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Developing a novel set of quality performance indicators (QPIs) for metastatic bone disease (MBD)

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Abstract

Objectives

Patients with metastatic bone disease (MBD) should receive the same standard of care regardless of which centre they are treated in. The aim was to develop and test a set of quality performance indicators (QPIs) to evaluate care for MBD patients referred to orthopaedics.

Methods

QPIs were adapted from the literature and ranked on feasibility and necessity during a modified RAND/Delphi consensus process. They were then validated and field tested in a retrospective cohort of 108 patients using indicator-specific targets set during consensus.

Results

2568 articles including six guidelines were reviewed. 43 quality objectives were extracted and 40 proceeded to expert consensus. After two rounds, 18 QPIs for MBD care were generated, with the following generating the highest consensus:

- “Patients with high fracture risk should receive urgent assessment” (combined mean 6.7/7, 95% CI 6.5-6.8)
- “Pre-operative work-up should include full blood tests including group and save” (combined mean 6.7/7, 95% CI 6.5-6.9)

In the pilot test, targets were met for 5/18 QPIs (mean 52%, STD 22%). The median deviation from projected target was -14% (IQR -11% to -31%, range -74% to 11%). The highest scoring QPI was “Adults with fractures should have surgery within 7 days” (target 80%:actual 92%).

Conclusions

The published evidence and guidelines were adapted into a set of validated QPIs for MBD care which can be used to evaluate variation in care between centres. These QPIs should be correlated with outcome scores to determine whether they can act as predictors of outcome after surgery.

Key messages box

1. Targets for good quality care need to be established for patients with bone metastases (MBD)
2. We developed a set of validated quality performance indicators (QPIs) for MBD care using published guidelines and RAND/Delphi expert consensus
3. These MBD QPIs allow comparison and standardisation of MBD care across centres

Introduction

Why we need markers of care quality in metastatic bone disease (MBD)

Patients with MBD are a complex cohort. They are under-researched in orthopaedics and have a high early mortality (80% at 12-months in pathological proximal femoral fractures)(1, 2). In addition, the unpredictable nature of their cancer complicates their management(3). Surgery to stabilise impending or pathological fractures in patients with bony metastases is often undertaken to relieve pain and improve function with careful consideration of predicted prognosis. Thus, in individuals undergoing surgery for MBD, focus should be on clinically-meaningful outcomes such as quality of life, function and mobility (4). However, these outcomes are not routinely collected data(4). For a bony metastasis requiring surgical input, patients need to be guaranteed high-quality care regardless of which secondary care site they present to(5). Those with complex lesions or a better prognosis should be referred on for specialist orthopaedic oncology input without delay(1).

Quality performance indicators in orthopaedics

Quality performance indicators (QPIs) are evidence-based items that can be used to measure quality of care in terms of structure (hospital set-up), process (treatment) and outcome(6). They provide insight into the quality of care provided and whether this is reflected in meaningful patient outcomes. QPIs are increasingly used in medicine and allow comparison between different centres to identify gaps and areas for improvement. They also provide evidence for claims of 'good quality care' and provide justification for increased healthcare spending in areas requiring improvement(6, 7).

QPIs are widely used in oncology and orthopaedics, such as the well-known National Institute for Health and Care Excellence (NICE) quality standards for Hip Fractures(8) and Care of Dying Adults(9). The British Orthopaedic Oncology Society (BOOS) and the British Association of Surgical Oncology (BASO) both provide excellent guidance on the management of metastatic bone disease (BOOS 2015(1) and BASO 1999(10)), but require adaptation to provide a set of targets for a minimally acceptable standard of care in non-specialist sites(11). We intended to adapt these with supplementation from the international literature to measure adequacy of initial management and identify future targets for improving care.

National guidance for developing QPIs

QPI standards should focus on identifying care priorities, based on the most up-to-date published evidence and must be specific and feasible to record for the condition of interest(6, 12). Finally, care should be taken to ensure that the QPIs measured accurately correlate with actual standard of care provided (if a gold standard exists)(6). There are a myriad of ways in which this can be done: expert consensus opinion using the RAND or Delphi method(13, 14), extraction from national published guidance(6, 15) or through systematic reviews on medical databases to identify common themes in a particular condition(16). Where published guidelines are present, it is generally recommended to base QPIs on this guidance(6).

For this reason, it was determined to combine the methods described by NICE and Kotter *et al.* in their 2012 systemic review (Supplementary File 1 - Figure) for this study. We would adapt the recommendations published by BOOS and BASO, supplement this with expert opinion from a cross-UK specialty multidisciplinary team and validate this through the RAND/Delphi expert consensus process(6, 17). The primary aim was to generate a set of MBD

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quality performance indicators to provide targets for assessing basic quality of care in patients with bone metastases referred for orthopaedic treatment.

Patients & methods

Guideline selection & extraction of recommendations

A systematic literature review was conducted using the PubMed and Web of Science® databases. The following search terms were used: <quality indicator> OR <quality performance*> OR <QI> OR <QPI> AND <bony metas*> OR <metastatic bone*> OR <MBD> OR <secondary bone*> OR <bone cancer> OR <pathological*> OR <palliative care> and dates were limited to studies from the past 30 years (25/09/1989-25/09/2019). From the articles reviewed, a list of quality objectives were derived comprising explicit statements e.g. ‘Patients should have a documented follow-up plan after surgery, BOOS 2015’. The 40 preliminary quality objectives (QOs, renamed quality performance indicators after validation) were reviewed by all of the authors, the attendees at the 2019 British Orthopaedic Oncology Society annual meeting (Leiden, 2019) and a lay representative before proceeding to expert panel review.

First expert panel review and interim analysis

Potential expert panel members were approached individually and via departmental email lists across multiple health boards in the UK. They had to be fully qualified in their field (i.e. consultants not registrars) and working regularly (i.e. at least once a month) with MBD patients to participate. The consensus plan was to complete two rounds, with the addition of targets after the first round. If the predetermined criteria for consensus were not met after the second round (see below), a third round would be completed.

During the first expert panel review, participants scored every QO on a Likert scale out of 7 (from 1=strongly disagree to 7=strongly agree according to the modified RAND/Delphi criteria) according to how 1) appropriate, 2) necessary and 3) feasible each objective was considered(13, 18). Individual scores were combined to generate combined mean scores for each quality objective with 95% confidence intervals (95% CIs). Panel members were also asked to suggest any additional QOs missing from the preliminary list. To proceed to the second expert panel review, QOs had to achieve a combined mean of $\geq 5/7$ (agree-strongly agree)(13, 19).

