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SPECIAL ARTICLE

Development of the American College of Rheumatology Electronic Clinical Quality Measures for Gout

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Objective. **Electronic clinical quality measures (eCQMs) are increasingly used by health registries and third parties to evaluate and improve the quality of health care. To complete these eCQMs, data are extracted from electronic health records (EHRs). The treatment of gout has been an area identified with gaps in quality of care. On behalf of the American College of Rheumatology (ACR), we sought to develop and test eCQMs to evaluate gout care.**

Methods. **Drawing from the 2012 ACR gout guidelines, a working group developed candidate gout process measures that were evaluated by an interdisciplinary panel of health care stakeholders, the ACR Quality Measures Subcommittee (QMS), and ultimately the ACR Board of Directors for formal validity testing. For each of the selected gout eCQMs, 3 clinical sites using different EHR systems tested the scientific feasibility and validity of the measures. Measures appropriate for accountability were presented for national endorsement.**

Results. **Of the 10 proposed eCQMs, 4 were endorsed by the ACR QMS, 3 were incorporated into the ACR's Rheumatology Informatics System for Effectiveness (RISE) Registry, and 2 were endorsed by the National Quality Forum. The 3 eCQMs incorporated into RISE (evaluating indications for urate-lowering therapy [ULT]), monitoring serum urate, and treat-to-target outcome) demonstrated high validity and reliability. Proportions of patients passing these 3 eCQMs in RISE and at the 3 clinical testing sites ranged between 32% and 58%, indicating significant room for improvement in care.**

Conclusion. **Three eCQMs have been validated and implemented into RISE. Two of these measures (evaluating indications for ULT and monitoring serum urate) are available for use in federal quality reporting programs. Performance on these measures suggests there is significant room for improvement in the management of gout.**

INTRODUCTION

In response to national quality measurement initiatives, the American College of Rheumatology (ACR) developed a quality measure (QM) development program (1). Current ACR QMs are derived from their respective ACR guideline publications and have been published for rheumatoid arthritis (2).

Gout affects 8.3 million US adults (3). Furthermore, significant gaps in the quality of care for gout patients have been described (4–11). These gaps persist despite multiple international educational attempts through guideline development to improve care for patients with gout (12–18). Given the prevalence of gout and the persistence of gaps in care despite recent guidelines, gout was selected as an ideal target condition for the development of QMs.

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Significance & Innovations

- Three electronic clinical quality measures for gout have been developed by the American College of Rheumatology and validated for use with electronic health records.
- Performance on these measures suggests that there is room for improvement in the management of gout.

To develop gout QMs, the ACR Board of Directors and ACR Committee on Quality of Care tasked the ACR Quality Measures Subcommittee (QMS) to develop electronically specified clinical quality measures (eCQMs) for gout (19) that can be implemented using electronic health records (EHRs). The ACR QMS then formed a committee of gout specialists (Gout QM Working Group) to develop the eCQMs (for working group composition and disclosures, see Supplementary Appendix A, available on the *Arthritis Care & Research* web site at http://onlinelibrary.wiley.com/doi/10.1002/acr.23500/abstract). The purpose of this article is to describe the development, testing, and evaluation of ACR gout eCQMs.

METHODS

As per prior methodology (2), the ACR instructed the Gout QM Working Group to develop eCQMs based upon the 2012 ACR gout guidelines (16,17) as outlined in Figure 1. In brief, the working group developed the eCQMs as "If…then…because…" statements. In general terms, IF a condition exists, THEN an intervention should be done, BECAUSE the evidence shows that the intervention will improve patient outcomes. The eCQMs described here are appropriate for patients with clinical gout, not patients with asymptomatic hyperuricemia.

After evaluating gaps in quality of care, the availability of existing gout QMs, and strength of evidence for various recommendations in the 2012 ACR gout guidelines, the working group developed an extensive list of candidate eCQMs for consideration. Through a series of teleconferences, the working group iteratively refined and internally ranked the candidate eCQMs for importance and

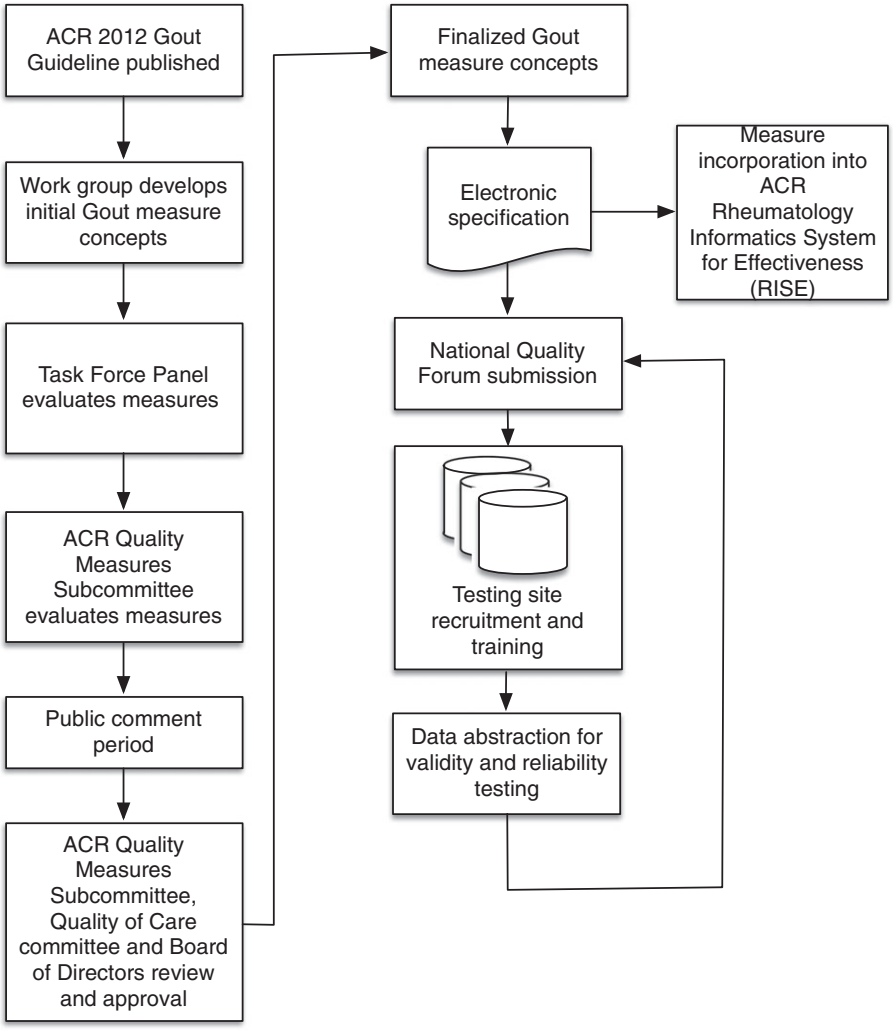

Figure 1. Overview of the American College of Rheumatology (ACR) gout electronic clinical quality measure development.

