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Implementation of Patient-Reported Outcomes (PROMs) from specialist pain clinics in England and Wales

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Implementation of Patient Reported Outcomes from Specialist Pain clinics in England and Wales: experience from a nationwide study

Short Title: Patient Reported Outcomes from Specialist Pain Clinic in England and Wales

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Abstract

Introduction

Evaluating outcomes in routine clinical practice is a significant challenge for specialist pain clinics due to the complexity of interventions provided and the subjective nature of pain. This study reports findings from implementation of Patient Reported Outcomes (PROMs) in pain clinics in England and Wales between 2011-2013.

Methods

A paper-based questionnaire was administered at a first appointment in participating centres. This assessed quality of life, experience of health care and health care usage with postal follow-up at 6 and 12 months by the research team. Feasibility was assessed in terms of response rates, completion rates and outcomes.

Results:

Ninety-one (56%) clinics participated, entering 9588 patients (19% of those eligible). For responders there was a 92% item completion rate. The drop-out rate was high, 46% and 19% returned questions at 6 and 12 months respectively. Quality of life at baseline was low, with a mean EQ5D-3L Time Trade Off (TTO) value of 0.32. Amongst responders at 12 months, 92% continued to experience significant pain. For those with planned discharges 30% achieved the Minimal Important Change (MIC) for quality of life. Nonetheless, 70% reported positive experiences of care.

Conclusions:

Patients attending UK pain clinics report an extraordinarily poor quality of life and difficulty with understanding their condition. Problems with PROMs implementation included initial recruitment, follow-up response rates, classification systems and benchmarking. Successful implementation should include use of electronic data capture, feedback and focus on gradual improvement. To achieve this would require extended periods of funding.

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Introduction

Specialist multi-disciplinary pain services were developed to meet the needs of patients who cannot be managed by a generalist practitioner. Services are expected to assess and treat complex pain disorders by adopting a biopsychosocial approach through various interdisciplinary, multimodal interventions.(Gallagher 2005, Turk 2002). Government-sponsored reviews of specialist pain services have highlighted the lack of information on the patient population, treatment offered, and their outcomes.(Department of Health England 2008, Quality Improvement Scotland 2007)

The work of IMMPACT has helped the research community with data collection (Dworkin, Turk et al 2005). There is also consensus on which Patient Reported Outcome Measures (PROMs) should be collected in clinical practice (Devlin and Appleby 2010, Clarke et al 2003, Ashburn 2012, Tauben 2012, Kaiser et al 2017), with broad support from the clinical community (Holmes et al 2017). Currently, however, there is only limited information on the practical implementation of patient-reported outcome measures (PROMs) in pain services. The benefits of PROMS in improving clinical and cost effectiveness have been shown in diverse areas such as cancer care, joint replacement surgery, wound healing and diabetes (Hoque 2015).

In the UK, a clinical registry to collect patient outcomes PACS (Pain Audit Collection System) was established in 2003 and worked well for a small number of services. However, large scale implementation was hampered by incompatibility of software systems, the lack of funding for data analysis and poor quality data from many centres (Griffths, Campbell et al 2003, Hall, Merrett et al 2008). It ceased operation in 2008. Outside the UK other clinical registries have been attempted to a limited extent. In Quebec, Choinere described formation of a patient registry with follow-up at six months using PROMs, but only in 5 tertiary centres (Choinere et al 2017). Tardif described a similar process to PACS in Australia to establish the electronic Persistent Pain Outcomes Collaboration (ePOCC: Blanchard et al 2017), and this continues to grow. In the USA, the development of the PROMIS database for capturing patient outcomes (Cella, Yount et al 2010) was then taken up by The Pain Assessment Screening Tool and Outcomes Registry (PASTOR: Cook, Buckenmaier et al 2014). However, no comparison of US centres has been published. Garcia reported successful implementation of PROMs in 316 Spanish pain services, but the use of researchers to recruit and short follow-up times limit its generalisability (Garcia et al 2016).