After the first consensus stage, all QOs would be reviewed and any ambiguities of terminology clarified. QOs were then analysed by the authors and combined or excluded if deemed not pertinent to the orthopaedic MBD care setting (e.g. of more relevance to primary care setting).

This revised list of QOs was assessed in a small retrospective population of 34 MBD patients selected using a random numbers generator from a regional MBD database. This was used to briefly assess feasibility of the 20 proposed QOs and to identify early ‘targets’ for review and feedback at the second expert panel review (for example, “Preoperative blood tests should be completed for 85% of patients within 48 hours of surgery”). Interim analysis was undertaken amongst the author group as an alternative to a face to face meeting with expert panel members according to an established precedent(19, 20).

Second expert panel review

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The second draft of QOs was reviewed by the same expert panel with feedback on initial scores and the addition of provisional targets. From this point, the items were termed quality performance indicators (QPIs). The QPIs were scored by the expert members in terms of 1) necessity and 2) degree of leniency of proposed targets(13). This generated the final set of metastatic bone disease quality indicators (MBD QPIs) which proceeded to the pilot test. To proceed to pilot testing, QPIs had to be deemed as 'necessary' (yes/no question) by $\geq 70\%$ of participants. If more than 75% of the QPIs met this criteria, it was agreed amongst the author group *a priori* that this would complete the expert consensus process(19, 21).

Pilot 'practice' test

This was considered a precursor to a powered, multi-centre validation study. The goals of the pilot test were to test out practicality of using the QPIs, identify the number in each group of interest (e.g. surgical patients, dying patients) and identify numbers that would be required for a large multi-centre validation study.

Pilot testing took place using retrospective electronic-only data from an anonymised regional MBD database. Consecutive patients referred to orthopaedics with a bone metastasis over a 2-year period were included (exclusion criteria age $<16y$ and lesion due to primary bone tumour). Caldicott Guardian permission was secured (ref: IGTCAL3289). Recording of QPI results for patients was conducted by the first author (SD) with a randomly-identified subset of 25 correlated by a second blinded reviewer (JC) (22).

Statistical analysis

Missing data, where present, have been indicated. Where study groups have been directly compared with one another, dataset analysis comprised the chi-squared test for categorical variables and the paired *t*-test or non-parametric Mann-Whitney U test as appropriate for continuous variables. Statistical significance was set at $p < 0.05$. Cohen's κ (Kappa statistic) was used to determine interobserver variation between the two reviewers in the pilot test (>0.61 'substantial' agreement required, otherwise second reviewer would review all records)(19, 23, 24).

Results

Extraction of recommendations

2568 articles were identified and after removal of duplicates and a title/abstract review, the full text articles for 48 records (including six national published guidelines(1, 9, 10, 25-27)) were reviewed (Figure 1). From these articles, the first author extracted 43 quality objectives covering 9 care domains (Table 1). These were reviewed by all authors and three removed as they contravened national guidance for MBD care from the British Orthopaedic Oncology Society (BOOS).

First expert panel review

75 potential panel members were approached by email, and further experts were recruited by local Health Board specialty emailing lists. There were 24 respondents (32% response rate). The resultant expert panel included consultants in orthopaedic trauma, oncology, palliative medicine, anaesthetics and radiology, and specialty orthopaedic nurses, nurse

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practitioners, physiotherapists and a lay patient representative. Experience in working with patients with MBD ranged from <2 to >21 years and 58% (14/24) of participants had more than 10 years' experience in MBD (Table 2).

Panellists rated each quality objective on appropriateness, necessity and feasibility (**Supplementary File 2 – Table**) then combined means were calculated using the raw data. Combined means were chosen over combined medians as data was deemed to be parametric (mean difference 0.5, median difference 0.5, 98% 39/40 combined mean and medians within 1 of each another). Combined mean scores ranged from 4.3 to 6.7/7 (mean 5.9, 95% CI 5.8-6.1).

Interim analysis

During the interim analysis after the first expert panel review, two QOs were excluded for a combined mean score of less than 5 (Supplementary File 2 - Table). 11 QOs were combined into other objectives and 13 QOs were excluded for other reasons (3 no direct orthopaedic care relevance, 5 deemed 'surgeon choice' e.g. selection of implant and 5 no relevance to MBD care e.g. more applicable to traumatic fractures). 6 new QOs were considered based on the results of the first expert panel review with 2 included in the revised QO list. This generated a list of 20 revised quality objectives which would proceed to second expert panel review.

Data from 34 MBD patients (identified at random from a regional MBD database) was used to generate provisional targets for each revised QO, which were now termed provisional QPIs (pQPIS, Supplementary File 3 - Table).

Second expert panel review

Of the original 24 expert panel members, 10 completed the second consensus stage (42% response rate). Table 3 summarises the raw data for necessity score and feedback on provisional targets for each of the 20 provisional QPIs. Two QPIs were excluded from the final list for a necessity score less than 70%. As 90% (17/19) of provisional QPIs met the predetermined criteria of $\geq 75\%$ of QPIs meeting necessity targets (see Methods), the expert consensus process was stopped at this stage and the final list of 18 MBD QPIs proceeded to the pilot test.

Pilot test

Evaluated in the field test were 108 patients referred consecutively over a 2-year period (01/01/2017-31/12/2018) to the regional trauma centre (Table 4). Patients were 47% female with a mean age of 71.6 years. 56% had a pathological fracture and 63% underwent surgery for their bone metastasis. Mortality at 90 days was 32% and this increased to 61% at one year. Patients who were still alive during pilot testing study had a median follow-up of 25.2 months (minimum 19.3 months, IQR 32.1-20.9 n=19). No patient was lost to follow-up.

The combined mean kappa coefficient for concordance between the two reviewers was 0.692 (SD 0.176, range 0.409-1). This met the predetermined threshold of >0.61 (substantial concordance).

Of the 14 QPIs with provisional targets (QPIs 15-18 are systemic targets and have a binary target met/not met outcome), mean % of QPIs met was 52% (standard deviation SD 22%, range 2-91%). Targets were met for 5/18 QPIs, with a further 5/18 within 15% of target. The

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median deviation from projected target was -14% (IQR -11% to -31%, range -74% to 11%). The two lowest scoring QPIs were: “surgical patients should start rehabilitation within 72 hours of surgery” (target 75%: actual 2%) and “dying patients should have documentation of CPR status” (target 65%: actual 27%).

Overall, the MBD care of 11/108 patients met all appropriate targets for that individual (10%). Table 5 summarises the final list of MBD QPIs with finalised targets and inclusion/exclusion criteria.

