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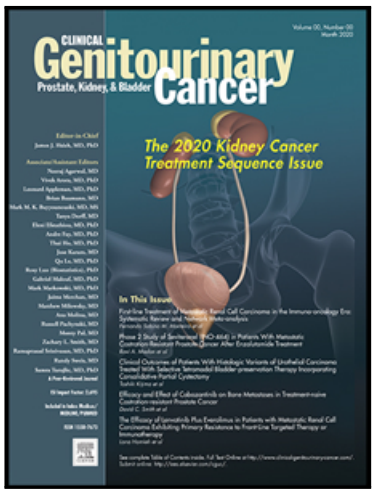

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Original Study

Establishing metastatic prostate cancer quality indicators using a modified Delphi approach

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ABSTRACT

Background – There is variation in the care provided to men with metastatic prostate cancer (mPCa). There has been no previous set of quality indicators (QIs) regarding the management of men with mPCa. The objective of this study is to develop a set of international mPCa-specific QIs, which will enable global benchmarking of quality of care.

Materials and methods – Potential QIs were identified through a literature review. Fourteen multidisciplinary mPCa experts (representing medical and radiation oncology, nursing, psychology, palliative care and urology) from eight countries participated in a modified Delphi process, which consisted of two online surveys, one face-to-face meeting and two teleconferences. Panellists were asked to rate each indicator's importance and feasibility on a Likert scale from 1-9. Indicators that received median importance and median feasibility scores ≥7.5, and a disagreement index <1 for both measures, on the final round of voting were included in the final set.

Results - There was consensus on 23 QIs out of total of 662. Four regarding "general management", 12 "therapies", three "complications" and four "patient-reported quality of life". One of the inherent limitations of the Delphi process is that there is a small expert panel involved.

Conclusion – The quality indicator set defined by our process for management of men with mPCa will enable greater understanding of the standard and variation of care globally and will promote consistency of good practice. Future directions will include retrospective evaluation for compliance with these indicators, as well as prospective monitoring.

Microabstract: There has been no previous set of quality indicators (QIs) regarding the management of men with metastatic prostate cancer. Using a modified Delphi process, a panel of fourteen multidisciplinary experts identified 23 quality indicators. The QIs will enable comparison between the quality of care delivered by institutions and can be used to identify potential targets for improvements.

Key words

expert panel, metastatic disease, multidisciplinary, quality of care, survey

INTRODUCTION

Limited data are available to demonstrate adherence to recommended practices for the management of metastatic prostate cancer (mPCa) despite frequent updates of guidelines. Deviation from standard of care can be generally assessed using quality indicators (QIs) representing explicitly defined, measurable items.[1] Whilst QIs have

been readily developed for localised PCa and PCa in general[2], no previous QI sets have been specifically targeted towards the care of men with mPCa. The rapidly evolving treatment landscape in mPCa makes it challenging to create enduring QIs which will be relevant and evidence-based in five years' time. Management also often needs to be individualised to the patient and health systems, which is difficult to capture in standardised international QIs.

The limited data available does suggest wide variation in care between institutions and geographical regions. In the Ticino Cancer Registry in Switzerland, one QI in their 13 PCa-related QIs focussed on men with mPCa.[3] They reported that 73.5% of patients with mPCa received androgen deprivation therapy (ADT) within 3 months of diagnosis. In the Danish registry, the sole indicator regarding men with mPCa demonstrated that 52% of patients in 2014 were receiving ADT within 6 months of diagnosis,[4] much lower than their pre-determined standard of ≥75%[4]. In the Scottish Registry, the proportion of men with mPCa commencing immediate ADT (within 31 days of multidisciplinary team [MDT] discussion) ranged from 44.4% to 100% among sites.[5] In the National Prostate Cancer Registry of Sweden, the proportion of men diagnosed with metastatic disease in 2018 having an MDT meeting ranged from 25-100%.[6] These data at national level suggest that there is opportunity for improvement, and that international comparisons may reveal even greater disparity in practice.