The UK government funded a National Pain Audit over a four year cycle from 2010 to 2014 in England and Wales (Price et al 2012) to improve specialist pain care Details of clinics and case-mix are described previously .(Price 2018) The brief was to develop a robust database that all specialist pain services could submit to (Department of Health 2008). This paper aims to evaluate the feasibility of PROMS collection through formation of a patient registry to over a one year journey, (from 2011-13) in order to inform future data collection across the spectrum of pain clinics in England and Wales, using clinic-based recruitment with postal follow-up by researchers.

Methods

Study Design and setting

This was a cohort study nested within a National Pain Audit (Price et al 2012) with a focus on assessing the feasibility of data completion and response rates to a PROMS questionnaire. One hundred and sixty-one pain clinics in England or Wales, identified in the National Pain Audit as specialist pain services (International Association for the Study of

Pain 2009), were invited to recruit patients to this PROMs study. Participation in National Audits is expected for National Health Service (NHS) organisations although there are no penalties for non-participation.

Subjects

All children over 12 years old and adult patients in England or Wales attending for the first time during a three-month period between 2011 and 2012 were eligible for inclusion. Patients with cognitive or language difficulties were included if they were able to successfully complete a questionnaire with an interpreter or with help as judged appropriate by the clinic. Patients who declined to complete the questionnaire, or for whom the clinician failed to enter sufficient details on the case-mix tool (see below), were excluded. Support with data collection was provided for the clinics through a series of Frequently Answered Questions on the National Pain Audit webpages and a helpline.

Data Collection Period

The patient-reported outcomes element consisted of three phases. In year 1, while services were being identified and enrolled, the questionnaire and a web tool for clinicians to enter clinical details were assembled and piloted in 12 centres. In year 2 of the audit, each participating clinic was asked to enrol patients over three months of continuous data collection throughout the period of one year at a point when a provider felt most ready to start collection. It was felt that the focused period would maximise the likelihood of collection.
Clinical details were entered into a web tool by the clinician seeing the patient. This was developed by Dr Foster Research UK, the main contractor for the Audit. Each patient completed a paper set of questions that was retained by the clinic and returned to the study team. This cohort was then followed up after 6 and 12 months from entry by direct mailing by post of follow-up questions by Dr Foster Research UK, with patients invited to telephone if they had difficulty. Further reminders to complete the questions were not issued.

Web tool development

An earlier entry of patient data into a Pain Collection System that was Microsoft Access-based (Griffiths 2003) produced problems at interfaces with hospital IT systems, especially when Access was upgraded. A web-based system was therefore developed by the main contractor to enter patient details and case-mix (supplemental data). A pilot of this over a six-month period with 12 clinicians across England demonstrated that clinicians struggled to enter ICD-10 codes, with many refusing to enter data. For this reason, and to ensure maximal uptake of the audit, free text diagnoses were permitted.

Questionnaire Development

The selection of PROMS was guided by the Department of health guidance on PROMS which recommends a generic measure and a disease specific measure. We had previously used the Brief Pain Inventory in the PACS database (Griffiths 2003) after substantial testing of alternatives. The generic quality of life measure EQ5D was selected as it is used by the national PROMS audit (Department of Health 2012).Treatments were grouped based on a previous database PACS (Griffiths 2003). As in the well-established PROMS Hip and Knee Audits (NHS Digital 2014), a disease-specific scale (the Brief Pain Inventory) and a global scale of health (Euroqol 5D-3L) were chosen. The Brief Pain Inventory (Keller et al 2004,

Tan et al 2004) has demonstrated utility in terms of data entry and analysis in UK pain clinics (Hall et al 2008). The Euroqol 5D-3L (EQ5D-3L) has been shown to be relatively responsive in the chronic pain population (Obradovic 2013) and its use enables quality of life comparisons with people with other long-term disabling conditions. Work and healthcare resource questions that elicited data on unemployment, presenteeism and absenteeism were chosen on advice of experts. Ratings of the usefulness of the service and patient satisfaction were developed with patient groups. Personal data collected were age and sex; ethnicity (Office for National Statistics 2011) was collected only for the final follow-up. Patients were also asked what treatment they had received using a classification that had earlier been developed with the Department of Health in relation to waiting times for care pathways (Department of Health 2010). The patient groups and clinicians reviewed and approved the PROMs and a pilot group of 12 sites tested the questionnaire. The final data items are available in Supplementary Table S1.

