Spine

SPINE Volume 40, Number 6, pp 405-414

HEALTH SERVICES RESEARCH

OPEN

Implementing Stratified Primary Care Management for Low Back Pain

Cost-Utility Analysis Alongside a Prospective, Population-Based, Sequential Comparison Study

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Study Design. Within-study cost-utility analysis.

Objective. To explore the cost-utility of implementing stratified care for low back pain (LBP) in general practice, compared with usual care, within risk-defined patient subgroups (that is, patients at low, medium, and high risk of persistent disabling pain).

Summary of Background Data. Individual-level data collected alongside a prospective, sequential comparison of separate patient cohorts with 6-month follow-up.

Methods. Adopting a cost-utility framework, the base case analysis estimated the incremental LBP-related health care cost per additional quality-adjusted life year (QALY) by risk subgroup. QALYs were constructed from responses to the 3-level EQ-5D, a preference-based health-related quality of life instrument. Uncertainty was explored with cost-utility planes and acceptability curves. Sensitivity analyses examined alternative methodological approaches, including a complete case analysis, the incorporation of non–back pain-related health care use and estimation of societal costs relating to work absence.

Results. Stratified care was a dominant treatment strategy compared with usual care for patients at high risk, with mean health care cost savings of £124 and an incremental QALY estimate of 0.023. The likelihood that stratified care provides a cost-effective use of resources for patients at low and medium risk is no greater than 60% irrespective of a decision makers' willingness-to-pay for additional QALYs. Patients at medium and high risk of persistent disability in paid employment at 6-month follow-up reported, on average, 6 fewer days of LBP-related work absence in the stratified care cohort compared with usual care (associated societal cost savings per employed patient of £736 and £652, respectively).

Conclusion. At the observed level of adherence to screening tool recommendations for matched treatments, stratified care for LBP is cost-effective for patients at high risk of persistent disabling LBP only.

Key words: cost-utility, economic evaluation, low back pain, stratified care, quality-adjusted life year, cost, primary care.

Level of Evidence: 2

Spine 2015;40:405–414

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Acknowledgment date: August 12, 2014. Revision date: November 21, 2014. Acceptance date: December 30, 2014.

The manuscript submitted does not contain information about medical device(s)/drug(s).

The IMPaCT Back study was funded by the Health Foundation (grant code: 346/4540) with support from the National Institutes for Health Research (NIHR) Primary Care Research Network-North West, the Keele Academic General Practice Partnership and the Primary Care Musculoskeletal Research Consortium. NEF was supported, in part, by a National Coordinating Centre for Research Capacity Development (NCCRCD) Primary Care Career Scientist Award and is currently supported by an NIHR Research Professorship (NIHR-RP-011-015). The views expressed in this publication are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

Relevant financial activities outside the submitted work: employment.

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DOI: 10.1097/BRS.0000000000000770

A wealth of empirical evidence reported in the biomedical and health services literature identifies the global burden of low back pain (LBP) and the challenges regarding the provision of effective primary care.[1–3] In the United Kingdom, LBP accounts for approximately 14% of all primary care consultations[4]; 60% to 80% of primary care LBP consulters continue to report pain and disability 12 months on, despite the fact that many stop seeing their general practitioner (GP) in the first 3 months.[5,6] A study published in 2000, using 1998 prices, estimated the societal impact of LBP-related health service resource use and periods of work absence to be £7 to £12 billion, with National Health Service (NHS) and community costs alone in excess of £1 billion.[7]

Clinical guidelines recommend first line treatments such as exercise and manual therapy for LBP, although optimal approaches for use in primary care remain elusive.[8] Although

active intervention is preferred over no treatment,[9,10] many existing active treatments tend to show, at best, small benefits when tested in heterogeneous samples of patients.[11] Identifying ways to better match treatments to patient subgroups, in ways that enhance patient outcomes, is an international research priority.[12] A recent randomized controlled trial (the STarT Back trial) demonstrated the clinical and cost-effectiveness of stratified care for nonspecific LBP in a primary care physiotherapy setting.[13,14] A prognostic risk stratification tool (the STarT Back tool) was used to identify patients at low, medium, and high risk of persistent disabling LBP that were subsequently matched to targeted treatments. In that trial, the GP was not involved in delivering stratified care; all potentially eligible study participants were referred to a physiotherapy-led community-based clinic. Consequently, the trial did not reflect usual practice internationally, where the minority of patients with LBP are referred to physiotherapy services.[15]

The question as to whether stratified care implemented in primary care, with GPs as the first contact practitioner, provides the same clinical and societal benefits has been explored in a recent population-based, sequential comparison study (the IMPaCT Back study).[16,17] The IMPaCT Back study design permitted analyses of process, clinical and economic outcomes for the overall comparison of stratified care with usual care, as well as prespecified analyses within each patient subgroup. The study demonstrated modest improvements in patients' outcomes overall, more targeted use of health care resources and reduced sick certification, without any associated increase in health care costs. This article reports new data from the prespecified subgroup analyses, exploring cost-utility considerations within each patient subgroup to help inform decision making by clinicians, service managers, and policy makers.