QIs not only carry the potential to reveal variation in treatment practices but also encourage institutions to reflect on their performance and improve. Promising examples of the positive impact of QIs can be observed in the localised disease

setting. Provider performance feedback to urologists in Victoria, Australia was associated with improved adherence to three QIs over five years, including a greater proportion of men with high risk and locally advanced disease receiving treatment within 12 months of diagnosis.[7] There was improvement on six of the nine QIs for very-low-risk PCa measured in Sweden over a three-year period.[8] The Michigan Urological Surgery Improvement Collaborative demonstrated that documentation of clinical tumour-node-metastasis stage improved from 58% to 79% after a collaborative-wide meeting and comparative performance feedback.[9]

The recent construction of an international standardised set of patient-centred outcomes for advanced prostate cancer by the International Consortium for Health Outcomes Measurement (ICHOM) presents new opportunities to measure and benchmark quality of care in men with mPCa using a consistently defined dataset.[10] This dataset is currently being collected globally by the International Registry for Men with Advanced Prostate Cancer (IRONMAN).[11] The objective of this project was to develop an international set of QIs that will enable global measurement of standard and variation in mPCa care.

METHODS

A modified Delphi process was selected to develop the set of mPCa QIs. The Delphi process involves multiple rounds of re-voting that ensures careful consideration of indicators and a structured feedback process, with a formula to quantify panel disagreement. Approval was received from the Monash University Human Research Ethics Committee.

Participant recruitment

A multi-disciplinary international panel with expertise in the management of mPCa was purposively recruited to encompass a range of specialties and nationalities. All panellists had a strong academic track record and were investigators on the IRONMAN project.[11] The modified Delphi process recommends seven to 15 participants; a number large enough to permit diversity in members, but small enough to ensure that each panellist is able to actively participate in discussion.[12] Invitees were sent email invitations with study explanatory statements.

Literature review

International and national guidelines, evidence-based and consensus-made recommendations regarding mPCa management, published in English from 2010 onwards, were reviewed (Appendix A). All recommendations relevant to men with mPCa were extracted. Guidelines that used vague terminology ('consider', 'is an option', 'may be') were excluded, whereas recommendations describing concrete actions ('offer', 'discuss') were included. Guidelines regarding oligometastases were removed as there is currently no consensus definition.

Online surveys (Round 1)

Due to the large volume of recommendations, the online survey was distributed in two rounds through Qualtrics (Provo, Utah 2019). Supplementary documents sent to panellists detailed each proposed indicator's level of evidence and reference. Panellists were asked to rate each proposed indicator's importance on a Likert scale from 1-9 to one decimal place, with higher ratings indicating greater importance.

Panellists could select “unable to comment” option if it was not within their area of expertise. Each recommendation required a response to proceed.

Analysis of results

For each indicator, the median importance (MI) score was calculated, as well as the disagreement index (DI). For panellists who chose not to provide a rating, they were not included when calculating the MI and DI for that particular QI. Indicators were considered important if they had a MI≥7.5. A DI<1 indicates ‘agreement’ among the panellists and DI≥1 indicates ‘disagreement’.[12] Indicators were classified into three categories: group A (important with agreement amongst panellists), B (disagreement among panellists) and C (not important with agreement amongst panellists) (*Figure 1*).

Figure 1. Classifying indicators from the Round 1 online survey using the median importance and the disagreement index

Median importance	1	2	3	4	5	6	7	8	9
DI<1	**Group C**							**Group A**	
DI≥1	**Group B**								

DI = disagreement index

Face-to-face meeting (Round 2)

Panellists attended a face-to-face meeting moderated by an independent academic researcher and structured to methodically review recommendations. Panellists who could not attend the face-to-face meeting were invited to attend a separate

teleconference. While there was opportunity to discuss any recommendation, the panel focussed on those with a high importance and low DI. Panellists rated importance and feasibility for recommendations after discussion. Indicators which had a MI≥7.5, a median feasibility (MF)≥7.5 and a DI<1 upon re-rating were included in the provisional set of indicators.