Discussion

We have developed the first QPIs for care of orthopaedic patients with metastatic bone disease (MBD QPIs). We have used a combination of validated, evidence-based approaches and have generated the list of QPIs from a systematic review of the published literature. The final QPI set is shown in Table 5 and is validated through pilot testing in a single UK trauma centre.

Development of QPIs

The method used to generate the MBD QPIs in this paper is based on a method described by Kotter and colleagues(6) with preliminary validation using data from a regional trauma centre MBD database. Through extraction from a systematic review and all of the available published guidelines on MBD care, two-stage expert consensus and feasibility testing, we have generated a set of comprehensive QPIs of care that should be considered as the starting point for comparing and standardising basic care for patients with MBD across the UK.

A number of initial quality outcomes were disregarded at the interim analysis stage as these were deemed to be ‘at the discretion of the treating surgeon’ or not directly applicable to orthopaedic and/or MBD care. This was because the authors felt that the purpose of these QPIs should not be to supersede expert orthopaedic opinion, but to provide a tool to augment comparison and standardisation of surgical care between centres and identify high and low-scoring outliers in MBD care. There is a precedent for being selective in choice of final QPIs(6), with justification including the variable impact on patient health, value for money and feasibility of monitoring specific indicators. This is a particular strength of the RAND/Delphi method, whereby the input from a wide group of specialists in the healthcare topic of interest provides an assessment of feasibility and suitability (appropriateness), as well as justification for the necessity of measuring specific indicators(12).

The initial results from the pilot test indicated a number of QPIs that performed well, and a number that performed poorly. The two QPIs that achieved their targets were the number of patients who had surgery within 7 days (actual 91%:target 80%) and those with documented input from oncology prior to surgery (actual 70%:target 60%). However, the majority of targets were not met and overall, only 10% of patients had all the QPIs appropriate to their care met. Although low, this should be considered a starting point for service improvement and is considerably higher than the number of patients meeting their QPI targets in a comparable publication on inpatient mortality (1% 4/300)(28).

Notably, the initial target of 60% with possible solitary lesions having full pre-operative investigations or documented reason for not investigating (e.g. patient frailty), would be considered by many orthopaedic oncology surgeons as inappropriately low, given the risk of missing any diagnosis of a new primary bone lesion. This issue was been raised by the

members of the expert panel and during presentation of initial results. Given these concerns, we have revised the target to 95% to reflect the importance of this target and emphasise that meeting these QPIs in patients with metastases should not contribute to missed diagnoses of new primary bone malignancies.

The demographics of the patients included in this field test (47% female, average age 72 years, rate of pathological fracture 56% and commonest primaries lung, breast and prostate) were largely comparable to the general MBD population in the international literature (range female gender 52-55%(3, 29, 30), age 63-72 years(3, 29-31) and commonest primaries breast, prostate, kidney and lung(3, 29-31). The rate of pathological fracture was highly variable in the literature (range 30-74%)(2, 3, 31).

Utility of MBD QPIs

We would recommend that these QPIs form the basis for an ongoing programme to assess, standardise and improve care for patients with MBD who are referred for orthopaedic management, regardless of where they present. Although developed in Scotland, we will aim to validate these across a range of centres in terms of reproducibility and as predictors of good outcome after orthopaedic treatment. This future multi-centre study will also incorporate outcome assessment. The results from the field test have already been fed back to the regional centre with a commitment from the Clinical Director to improve the poorly performing and maintain the highly scoring QPIs. Future studies will ascertain whether this can improve practice in MBD care.

There is evidence that QPIs can be extrapolated to different countries if an appropriate process is followed to identify any cultural or clinical differences(32). Evidence for the benefit of QPI implementation and improvement in care via outcome measures has suggested a limited but positive impact, but focus on the potential for QPI implementation changing the “way of doing business” of a specialty in raising awareness and identifying deficits in care for conditions such as MBD is vital(33). A recent study in the palliative care setting in England highlighted the importance of clinician ‘buy-in’ in implementing QPIs for improving care and reflected that indicators should be specific to the population, both in terms of condition and care setting they are applied to(34). Our QPI dataset is specifically developed and targeted for use in MBD care in patients referred for orthopaedic management of bone metastases, and would not be appropriate for use in the oncology or primary care setting without adaptation and further validation. Improving and standardising quality of care in MBD patients should never come at the detriment to diagnosis and appropriate management of primary bone malignancies, and our revised target of 95% adequate documentation of further investigations required for suspected solitary bone lesions reflects this. During the multi-centre validation study, we will specifically collect data on any missed primary bone malignancy diagnoses to identify whether adherence to these performance indicators has any influence on sarcoma care.

Limitations

The study had several limitations, several of which will be addressed in future work building upon the foundation of the QPIs generated in this study. For example, the focus on the QPIs developed has been on the process of care rather than its outcome (e.g. was the patient assessed within a set period rather than did this lead to a better outcome e.g. reduced inpatient stay). This has been done to address the primary issue in this area, which is a lack of standardisation in terms of care delivery and assessment. There is no current consensus

on the appropriate outcomes of care in the MBD population, since mortality and rate of revision surgery would likely be considered inappropriate in surgical management of an essentially palliative condition(4). Our team is currently working on development of patient-validated indicators of good care outcomes in this population, and we hope to publish these results within the next 12 months.

Secondly, a significant limitation of our pilot test is the reliance on electronic records for documentation of QPI targets (no use of paper notes). It is likely that this will account for several of the very low-scoring QPIs (e.g. physiotherapy input is infrequently documented electronically). However there is a precedent for this due to the significantly increased workload and general shift towards electronic patient records within the UK(35) and in order to fairly assess care between centres, there should be a drive towards improving electronic documentation for these QPIs in general(13).

Finally, there is no power calculation for the field test aspect of this study, and indeed there is no example in the literature that has addressed this adequately(36)). We consider this a pilot study and have included a provisional power calculation within the final section as part of our future implementation strategy (see below).

Future work

At this stage, we have developed a list of novel QPIs specific to the orthopaedic care of MBD patients. As part of our implementation strategy, we would recommend that these are validated in a powered, multi-centre study to assess the sensitivity of these QPIs in identifying centres which are high and low-performing outliers across the UK (6). We are currently conducting a multi-centre validation study to validate these performance indicators(37). QPIs will be assessed at each centre with a minimum sample size of 142 required at each centre to allow comparison between centres to detect a 5% difference in the combined mean score of QPI targets (Supplementary File 4 - Table). Results will be fed back to individual centres and a commitment made to audit change in practice after 12 months to ascertain the change in care as a result of instituting these QPIs for improving orthopaedic care for MBD patients.