MATERIALS AND METHODS

Study Design

Details of the IMPaCT Back study design have been reported elsewhere,[16,17] as have descriptions of the risk stratification tool and matched treatments for each subgroup.[18–20] Brief details are provided here and in Supplemental Digital Content, Appendix 1 available at http://links.lww.com/BRS/A933. Sixty-four GPs from 5 practices in Cheshire, England, participated in the 3 phases of the study. Phase 1 was an observation of usual care (with a 6-mo patient recruitment period), Phase 2 was the implementation phase (stratified care was introduced and supported during a 3-mo period),[16] and Phase 3 was the observation of care after implementation (with a 12-mo patient recruitment period). Adults aged 18 years or older consulting with nonspecific LBP of any episode duration were identified using a standardized set of diagnostic and symptom Read codes; recruitment during Phase 1 and Phase 3 identified separate patient cohorts.[16] For the patient-focused component of the study, self-report postal questionnaires were administered at baseline (shortly after GP consultation), and at 2 months and 6 months after consultation.

The base case cost-utility analysis adopted a health care perspective, incorporating NHS and private LBP-related health care resources used during the 6-month follow-up. Techniques used in cost-utility analysis (described in the following text) reflect fundamental differences between clinical and economic evaluation.[21,22]

Data

Health Outcomes

The 3-level EQ-5D was used to measure preference-based health-related quality of life at baseline, 2 months, and 6 months.[23] Health state valuations for EQ-5D responses were estimated using the York A1 tariff; data for this scoring algorithm were elicited from a representative sample of the UK adult population, providing index scores in the range from −0.594 (lowest level on each dimension) to 1.000 (highest level on each dimension).[24] Index scores are interpreted on a 0 to 1 scale, where 1 indicates full health and zero represents a health state equivalent to being dead. Negative index scores represent health state valuations considered to be worse than being dead. Using area-under-the-curve analysis,[25] EQ-5D responses were used to calculate quality-adjusted life years (QALYs). QALYs represent health over time as a series of quality-weighted health states, incorporating the impacts on quantity of life (survival) and quality of life (morbidity) within a single measure. Given the 6-month follow-up period the maximum QALY score was 0.500.

Health Care Resource Use and Unit Costs

The 6-month follow-up questionnaire collected resource use data for a range of health care services: primary care consultations (GPs and practice nurses), consultations with other health care professionals (*e.g.*, hospital consultants and physiotherapists), hospital-based procedures (diagnostic tests, epidural injections, and inpatient episodes), prescribed medication, and out-of-pocket expenditures on treatments and/or aids. Where appropriate, participants were required to distinguish between NHS and private provision, and make a distinction between care regarding LBP and care for "other reasons." Unit costs are reported in Supplemental Digital Content, Appendix 2 available at http://links.lww.com/BRS/A933 (UK averages in 2008/2009 prices).[26–31]

Work-Related Outcomes

A secondary analysis explored potential benefits of GP-led stratified care beyond health care resources. At 6-month follow-up, participants in paid employment completed questions about their work activities and periods of LBP-related work absence. Costs were assigned using the human capital approach.[32] Self-reported days of work absence were multiplied by respondent-specific wage estimates based on annual earnings data and UK Standard Occupational Classification codes.[33,34] Standard Occupational Classification codes were assigned on the basis of participants' current or most recent paid job title reported at baseline.

Statistical Analysis

Analysis was performed according to the intention-to-treat principle. Imputation techniques were used to deal with incomplete data. Missing or indecipherable responses to resource use questions in returned 6-month questionnaires were imputed using mean substitution based on observed data for the respective resource category. Multiple imputation was used to impute missing values for the EQ-5D and total cost estimates for nonresponders to the 6-month questionnaire[35]; all key baseline predictors, primary and secondary outcomes, treatment group allocation, and interaction of treatment and baseline STarT Back tool score were variables used in the imputation model.[17] No discounting of costs and health benefits was applied.