Data collection and oversight

Piloting at twelve sites indicated that paper-based questionnaires and electronic capture of patient details were the optimal combination to enrol patients. Patients were assigned a unique study Identifier (ID) via the paper-based questionnaire. This ID was then entered into the web tool to collect diagnosis and demographic details. At the end of 3 months, paper-based patient questionnaires were collected by courier from each site. These were scanned, uploaded and linked to the case-mix tool data. Patients were sent follow-up questions at 6 months and 12 months after their first appointment via the research team. Findings were reported in line with STROBE guidance for cohort studies (Von Elm 2008).

Data validation

The number of patients entering the study was cross-referenced with activity returns from the national hospital administrative database for England, Hospital Episode Statistics (HES), for pain clinics during the recruitment period (new patients seen). The denominator was also calculated as the estimated numbers seen by the clinic in three months. The proportion entering the study was then calculated. Patient data were analysed for completeness and a deeper analysis was undertaken to improve follow-up questionnaire design. Questions that were conditional on a previous answer, work-related, or required an opinion were found to be less well answered and so these types of questions were adjusted on the final round.

Data Analysis

Data were uploaded to Excel and SPSS. Diagnostic results were grouped by International Classification of Diseases, version 10 (WHO) chapter, e.g. musculoskeletal pain. Free text diagnoses were mapped to ICD-10 by three clinical members of the National Pain Audit scientific committee.

Mean Time Trade Off (TTO) values for the EQ5D and mean values for Brief Pain Inventory (BPI) subscales of Pain Severity and Pain Interference were reported in line with manuals for both questionnaires. Differences between time points were tested using paired t tests for parametric data. However, as this may not provide a true representation of important changes in patient outcomes, the Minimal Important Change (MIC) was used to define a good improvement in pain. For the BPI the MIC was defined as a 2 point change in the Pain Severity Scale and a 1 point decrease in mean Pain Interference score (Mease 2011,

Susan 2011, IMMPACT 2008); for the EQ5D-3L 0.074 increase in TTO value was used as the MIC value (Walters 2005). EQ5D-3L scores were compared with UK population norms for other conditions (Sullivan 2011).

Pain clinics see a wide variety of cases with some tertiary providers seeing many highly complex cases. Since case-mix may affect outcome, for direct comparison of provider case-mix and outcomes, a case-mix adjustment model was built. Details of this are in Supplementary Information Methods S1.

Funnel plots for the risk-adjusted PROMs were calculated to show variation by unit by change in BPI score and EQ5D-3L TTO value using the Department of Health guidance on case mix adjustment (Supplementary information 1). (Department of Health 2012)

Feedback

A key feature of any patient registry is feedback. Direct feedback to services was limited: results were issued in a series of annual reports and individual clinic outcomes uploaded onto a public facing website (**{ HYPERLINK "http://www.nationalpainaudit.org.uk" }**) which linked to NHS choices, the main source of information on healthcare providers in the NHS. Public facing data have been shown to improve quality of data and feedback (Hoque 2015).

Ethical Considerations

There was no transfer of patient identifiable data. The patient questionnaire contained patient details which were scanned in, linked to the Study ID then held separately to their data. Consent was formally sought from patients to link their questionnaire data anonymously with Hospital Episode Statistics Data and, where this was declined, questionnaires were destroyed immediately after data entry. Information was managed by Dr Foster Research UK whose Information Security Management System (ISMS) is certified to ISO 27001:2013 by Certification Europe. A full explanation of Dr Foster Research UK's approach to data management is given on their website (https://www.drfoster.com/company/information-governance/patient-privacy/).

Oversight of the data processes, permissions for the study and handling of data were managed by the Health Quality Improvement Partnership who oversee all contracts for National Audits. (**{ HYPERLINK "http://www.hqip.org.uk" }**).

Following completion of the audit, anonymised patient data were uploaded to the UK Government data website (**{ HYPERLINK "https://data.gov.uk/" }**) by the main contractor, as stipulated by the contract with the Department of Health for each period of collection.