Tables

Table 1

Metastatic bone disease (MBD) quality objectives (QOs) reviewed during first stage of Delphi expert consensus process

No.	Quality objective	Care domain
1	Patients with the suspicion of new metastatic bone disease should be promptly assessed to exclude emergency complications such as spinal cord compression and hypercalcaemia(10)	Referral with new bony metastasis
2	Patients who are referred with new metastatic bone disease should be seen and investigated promptly by an oncologist(10)	New metastasis work-up
3	Patients with symptomatic lesions should receive prompt orthopaedic assessment(10)	
4	Patients with lesions at high risk of fracture should receive urgent orthopaedic assessment(10)	
5	Pre-operative work up should include blood tests (full blood count, urea & electrolytes, liver function tests and bone profile) (10)	
6	Appropriate and timely staging investigations should be completed for every patient with new bone metastases(10)	
7	Patients should be seen by their clinician with the results of staging investigations and decision on management given with minimal delay(10)	
8	Patients with a possible solitary metastasis should receive a prompt and full work-up(10)	
9	Patients with an unconfirmed solitary metastasis must have histological proof of diagnosis before treatment(10)	Multidisciplinary team management
10	Orthopaedic treatment should be discussed with the patient's oncologist and seen in the context of the underlying malignancy(1)	
11	All patients with metastatic bone disease (secondary bone cancer) should have access to an expert (tertiary) orthopaedic opinion (e.g. an orthopaedic oncology surgeon) (1)	Operative principles
12	Impending fractures in long bone metastases should be fixed before the lesion causes a pathological fracture(1)	
13	Metastatic fractures may not unite, especially if given radiotherapy. Surgery should aim to replace rather than fix bone(1)	
14	Where internal fixation is planned, load sharing (e.g. intramedullary nail) should be chosen over load bearing (e.g. sliding hip screw) devices(1)	
15	Surgical reconstruction should allow immediate weight-bearing(1)	
16	Wide excision of solitary bone metastases should be considered if reasonable to do so(1)	
17	Adults with hip fractures should be cared for within a Hip Fracture Programme at every stage of the care pathway(25)	Pathological hip fractures
18	Adults with hip fractures should have surgery on a planned trauma list within the normal working day(25)	

*	Adults with hip fracture have surgery on the day of, or the day after, admission(25)	
19	Displaced intracapsular hip fractures should have consideration of a total hip replacement rather than a hemiarthroplasty(25)	
*	Adults with trochanteric fractures above and including the lesser trochanter should receive an extramedullary implant(25)	
*	Adults with subtrochanteric fractures should be treated with an intramedullary nail(25)	
20	Cemented hip prostheses (standard or tumour prostheses) should be considered over uncemented prostheses to minimise risk of failure(1)	
21	Patients with a prognosis >12 months should be considered for an endoprosthetic replacement of the proximal femur(1)	
22	Extracapsular hip fractures should receive a load sharing implant (e.g. intramedullary nail) or long stem/intercalary prosthesis(1)	
23	Adults with hip fractures should start rehabilitation at least once a day, no later than the day after surgery(25)	
24	Patients should have an inpatient hospital stay (in orthopaedic ward) of less than 7 days after surgery(38)	Inpatient hospital stay
25	Patients should not require further surgery within 7 days of index procedure(38)	
26	Patients should not require a post-operative blood transfusion(38)	
27	Patients should have documentation of their expected prognosis(39)	End of life care
28	Dying patients should have this recognised and documented(39)	
29	Patients who are dying should have input from palliative care(39)	
30	Patients who are dying should have a supportive plan made (e.g. symptomatic treatment plan, nomination of next of kin etc) (39)	
31	Patients who are dying should have a plan for ceiling of treatment and resuscitation (including DNA CPR) (39)	
32	Patients who are dying should not be subjected to overly aggressive, burdensome or futile treatment(39)	
33	Dying patients should have their symptom control optimised(39)	Follow up
34	Patients should have a documented follow-up plan after surgery(25)	
35	Patients who undergo follow-up in an orthopaedic clinic should have documented evaluation of fracture union, local disease progression and impending/actual failure of the reconstruction(1)	
36	Every orthopaedic service should nominate a clinician to lead on the management of patients with metastatic bone disease(1)	Service improvement & audit
37	Orthopaedic services should provide education on metastatic bone disease for the healthcare team(39)	
38	Data should be collected about the orthopaedic management of patients with metastatic bone disease to improve understanding of patient experience and optimise approaches to surgery(1)	
39	Peri-operative mortality should be below an 'acceptable level'(40)	System organisation
40	Peri-operative complications should be below an 'acceptable level'(40)	
*excluded prior to first expert panel review as contravened national guidelines for management of MBD from BOOS(1)		

Table 2

Makeup of expert advisory panel in metastatic bone disease (MBD) involved in Delphi consensus process

Role, n (%/24)	
Consultant	17 (71)
Nurse/Advanced Scrub Practitioner	2 (8)
Physiotherapist	3 (13)
Researcher	1 (4)
Lay reviewer	1 (4)
Specialty, n (%/24)	
Orthopaedics	13 (54)
Orthopaedic oncology	2 (8)
Radiology	2 (8)
Anaesthetics	4 (17)
Oncology	1 (4)
Palliative medicine	1 (4)
Lay	1 (4)
Experience, yrs n (%/24)	
Not specified	1 (4)
N/A (lay)	1 (4)
<2 years	1 (4)
2-5 years	2 (8)
6-10 years	5 (21)
11-20 years	9 (38)
>21 years	5 (21)

Table 3

Results of second expert panel review and feedback on quality performance indicator (QPI) targets

	Provisional quality performance indicator (pQPI) [Provisional target]	Necessary indicator?			Target feedback			
		Yes	No	Not sure	Too lenient	About right	Too strict	Not sure
All MBD patients								
1	Patients with impending fractures should receive prompt orthopaedic assessment [75% assessed within 48h of referral]	8	1	1	3	4	2	1
2	Where staging or preoperative investigations are required, these should be completed without delay [75% inpatients requiring imaging have this completed within 7d]	9	0	1	3	5	2	0
3	Patient should be seen by orthopaedics and a treatment decision made without delay [80% have documented treatment decision within 48h of first ortho review OR after completing investigations, whichever is latest]	9	0	1	2	6	1	1
4	Patients with a solitary lesion with concern of malignancy should receive a full work-up including biopsy before a decision is made [60% with possible solitary lesions should have further imaging OR documentation of reason for no further imaging]	9	0	1	4	5	0	1
5	Patients with impending fractures should be discussed with oncology and a treatment decision made in the context of the underlying malignancy [60% should have documented input from oncology before treatment]	8	1	1	1	9	0	0
Surgical patients								
6	Surgical work-up should include up-to-date blood tests (including full blood count, urea & electrolytes, <u>coagulation screen</u> , liver function tests, bone profile and group & screen) [75% have complete bloods within 48h of surgery]	10	0	0	5	5	0	0
7	Patients for surgery should have regular assessment of pain and function with adequate analgesia where appropriate [75% should have documentation of pre and post-op pain]	10	0	0	5	5	0	0
8	Where internal fixation is to be undertaken, load sharing (e.g. intramedullary nail) should	6*	2	2	0	7	0	0