Within each risk-defined patient subgroup, the analytic comparison focused on the joint estimation of incremental costs and incremental QALYs. The primary outcome was the incremental cost per QALY (incremental cost divided by incremental QALY), which is a ratio measure that provides an estimate of the cost required to achieve 1 additional QALY. Ratios are calculated irrespective of the magnitude of the incremental cost and QALY estimates.[21,22] Costs relating to periods of work absence were analyzed separately, without incorporation into the incremental ratio. For the incremental QALY estimates, a multiple regression-based adjustment was used to control for between-phase imbalances in age, sex, practice, duration of pain at baseline, and baseline scores on the primary clinical outcome measure (Roland-Morris Disability Questionnaire [RMDQ][17,36]) and EQ-5D.[37]

Cost-utility planes and acceptability curves were used to display and quantify uncertainty around ratio point estimates through the application of bootstrap techniques[38]; 25000 bootstrapped replications of incremental cost-utility pairs were used (5000 for each imputed data set). To explore variation in disaggregated outcomes (for costs, QALYs and EQ-5D scores), confidence interval (CI) estimation was performed. Given the level of skewness typically observed for cost data, CIs were generated using parametric methods and bias-corrected and accelerated bootstrapping.[39] Statistical analysis was performed using SPSS (SPSS Inc. Released 2008. SPSS Statistics for Windows, Version 17.0. Chicago: SPSS Inc.) and STATA (StataCorp. 2009. Stata Statistical Software: Release 11. College Station, TX: StataCorp LP.

Sensitivity Analysis

The base case analysis was replicated using a NHS perspective (that is, inclusion of health care resources funded by the NHS only), in line with recommendations from the National Institute for Health and Care Excellence.[40] A complete case analysis was also performed to examine the robustness of study findings to missing data; participants providing EQ-5D responses at each time point and complete health care resource use data at 6-month follow-up were included. The final 2 sensitivity analyses further investigated costing assumptions; (1) the incorporation of non–LBP-related consultations with health care professionals ("generic" health care resource use) and (2) consideration of variation in the unit cost of private health care. Three of the sensitivity analyses explore issues pertinent to the numerator of the cost per QALY ratio only; accordingly, base case QALY estimates are relevant for all analyses except the complete case analysis.

RESULTS

Comprehensive details of baseline characteristics, process, and clinical outcomes (overall and subgroup analyses), and economic evaluation (overall analysis) have been reported elsewhere.[17] A total of 922 participants were recruited (Phase 1 = 368; Phase 3 = 554). Individuals declining an invitation to participate were younger and more likely to be male. There were minimal differences in baseline demographics and clinical characteristics, and subgroup proportions, between Phase 1 and Phase 3. On the basis of an intention-to-treat analysis, small but significant between-phase reductions in LBP disability were observed at 6 months for the overall comparison (mean difference [95% CI] in RMDQ = 0.7 (0.1–1.4)); in the high-risk subgroup, large, clinically important differences in RMDQ scores were observed (mean difference [95% CI] in RMDQ = 2.3 (0.8–3.9)). Stratified care was also associated with a reduction in LBP-related work absence and sickness certifications, and mean health care cost savings of £34. GPs followed screening tool recommendations for matched treatment in 71% of cases in Phase 3.

Observed Responses and Presentation of Data

Total cost estimates were derived from all questionnaires returned at 6 months (n = 547 [59%]); the simplistic mean substitution approach addressed a small number of missing resource use values (<3%) within returned questionnaires. Complete EQ-5D data were provided by 447 (48%) participants; response rates were 98%, 58%, and 56% at baseline, 2 months, and 6 months, respectively. Multiple imputation ensured that the base case analysis included the total sample (n = 922). Nonresponders at 6 months were significantly younger, were more likely to be male, and had lower LBP disability. Table 1 reports LBP-related health care costs for each risk subgroup by study phase (observed data; n = 547), along with total cost estimates and the difference in total costs between study phases for the base case analysis. Supplemental Digital Content, Appendix 3 available at http://links.lww.com/BRS/A933 reports health care costs and resource use data in a more disaggregated format. Table 2 reports health-related quality of life data (EQ-5D and QALYs) for the base case and complete case analyses.

Estimation of Cost-Utility

Table 3 reports incremental cost per QALY ratios for the base case and sensitivity analyses; mean estimates of total costs and incremental costs for the sensitivity analyses are reported in Supplemental Digital Content, Appendix 4 available at http://links.lww.com/BRS/A933. Point estimates of incremental costs and incremental QALYs demonstrate stratified care to be cost-effective for patients at high risk of persistent disability. A "dominant" finding was observed; that is, health benefits (0.023 additional QALYs) and lower mean health care costs (£124) compared with usual care. The dominant result for

TABLE 1. LBP-Related Health Care Costs Per Patient, by Study Phase and Risk Subgroup, for Participants Providing Resource Use Data at 6 mo (n = 547)