feasibility. The working group submitted the top 10 candidate eCQMs with the highest internal rankings to an independent, multidisciplinary task force panel (TFP) convened to rate these measures using the RAND/UCLA Appropriateness Method (20) (for further information, including detailed disclosures, see Supplementary Appendix A, available on the *Arthritis Care & Research* web site at http://onlinelibrary.wiley.com/doi/10.1002/acr.23500/abstract).

The gout TFP was composed of 5 academic and 4 community physicians representing the following specialties: rheumatology (n = 4), internal medicine (n = 3), geriatrics (n = 1), and nephrology (n = 1). Additionally, there was 1 patient representative and 1 third-party payer (insurance industry) representative. The TFP moderator was an internist with several years of experience moderating UCLA/RAND consensus meetings (including moderating the consensus meeting for the original ACR 2012 gout guidelines process). Less than 45% of the group had potential conflicts of interest. Three of the 12 TFP members and the moderator were coauthors from the 2012 ACR gout guidelines.

The TFP convened by webinar on November 8, 2013 to discuss results from the first round of voting. Where variation in opinion existed, using a Delphi consensus methodology (20), the panel discussed disagreements and then revoted to reach a final consensus position for each eCQM. The TFP endorsed all 10 candidate eCQMs, which the ACR posted online for public comment between February 1 and February 25, 2014. The working group members reviewed the 14 public comments. The working group modified measure (M) 9: allopurinol starting dose in response to public comment (changing the recommended starting dose; see Table 1 for details) and returned the modified measure to the TFP for re-voting.

The TFP and working group then jointly ranked the endorsed eCQMs using a 1–9 scale for a single summary score, incorporating measure importance, feasibility, and validity. The ACR QMS reviewed each eCQM, its summary score, and perceived feasibility to select eCQMs to advance to field testing for the purpose of formal validity and reliability testing (2). To recruit 3 clinical sites for field testing, the ACR staff sent an e-mail solicitation to all ACR members describing the methodology. From the 6 sites that responded to the solicitation, the ACR staff selected 3 sites with an EHR system and geographic diversity (2 sites withdrew their submission after reviewing details of the work request, and 1 site was not able to get internal review board approval. See Acknowledgments for details on participating sites, type of EHR, and local investigators). As described by Yazdany et al (2), each site, using an automated abstraction program, abstracted cases that met the denominator definition (for each measure) from the EHR and scored each case as pass, fail, or excluded (if exclusion criteria were present).

The American Medical Association–convened Physician Consortium for Performance Improvement, functioning as an external consulting agency (with experience validating QMs), determined the number of cases per QM per site to be manually abstracted. Those cases were then randomly sampled from the full sample of cases from each site that had met the case denominator definition. At each site, for each QM, a physician manually abstracted the data and coded the selected case as pass, fail, or excluded (where exclusion criteria were present). Agreement between manually abstracted results and the automated abstraction were compared by calculating percent agreement and kappa scores.

The eCQMs selected by the QMS were incorporated into the ACR's Rheumatology Informatics System for Effectiveness (RISE) Registry (21), a clinical data registry developed by the ACR with the goal of helping rheumatologists adapt to evolving regulatory changes in the era of "pay-for-performance."

RESULTS

Below we list the 10 eCQMs developed by the working group and submitted to the TFP for review, organized by areas of care: management of acute gouty arthritis (M1), urate-lowering therapy (ULT) (M2–M9), and prophylaxis against acute gout attacks (M10). All 10 eCQMs were reviewed favorably by the TFP. Three eCQMs (M2, M4, and M10) and 1 hybrid eCQM (M7 and M8 combined into a single eCQM) were approved by QMS for field testing and submission to the National Quality Forum (NQF). Two eCQMs (M2 and M7/8) addressing "indications for ULT" and "treat-to-target" objectives were given NQF eMeasure Trial Approval status (NQF 2550 and NQF 2549, respectively), which supports eCQMs undergoing reliability and validity testing (22). These 2 eCQMs (M2 and M7/8) with M4, addressing serum urate (sUA) surveillance after starting or changing ULT, were incorporated into RISE beginning January 2016 and completed field testing (described below) to evaluate reliability and validity as specified by the NQF.

For all of the eCQMs, we list the title, the "if…then…because…" statement, a brief background, and measure status with respect to the TFP, QMS, RISE, and the NQF. For measures submitted by the QMS for field testing (M2, M4, and M7/M8), literature supporting the measure is included below; literature supporting the other measures is provided in Supplementary Appendix B (available on the *Arthritis Care & Research* web site at http://onlinelibrary.wiley.com/doi/10.1002/acr.23500/abstract). On the measure title line, endorsement status (TFP, QMS, or NQF) or adoption into RISE is denoted in parentheses (TFP, QMS, NQF, or RISE) where applicable.

Gout flare management

Measure 1: colchicine dosing (TFP endorsed). "IF a patient receives colchicine for treatment of gout, THEN the dose of colchicine should not exceed 2.4 mg in any 24-hour period, BECAUSE higher doses of colchicine are associated with increased risk of adverse drug events and do not provide additional therapeutic benefit."