Results

Flow and numbers

Figure 1 shows the extent of data capture. Ninety-one clinics out of 169 (a response rate of 56%) recruited 9,588 patients. Hospital Episode Statistics data showed that 49,460 patients attended these clinics over a quarter year in 2011-12, giving an overall estimated patient capture of 19%. There was wide variation between clinics in the numbers entered per head of population, with an average of 11 patients per 100,000. No single-modality clinic (ie service offering a single treatment) returned patient level data. Clinics ranged from one

seeing 16 patients per year to one seeing 2000, and ranged from single operator pain clinics to tertiary, sub-specialist services. The type of service was not predictive of the response rate. Three returns were spoilt. HES data proved unreliable as a baseline as we discovered significant under-reporting of activity compared to responses in some centres, so it was difficult to truly estimate response rate.

In terms of responders being able to complete the questionnaire, there was a 92% overall item completion rate in both initial and six-month follow-up questions. From the initial set, seven questions were poorly completed, five due to their structure (sub-questions were often missed out). Older (over 75 years) and younger patients (15-25 years) completed questions less well.

By 6 months, patients reported receiving a range of treatments, with 31% having received psychologically based treatments and 60% multimodal care.

Demographics & Case-Mix

Table 1 shows the demographic data collected at different time points. The median age of those entered on the case-mix tool was 54, with 6,158 (64%) being female patients. Two-thirds of patients were reported by clinicians to have musculoskeletal pain.

Both baseline BPI and EQ5D-3L scores suggested severe pain and a very poor quality of life for most respondents (Table 2). The mean BPI score was 6.32/10 for pain intensity, and 6.16/10 for pain interference with life. The mean EQ5D-3L Summary Health Score was 52, and the mean Time Trade-off (TTO) value was 0.32, which is lower than the value for any single condition, suggesting significant levels of multi-morbidity. One thousand six hundred and fifty patients (16%) had a negative TTO value, denoting a quality of life that is "worse than death". One thousand nine hundred and fifty-six patients (20%)had attended Accident and Emergency Departments looking for help with their pain in the six months prior to being seen.

Patients who responded at 12 months were on average older than those who did not (59 years versus 54 years) and 92% were white British. The ratio of male to female remained the same (65% female to 35% male). Initial BPI scores were very similar (Baseline mean Pain Severity = 6.3, standard deviation 1.2 at 0 months for non-responders , 1.9 for responders , baseline mean Pain Interference 6.6, standard deviation 2.2 for both responders and non-responders). We did not collect data on ethnicity at the outset and so it is unknown whether the ethnic diversity was similar at baseline and follow-up. At baseline, one-fifth reported being able to work, and one-third unable to work; at 12 months one-third were able to work and half unable to do so (Table 2). Twelve per cent were working reduced hours at baseline (Table 2).

Benchmarking outcomes between providers

The case-mix adjustment model was able to account for 40% of the variability in scores. However, funnel plots were very over-dispersed, i.e. showing more variation than expected purely by chance. We cannot be sure of the reasons for this over dispersion, which could include some mix of data noise (data quality issues), unaccounted-for case-mix factors and quality of care, all in unknown proportions. We concluded that the case-mix adjusted model requires further refinement before being used to make fair comparisons between the quality of care at different providers and therefore did not report the funnel plot.

Patient experience of care

Patient-reported experiences of the services at 6 and 12 months are displayed in Table 3. Overall, 70% reported having sufficient information and being involved in treatment decisions. Interestingly, 29% did not want any information on how to manage pain.

Outcomes reported by clinics

Of the 1,799 (19%) who completed both 6- and 12-month follow-up questions, 1,626 (92.9%) continued to have moderate to severe pain at 12 months. Thirty-eight per cent of the cohort who completed the questionnaire had been discharged from the clinic by the end of the study ie at one year. Six per cent did not respond leaving 56% still attending treatment. For the small numbers completing 12 month follow-up questionnaires, mean BPI Pain Severity and Pain Interference scores and mean EQ5D-3L scores at 6 and 12 months are shown in Table 2. Nearly two-thirds of responding patients reported treatment to be of moderate to good benefit, with only 11% reporting no benefit. There was a statistical improvement in the mean pain specific measure (BPI) at 6 months (mean decrease 0.43 $P<0.001$ in Pain Severity, Mean decrease in Pain Interference 0.41 $P<0.001$). However, by 12 months this was not maintained apart from for those who had been discharged (Mean decrease in Pain Severity for discharged patients 0.68 $P<0.001$ Mean decrease in pain interference 0.76, $p<0.001$). The mean EQ5D-3L TTO value set also showed statistical improvement (mean change -0.03, $p<0.05$) as did the mean EQ5D-3L wellbeing score but this did not reach statistical significance (mean change 2 NS (Table 2).Those in the cohort who were discharged by 12 months had lower initial scores, suggesting they were less severe cases.

