2015 ACR/EULAR Gout Classification Criteria





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SPECIAL ARTICLE

2015 Gout Classification Criteria

An American College of Rheumatology/European League Against Rheumatism Collaborative Initiative

Tuhina Neogi,¹ Tim L. Th. A. Jansen,² Nicola Dalbeth,³ Jaap Fransen,⁴ H. Ralph Schumacher,⁵ Dianne Berendsen,⁴ Melanie Brown,⁶ Hyon Choi,¹ N. Lawrence Edwards,⁷
Hein J. E. M. Janssens,⁴ Frédéric Lioté,⁸ Raymond P. Naden,⁹ George Nuki,¹⁰ Alexis Ogdie,⁵ Fernando Perez-Ruiz,¹¹ Kenneth Saag,¹² Jasvinder A. Singh,¹³ John S. Sundy,¹⁴
Anne-Kathrin Tausche,¹⁵ Janitzia Vaquez-Mellado,¹⁶ Steven A. Yarows,¹⁷ and William J. Taylor⁶

Criteria

2015 Gout classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative

Tuhina Neogi,¹ Tim L Th A Jansen,^{2,3} Nicola Dalbeth,⁴ Jaap Fransen,³ H Ralph Schumacher,⁵ Dianne Berendsen,³ Melanie Brown,⁶ Hyon Choi,¹ N Lawrence Edwards,⁷ Hein J E M Janssens,³ Frédéric Lioté,⁸ Raymond P Naden,⁹ George Nuki,¹⁰ Alexis Ogdie,⁵ Fernando Perez-Ruiz,¹¹ Kenneth Saag,¹² Jasvinder A Singh,¹³ John S Sundy,^{14,15} Anne-Kathrin Tausche,¹⁶ Janitzia Vaquez-Mellado,¹⁷ Steven A Yarows,¹⁸ William J Taylor⁶

Neogi T, et al. Ann Rheum Dis 2015;0:1-10. doi:10.1136/annrheumdis-2015-208237

BMJ







Intent of Gout Classification Criteria

- To identify, in a standardized manner, a relatively homogeneous group of individuals with gout for enrollment into clinical studies
- Gout classification criteria focus on key features of the disease intended to capture the majority of patients with gout
 - Classification criteria cannot capture all possible presentations of a disease nor avoid capturing presentations of other diseases

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Overall Project Structure



Delphi Exercise

Prowse, et al. J Rheumatol. 2013;40:498-505





Delphi Results: Item Generation

Items rated as definitely discriminatory by physicians and/or patients with gout:



Imaging Systematic Literature Review

Ogdie, et al. ARD. 2014. Online first 10-JUN-14. doi:10.1136/annrheumdis-2014-205431





Imaging Review Results

- 10 studies met inclusion/exclusion criteria
 - Studies in which diagnosis was confirmed by MSU identification
 - Literature reviewed to March 2013, plus abstracts from ACR + EULAR 2007-2013





Two Key Ultrasound Features





Ultrasound – tophus Sensitivity: 0.65 Specificity: 0.80



AMERICAN COLLEGE OF RHEUMATOLOGY EDUCATION • TREATMENT • RESEARCH Ultrasound – double contour sign Sensitivity: 0.80 Specificity: 0.76 **eular**

Dual Energy CT (DECT)



DECT-evidence of urate deposition Sensitivity: 0.87 Specificity: 0.76



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SUGAR: <u>Study for Updated Gout</u> Classification Criteria

Taylor, et al. *AC&R.* 2015. Online first 16-MAR-15. doi:10.1002/acr.22585





SUGAR

 International, multicenter cross-sectional study of patients with possibility of gout

25 centers from 16 countries and 4 continents

- 983 subjects; 653 used as development sample

 Aim: to identify key features that differentiate MSU-crystal proven gout from MSU-negative conditions in patients presenting with joint pain and/or swelling



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SUGAR

 All patients underwent synovial fluid or tophus aspirate with polarizing microscopy by a certified* observer to ascertain MSU status, irrespective of clinical diagnosis

*All participating investigators passed a web-based crystal certification examination and examination of a reference set of synovial fluid samples



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Final model with optimal performance (c-statistic 0.93):