Of the potential recommendations on the management of gout flares, the working group focused on low-dose colchicine dosing regimens as an area that would benefit from a quality improvement measure. Originally conceived to directly address the loading dose of colchicine, the group felt that identification of loading doses by medical record abstraction would be impractical, and therefore the simpler definition of a maximum daily dose was recommended. Recent American College of Physicians (ACP) clinical

Table 1. Summary of gout quality measures*

	Mean rating (0–10)	Endorsements				Comments
		TFP	ACR QMS	NQF	RISE	
Acute gout management (1 quality measure for this domain)						
Measure 1. Colchicine dosing						
IF a patient receives colchicine for treatment of gout, THEN the dose of colchicine should not exceed 2.4 mg in any 24-hour period, BECAUSE higher doses of colchicine are associated with increased risk of adverse drug events and do not provide additional therapeutic benefit.	7.5	+				The original QM was developed specifically to address loading doses of colchicine for acute gouty attacks. This was thought to be too challenging for chart abstraction and the more general recommendation as described was approved by the TFP.
Management of ULT (8 quality measures for this domain)						
Measure 2. Indications for ULT						
IF a patient with gout has sUA >6 mg/dl and has 1 of the following: tophus/tophi or 2 or more attacks per year, THEN ULT should be prescribed, BECAUSE such therapy will improve sUA levels, decrease the risk for recurrent attacks, and reduce tophus deposition.	8.6	+	+	+	+	The original measure did not include the sUA >6 mg/dl condition. The TFP recommended avoiding the rare patient who has evidence of active gout or tophi and sUA <6 mg/dl (off ULT). For the proposed NQF QM, erosions were dropped from the measure for feasibility consideration.
Measure 3. Uninterrupted ULT						
IF a patient has gout and receives ULT, THEN ULT should be uninterrupted, BECAUSE interrupting ULT may cause or exacerbate gout flare.	7.5	+				The original QM was designed to be restricted to patients with acute gout attacks in the inpatient setting as this is common management error. However, the feasibility of identifying acute gout attacks was thought to be too challenging.
Measure 4. sUA surveillance after start or change in ULT						
IF a patient with gout starts on or changes ULT, THEN sUA should be measured within 6 months after dose change, BECAUSE sUA levels are necessary to optimize ULT management.	8.6	+	+		+	This measure was rejected by NQF citing concerns about use of intermediary biomarkers.
Measure 5. sUA surveillance for patients with active gout or tophi						
IF a patient with gout has persistent tophus/tophi or 2 or more attacks per year, THEN sUA should be measured at least every 6 months, BECAUSE optimal sUA control is necessary to reduce gouty flares and decrease tophaceous deposits.	8.0	+				Ranked fifth highest, QMS opted to develop other more highly ranked QMs.
Measure 6. Optimize ULT						
IF a patient with gout has persistent tophus/tophi or 2 or more attacks per year AND sUA is >6.8 mg/dl, THEN ULT management should be optimized, BECAUSE optimization of ULT management will improve sUA levels, decrease the risk for recurrent attacks, and reduce tophus deposition.	7.8	+				Ranked sixth highest with concerns that "optimizing" ULT could be interpreted broadly, including ULT dose change or drug change, patient education or adherence review, or addressing other causes of hyperuricemia (such as discontinuing thiazides, reinforcing diet, etc.), which would make implementation difficult.

(continued)

Table 1. *(Cont'd)*

	Mean rating (0–10)	Endorsements				Comments
		TFP	ACR QMS	NQF	RISE	
Measure 7. sUA surveillance for all patients on ULT IF a patient with gout is receiving ULT, THEN sUA should be measured at least once every 12 months, BECAUSE sUA levels are necessary to optimize ULT management.	8.1	+	See QM 7/8			This QM was merged with QM8 by the ACR QMS. The combined measure was ultimately endorsed by the NQF.
Measure 8. sUA target for all patients on ULT IF a patient with gout has been treated with ULT for at least 12 months, THEN sUA should be <6.8 mg/dl, BECAUSE adequate control of sUA is needed to reduce acute gouty attacks and reduce tophus size.	6.3	+	See QM 7/8			This measure was introduced by the TFP during the consensus meeting. The sUA target was originally set at 6 mg/dl designed to match the guidelines. The expert panel preferred to use a less stringent target (as is done for QM) and recommended 7 mg/dl, which was seen as arbitrary and possibly confusing to the guideline message of treat-to-target of <6 mg/dl. The expert panel ultimately settled on the solubility concentration of 6.8 mg/dl as a less stringent and less arbitrary value, which was approved by the ACR QMS and conditionally supported by the NQF.
Measure 7/8. Treat-to-target IF a patient with gout has been treated with ULT for at least 12 months, THEN sUA should be checked at least once yearly AND be <6.8 mg/dl, BECAUSE adequate control of sUA is needed to reduce acute gouty attacks and reduce tophus size.	NA	NA	+	+	+	
Measure 9. Allopurinol starting dose IF a patient is newly started on allopurinol, THEN the starting dose should be <300 mg/day, BECAUSE this strategy may reduce risk of early gout flares and reduce the risk of hypersensitivity reactions. Stricter dose limitations required for patients with renal disease (as an example for patients with CKD ≥4 (GFR <30 ml/min), THEN, the starting dose of allopurinol should be ≤50 mg/day).	7.7	+				The original measure conformed to the guideline recommendations to start allopurinol at 100 mg/day (≤50 mg/day for patients with CKD ≥4 [GFR <30 ml/min]). There was strong public comment that many physicians use the 150 mg (half of the 300-mg tablet) as an appropriate starting dose, and that there was little data to suggest 100 mg was safer than 150 mg for patients with no or mild renal disease. Neither the gout guidelines nor this quality measure provide specific dose guidance for each stage of kidney disease.
Acute gout prophylaxis (1 quality measure for this domain)						
Measure 10. Gout flare prophylaxis IF a patient with gout is initiated on ULT, THEN antiinflammatory prophylaxis should be used concomitantly consisting of low-dose colchicine, NSAID, or glucocorticoid, BECAUSE concomitant use of prophylaxis reduces the risk of gout flares.	8.1	+	+			Submitted to NQF, the measure did not pass citing significant practical concerns about defining and capturing use of low-dose NSAIDs (potentially over the counter) and concerns about prolonged steroid use led to its failure to receive NQF endorsement. Based on this feedback, the measure was not implemented into RISE.