The proportions achieving the MIC in Pain Severity and Pain Interference on the Brief Pain Inventory and on the EQ5D-3L at 6 months and 12 months are shown in Table 4. Mean summary health scores were unchanged. Thirty per cent of those discharged achieved the MIC value.

Discussion

This was a first attempt at implementing PROMs at scale in pain clinics in England and Wales. A sizeable cohort of nearly 10,000 patients was recruited with a large number of participating sites. We were able to measure some key case-mix variables and clinicians found a web tool easy to use. We have reported the findings and lessons from the data collection and analysis, including some limited outcomes relating to clinical effectiveness and patient experience. We found the quality of life of patients attending pain clinics was very poor as reported by the EQ5D-3L, with high use of Accident & Emergency departments. Challenges were disappointing recruitment and response rates; these limit any conclusions that can be drawn regarding outcomes from pain clinics.

The study has several limitations which can be summarised as: low and variable rate of recruitment, low patient response rates at follow up; problems with coding and classification of data into ICD /treatment groupings and the poor quality of HES outpatient data, Difficulties in recruitment may have been due to clinics not distributing questionnaires or supervising questionnaire completion as well as clinical buy-in to the study. Electronic data capture is now recommended for clinical quality registries (Hoque et al 2017) which should

help. Factors that can act as barriers to participation include fear of scrutiny of clinic practices, the additional workload of participating and possible implications for changing practice (Black and Thompson 1999, Antunes, Harding et al 2014). The expectation that all centres would participate in the study as it was part of a National Audit was not borne out, and our earlier recommendation of sampling only a small number of committed centres, ensuring feedback and growing gradually might well have been more effective (Hall 2008, Hoque et al 2017). However this may bias responses as the most enthusiastic clinics are also the most likely to complete questionnaires. Additionally, only one time period was permitted to recruit and so we were unable to act upon and improve recruitment strategies. The patient response rate was disappointingly low at 6 and 12 months; many other audits have experienced low response rates (Royal College of Psychiatrists 2012, NHS Digital 2014, Blanchard 2017). The National Bowel Cancer Audit found the main factors in poor response rates were being elderly, high deprivation, greater co-morbidity, and being admitted as an emergency (HQIP 2018). The International Society of Arthroscopy Registries recommends a 60% response to PROMS as a measure of an adequate response (Rolfson et al). Providers in the National PROMS Hip and Knee programme were financially incentivised to respond. Public facing feedback, a clear explanation of the goals of the programme to patients, reminders and dedicated staff for PROMS data collection may improve response rates (Rolfson et al 2016). The National Dementia Audit (Royal College of Psychiatrists 2018) recommends greater participation of sites to ensure better response rates. We were aware, however, this was a first attempt and were concerned to not overburden services. Clinicians struggled to classify pain using ICD-10 with 30% of patients having a free text diagnosis initially. The new ICD-11 classification for pain should help (Treede et al 2015). We would recommend tailored support and training for clinicians to enter diagnoses. HES outpatient data proved unreliable which meant that there was no easy denominator to provide numbers seen apart from clinic estimates. Further work with clinics to assist with routine returns on clinic activity to HES together with some monitoring and feedback might improve this. Treatment currently has no recognisable classification system leading to inconsistencies over the study period on how treatments were grouped. Guidance is needed in this area.