	Cost (£)	
Health Care Resource	**Phase 1**	**Phase 3**
Patients at low risk (n = 191)	(n = 81)	(n = 110)
Primary care consultations	19.15 (30.7)	29.69 (64.6)
Consultant consultations	15.88 (46.8)	25.72 (86.3)
Hospital admissions	6.94 (62.4)	5.11 (53.6)
Diagnostic tests and epidural injections	13.45 (46.8)	10.88 (40.7)
Consultations with other health care professionals*	57.23 (99.2)	56.02 (107.1)
Prescribed medication†	9.21 (51.6)	5.11 (27.4)
"Over-the-counter" treatments†	6.53 (19.0)	3.68 (9.2)
Patients at medium risk (n = 247)	(n = 104)	(n = 143)
Primary care consultations	42.22 (51.1)	36.64 (51.9)
Consultant consultations	54.62 (127.5)	37.76 (95.7)
Hospital admissions	27.65 (168.2)	32.36 (191.5)
Diagnostic tests and epidural injections	34.57 (83.3)	31.70 (69.4)
Consultations with other health care professionals*	98.72 (190.9)	93.91 (115.6)
Prescribed medication†	19.20 (101.4)	6.42 (11.3)
Over-the-counter treatments†	13.87 (42.8)	21.57 (86.4)
Patients at high risk (n = 109)	(n = 48)	(n = 61)
Primary care consultations	64.89 (80.0)	42.21 (42.4)
Consultant consultations	93.62 (138.9)	66.88 (116.2)
Hospital admissions	0.00 (-)	0.00 (-)
Diagnostic tests and epidural injections	45.52 (87.9)	53.45 (105.9)
Consultations with other health care professionals*	157.87 (185.6)	112.17 (128.2)
Prescribed medication†	26.95 (66.1)	9.51 (17.5)
Over-the-counter treatments†	35.07 (93.1)	32.89 (134.5)
Estimates for the base case analysis (n = 922)‡		
Total health care cost: low-risk subgroup (n = 350)	138.13 (258.1)	141.12 (329.5)
Mean difference (95% confidence interval; *P*)§	2.98 (−63.3 to 69.2; 0.93)	
Total health care cost: medium-risk subgroup (n = 383)	292.29 (560.3)	284.49 (491.1)
Mean difference (95% confidence interval; *P*)§	−7.80 (−107.6 to 92.0; 0.88)	
Total health care cost: high-risk subgroup (n = 189)	479.29 (891.5)	355.46 (617.0)
Mean difference (95% confidence interval; *P*)§	−123.83 (−348.5 to 100.8; 0.28)	

Values are mean (SD) costs unless stated otherwise.

Reported cost estimates combine NHS and private care (with the exception of primary care). Health care costs and resource use data are reported in a more disaggregated format in Supplemental Digital Content, Appendix 3 available at http://links.lww.com/BRS/A933.

**Including physiotherapists, acupuncturists, osteopaths, etc. (NHS and private practice).*

†Aggregate estimate that combines analgesics (nonopioid and weak opioid), gels, creams, nonsteroidal anti-inflammatory drugs, sprays, aids, and appliances.

‡The base case analysis focuses on LBP-related health care resource use (private and NHS care), using multiple imputation to deal with missing data.

§Difference = Phase 3 − Phase 1. Reported confidence intervals were generated using conventional parametric methods.

SD indicates standard deviation; NHS, National Health Service; LBP, low back pain.

TABLE 2. Descriptive and Incremental Health Outcomes During 6 mo for the Base Case and Complete Case Analyses

Health Outcomes	Phase 1	Phase 3	Mean Difference* (95% CI)
Patients at low risk	(n = 136)	(n = 214)	
Baseline EQ-5D	0.779 (0.17)	0.776 (0.19)	−0.003 (−0.04 to 0.04; 0.88)
2-mo EQ-5D	0.809 (0.24)	0.815 (0.26)	0.006 (−0.05 to 0.06; 0.82)
6-mo EQ-5D	0.812 (0.25)	0.815 (0.24)	0.003 (−0.06 to 0.06; 0.92)
QALYs more than 6 mo†	…	…	0.003 (−0.02 to 0.02; 0.80)
Patients at medium risk	(n = 151)	(n = 232)	
Baseline EQ-5D	0.568 (0.28)	0.602 (0.26)	0.034 (−0.02 to 0.09; 0.23)
2-mo EQ-5D	0.689 (0.25)	0.669 (0.35)	−0.019 (−0.08 to 0.04; 0.50)
6-mo EQ-5D	0.688 (0.30)	0.693 (0.29)	0.005 (−0.05 to 0.06; 0.85)
QALYs more than 6 mo†	…	…	−0.007 (−0.03 to 0.01; 0.45)
Patients at high risk	(n = 81)	(n = 108)	
Baseline EQ-5D	0.368 (0.36)	0.392 (0.35)	0.024 (−0.08 to 0.13; 0.66)
2-mo EQ-5D	0.431 (0.38)	0.494 (0.44)	0.063 (−0.06 to 0.18; 0.29)
6-mo EQ-5D	0.543 (0.37)	0.615 (0.37)	0.072 (−0.03 to 0.17; 0.16)
QALYs more than 6 mo†	…	…	0.023 (−0.01 to 0.06; 0.17)
Complete case analysis†			
Low risk (n = 154)	…	…	0.006 (−0.01 to 0.02; 0.42)
Medium risk (n = 211)	…	…	−0.001 (−0.02 to 0.02; 0.91)
High risk (n = 82)	…	…	0.033 (−0.01 to 0.07; 0.12)

**Difference = Phase 3− Phase 1. Reported confidence intervals were generated using conventional parametric methods.*

†Incremental QALY estimates following multiple regression-based adjustment for age, sex, practice, duration of pain at baseline, and baseline scores on the RMDQ and EQ-5D. For the complete case analyses, only incremental QALY estimates are provided.