* TFP = Task Force Panel; ACR QMS = American College of Rheumatology Quality Measures Subcommittee; NQF = National Quality Foundation; RISE = Rheumatology Informatics System for Effectiveness; QM = quality measure; ULT = urate-lowering therapy; sUA = serum urate; CKD = chronic kidney disease; GFR = glomerular filtration rate; NSAID = nonsteroidal antiinflammatory drug.

practice guidelines for the management of acute and recurrent gout also recommended using low-dose colchicine (23).

Measure status. Although endorsed by the TFP, the eCQM was ranked in a tie for eighth highest, with concerns about the ability to accurately abstract drug use and dose using current EHR technology. This measure was not advanced to field testing, or incorporated into the ACR RISE registry, nor submitted to the NQF for consideration due to these feasibility concerns.

Management of ULT

The majority of the eCQMs focus on the use of ULT. Derived from the ACR gout guidelines (16), the conceptual strategy for managing patients requiring ULT is summarized in Figure 2. The eCQMs in this group cover indications for starting ULT (M2), and, once a patient is on ULT, parameters for monitoring therapy (M4, M5, and M7), with more frequent monitoring dependent upon symptom activity and conditional treatment responses based on sUA values (M6). The underlying strategy to the ULT algorithm is "treat-to-target," with a specific eCQM mandating reaching target, defined as sUA <6.8 mg/dl after 12 months of ULT (M8). More detailed discussion for each eCQM follows below, including the decision to combine M7 and M8 and the rationale for an sUA target of 6.8 mg/dl.

Measure 2: indications for ULT (TFP, QMS, NQF endorsed, RISE incorporated). Logically, identifying gout patients with hyperuricemia and in need of ULT is the first step in managing gout. M2 specifies this objective. "IF a patient with gout has sUA >6 mg/dl and has 1 of the following: tophus/tophi or 2 or more attacks per year, THEN ULT should be prescribed, BECAUSE such therapy will improve sUA levels, decrease the risk for recurrent attacks and reduce tophus deposition."

The ACR gout treatment guidelines specify that patients with 2 or more gout attacks/year, tophi, or radiographic erosions specific for gout should be started on ULT (16). The European League Against Rheumatism (EULAR) developed a similar recommendation in its gout treatment guidelines (14) and the subsequent 2016 update (18). A similar measure concept was previously proposed by clinical experts (24). The 2016 EULAR guideline update included additional conditions for treatment after an initial flare, including "...a young age (<40 years) or with a very high sUA level (>8.0 mg/dl; 480 μmoles/liter) and/or comorbidities (renal impairment, hypertension, ischemic heart disease, heart failure)" (18).

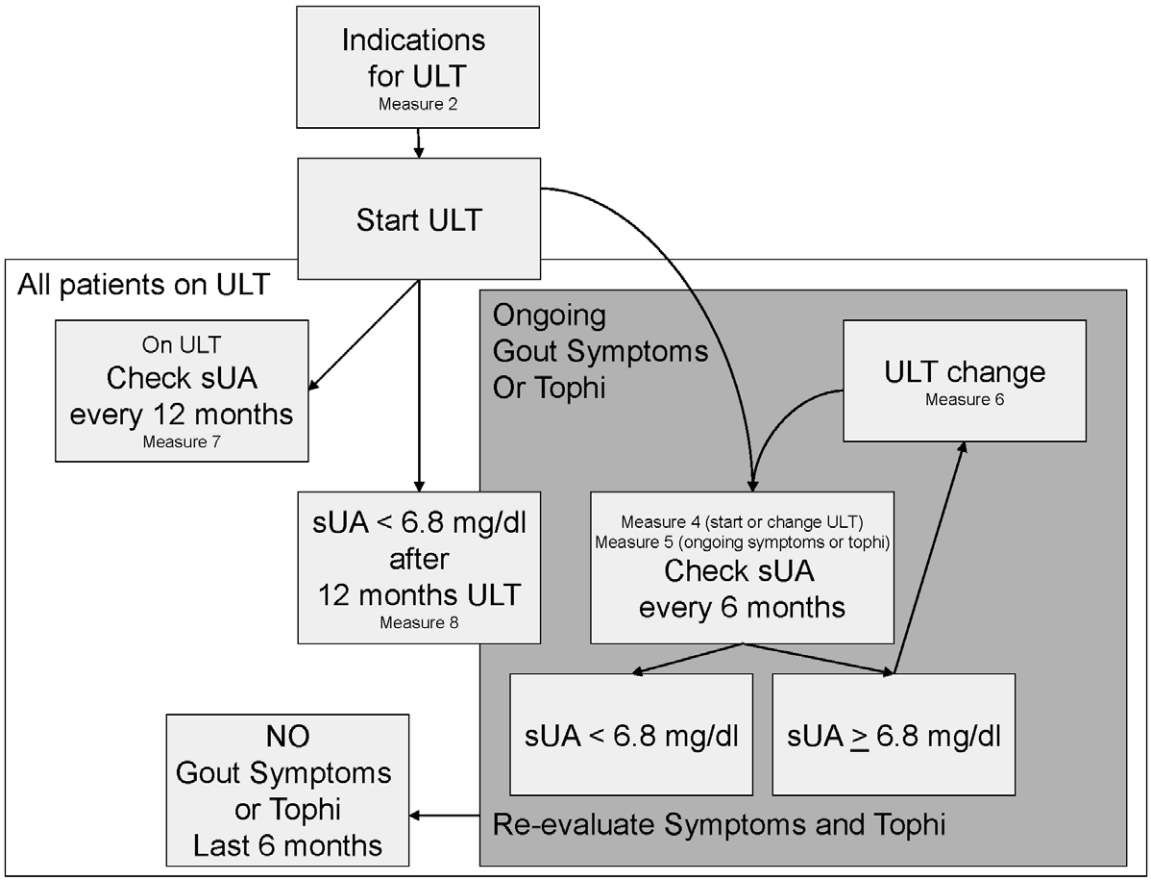

Figure 2. Conceptual model for management of urate-lowering therapy (ULT) in gout management. Measure (M) 2 = indications for ULT; M4 = serum urate (sUA) surveillance after start or change in ULT; M5 = sUA surveillance for patients with ongoing symptoms or tophi; M6 = optimize ULT; M7 = sUA surveillance for all patients on ULT, regardless of symptoms; M8 = sUA target for all patients on ULT.