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	be chosen over load bearing (e.g. sliding hip screw) devices							
9	Adults with metastatic fractures should have surgery on a planned trauma list without delay [75% should have surgery within 7 days of decision of operate]	10	0	0	4	6	0	0
10	Surgical patients should start rehabilitation within 72h of surgery [75% should have documentation of physiotherapy by day 3]	9	1	0	2	8	0	0
11	All patients for surgery should have prognosis estimated and documented [50% of surgical patients should have documentation of prognosis before surgery]	6*	3	1	3	4	0	3
12	Patients should have a post-operative plan including indications for follow-up and weight-bearing status [75% should have a post-operative plan]	9	0	1	8	2	0	0
13	Patients followed-up should have evaluation of fracture union, lesion progression and stability of reconstruction [50% have documentation of all relevant parameters at clinical follow-up (any time period)]	8	0	2	4	5	0	1
Dying patients								
14	Dying patients should have this recognised & documented [50% of those who die within 90 days identified as 'dying' or 'frail']	8	1	1	3	6	0	1
15	Dying patients with treatment-resistant symptoms should have input from palliative care [50% should have palliative care input during admission]	8	1	1	8	1	0	1
16	Dying patients should have a documented plan for ceiling of care and resuscitation [50% should have DNA CPR status documented]	9	0	1	5	5	0	0
System management								
17	Complex patients should be discussed at an MDT and the outcome relayed to the patient within 7 days of completion of investigations	7	2	1				
18	Patients with MBD should be managed in centres with a specified MBD care pathway	7	2	1				
19	Centres should provide MBD education for the healthcare team	8	1	1				
20	Centres should have a system for collecting MBD patients outcome data including mortality and perioperative complications	10	0	0				
*Two provisional QPIs removed for necessity score <70%								

Table 4

Final metastatic bone disease (MBD) quality performance indicators (QPIs) with pilot test results

Dates, range (duration yrs)	01/01/2017-31/12/2018 (2)		
Number of consecutive patients	132		
Number of records excluded	24 (16 not MBD, 8 duplicate presentations for same lesion)		
Number of patients proceeding to pilot test	108		
Female, n (%/108)	51 (47), 0 unknown		
Mean age, yrs (SD; range)	72 (12; 38-93)		
Primary cancer, n (%/108)			
Lung	26 (24)		
Breast	22 (20)		
Prostate	22 (20)		
Lymphoma	7 (7)		
Renal	7 (7)		
Colorectal	6 (6)		
Bladder	6 (6)		
Myeloma	5 (5)		
Primary of unknown origin (PUO)	1 (1)		
Other	6 (6)		
Location of metastases, n (%/112)			
Upper limb	22 (20)		
Lower limb	69 (62)		
Pelvis	19 (17)		
Spine	2 (2)		
Pathological fracture, n (%/108)	60 (56), 0 unknown		
Surgery, n (%/108)	68 (63), 0 unknown		
Procedure, n (%/68)			
Intramedullary nail (IMN)	34 (50)		
Plate (inc. sliding hip screw SHS)	8 (12)		
Hemiarthroplasty	15 (22)		
Total joint replacement/complex arthroplasty	10 (15)		
Salvage (e.g. girdlestone, fusion)	1 (2)		
Mortality, n (%/108)			
7 days	4 (4)		
30 days	10 (9)		
90 days	34 (32)		
1 year	66 (61)		
Median follow-up (living patients), months (IQR; range) n=19	25.2 (32.1-20.9; 19.3-37.4)		
QPI no.	Target	Target met, n/* (%)	Achieved?
1	75% assessed within 48 hours of referral	24/33 (73)	No
2	75% of patients requiring further imaging should have this completed within 7 days	22/35 (63)	No

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3	80% have treatment decision documented within 48 hours of referral/completion of investigations	59/108 (55)	No
4	95% with possible solitary lesions should have further imaging/documentation of reason for no further imaging	6/16 (38)	No
5	60% with impending fractures should have documented input from oncology before orthopaedic treatment	23/33 (70)	Yes
6	85% should have complete bloods within 48 hours before surgery	49/68 (72)	No
7	85% of surgical patients should have documentation of pre and post-op pain	27/68 (40)	No
8	80% with pathological fractures should have surgery within 7 days of decision of operate	42/46 (91)	Yes
9	75% should have documentation of physiotherapy input by day 3 after surgery	1/68 (2)	No
10	75% should have a post-operative plan (documented electronically) which includes weightbearing status and plan for follow-up	33/68 (49)	No
11	65% have documentation of all relevant parameters at clinical follow-up (any time period)	14/26 (54)	No
12	60% of those who die within 90 days of referral are identified as 'dying' or 'frail'	15/34 (44)	No
13	65% of patients who are dying should have palliative care input during admission	18/34 (53)	No
14	65% of patients who are dying should have DNA CPR status documented	9/34 (27)	No
15	Result of tertiary/MDT discussion relayed to patient within 7 days of completion of staging investigations	No data	Unknown
16	Specified MBD care pathway in place	-	Yes
17	MBD education provided for members of healthcare team	-	Yes
18	MBD outcome data including mortality and complications collected and audited locally	-	Yes
*Population sizes: all patients (n=108), patients with impending fractures (n=33), patients requiring further investigations (n=35), patients with possible solitary lesion (n=16), patients undergoing surgery (n=68), patients undergoing surgery for pathological fracture (n=46), patients with planned follow-up (n=26), patients who died within 90 days of referral (n=34)			

Table 5

Final quality performance indicators for patients with confirmed metastatic bone disease (MBD QPIs) with validated targets and inclusion/exclusion criteria