QALY indicates quality-adjusted life year; 95% CI, 95% confidence interval; SD, standard deviation; RMDQ, Roland-Morris Disability Questionnaire.

patients at high risk was common in all sensitivity analyses. Base case results for patients in the low- and medium-risk subgroups show negligible incremental cost and QALY estimates.

Figure 1 presents cost-utility planes for each risk-group analysis, illustrating the uncertainty regarding incremental costs and QALYs for patients at low and medium risk (Figure 1A, B, respectively), and the likelihood of cost savings and health benefits associated with stratified care for patients at high risk (Figure 1C). Stratified care is associated with a probability greater than 0.89 of providing better value for money compared with usual care for patients at high risk irrespective of a decision maker's willingness-to-pay threshold for additional QALYs (Figure 2). This probability rises above 0.95 at threshold values in excess of £1600 (UK thresholds are, approximately, £20000[41]). For patients in the low- and medium-risk subgroups, the chance that stratified care provides a cost-effective use of resources is no greater than 60% at any willingness-to-pay threshold (Figure 2).

Work-Related Outcomes

Within the risk subgroups, the proportion of patients reporting time off work due to LBP was similar across the study phases (Table 4). On average, patients at low risk reported less than 1 day of LBP-related work absence in the stratified care and usual care groups. Approximately, 6 fewer days of work absence were reported in the stratified care group compared with usual care for those patients in the medium (a 55% reduction) and high-risk (a 39% reduction) subgroups, with associated societal cost savings per employed patient of £736 and £652, respectively.

DISCUSSION

This study provides the first cost-effectiveness report for LBP patient risk subgroups regarding stratified care implemented by GPs. Adopting a health care perspective, and based on a 6-month follow-up period, stratified care is a highly cost-effective intervention compared with usual care for the most

TABLE 3. Mean Incremental Cost Estimates, QALY Estimates, and Cost per QALY Ratios for the Base Case and Selected Sensitivity Analyses

	Incremental Cost (£)	Incremental QALY*	Incremental Cost per QALY Ratio (£) or Comment†
Base case analysis			
Patients at low risk	2.98	0.003	1128
Patients at medium risk	−7.80	−0.007	1088‡
Patients at high risk	−123.83	0.023	Stratified care is dominant
Sensitivity: NHS perspective			
Patients at low risk	−5.99	0.003	Stratified care is dominant
Patients at medium risk	13.63	−0.007	Stratified care is *dominated*
Patients at high risk	−12.14	0.023	Stratified care is dominant
Sensitivity: complete case analysis			
Patients at low risk	−34.05	0.006	Stratified care is dominant
Patients at medium risk	−57.39	−0.001	44076‡
Patients at high risk	−135.72	0.033	Stratified care is dominant
Sensitivity: generic health care§			
Patients at low risk	5.10	0.003	1929
Patients at medium risk	6.98	−0.007	Stratified care is *dominated*
Patients at high risk	−157.95	0.023	Stratified care is dominant
Sensitivity: private care premium¶			
Patients at low risk	18.79	0.003	7110
Patients at medium risk	−51.01	−0.007	7118‡
Patients at high risk	−308.19	0.023	Stratified care is dominant

Only incremental mean costs and QALYs are reported; confidence intervals and P values relating to all incremental mean values in this table are reported elsewhere (in Table 1, Table 2, or Supplemental Digital Content, Appendix 4 available at http://links.lww.com/BRS/A933).

**Incremental QALY estimates following multiple regression-based adjustment for age, sex, practice, duration of pain at baseline, and baseline scores on the RMDQ and EQ-5D.*

†Dominant refers to a scenario where the experimental intervention (Phase 3) is more effective and less expensive—based on point estimates alone—than the control group (Phase 1). Dominated refers to a scenario where the experimental intervention is less effective and more expensive—based on point estimates alone—than the control group.