There is extensive literature on the benefits of ULT for gout patients with active disease, specifically, reduced symptoms and morbidity (25–29). Gout patients who have persistent hyperuricemia are at risk of formation of urate deposits (tophi), which can lead to joint and other tissue damage. ULT is effective at improving outcomes in gout (both frequency of attacks and tophus resolution). Various well-designed cohort studies have shown that ULT reduces the frequency of gout attacks (30–33), the rate of growth of gouty tophi, and the size of tophi (25). In the Febuxostat Versus Allopurinol Controlled Trial that included 762 patients with gout and with sUA levels ≥8.0 mg/dl, ULT was associated with reduction of sUA, tophi, and clinical gout flares (27). Pegloticase studies have demonstrated that lowering of sUA led to reduced frequency of gout flares (4–6 months after treatment) (34), improved health-related quality of life, (35), and reduction in tophus burden (36). In a recent randomized trial, patients assigned to an intensive, nurse-led, treat-to-target intervention (versus standard of care) were more likely to achieve sUA target (95% versus 29%), fewer gout flares during the second year (0.33 versus 0.94 flares per year), and reduction in tophi (2.6% versus 13.7%) (37).

Additional data supporting the impact of lowering sUA on gout outcomes come from studies where patients taking allopurinol were asked to either stop the medication or to take it intermittently (38,39). Following complete cessation of allopurinol by patients who had been well controlled (years without gout attacks), one-third of patients had recurrent attacks after a mean followup of 86 weeks (39). In an open-label extension study, 1,086 gout patients were treated with fixed-dose daily ULT with febuxostat (80 mg or 120 mg) or allopurinol (300 mg) to achieve sUA <6 mg/dl and maintenance for up to 40 months (26). Maintenance of sUA <6 mg/dl resulted in near absence of any gout flares requiring treatment and tophus resolution in 29–46% of subjects (26). In the Febuxostat Open-Label Clinical Trial of Urate-Lowering Efficacy and Safety (FOCUS) study, a 5-year open-label extension study, patients were treated with febuxostat 40–120 mg/day (26). Patients had a sustained reduction of sUA, nearly complete elimination of gout flares, and resolution of tophi (26).

Measure status. M2 was endorsed by the TFP (mean rating 8.6, on a 1–9 scale). This measure was further supported by the QMS for formal field testing and incorporation into RISE. It was submitted to the NQF and given eMeasure Trial Approval, with the condition that presence of gouty erosions be dropped as an indication for ULT, citing lack of direct data supporting use of radiographs as an indication for ULT.

In field testing, the measure demonstrated excellent agreement between automated EHR abstraction and physician chart abstraction (Table 2), while site investigators reported that identifying prior gout flares was challenging (denominator specification). However, when cases were identified, the false positive rate was zero. The proportion of patients meeting the measure quality specification (use of ULT in active or tophaceous gout) was 58% (n = 96 cases) from the 3 clinical sites and 56% (n = 515 cases) from the fourth quarter of 2015 in RISE (Table 3). While this measure may miss some denominator cases (in which a patient should be receiving ULT), testing results support that it does not misidentify numerator cases, and therefore still identifies an important performance gap despite failing to capture all potential denominator cases.

Management of patients on ULT therapy

Once ULT is initiated, its use ought to be titrated until the sUA target is achieved. There is extensive literature documenting gaps in care, which include lack of monitoring the efficacy of ULT medication, failure to assess adherence, and lack of titration of ULT to achieve target (see Supplementary Appendix B, available on the *Arthritis Care & Research* web site at http://onlinelibrary.wiley.com/doi/10.1002/acr.23500/abstract).

For patients taking ULT, eCQMs 3–7 address the necessary steps of ULT administration to optimize clinical outcomes (reduce gout flare frequency and tophus burden). The rationale for these eCQMs is dependent upon the following

Table 2. Agreement between automated electronic health record abstraction and physician chart abstraction*

	Site 1	Site 2	Site 3	Overall
M2: Indications (n = 96)				
Denominator	100 (1.0)	100 (1.0)	100 (1.0)	100 (1.0)
Numerator	100 (1.0)	100 (1.0)	100 (1.0)	100 (1.0)
Exclusions	NA	NA	NA	NA
Overall	100 (1.0)	100 (1.0)	100 (1.0)	100 (1.0)
M4: Serum urate monitoring (n = 197)				
Denominator	100 (1.0)	90 (0.75)	85 (0)†	92 (0.60)
Numerator	92 (0.83)	100 (1.0)	93 (0.85)	95 (0.90)
Exclusions	NA	NA	NA	NA
Overall	92 (0.83)	76 (0.64)	86 (0.69)	85 (0.74)
M7/8: Serum urate target (n = 171)				
Denominator	99 (0.83)	100 (1.0)	95 (0.83)	98 (0.91)
Numerator	96 (0.93)	90 (0.78)	96 (0.93)	95 (0.90)
Exclusions	100 (1.0)	98 (0.95)	98 (0.94)	100 (1.0)
Overall	96 (0.93)	90 (0.78)	100 (1.0)	96 (0.92)

* Values are the percent agreement (kappa). M = measure; NA = not applicable.
† Probability of random agreement equals observed agreement resulting in $\kappa = 0$.