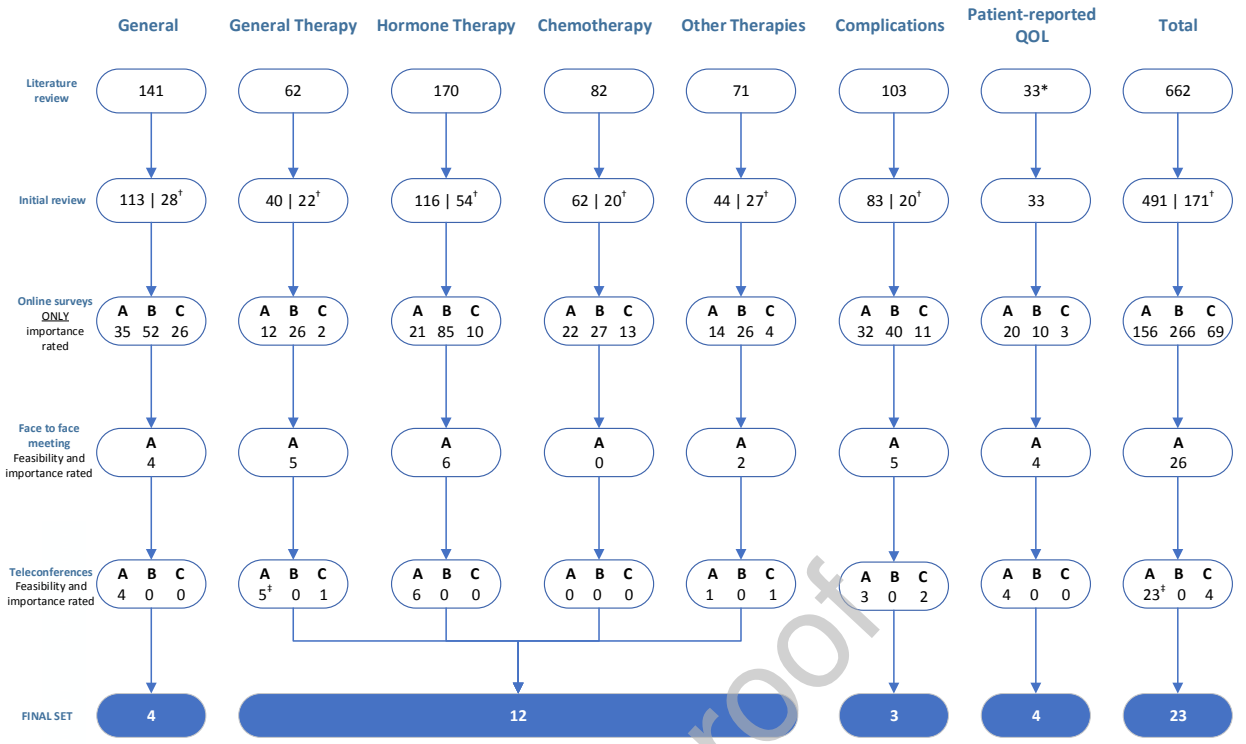
Finalisation of indicators (Round 3)

All panellists re-rated the importance and feasibility of all provisional indicators in two subsequent teleconferences after discussion. Indicators which again achieved a MI≥7.5, a MF≥7.5 and a DI<1 (Group A) were included in the final set.

RESULTS

Twenty-one guidelines (3 Australian, 9 American/Canadian, 6 European, 2 Asian and 1 African), as well as 12 articles with consensus-based recommendations from expert panels were reviewed. Two of the articles were published by South American expert panels. 629 potential QIs were extracted; this included 141 general, 385 therapies and 103 complications (Figure 2). As no recommendations regarding patient-reported QoL were identified, 33 QIs were extrapolated from existing validated prostate cancer QoL questionnaires and developed for consideration, creating a total of 662 QIs. 171 indicators were removed using the exclusion criteria. 229 indicators were included in survey 1 (113 general, 83 complications and 33 patient-reported QoL), and 262 therapy indicators were included in survey 2.

Figure 2. Flowchart of the number of indicators at each stage of the Delphi process



* No recommendations extracted during literature review. New indicators developed for consideration.

† Indicators removed due to vague terminology

‡ New indicator added in this round

A = median importance ≥7.5, median feasibility ≥7.5, DI <1; B = DI>1; C = median importance <7.5, median feasibility <7.5 and DI <1

QOL = quality of life

Of the 19 individuals invited to participate, 15 (78.9%) accepted the invitation. Fourteen individuals completed both online surveys. The specialties and countries in which these fourteen individuals practise are shown in *Table 1*. After the online surveys, there was agreement that 156 indicators (35 general, 69 therapies, 32 complications and 20 patient-reported QoL) were important.