‡These cost per QALY estimates require further explanation because health benefits were greater in the usual care group (the incremental QALY estimate is negative). Interpretation with respect to stratified care is as follows: the cost per QALY ratios for the base case and private care premium scenarios indicate that the associated cost savings are likely to be insufficient to justify the decrement in QALYs (here, lower ratios mean there is less chance an intervention will be considered cost-effective), whereas cost savings observed in the complete case analysis (£57) could be deemed sufficient to warrant the decrement of 0.001 QALYs. In the situation where a new intervention is more costly and more effective, the incremental cost per QALY ratio provides an estimate of how much resource is required to "buy" an additional QALY. When a new intervention is associated with cost savings and a health decrement, a decision maker has to consider if they are willing to accept health loss for the indicated cost saving.

§The generic health care sensitivity analysis combines health care resource use related to LBP and care for "other reasons." Health care resource use data for other reasons were collected for all categories listed in Supplemental Digital Content, Appendix 3 available at http://links.lww.com/BRS/A933 with the exception of hospital admissions, over-the-counter treatments and prescribed medications.

¶Unit costs of private health care were multiplied by a price premium ranging from 1 (base case scenario were the unit costs of private health care were assumed to be equivalent to the NHS equivalent) to 3 (unit costs of private health care are 3 times that of the NHS equivalent). Results reported here are for a premium equal to 3.

QALY indicates quality-adjusted life year; LBP, low back pain; RMDQ, Roland-Morris Disability Questionnaire; NHS, National Health Service.

complex patients in primary care, that is, those at high risk of persistent disabling LBP. For patients in the low- and medium-risk subgroups, the level of uncertainty in incremental cost and QALY estimates indicates that stratified care cannot be considered cost-effective at the level of implementation observed in the IMPaCT Back study. Sensitivity analyses provided further support for these base case conclusions. If decision makers—such as clinical commissioning groups in England and clinical guideline panels—were to consider costs beyond the health care system, analysis of work-related outcomes demonstrates that stratified care could provide sizeable societal benefits due