Quality indicator		Target	Inclusion	Exclusion
1	Patients with impending fractures should receive prompt orthopaedic assessment	75% inpatients assessed within 48 hours of referral	Impending fractures (identified radiologically or severe pain/unable to weight-bear)	Patients managed as outpatients & those with pathological fractures
2	Where pre-treatment investigations are required, these should be completed without delay	75% of patients requiring further imaging should have this completed within 7 days	Patients with plan for further investigation on ortho review	Patients with management plan documented on first ortho review
3	Patients should be seen with investigation results and a treatment decision made without delay	80% have treatment decision within 48h of referral/ completion of investigations	All patients	-
4	Patients with a solitary lesion suspicious of malignancy should receive a full work-up including biopsy before a treatment decision is made. Biopsy should be undertaken in consultation with a specialist MDT.	95% with possible solitary lesions should have further imaging/documentation of reason for no further imaging	Patients with isolated bone lesion and no radiologically confirmed metastatic disease	-
5	Patients with impending fractures should be discussed with oncology and a treatment decision made in the context of the underlying malignancy	60% with impending fractures should have documented input from oncology before orthopaedic treatment	Patients with impending fractures (see 1)	Patients with completed fractures
6	Surgical work-up should include recent blood tests (full blood count, urea & electrolytes, coagulation, liver function tests, bone profile and group & screen)	85% should have complete bloods within 48 hours before surgery	All surgical patients	Group and screen not required for upper limb lesions
7	Patients for surgery should have regular assessment of	85% of surgical patients should have	All surgical patients	-

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	pain and function with adequate analgesia	documentation of pre and post-op pain		
8	Adults with fractures should have surgery on a planned trauma list without delay	80% should have surgery within 7 days of decision of operate	All surgical patients with pathological fractures	-
9	Surgical patients should start rehabilitation within 72 hours of surgery	75% should have documented physiotherapy by day 3 post-surgery	All surgical patients	-
10	Patients should have a documented post-operative plan including indications for follow-up and weight-bearing status	75% should have a post-operative plan including weightbearing status & planned follow-up	All surgical patients	-
11	Patients followed-up should have evaluation of fracture union, lesion progression and construct stability	65% have documentation of all relevant parameters at clinical follow-up (any time period)	All surgical patients undergoing follow-up	Documentation of union not required if arthroplasty
12	Patients who are dying should have this recognised and documented	60% of patients who are dying are identified as 'dying' or 'frail'	Patients who die within 90 days of orthopaedic referral	-
13	Dying patients with treatment-resistant symptoms should have input from palliative care	65% of patients who are dying should have palliative care input during admission	Patients who die within 90 days of orthopaedic referral	-
14	Dying patients have a documented plan for ceiling of care & resuscitation (including DNA CPR)	65% of patients who are dying should have DNA CPR status documented	Patients who die within 90 days of orthopaedic referral	-
15	Result of MDT discussion relayed to patient within 7 days of completion of investigations	No data	-	-
16	Specified MBD care pathway in place	Binary yes/no	-	-
17	Education provided for healthcare team	Binary yes/no	-	-
18	Outcome data including mortality & complications collected & audited locally	Binary yes/no	-	-

Figures

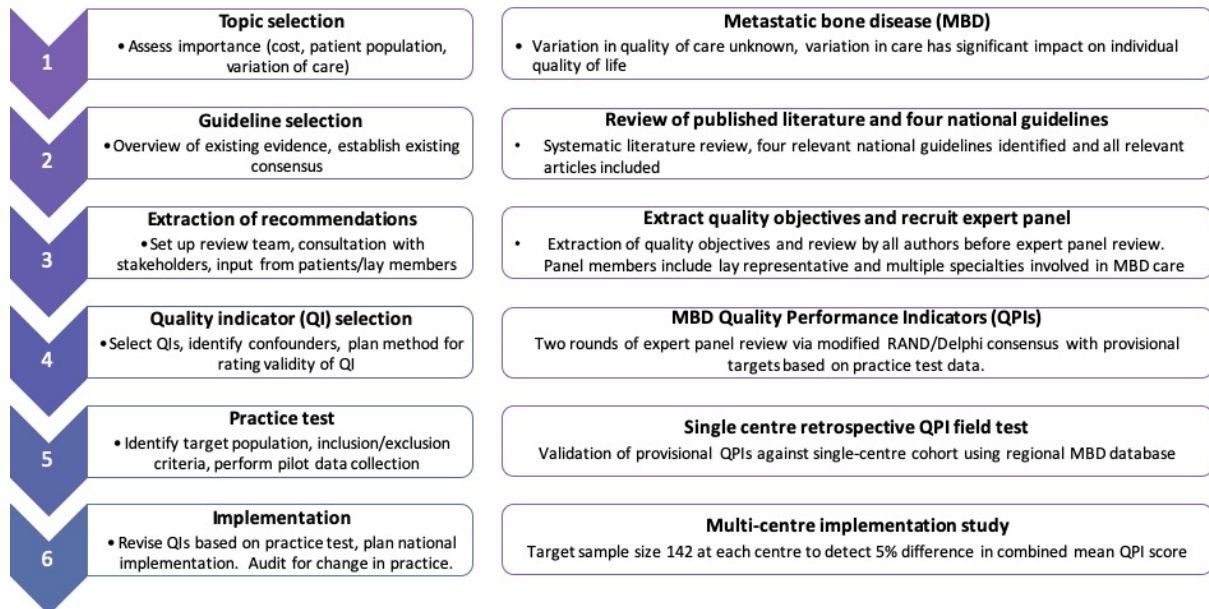
Figure 1

Flowchart summarising the method used in this study for developing a novel set of quality performance indicators for metastatic bone disease (MBD QPIs)

Supplementary Files

Supplementary File 1 - Figure

Schematic overview of the process of guideline-based quality performance indicator (QPI) development, based on the methods described by Kotter *et al.*(6) and utilising guidance from Mainz *et al.*(15) as applied to metastatic bone disease (MBD).