Table 1. Specialities and countries of practice of the panellists

	United States	United Kingdom	Canada	Australia	Ireland	Singapore	Switzerland	Sweden
Medical oncologist	2	1		1		1	1	
Palliative care physician	1							
Psychologist			1					
Nurse			1	1				
Radiation oncologist				1	1			
Urologist			1					1

Ten panellists attended the face-to-face meeting completed over 11 hours. Prior to this, all four non-attending panellists participated in teleconferences. At the conclusion of the face-to-face meeting, 26 QIs had obtained a MI≥7.5, a MF≥7.5 and a DI<1 on re-rating (Group A). This comprised of four general, 13 therapies, five complications and four patient-reported QoL indicators (*Table 2; Appendix B*). When grouped according to Donabedian's dimensions[1], there were 12 structural, 14 process and 0 outcome indicators. Three of the 14 process indicators (Table 2 indicators 3, 8 and 16) consisted of two or more sub-components. It was proposed

that structural indicators be measured with an annual audit survey (*Appendix C*), while process indicators would be measured using data available from medical records and reported every six months.

Table 2. List of quality indicators in the final set

General management	
1	An institution with men with metastatic PCa should have multidisciplinary management, including a medical oncologist, urologist, imaging specialist, radiation oncologist, nuclear medicine specialist, supportive and/or palliative care specialist and a pathologist.†
2	All men with metastatic PCa should have performance status recorded at an MDT meeting.
3	In men with metastatic PCa, clinicians should screen for the presence of symptoms including pain, psychosocial distress (e.g. depression), fatigue, weakness, falls risk and changes to daily life; a comprehensive needs assessment should follow a positive screen.
4	Baseline staging or restaging in men with metastatic PCa includes physical exam (including performance status), laboratory assessment of blood counts, bone, kidney and liver function, PSA, testosterone (only in men with mCRPC) prior to initiating treatment; baseline whole body imaging should be obtained within three months of treatment decision.
Therapies	
5	In men with symptomatic metastatic PCa, initiate first-line systemic anti-cancer treatment within 72 hours to palliate symptoms and reduce risk of potentially serious sequelae.

6	In men with mCPRC, institution provides access to available life prolonging agents for example novel androgen receptor targeted therapies, chemotherapy, radiopharmaceuticals, immunotherapy.†
7	Institution provides men with metastatic PCa access to clinical trials †
8	Provision of palliative care for men with metastatic PCa includes: - The documentation of goals of care with the patient and patient-defined family, including surrogate decision maker and wishes regarding attempts at resuscitation - A documented plan of treatment, created with family discussion where appropriate - A documented assessment and plan for addressing physical, psychological, social, emotional and spiritual causes of distress.
9	Men with metastatic PCa should have access to castration (surgical or medical). †
10	Men with asymptomatic metastatic PCa are commenced on castration (medical or surgical).*
11	Men with mHSPC are provided available combination therapy with ADT (e.g. docetaxel, abiraterone, or novel AR inhibitors) as first-line treatment within 4 months of initiating ADT.*
12	In men with mCRPC, continuous ADT is provided.*
13	Discussion of side effects is documented before men with metastatic prostate cancer commence ADT.
14	In men with mCRPC who are on AR targeted therapies, measure PSA at least every 4 months.
15	Men with symptomatic metastases have access to external beam RT. †

16	Management of refractory pain should include access to - Opioids (and) - External beam RT (and) - Palliative care consults.†
Complications	
17	Bone health assessment (e.g. FRAX or equivalent, DEXA) is documented in men with mHSPC within the first year of ADT commencement and annually during treatment.
18	In men with mHSPC and documented high risk of fracture and ADT, bone modifying agents (e.g. denosumab (60mg every 6 months), zoledronic acid or alendronate sodium), calcium and vitamin D are given. High-risk defined by FRAX, DEXA or equivalents.
19	In men with metastatic PCa, treatment with steroids, and surgery or RT, is initiated within 24 hours of radiographic diagnosis of spinal cord compression.
Patient-reported quality of life	
20	A PROM tool validated in a PCa population is repeatedly and systematically administered to all men with metastatic PCa†
21	There is a mechanism which ensures that men receive acknowledgement of their PROMs responses†
22	There is a systematic response pathway to act on PROMs at a patient level†
23	There is a systematic response pathway to act on PROMs at system level†