Table 3. Constructs for numerators, denominators, and exclusions for the gout quality measures put forward by the ACR QMS for inclusion in RISE and tested for reliability and validity*

Measure title†	Brief description of measure	Denominator	Numerator	Exclusions
Measure 2: indications for ULT	Proportion of patients ages ≥18 years with a diagnosis of gout and either tophus/tophi or at least 2 gout flares (attacks) in the past year who have sUA level >6.0 mg/dl, who are prescribed ULT	Adult patients ages ≥18 years with a diagnosis of gout and sUA level >6.0 mg/dl who have ≥1 of the following: presence of tophus/tophi or ≥2 gout flares (attacks) in the past year	Patients who are prescribed ULT	Not applicable
Measure 4: sUA surveillance after start or change in ULT	Proportion of patients ages ≥18 years with a diagnosis of gout who were either started on ULT or whose dose of ULT was changed in the year prior to the measurement period, and who had their sUA level measured within 6 months of dose change or start date	Adult patients ages ≥18 years with a diagnosis of gout who were either started on ULT or whose ULT dose was changed in the year prior to the measurement period	Patients whose sUA level was measured within 6 months after initiating ULT or after changing ULT dose	Not applicable
Measure 7/8: treat-to-target	Proportion of patients ages ≥18 years with a diagnosis of gout treated with ULT for at least 12 months, whose most recent sUA result is <6.8 mg/dl	Adult patients ages ≥18 years with a diagnosis of gout treated with ULT for at least 12 months	Patients whose most recent sUA level is <6.8 mg/dl.	Patients with a history of solid organ transplant, use of tacrolimus, or cyclosporine, or eGFR level <30 ml/min or stage 4 or greater CKD or ESRD in the measurement year or year prior

* ACR QMS = American College of Rheumatology Quality Measures Subcommittee; RISE = Rheumatology Informatics System for Effectiveness; ULT = urate-lowering therapy; sUA = serum urate; eGFR = estimated glomerular filtration rate; CKD = chronic kidney disease; ESRD = end-stage renal disease.
† Measures 2 and 4 are process measures. Measure 7/8 is an outcome measure. All measures are designed to be abstracted from electronic clinical data/electronic health records. Level of analysis is based on the individual clinician over a 12-month time period.

tenets: 1) sUA is a valid intermediary for clinical outcomes (14,15,18,30,34–36,40–43), 2) current ULT administration (as measured by sUA outcome) is suboptimal (4–11), and 3) improvement in the use of ULT and better sUA outcomes will lead to improved patient quality of life through fewer flares and limiting or preventing damage of tissues through reduction of tophi (4,10,11,25,27,28,30–33,35,44–47). For detailed discussion of the literature supporting these points, please refer to Supplementary Appendix B, available on the *Arthritis Care & Research* web site at http://onlinelibrary.wiley.com/doi/10.1002/acr.23500/abstract.

Measure 3: uninterrupted ULT treatment (TFP endorsed)

"IF a patient has gout and receives ULT, THEN ULT should be uninterrupted, BECAUSE interrupting ULT may cause or exacerbate gout flare."

The measure was initially conceived for use in either the inpatient setting (to address the common misunderstanding that ULT be held during a gout flare) or outpatient setting (to address issues of adherence). Due to the complexity of inpatient medication reconciliation through chart abstraction, the development of this measure for inpatient use was dropped, and instead the working group focused only on outpatient use.

Measure status. Although M3 was endorsed by the TFP, it was ranked in a tie for eighth highest by the QMS, so it did not advance to the field testing, implementation in RISE, or NQF submission stages.

Serum urate monitoring and management

Measure 4: sUA surveillance after start or change in ULT (TFP, QMS endorsed, RISE incorporated). "IF a patient with gout starts on or changes ULT, THEN serum urate should be measured within 6 months after dose change, BECAUSE serum urate levels are necessary to optimize ULT management."

M4 focuses on patients newly started on ULT or with recent ULT change. In order to adhere to treat-to-target guidelines, sUA should be checked within 6 months of dose start or dose change. This measure builds upon a prior measure concept proposed by other clinical experts (24).

Measure status. M4 was ranked highly with global rating 8.6 (on 1–9 scale) and supported by the QMS for field testing, implementation in RISE, and submission to the NQF. The measure performed well in field testing, with 85% agreement ($\kappa = 0.74$) between the automated EHR and physician chart abstraction. At the clinical sites, for the 197 patients meeting the denominator specification (new ULT start or dose change), 56% met the QM specification (sUA was checked within 6 months). From 1,383 patients meeting the denominator specification in RISE, 33% met the QM specification. Concern was raised from the clinical sites that accurate attribution for the date of a ULT dose change was difficult to abstract. The measure did not receive NQF endorsement, as NQF panel members expressed concerns about the use of intermediary biomarkers as quality measurement targets, citing unfavorable outcomes from treat-to-target trials in dyslipidemia (48) and diabetes mellitus (49).

Measure 5: sUA surveillance for patients with ongoing symptoms or tophi (TFP endorsed). "IF a patient with gout has persistent tophus/tophi or 2 or more attacks per year, THEN serum urate should be measured at least every 6 months, BECAUSE optimal serum urate control is necessary to reduce gouty flares and decrease tophaceous deposits." M5 recommends regular monitoring (sUA every 6 months) for patients with active gouty symptoms or tophi.

Measure status. This measure was ranked fifth highest, falling short of recommendation by the QMS for field testing, incorporation in RISE, or NQF submission. The subcommittee felt that implementation of other QMs had greater potential to impact patient care.

Measure 6: optimize ULT (TFP endorsed). "IF a patient with gout has persistent tophus/tophi or 2 or more attacks per year AND serum urate ≥6.8 mg/dl, THEN ULT management should optimized, BECAUSE optimization of ULT management will improve serum urate levels, decrease the risk for recurrent attacks, and reduce tophus deposition."

Measuring sUA is necessary, but insufficient independently, to improve gout quality of care. Therefore, M6 was designed to encourage a change in management for patients with either tophus or active gout (2 or more attacks per year) whose sUA is ≥6.8 mg/dl.

Measure status. M6 was supported by the TFP, but it was noted that "optimization" could mean anything from ULT dose change or drug change, to patient education or adherence review, or addressing other causes of hyperuricemia (such as discontinuing thiazides, reinforcing diet, etc.). Due to concerns that "optimization" was vague, resulting in feasibility concerns, it was ranked sixth highest and, therefore, not supported by the QMS for further development.