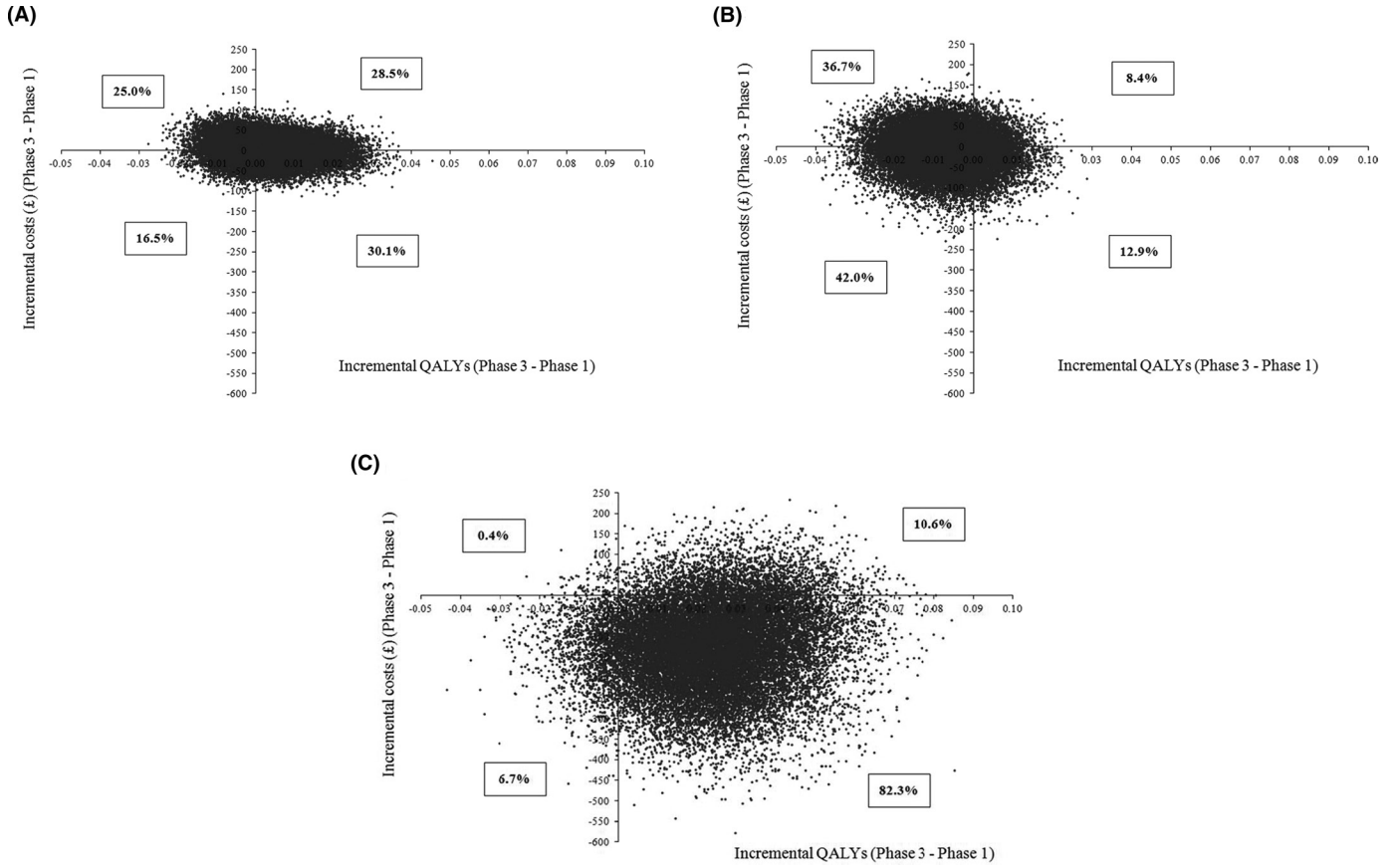

Figure 1. Cost-utility planes comparing stratified care (Phase 3) with usual care (Phase 1) for patients in the (**A**) low-risk, (**B**) medium-risk, and (**C**) high-risk subgroups. Numbers in boxes represent the percentage of bootstrapped cost-utility pairs in each quadrant.

to reductions in LBP-related work absence in patients who are at medium and high risk of persistent problems.

Broader Context of Findings

Caution should be exercised when drawing comparisons with other LBP literature. Our results are applicable to a particular group of patients and health care professionals, and the evaluation was performed alongside an implementation study rather than a randomized controlled trial. In general, the incremental QALY estimates attributable to stratified care in patients at high risk of persistent problems are of similar magnitude to other interventions deemed "cost-effective" for patients with LBP.[42–45]

Placing results of this study in the context of the stratified care literature is aided by consideration of previously published findings from the STarT Back trial and the IMPaCT Back study.[13,14,17] In the STarT Back trial, stratified care was highly cost-effective in the overall analysis and within each patient subgroup.[13,14] The IMPaCT Back study then explored whether stratified care could be implemented in everyday general practice and whether the positive clinical and economic findings would be maintained. A previous IMPaCT Back study publication reported that, overall, stratified care was associated with small but significant clinical benefits, mean health care cost savings (£34) and a negligible incremental QALY (0.003) relative to usual care.[17] The positive economic message from the overall analysis—that improvements in patient disability outcomes and a reduction in time off work can be achieved without an increase in health care costs—seems to be driven by the cost savings and quality of life improvements observed in patients who are at high risk of persistent pain and disability.

The costs associated with implementing and maintaining stratified primary care management are important considerations. Policy makers should interpret our findings alongside the resources needed to equip and support both GPs and

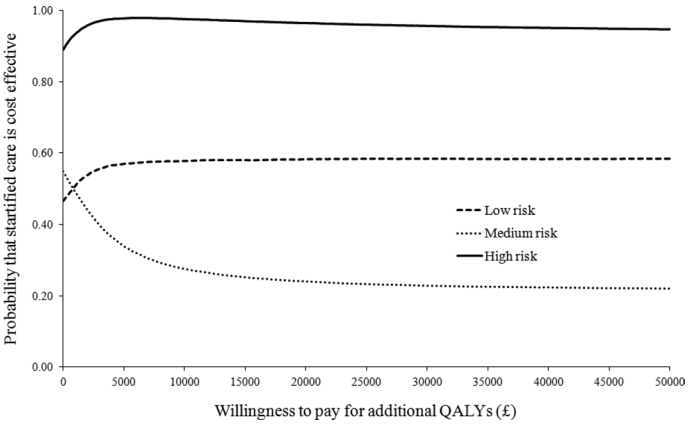

Figure 2. Cost-utility acceptability curves for the 3 risk-defined subgroup comparisons of stratified primary care management (Phase 3) compared with usual care (Phase 1).

TABLE 4. Description of Work-Related Outcomes for Participants in Paid Employment (Work Status, Absence, and Indirect Cost Estimates), by Treatment and Risk Group