*Quality indicators not requiring 100% compliance

† Structural indicator

PCa = prostate cancer, MDT = multidisciplinary team, PSA = prostate-specific antigen, mCRPC = metastatic castrate-resistant prostate cancer, mHSPC =

metastatic hormone-sensitive prostate cancer, ADT = androgen deprivation therapy, RT = radiotherapy, FRAX = fracture risk assessment tool, DEXA = dual-energy x-ray absorptiometry, PROM = patient-reported outcome measure

During the two teleconferences, all 26 QIs were re-rated. A new indicator (indicator 16) was proposed that combined two existing QIs ("Institutions provide access to opioid medications for men with mPCa and refractory pain" and "Men with mCRPC, symptomatic bone metastases but without visceral metastases have access to radium-223"). At the conclusion, 23 QIs were considered to be important and feasible.

DISCUSSION

This study was conducted to develop a set of QIs regarding the management of men with mPCa and reached a consensus on 23 QIs. This consisted of four general management, 12 therapies, three complications and four patient-reported QoL indicators.

A total of 10 structural indicators received high importance and feasibility ratings from the panel. These were distributed across general management (n=1), therapies (n=5) and patient-reported QoL (n=4). Within the general management section, the panel strongly advocated for the collection of an indicator that assesses patient access to multidisciplinary management. Multidisciplinary cancer clinics have been

associated with decreased time between diagnosis and treatment initiation, and greater adherence to evidence-based guidelines. It is a vehicle for cross-referral and inclusion in clinical trials.[13, 14]

One structural indicator was created within the therapies section to assess organisational access to specific classes of life-prolonging agents - androgen receptor targeted therapies, chemotherapies, radiopharmaceuticals and immunotherapies. Individual therapies were not listed as there is variability in accessibility between countries, usually based on funding and regulatory restrictions. For this reason, a drug class “not approved” option was included in the audit survey, as institutions do not necessarily have the authority to change which drugs are approved.

Access to opioid medications for men with refractory pain[15] was the subject of debate among the panellists. Restrictions on opioid prescribing in some countries and fear of opioid dependence have contributed to the undertreatment of cancer-related pain.[16] A structural indicator measuring access to opioid medication was initially proposed but was deemed too specific in its focus on one pain management modality. Instead, the panellists decided to incorporate several modalities of pain management into one structural quality indicator (indicator 16).

Four QIs relating to the appropriate use of androgen deprivation therapy (ADT) were developed (one structural (indicator 9) and three process indicators (indicators 10, 12, 13)). Discrepancies in the definition of ADT across guidelines[17-19] necessitated the panel to ensure a clear definition be included across all QIs. Orchiectomy,

luteinising hormone-releasing hormone agonist and antagonists, were considered ADT as they result in castrate levels of testosterone. Androgen synthesis inhibitors, estrogen, corticosteroids and anti-androgens were considered secondary hormonal therapies, usually given in conjunction with ADT.

The panel endorsed 13 process indicators across general management (n=3), therapies (n=7) and complications (n=3). For three endorsed process QIs, the panel felt they could not mandate 100% compliance among all men, as there would be a small number of men where the intervention would not be appropriate or the patient had opted not to undergo treatment. For example, commencement of castration-based therapy (indicator 10) may not be appropriate in men with medical comorbidities or a slow prostate-specific antigen doubling time.

Effective and consistent symptom assessment was considered by the panel to be critical in understanding patient experiences and guiding clinical care, garnering high ratings as a process indicator. Immediate treatment with steroids, and surgery or radiotherapy, within 24 hours of radiographic diagnosis of spinal cord compression was a process indicator unanimously considered of the highest importance (rating of 9). Metastatic spinal cord compression is an oncologic emergency that can lead to permanent neurologic impairment and serious deterioration of QoL. Shorter time from loss of ambulation to surgery has been associated with more favourable neurological outcomes[20].

There was unanimous support for collection of process QIs assessing provision and quality of palliative care services. The panel reflected that palliative care should

include management of physical, psychological, social, emotional and spiritual causes of distress and not be limited to the end-of-life stage. Early integration of palliative care has been associated with improved QoL, reduction in acute hospital admissions and less aggressive treatments at end-of-life[21].