Measure 7: sUA surveillance for all patients on ULT, regardless of symptoms (TFP endorsed, see combined M7/8). "IF a patient with gout is receiving ULT, THEN serum urate should be measured at least once every 12 months, BECAUSE serum urate levels are necessary to optimize ULT management." M7 defines the maximum duration between sUA laboratory testing (12 months) for any gout patient on ULT.

Measure status. M7 was ranked highly (mean rating 8.1). To create as parsimonious a list of measures as possible, the QMS voted to combine M7 with M8 and push the combined measures forward for field testing, incorporation in RISE, and submission to NQF. The NQF endorsed the combined eCQM for eMeasure Trial Approval (see additional details below).

Measure 8: sUA target for all patients on ULT (TFP endorsed, see combined M7/8). "IF a patient with gout has been treated with ULT for at least 12 months, THEN serum urate should be less than 6.8 mg/dl, BECAUSE adequate control of serum urate is needed to reduce acute gouty attacks and reduce tophus size."

The conservative sUA target advocated by international organizations is <6 mg/dl, while some situations and guidelines argue for <5 mg/dl (14–16,18). eCQMs are meant to define a minimum threshold of care for most patients (with some exceptions), and, therefore, an eCQM threshold

(minimum level of quality care) is typically more lenient than clinical guideline statements (optimal level of care). For example, for patients with diabetes mellitus, the NQF measure addressing glycosylated hemoglobin (HbA_{1c}) (NQF-0575) "...looks at the percent of patients whose most recent HbA_{1c} level is less than 8.0% during the measurement year" (50), recognizing that treatment guidelines may advocate the achievement of even lower HbA_{1c} goals in practice.

For patients with continued gout symptoms, it is clear that the treatment target ought to be <6 mg/dl (or lower). For patients in symptomatic remission (but still on ULT), a less stringent criterion could be clinically reasonable. Recent research has begun to question whether ULT can be safely discontinued in some patients whose sUA remains <7 mg/dl (off ULT) (51). In this observational cohort, of the 27 patients with sUA remaining <7 mg/dl, no patient was found to have a clinical gout attack during the median 2 years of followup off ULT. However, frequency of gout attacks rose quickly with higher sUA levels off ULT.

The working group ultimately selected the solubility concentration of urate (6.8 mg/dl) (52) as a physiologically sound but less stringent threshold for quality measurement purposes. The working group reinforced that for patients with symptomatic gout or tophi, sUA <6 mg/dl (or lower) ought to be the goal, but did not want to penalize clinicians whose patients might be in clinical remission with sUAs that might be slightly higher than 6 mg/dl.

With a vibrant internal debate about the precise threshold to specify, this eCQM was initially ranked lowest by the TFP (mean rating 6.3), with some members ranking the eCQM very low, voicing concern against promulgating a treatment target >6.0 mg/dl that did not directly align with the ACR gout guideline recommendations. Despite this controversy, the QMS felt that this eCQM was the key component of the overall treat-to-target strategy emphasized in the 2012 ACR gout guidelines, and therefore this eCQM was advanced to testing by the QMS after combining it with M7.

Measure 7/8: treat-to-target (QMS, NQF endorsed, RISE incorporated). "IF a patient with gout has been treated with ULT for at least 12 months, THEN serum urate should be checked at least once yearly AND be <6.8 mg/dl, BECAUSE adequate control of serum urate is needed to reduce acute gouty attacks and reduce tophus size."

The QMS combined M7 and M8 to create a new eCQM. M8 (sUA <6.8 mg/dl) is conditional on sUA being checked, as noted in M7 (annual sUA monitoring for all patients on ULT). However, NQF limits the number of QMs to be approved, and the QMS was concerned about the number of QMs to be submitted; if both measures were not approved then M8 would not address patients where sUA was not checked, a frequent occurrence (72% of patients in a managed care study [43] and 85–90% of patients in an international study [42]). The combined measure (M7/8) was recommended for field testing and NQF submission, and subsequently received NQF eMeasure Trial Approval.

The measure is easy to abstract, simply requiring identification of gout patients on ULT and then evaluating laboratory results. At the validation sites, the measure performed well, with 96% agreement ($\kappa = 0.92$). Of the 171 patients identified on ULT at the validation sites, 54% had a recent sUA <6.8 mg/dl. From RISE, of the 1,929 gout patients identified on ULT, 32% had a recent sUA <6.8 mg/dl.

Allopurinol-specific considerations

Measure 9: allopurinol starting dose (TFP endorsed). "IF a patient is newly started on allopurinol, THEN the starting dose should be less than 300 mg/day (stricter dose limitations required for patients with renal disease [e.g., for patients with chronic kidney disease (CKD) ≥4 (glomerular filtration rate <30 ml/minute)], THEN, the starting dose of allopurinol should be ≤50 mg per day), BECAUSE this strategy may reduce risk of early gout flares and reduce the risk of hypersensitivity reactions.

Allopurinol is by far the most commonly prescribed ULT and deserving of special attention. The 2012 ACR gout guidelines recommend starting all patients at 100 mg/day (lower in the presence of significant renal dysfunction). Public feedback included comments noting that 150 mg/day is a commonly prescribed and patient-friendly dose (as 300-mg pills can be split into 150-mg halves), consistent with the intent of the guideline recommendations. Therefore, the eCQM allopurinol starting dose specification was modified to <300 mg/day, and ≤50 mg/day for those with CKD ≥4 or end-stage renal disease. This change was again consistent with the desire to generate QMs that prioritize minimal standards as compared to best practices promoted in treatment guidelines.

Measure status. This measure, although endorsed by the TFP, was ranked seventh highest by the QMS, which was insufficient to gain support for field testing, inclusion in RISE, or submission to the NQF.

Gout flare prophylaxis

Measure 10: gout flare prophylaxis (TFP, QMS endorsed). "IF a patient with gout is initiated on ULT, THEN antiinflammatory prophylaxis should be used concomitantly consisting of low-dose colchicine, nonsteroidal antiinflammatory drugs (NSAIDs), or glucocorticoid, BECAUSE concomitant use of prophylaxis reduces the risk of gout flares."