	Phase 1	Phase 3
Patients at low risk: in paid employment at baseline	88 of 136 (65)	140 of 213 (66)
Patients at low risk: in paid employment at 6 mo	52 of 80 (65)	62 of 108 (57)
Doing usual job*	49 (94)	57 (92)
Working fewer hours*	0 (0)	1 (2)
Doing lighter duties*	1 (2)	0 (0)
On paid/unpaid sick leave*	0 (0)	3 (5)
Reported time off work due to LBP*	5 (10)	7 (11)
Mean (SD) number of days absence	0.52 (2.3)	0.85 (3.4)
Mean (SD) cost (£) of LBP-related work absence	30.06 (110.1)	106.10 (427.9)
Patients at medium risk: in paid employment at baseline	88 of 151 (58)	126 of 231 (55)
Patients at medium risk: in paid employment at 6 mo	56 of 102 (55)	67 of 141 (48)
Doing usual job*	43 (77)	52 (78)
Working fewer hours*	1 (2)	0 (0)
Doing lighter duties*	6 (11)	6 (9)
On paid/unpaid sick leave*	5 (9)	4 (6)
Reported time off work due to LBP*	19 (34)	19 (28)
Mean (SD) number of days absence	11.14 (26.1)	5.03 (18.3)
Mean (SD) cost (£) of LBP-related work absence	1135.06 (2875.7)	398.66 (1350.3)
Patients at high risk: in paid employment at baseline	51 of 81 (63)	58 of 108 (54)
Patients at high risk: in paid employment at 6 mo	24 of 47 (51)	29 of 61 (48)
Doing usual job*	18 (75)	25 (86)
Working fewer hours*	2 (8)	0 (0)
Doing lighter duties*	1 (4)	2 (7)
On paid/unpaid sick leave*	2 (8)	0 (0)
Reported time off work due to LBP*	11 (46)	13 (45)
Mean (SD) number of days absence	15.46 (35.5)	9.41 (16.8)
Mean (SD) cost (£) of LBP-related work absence	1459.54 (3634.3)	807.81 (1581.0)

Values are numbers (percentages) unless stated otherwise. Analyses focused on the subsample of 290 (53%) respondents who reported being in paid employment (full-time or part-time) at 6-mo follow-up. Percentages relate to the number of employed participants (numerator), specific to the number of valid 6-mo questionnaire responses (denominator) within each risk group. Numbers do not add up to totals in all cases because of missing data.

**Categories are not mutually exclusive.*

LBP indicates low back pain.

physiotherapists to use the prognostic screening tool and deliver the systematic targeted treatments. The naturalistic design of within-study economic evaluations means that the cost-effectiveness results correspond to the level of implementation observed in the IMPaCT Back study, where GPs followed screening tool recommendations for matched treatment in 71% of participants in Phase 3.[17,46] It is feasible that efforts to support GPs to improve their use of stratified care could result in more favorable cost-effectiveness results. For example, for patients at low risk of persistent disability, the STarT Back trial demonstrated that noninferior outcomes and health care cost savings (£64) could be achieved[13,14]; in the IMPaCT Back study, noninferior outcomes were observed but there was no associated reduction is health care use during the study follow-up.

Strengths and Limitations

The strengths of the analysis relate to the adopted methodologies, comprehensive sensitivity and secondary analyses, and the disaggregated presentation of results. Although our analysis

provides a robust evaluation of the cost-effectiveness of implementing stratified care for LBP patient risk subgroups, the findings are not without limitations. A reliance on self-reported health care resource use during a 6-month recall period may be regarded as a limitation.[47] Asking people to remember their health care use can introduce recall bias (such as the failure to remember a particular event) and/or forward telescoping (the tendency to remember an event occurring earlier than its actual date). However, self-report resource use questions embedded within study questionnaires provides an efficient method of collecting information in the absence of routine data sources and such approaches have been used extensively in clinical trials.[42,45,48] Identifying efficient and valid methods for collecting resource use data alongside clinical studies is an important research area in health economics.[49,50] A further potential limitation relates to the low response rates for cost and QALY outcomes (59% and 48%, respectively) and the associated bias regarding data missing not at random.[51] This was explored in a complete case analysis; point estimates for incremental costs and incremental QALYs differed across the base case and complete case analyses but the interpretation of results in terms of policy implications was similar.

CONCLUSION

From a health care perspective, at the observed level of GP adherence to the screening tool recommendations for matched treatments, stratified care for LBP is cost-effective for patients at high risk of persistent disabling LBP only. Further economic benefits of stratified care relate to societal cost savings due to a reduction in LBP-related work absence (medium- and high-risk subgroups).

➢ Key Points

- ❑ Stratified care is cost-effective for patients at high risk of persistent disabling LBP.
- ❑ Reductions in LBP-related work absence were observed in the medium- and high-risk subgroups.
- ❑ Stratified care did not reduce health care use for patients at low risk.

Acknowledgments

The authors thank all members of the wider IMPaCT Back study team including: Carol Doyle, Jackie Gray, June Handy, Adele Higginbottom, Jonathan Hill, Rhian Hughes, Meenee Khanna, Kika Konstantinou, Chris Main, Pauline Ong, Paula Salmon, Simon Somerville, Gail Sowden, Stephanie Tooth, Simon Wathall, Tracy Whitehurst, and Julie Young. They also thank the participating GP practices, physiotherapy services, and patients, as well as the independent steering group and clinical advisory group for their advice and support.

Supplemental digital content is available for this article. Direct URL citations appearing in the printed text are provided in the HTML and PDF version of this article on the journal's web site (www.spinejournal.com).

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