Despite a global movement advocating for measurement of health outcomes to monitor the value of health interventions[22], the panel did not endorse any outcome measures to be collected as QIs. The panel reported that as the use of PROMS in clinical practice is in its early stage of development, the focus should be on ensuring that adequate structures are in place to report and provide feedback of PROMS. As such, the four process indicators relating to patient-reported QoL outline the expectation that the PROM tools selected for collection by institutions should be psychometrically validated in a mPCa population, repeatedly administered and assess multiple facets of wellbeing. The next step will be to reflect on the PROMS data that becomes available, to identify which tools and domains are useful and what are the most appropriate cut-offs for QIs.

There was lengthy discussion about several indicators which were considered important but were ultimately not currently feasible, such as access to specialised services for men with bothersome symptoms. It included process measures which would be challenging to objectively collect, such as the shared decision-making between patient and doctor[23] and the tone of the discussion, such as in asking about use of complementary therapies in a “supportive, understanding and non-judgemental way”[24]. Despite the importance of a spinal MRI in men with suspected spinal cord compression[25], “suspicion” is likely to be difficult to quantify in medical

record documentation. For some indicators, there was insufficient evidence to define high-quality care, such as the optimal frequency of laboratory tests and imaging. In other cases, QIs focussing on smaller populations were not prioritised, such as the use of platinum-based chemotherapy in men with biopsy-proven neuroendocrine differentiation.

While the ICHOM has provided a framework so that a common dataset for advanced prostate cancer can be shared between institutions, a major strength of this study is that for the first time, we define a QI set from a large number of evidence-based international recommendations that uniquely assesses the quality of care delivered to men with mPCa. It incorporates perspectives of 14 multidisciplinary experts from eight countries and six specialties. All efforts were ensured that each QI is endurable, by focusing on drug classes rather than specific agents where possible, allowing equivalents for tools or scans suggested, and not dictating certain sequences of drugs. It has been constructed with an international mindset; the panel strived to create quality indicators that could be achieved by smaller institutions. The option to select drug “not approved” in the audit survey was added so that institutions in countries with limited resources were not penalised for not providing medications that were unavailable in their region. It has not been limited to any specific dataset. Five of the QIs are able to be measured with the data currently collected by the IRONMAN study. As of October 2021, the IRONMAN study has 93 active sites across ten countries. The next steps will include consideration of expanding data collection by IRONMAN so that all 23 QIs can be measured, and construction of a performance report that can be provided to the participating sites.

There were a number of limitations, including the restriction to publications in the English language when creating an internationally relevant set of indicators. The Delphi process inherently means that there is only the highly subjective view of a small number of panellists. Selection bias is an inherent limitation of the purposive sampling method used. There was no representative from South America or Africa, and only one from Asia. Furthermore, we were not able to identify outcome indicators that met our criteria; however, the structural indicators included give the potential for evidence-based outcome indicators to be created in the future.

CONCLUSION

This is the first set of QIs specifically focussing on men with mPCa to be developed. The implementation of this QI set will be extremely valuable in allowing us to understand the standard and variation of care internationally and move towards higher quality of care for men. This QI set will need to be regularly reviewed as indicators may become feasible with the implementation of electronic medical records and adoption of smart phrases, or as data becomes available to create new standards of care.

Clinical Practice Points

Deviation from standard of care can be generally assessed using quality indicators (QIs) representing explicitly defined, measurable items. QIs not only carry the potential to reveal variation in treatment practices but performance feedback can encourage institutions to improve. Promising examples of the positive impact of QIs can be observed in the localised prostate cancer setting; however, no previous QI sets specifically regarding the care of men with metastatic prostate cancer have been developed.

A panel of fourteen multidisciplinary experts reached a consensus on 23 QIs that were considered important in prostate cancer management and feasible to be measured. Immediate treatment with steroids, and surgery or radiotherapy, within 24 hours of radiographic diagnosis of spinal cord compression was a process indicator unanimously considered of the highest importance. There was also unanimous support for collection of process QIs assessing provision and quality of palliative care services. Despite a global movement advocating for measurement of health outcomes to monitor the value of health interventions, the panel did not endorse any outcome measures to be collected as QIs.

The next steps will include consideration of expanding the current dataset being collected globally by the International Registry for Men with Advanced Prostate Cancer (IRONMAN) so that all 23 QIs can be measured. The implementation of this QI set will enable greater understanding of the variation in care of men with metastatic cancer internationally.

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