It is as if I were a geni, and could offer you four wishes, but the wishes must be things that you want to be able to do. What would you wish for?"**

OUTCOMES AUDIT

[INSERT NAME OF PARTICIPATING SURGEON]

ASSESSMENT FORM - INCEPTION DATA **PAGE TWO**

Patient ID : ..... ***Date :*** .....

CURRENT HEALTH CARE				
"What treatment or treatments are you currently using for your back pain ?"				
Record:			**nature**	**dose (per week)**
Medication	**NO**	**YES**		
GP	**NO**	**YES**		
Specialist	**NO**	**YES**		
Surgery	**NO**	**YES**		
Pain Clinic	**NO**	**YES**		
Physiotherapy	**NO**	**YES**		
Other	**NO**	**YES**		

VOCATION: (enter job description)				
Employed	**FT**	**PT**	**Hours per week:**	**Unemployed**
Notes:				

OUTCOMES AUDIT

[INSERT NAME OF PARTICIPATING SURGEON]

ASSESSMENT FORM - PROGRESS DATA **PAGE ONE**

Patient ID : ..... ***Date :*** .....

PAIN COMPARISON

Please circle the word that best describes your average pain level now compared to what it was like when your pain started.

worse **same** **less** **nil**

NUMERICAL PAIN SCALE

Pain at present: ……. (0 - 10)

Pain last week: ……(0 - 10)

FOUR ACTIVITIES OF DAILY LIVING

A. Transfer from Inception data
B. Indicate if ADL restored or not. **RESTORED**

1. ……NO A BIT A LOT COMPLETELY

2 …… NO A BIT A LOT COMPLETELY

3..…… NO A BIT A LOT COMPLETELY

4..…… NO A BIT A LOT COMPLETELY

OUTCOMES AUDIT

[INSERT NAME OF PARTICIPATING SURGEON]

ASSESSMENT FORM - PROGRESS DATA PAGE TWO

CONTINUING HEALTH CARE				
"Are you having, or intending to have, any form of treatment for your back pain ?"			**NO**	**YES**
If so, record:			**nature**	**dose**
Medication	**NO**	**YES**		
GP	**NO**	**YES**		
Specialist	**NO**	**YES**		
Surgery	**NO**	**YES**		
Pain Clinic	**NO**	**YES**		
Physiotherapy	**NO**	**YES**		
Other	**NO**	**YES**		

RETURNED TO WORK?					**Same load**		**Reduced level**		**Less demanding**	
Previous job?	**YES**	**NO**	**FT**	**PT**	**YES**	**NO**	**YES**	**NO**		
New job?	**YES**	**NO**	**FT**	**PT**	**YES**	**NO**			**YES**	**NO**
Retired?	**YES**	**NO**	**Still on compensation?**		**YES**	**NO**	**Pension?**		**YES**	**NO**