We found that the majority of patients were working-age adults with musculoskeletal disorders, with pain having greatest impact on work. That a greater proportion of respondents were women and the majority were working age adults is consistent with other secondary care pain surveys. (Blanchard 2017, Garcia 2016) suggesting our sample is reasonably representative. These findings are similar to cross-sectional surveys reported in Scotland and Canada in terms of age, employment status and quality of life (Health Improvement Scotland 2016, Racine 2014). However, a Norwegian study found 359 patients attending tertiary level clinics enjoyed a much better quality of life reported by the EQ5D-3L - a mean TTO score of 0.53 compared with ours of 0.33 (Vartiainen 2017) - whereas ePOCC reported worse disability scores (BPI Pain Interference mean 7.0). These discrepancies between high income countries with social insurance systems warrant further investigation. Amongst those responders to the follow up questionnaire, there were some statistically significant improvements in outcomes. Interpretation of these data is limited by the low response rate to follow-up questionnaires and likely bias or possible adverse selection among those who chose to remain in the audit. Depending on the measure, 18% to 25% per cent reported a clinically important improvement (using MIC) in pain and quality of life. A study in a single UK tertiary pain centre using the same MIC calculations reported that 16%–23% of patients improved (Shah 2015), a comparable proportion. Others have reported far greater improvement. ePOCC in Australia reported that 68% of respondents achieved the MIC for Pain Interference (Blanchard et al 2017); a Spanish cohort study (Garcia 2016) reported significant reductions in pain and improvement in quality of life. There may be good

reason for these differences. Garcia's results may have been affected by exclusion of patients with psychiatric and neurological co-morbidities, Blanchard's results were for those who had completed an episode of care. It is possible that individuals with more severe pain in this study were (a) more likely still be in contact with the pain service and (b) more likely to return a pain-related questionnaire (Smith 2005). We had only a short time frame to collect follow up data which meant only 708 (39%) had completed a care episode and may have differed in treatment received from those remaining. Whilst it is also possible that non-responder dischargees may have improved, non-responders to PROMS tend to be male, socially disadvantaged and with poorer literacy ie at risk of poorer health outcomes. (Hutchings 2012). In future we recommend that only completed care episodes are reported and specific ways to engage these groups are sought.

We were able to explain 40% of the variation in the PROMs scores with the case-mix variables we identified. The remaining 60% variance may be due to a wide range of factors, including the quality of care provided, other case-mix factors, within-person random variation and other un-identified factors. A systematic review in musculoskeletal patients recommended the use of baseline PROM score, age, sex, comorbidities, symptom duration, and surgical history. (Burgess 2018). However, outcomes from diabetes care have been extensively investigated for appropriate case-mix adjustment methods with the conclusion that this is an extremely complex process and ultimately, where multi-morbidity is the norm and it is unclear which characteristics require adjustment, robust models may be impossible to achieve (Calsbeek 2016). Pain care may be similar.

People attending specialist pain clinics experience a very poor quality of life reporting great difficulty in working with what is a long-term condition. The proportion reporting quality of life equivalent to "worse than death" (16%) was very similar to the proportion with neuropathic pain in a recent population study (17%) (Van Heck et al 2014). This level of difficulty and the slow progress through treatment suggest that there is considerable room for improvement in care including improving flow and greater involvement of carers and support agencies. The poor coding and classification systems that exist currently act as barriers to accurate epidemiological data related to chronic pain and prevent the development and implementation of new therapies. Given the current difficulties with chronic pain management this situation urgently needs to change with training for clinicians and coders, and development of a treatment classification.

We were unable to answer whether the health of chronic pain patients is observed to improve following input of specialist services in England and Wales and whether we can benchmark services adequately with each other. Collection of PROMs in specialist pain services requires improved methodology before this can be achieved. Based on our previous experience, this might include starting with clinics committed to good quality data collection only (though noting the likely bias), allowing a greater period of follow up to complete episodes and the use of web-based data collection. Sites should take ownership of collection of data and a public facing feedback process should be in place. To deliver this, significant funding is required. However, two reports have emphasised that disease registries more than pay for themselves by improving the quality of care and patient outcomes if they are funded over several cycles to maximise reliability and quality (Larsson et al 2012, ACSHQC 2013). Cost-effectiveness data therefore also should be collected. Case-mix adjustment to allow meaningful comparison between centres needs further research but could include co-morbidities and important variables that may impact a clinic's outcomes. This would permit identification of high-performing services and drive improvement in care.