The use of prophylactic antiinflammatory agents with ULT is seen as crucial because gout flares are among the most common complications of ULT, particularly poorly managed ULT, and their occurrence may jeopardize

Table 4. Number of gout patients meeting the denominator definition at the clinical testing sites and in the RISE registry, respectively, and the proportion (in parentheses) that passed each of the eCQM.

	Clinical testing sites	RISE
M2: ULT indications	96 (58)	515 (56)
M4: Serum urate monitoring	197 (56)	1,383 (33)
M7/8: Serum urate target	171 (54)	1,929 (32)

* RISE = Rheumatology Informatics System for Effectiveness; eCQM = electronically specified clinical quality measure; ULT = urate-lowering therapy.

adherence to otherwise highly effective treatments. The ACR gout guidelines recommended that pharmacologic antiinflammatory prophylaxis be used in all cases of gout where ULT is initiated (53).

Measure status. This measure was ranked highly, supported by the QMS, and recommended for field testing, incorporation into RISE, and NQF submission. Significant practical concerns about defining and capturing use of low-dose NSAIDs (potentially over the counter) and concerns about prolonged steroid use led to its failure to receive NQF endorsement. Though supported by the QMS, given the above feasibility concerns, field-testing and incorporation into RISE was not done.

Clinical testing and validation

As described above, 3 eCQMs (M2, M4, and M7/8) were incorporated into RISE for use by ACR members; Table 2 contains more specific denominator, numerator, and exclusion definitions for these measures. The results of field testing, including validation against medical record data, are provided in Tables 3 and 4. All electronically abstracted eCQMs demonstrated good validity with kappa values ≥0.74 when compared to physician-abstracted clinical data. The measure performance across the 3 field-testing sites ranged from 54–58% for the 3 measures, while initial performance results in RISE demonstrated a range of performance of 32–56% for the 3 measures, supporting room for improvement even among highly motivated rheumatology practices (Table 4).

DISCUSSION

Gout is often poorly managed, as noted above. Given the prevalence and growing public health burden posed by gout, along with the availability of relatively inexpensive but highly effective interventions, better treatment of gout should lead to meaningful improvements in patient quality of life and savings to the health care system. We have developed, tested, and gained preliminary NQF support of 2 eCQMs intended to improve the care of patients with gout. These represent a first step, beyond clinical guidelines, toward improving provider performance through measurement. They are valid, reliable, and electronically specified measures that have been implemented in a national registry and, as such, can immediately begin to support local practice improvement efforts, as well as potentially be implemented in federal reporting programs in the future.

Two of 4 measures submitted to NQF were given eMeasure Trial Approval as eCQMs. This is a new category of NQF endorsement focused on measures specifically developed and tested for use with EHRs. These eCQM undergo the same NQF scrutiny and evaluation as traditional QMs, with the following endorsement criteria: 1) importance to measure and report, 2) scientific acceptability of measure properties, 3) usability and use, and 4) related and competing measures. The ACR gout eCQMs were the first eCQMs to be reviewed by NQF in this category. The 2 eCQMs (M2 and M7/8) that received the time-limited endorsement as eMeasures from NQF will be re-submitted to NQF for full endorsement based on the supporting reliability data generated from clinical site testing (54).

The purpose of treatment guidelines is to serve as a resource when managing a variety of case scenarios in gout, whereas QMs serve as benchmarks for evaluation of standardized patient care to improve patient outcomes. QMs also serve as an opportunity for providers to benchmark their own performance against their peers, providing critical information for improving care and thus patient outcomes. The expansion of EHRs that can report QMs provides an opportunity to assess a wide range of clinical care. Such performance measures can assess health care structures, processes, outcomes, and patient perceptions of care. These standards can be used by institutions, providers, and health care consumers to 1) create reliable, comparative performance information to make informed decisions about their care, 2) ensure that providers are held accountable for the quality and efficiency of their performance, and 3) support future quality improvement activities.

No measure is perfect, and all measures have limitations. Each measure is developed with the goal of creating a tool that promotes transparency where there is obscurity, and to balance the challenges and burden of collecting data with providing sufficient detail for validity. As such, quality measurement is not without its controversies.

The ACP Clinical Guidelines Committee recently challenged the "treat-to-target" strategy, arguing for "treat-to-avoid-symptoms" in its place (55). They chose to adhere to a stricter interpretation of Institute of Medicine guidance on guideline development (56), favoring treating to avoid symptoms over treating to an intermediary target (57). However, several editorials pointed out concerns with the ACP position, including limited evidence to support a "treat-to-avoid-symptoms" approach (58,59). The QMs put forth in this document are based upon evidence-based guidelines with extensive clinical expert input, and specific QMs (including the "treat-to-target" QM) have been tested and vetted by the NQF. The ACR rationale for more directive guidelines is supported by a recent *Journal of the American Medical Association* viewpoint, where the authors argue that "…the purpose of practice guidelines must be to develop the best possible recommendations from a body of evidence that may be contradictory or inadequate. Because patient care requires action, treating physicians require guidance. Recommendations in practice guidelines should, therefore, define a standard of care for physicians who must act in the absence of evidentiary certainty. It should be acknowledged that the recommendations in guidelines may change as new data become available, but those recommendations should always represent the best evidence and the best expert opinion currently available" (60). After a decade of gout guideline development without measuring physician performance, data support that a significant performance gap continues to exist (61). Continued absence of measurement will not improve this situation.

Gout is a common clinical disease resulting in pain, disability, decreased quality of life, and excess health care costs. QMs to provide information about what care is being provided to patients and how providers can improve their care to optimize patient outcomes are badly needed. It is our hope that implementation of these QMs may contribute to meaningful improvement in the quality of gout

care by providing a tool for benchmarking providers and institutions. Followup studies will be needed to evaluate the impact of implementing gout QMs on patient outcomes.

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AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. FitzGerald had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. FitzGerald, Mikuls, Neogi, Singh, Khanna, Turner, Suter.

Acquisition of data. FitzGerald, Khanna.

Analysis and interpretation of data. FitzGerald, Mikuls, Singh, Robbins, Khanna, Myslinski, Suter.

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