Supplementary File 2 - Table

Results of first expert panel review

QO	'Not sure' /24	'Appropriate' score Mean (SD; range)	'Necessary' score Mean (SD; range)	'Feasible' score Mean (SD; range)	Combined mean (95% CI)	Outcome
1	3	6.6 (0.6; 5-7)	6.5 (0.9; 4-7)	5.5 (2; 1-7)	6.2 (5.9-6.6)	Exclude ²
2	2	6.3 (1.3; 2-7)	6.3 (1.5; 1-7)	5.9 (1.4; 2-7)	6.2 (5.8-6.5)	Exclude ²
3	2	6.2 (1.2; 3-7)	6.1 (1.3; 3-7)	6.2 (1; 4-7)	6.1 (5.9-6.4)	Include
4	4	6.9 (0.3; 6-7)	6.8 (0.6; 5-7)	6.3 (0.9; 4-7)	6.7 (6.5-6.8)	Combine [3]
5	5	6.8 (0.5; 5-7)	6.7 (0.8; 4-7)	6.7 (0.7; 5-7)	6.7 (6.5-6.9)	Include
6	5	6.4 (0.8; 5-7)	6.3 (0.9; 4-7)	6.3 (0.9; 4-7)	6.4 (6.1-6.6)	Include
7	4	6.4 (0.9; 4-7)	6.3 (1; 4-7)	5.8 (1.3; 3-7)	6.2 (6-6.5)	Include
8	4	6.7 (0.8; 4-7)	6.7 (0.8; 4-7)	5.9 (1.3; 4-7)	6.5 (6.2-6.7)	Include
9	3	5.7 (1.5; 3-7)	5.8 (1.4; 3-7)	5.6 (1.1; 3-7)	5.7 (5.3-6)	Combine [8]
10	4	6.4 (0.9; 4-7)	6.3 (1.1; 3-7)	5.7 (1.7; 1-7)	6.1 (5.8-6.4)	Include
11	2	4.8 (1.9; 1-7)	4.7 (1.8; 1-7)	5.1 (1.5; 2-7)	4.8 (4.4-5.3)	Exclude ¹
12	6	6.5 (0.8; 4-7)	6.3 (0.9; 4-7)	5.5 (1.6; 2-7)	6.1 (5.8-6.4)	Combine [7]
13	6	5.3 (1.3; 3-7)	5.3 (1.4; 3-7)	5.4 (1.5; 3-7)	5.3 (5-5.7)	Exclude ³
14	3	6 (1.2; 4-7)	5.8 (1.3; 3-7)	6 (1.4; 3-7)	5.9 (5.6-6.2)	Include
15	6	5.8 (1.3; 3-7)	5.5 (1.3; 3-7)	5.2 (1.6; 1-7)	5.5 (5.1-5.8)	Combine [34]
16	3	5.9 (1.3; 3-7)	5.7 (1.2; 3-7)	5.4 (1.3; 3-7)	5.7 (5.3-6)	Exclude ³
17	1	5.9 (1.5; 3-7)	5.9 (1.3; 3-7)	6 (1.4; 3-7)	5.9 (5.6-6.3)	Exclude ⁴
18	5	6.4 (1; 4-7)	6.3 (0.9; 4-7)	6.1 (1; 4-7)	6.3 (6.1-6.5)	Include
19	6	5.3 (1.2; 3-7)	5.3 (1.3; 3-7)	5.5 (1.4; 3-7)	5.4 (5.1-5.7)	Exclude ³
20	9	6 (1.3; 3-7)	5.6 (1.4; 3-7)	5.7 (1.5; 3-7)	5.7 (5.4-6.1)	Exclude ³
21	4	5.7 (1.1; 4-7)	5.7 (1.1; 4-7)	5.6 (1.3; 4-7)	5.7 (5.4-6)	Exclude ⁴
22	3	6.2 (1.1; 4-7)	6.1 (1.2; 4-7)	6.3 (1; 4-7)	6.2 (5.9-6.5)	Combine [14]
23	5	6.3 (1.1; 3-7)	6.2 (1.2; 3-7)	5.9 (1.5; 2-7)	6.1 (5.8-6.5)	Include
24	5	4.8 (1.1; 3-7)	4.8 (1.3; 3-7)	5.2 (1.4; 2-7)	5.0 (4.6-5.3)	Exclude ⁴
25	2	5.5 (1.2; 3-7)	5.1 (1.5; 1-7)	5.7 (1.2; 4-7)	5.4 (5.1-5.7)	Exclude ⁴
26	2	4.1 (1; 2-6)	4.1 (1.1; 2-6)	4.7 (1.5; 2-7)	4.3 (4-4.6)	Exclude ¹
27	2	6 (1.2; 3-7)	6 (1.3; 3-7)	5.4 (1.4; 3-7)	5.8 (5.5-6.1)	Include
28	1	6.5 (0.9; 4-7)	6.3 (1.3; 3-7)	6 (1.3; 3-7)	6.2 (6-6.5)	Include
29	2	6.6 (0.9; 4-7)	6.5 (1; 3-7)	5.9 (1.4; 3-7)	6.3 (6.1-6.6)	Include
30	1	6.7 (0.7; 5-7)	6.7 (0.7; 5-7)	5.7 (1.5; 3-7)	6.4 (6.1-6.6)	Combine [28]
31	1	6.7 (0.7; 5-7)	6.4 (1.1; 3-7)	6.1 (1.2; 4-7)	6.4 (6.2-6.7)	Include
32	1	6.8 (0.6; 5-7)	6.5 (0.9; 4-7)	5.6 (1.6; 3-7)	6.3 (6-6.6)	Exclude ⁴
33	2	6.7 (0.8; 4-7)	6.4 (1; 4-7)	5.4 (1.4; 2-7)	6.2 (5.9-6.5)	Combine [29]
34	3	6.6 (0.9; 4-7)	6.4 (1; 4-7)	6.1 (1.3; 3-7)	6.4 (6.1-6.6)	Include
35	1	6.4(0.9; 4-7)	6 (1.2; 4-7)	5.7 (1.2; 3-7)	6.0 (5.8-6.3)	Include
36	2	5.8 (1.4; 3-7)	5.7 (1.4; 3-7)	5.9 (1.3; 3-7)	5.8 (5.5-6.1)	Include
37	3	5.9 (0.9; 4-7)	5.5 (1.2; 3-7)	5.3 (1.3; 4-7)	5.6 (5.3-5.9)	Include
38	3	6.3 (0.9; 5-7)	6.3 (0.8; 5-7)	5.7 (1.5; 3-7)	6.1 (5.9-6.4)	Include
39	2	5.4 (1.5; 2-7)	5.6 (1.5; 2-7)	5.7 (1.6; 2-7)	5.6 (5.2-5.9)	Combine [38]

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40	1	5.8 (1.3; 3-7)	5.9 (1.2; 4-7)	5.6 (1.5; 2-7)	5.8 (5.5-6.1)	Combine [38]
6 additional QOs suggested by first expert panel members:						
41	Cross-sectional imaging completed prior to surgical fixation					Exclude ³
42	Documentation of a multidisciplinary team (MDT) meeting for complex patients					Include
43	Pain control for pathological fractures – use of regional anaesthesia ‘blocks’					Combine [44]
44	Pre and post-surgery assessment of pain and function (including patient reported outcome measures)					Include
45	Documented delay between decision to operate and surgery					Combine [18]
46	Documented delay between surgery and post-operative chemo-/radiotherapy					Exclude ²
Exclude ¹ : combined mean <5, consensus criteria not met Exclude ² : no direct orthopaedic care relevance Exclude ³ : surgeon choice Exclude ⁴ : not applicatory to MBD care						