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Figure 1: Patient flow through the study

Patients who returned initial PROMS questionnaire

N= 9588 (19% of total new patients in recruitment period)

Clinical details entered into web-tool by services (% of total)

N=9430 (98% of initial returns, 18% of all new clinic patients)

Patients completing 6-month follow-up PROMS questionnaires (% of initial)

N= 4414 (46% of initial returns, 8.7% of all new clinic patients)

Number of 12-month follow-up PROMS questionnaires (% of initial)*

N=1799 (19%, 3.6% of all new clinic patients)

*only those responding at 6 months were sent a 12-month follow-up questionnaire

Table 1. Demographic details and case mix for all patients through the audit

	Initial questions N=9684	6-month follow-up N=4337	12-month follow-up N=1777
Age (y) Mean (SD)	54 (16)	60 (16)	59 (15)
Sex M:F	0.36:0.64	0.35:0.65	0.35:0.65
Ethnicity (White British: Other)	n/k	n/k	93:7

ICD-10 diagnosis (%)
    Back Pain
    Other MSK
    Sciatica
Other
	
	26
	31
	15
	28
		
		27
		11
		15
		37
			
			28
			30
			15
			27

Discharged from service (%)	N/a	Not asked	708 (38%)

Table 2 Changes in Patient outcomes over the Study Period (1 year)

	Initial questions N=9684	6-month follow-up N=4337	Mean Difference (CI); P value	12-month follow-up N=1777	Mean Difference (CI); P value
Mean(SD) BPI Pain Severity Score	6.31 (1.90)	5.90 (2.10)	0.43 (0.33-0.51) **p<0.001**	5.98 (2.17)	-0.04 (-0.1-0.05) p=0.45
Mean (SD) BPI Pain Severity Score for those discharged N=708	5.95 (1.96)	N/a		5.26 (2.32)*	0.68 (0.52-0.83) **P<0.001**
Mean BPI (SD) Pain Interference Score (0-10)	6.72 (2.23)	6.26 (2.61)	0.41 (0.30-0.50) **P<0.001**	5.62 (2.68)	0.06 (-0.40-1.60) p=0.25
Mean (SD) BPI Pain Interference Score for those discharged N=708	6.16 (2.32)	N/a		5.4 (2.8)	0.76 (0.59-0.94) **P<0.001**
Mean (SD) EQ5D-3L TTO value	0.32 (0.007)	0.32 (0.011)	0.04 (-0.07-0.16) p=0.49	0.34 (0.19)	-0.002 (-0.17-0.12) p=0.76
Mean Health State EQ5Dl-3L	30	32	3.9 (2.6-5.3) **P<0.001**	30	-1.3 (-2.5-0.76) p=0.051
Mean EQ5D TTO value for those discharged N=645	0.4	N/a		(0.43 *)	-0.031 (-0.05-0.00) **p=0.02**
Mean EQ5D overall health state for those discharged N=676	53	56	2.9 (1.14-4.79) **P<0.05**	55	-2.1(-3.7-3.8) p=0.06
Hospital A&E visits (%) in a 6-month period	1956 (20)	504 (11)		279 (16)	
Work not impacted (%) N=1423	299 (21)	261 (19)		494 (34)	
Reduced work hours (%) N=1383	166 (12)	157 (11)		177 (12)	

Prevented from working if applicable (%) N=1402	477 (34)	469 (34)		738 (50)	
Work question not applicable (%) N=1418	468 (33)	502 (36)		65(4)	

N=Number   N/A - discharge data not available A&E = Accident and Emergency

Table 3: Patient experience of care in clinics at 12 months, for patients completing all three assessments (n=1799)

	Yes	No	Do not recall	Total
Given advice on managing pain (%)	1112 (71)	240 (15)	221 (14)	1573
Given information on the risks and benefits of treatment (%)	1124 (67)	299 (18)	257 (15)	1680
Felt sufficiently involved in planning treatment (%)	1202 (71)	500 (29)	0	1702

Table 4: Number of patients achieving at least the Minimal Important Change (MIC) in outcomes

PROMs	6 months	12 months	Discharged at 12 months
BPI Severity (%) (N=707)	499/3404 (15)	272 /1484 (18%	199 (29)
BPI Interference (%)(N=707)	1132/3187 (32)	319/1484 (35)	275 (40)
EQ5D-3L (N=645)	792 /3009(26)	350/1283 (27)	193 (30)

N= Number