Supplementary File 3 (Table)

Practice test data n=34 with list of provisional quality performance indicators (pQPIs) and provisional targets

Dates, range (duration yrs)		04/01/2017-6/12/2018 (2)	
Female, n (%/34)		18 (53), 0 unknown	
Mean age, yrs (SD; range)		73.9 (9.6; 51.4-88.6)	
Primary cancer, n (%/34)			
Lung		8 (24)	
Breast		7 (21)	
Prostate		6 (18)	
Lymphoma		2 (6)	
Renal		1 (3)	
Colorectal		1 (3)	
Bladder		3 (9)	
Myeloma		2 (6)	
Primary of unknown origin (PUO)		2 (6)	
Other		2 (6)	
Location of metastases, n (%/34)			
Upper limb		3 (9)	
Lower limb		26 (77)	
Pelvis		5 (15)	
Spine		0	
Pathological fracture, n (%/34)		18 (53), 0 unknown	
Surgery, n (%/34)		25 (74), 0 unknown	
Procedure, n (%/25)			
Intramedullary nail (IMN)		10 (40)	
Plate (inc. sliding hip screw SHS)		2 (8)	
Hemiarthroplasty		9 (36)	
Total joint replacement/complex arthroplasty		4 (16)	
Salvage (e.g. girdlestone, fusion)		0	
Mortality, n (%/34)			
7 days		2 (6)	
30 days		9 (27)	
90 days		14 (41)	
1 year		22 (65)	
Median follow-up (living patients), months (IQR; range) n=3		33.7 (33.8-32; 30.4-33.9)	
Quality indicator		Results	Proposed target
1	Patients with impending fractures should receive prompt orthopaedic assessment	Of 11 with impending fractures, 9 were seen within 2d (82% mean 0.6d)	75% should be seen within 48 hours of referral
2	Where pre-treatment investigations are required, these should be completed without delay	12/34 (35%) required further imaging at first review. Median 2d (IQR 4.5-1d) for completion (42%	75% of inpatients requiring further imaging

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		5/12 completed <2d, 75% 9/12 <7d). There were 2 outliers at 32d and 60d.	should have this completed within 1 week
3	Patients should be seen with investigation results and a treatment decision made without delay	Of 23 patients with a treatment decision documented, mean 0.6d (SD 1.6, range 0-7d). 20/23 87% had documented decision within 24 hours.	80% should have documented decision within 48h of referral OR completion of investigations
4	Patients with a solitary lesion with concern of malignancy should receive a full work-up (including biopsy if appropriate) before a treatment decision is made	10/34 had possible solitary lesion. Of these, 7/10 (70%) had no further imaging requested. Median survival of 10 with possible solitary metastases 341.5d (IQR 663-159d). 50% were still alive at 1 year	60% with possible solitary lesions should have further imaging OR documentation of reason for no further imaging
5	Patients with impending fractures should be discussed with oncology and a treatment decision made in the context of the underlying malignancy	4/11 with impending fractures had documented discussion with oncology and of these, 1/4 had documented treatment plan with oncology input.	60% with impending fractures should have input from oncology before orthopaedic treatment
6	Where surgery is planned, work-up should include up-to-date blood tests (including full blood count, urea & electrolytes, <u>coagulation screen</u> , liver function tests, bone profile and valid group & screen)	Of 22 who had surgery (36%), 100% had bloods (20/22 91% within 48h, 22/22 100% within 72h, range 0-3d). 19/22 (86%) had complete bloods	75% should have complete bloods within 48 hours of surgery
7	Patients for surgery should have regular assessment of pain and function with adequate analgesia where appropriate	Of 25 undergoing surgery, 15 (60%) had documentation of preop pain. 10 had documentation of postop pain (40%)	75% of surgical patients should have documentation of pre and post-op pain
8	Adults with fractures should have surgery on a planned trauma list without delay	Of 23 with known time from decision to surgery, 57% 13/23 had surgery <48h, 83% 19/23 <5d and 96% 22/23 <7d	75% should have surgery within 1 week of decision of operate
9	Surgical patients should start rehabilitation within 72 hours of surgery	Of 19 surgical patients where rehabilitation documented, 17 (90%) had	75% should have documentation

		documented rehabilitation. None had documented start date for rehabilitation.	of physiotherapy input by day 3 after surgery
10	All patients for surgery should have prognosis estimated and documented	0/25 surgical patients had documentation of prognosis at any stage before or after surgery	50% of surgical patients should have documentation of prognosis before surgery
11	Patients should have a documented post-operative plan including indications for follow-up and weight-bearing (WB) status	Of 25 patients undergoing surgery, 18/25 (72%) have a post-operative plan documented. Of 18 with a post-operative plan, 56% have WB status (10/18) and 72% have follow-up documented (13/18)	60% should have a post-operative plan documented including WB status and follow-up
12	Patients followed-up clinically should have documented evaluation of fracture union, lesion progression and stability of reconstruction (if appropriate)	Of 25 undergoing surgery, 5 had follow-up planned (1 did not attend). Of 4 who attended, all had documentation of union (where appropriate) and 50% had documentation of lesion progression and/or metalwork status	50% have documentation of all relevant parameters at clinical follow-up (any time period)
13	Patients who are dying should have this recognised and documented	14 patients died within 90 days of referral and were termed 'dying'. 33% 5/15 had documentation of expected death.	50% of those who die within 90 days of referral are identified as 'dying' or 'frail'
14	Patients who are dying or have treatment-resistant symptoms should have input from palliative care	60% 9/15 of those who were dying had palliative care input during admission.	50% of patients who are dying should have palliative care input during admission
15	Patients who are dying should have a documented plan for ceiling of care and resuscitation (including DNA CPR)	40% 6/16 of those who were dying had a documented plan for ceiling of care.	50% of patients who are dying should have DNA CPR status documented
16	Result of tertiary/MDT discussion relayed to patient	No data	No provisional target made

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	within 7 days of completion of staging investigations		
17	Specified MBD care pathway in place	-	Binary outcome yes/no
18	MBD education provided for members of healthcare team	-	Binary outcome yes/no
19	MBD outcome data including mortality and complications collected and audited locally	-	Binary outcome yes/no

Supplementary File 4 (Table)

Target sample size required for multi-centre validation study

Combined mean for QPI targets	Standard deviation	Target sample size per centre
35%	23%	26
40%	23%	51
45%	23%	142
47.5%	23%	318
50%	23%	1272
52.5% - this study	23%	-
55%	23%	1272
57.5%	23%	318
60%	23%	142
65%	23%	51
70%	23%	26

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