Item	Odds Ratio (95% CI), p-value
Joint erythema	2.1 (1.1-4.3), p=0.03
≥1 episode difficulty walking	7.3 (1.2-46.1), p=0.03
Time to maximal pain <24 hours	1.3 (0.7-2.5), p=0.4
Resolution by 2 weeks	3.6 (1.9-7.0), p=0.0002
Tophus	7.3 (2.4-22.0), p=0.0004
1 st MTP ever involved	2.3 (1.2-4.5), p=0.01
Location of currently tender joints Other foot/ankle joint 1 st MTP	(referent: proximal to ankle) 2.3 (1.0-5.2) 2.8 (1.4-5.8) p=0.01
Serum urate >6mg/dL (0.36mmol/L)	3.4 (1.6-7.2), p=0.002
Ultrasound double contour sign	7.2 (3.5-15.0), p<0.0001
Radiographic erosion or cyst	2.5 (1.3-4.9), p=0.009
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Distribution of Joint Involvement

Gout subjects		Non-gout subjects	
Joint pattern	Prevalence (%)	Joint pattern	Prevalence (%)
MTP1	39.4	Knee only	56.8
Knee/ankle	37.1	Any lower extremity joint	30.1
Elbow/wrist/hand	14.9	Wrist/hand + knee	8.0
Polyarticular	8.6	Polyarticular	5.1

Latent class analysis-derived clusters of joint involvement determined from currently tender or swollen joints within each patient group.





Consensus Meeting using Multicriterion Decision Analysis Methodology





Rationale for Final Phase

- SUGAR
 - Requirement for MSU determination could lead to potential for selection bias (larger joints, more severe disease, tophaceous disease)
- Imaging systematic literature review
 - Sufficient data may not be present in existing literature
- How to "value" and "weight" each item of information?



Complementary Phase

- To consider a broader spectrum of clinical gout through patient paper cases
- Use multicriterion decision analysis methodology (conjoint analysis) to derive weights for final criteria
 - Similar process to RA and SSc classification criteria





Overview of Approach Used



Entry and Sufficient Criteria

- Entry: at least one episode of swelling, pain, or tenderness in a peripheral joint or bursa
 - If not fulfilled, do not apply criteria
- Sufficient: Presence of MSU crystals in symptomatic joint or bursa (i.e., in synovial fluid) or tophus
 - If present, can classify as gout without further assessment of criteria
 - Microscopy should be performed by competent examiner





Exclusion Criteria

• There are no exclusion criteria

Gout can coexist with other conditions





Domains

- Clinical (4):
 - Pattern of joint/bursa involvement, characteristics of episodes, time-course of episodes, clinical evidence of tophus
- Laboratory (2):
 - MSU crystals, serum urate
- Imaging (2):
 - Evidence of urate deposition (ultrasound double contour sign or DECT), evidence of gout-related joint damage (radiographic gouty erosion)



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Clinical Domains





1. Pattern of Joint/Bursa Involvement

- During symptomatic episode(s) ever:
 - Involvement of 1st MTP joint as part of monoarticular or oligoarticular episode
 - Involvement of ankle OR midfoot as part of monoarticular or oligoarticular episode without involvement of the 1st MTP
 - Any other pattern, including 1st MTP/ankle/midfoot as part of *polyarticular* presentation





2. Characteristics of Episodes

- Characteristics of symptomatic episode(s) ever:
 - Erythema overlying affected joint
 - Can't bear touch or pressure to affected joint
 - Great difficulty with walking or inability to use joint

 Scored as none, one, two, or three characteristics present





3. Time-course of Episodes

- "<u>Typical episode</u>": Presence (ever) of ≥2 of the following during symptomatic episode(s), irrespective of anti-inflammatory treatment
 - Time to maximal pain <24 hours
 - Resolution of symptoms ≤14 days
 - Complete resolution (to baseline level) between symptomatic episodes
- Scored as none, one, or recurrent typical episodes





4. Clinical Evidence of Tophus

- Draining or chalk-like subcutaneous nodule under transparent skin with overlying vascularity
- Typical locations:
 - Ears, olecranon bursa, finger pads, tendon (e.g., Achilles)









Scored as absent or present



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Laboratory Domains





5. Serum Urate

- Measured by uricase method
- Ideally, should be scored at a time when patient was not taking ULT, and patient was beyond 4 weeks of start of an episode (i.e., during intercritical period)
- If practicable, retest under those conditions
- <u>Highest value</u>, irrespective of timing, should be scored





5. Serum Urate (continued)

- Scored based on SUA value:
 - <4 mg/dL (<0.24 mmol/L)</p>
 - 4-<6 mg/dL (0.24-<0.36 mmol/L)
 - 6-<8 mg/dL (0.36-<0.48 mmol/L)
 - 8-<10 mg/dL (0.48-<0.60 mmol/L)
 - ≥10 mg/dL (≥0.60 mmol/L)





6. Synovial Fluid Analysis

- Synovial fluid analysis of a symptomatic (ever) joint or bursa assessed by a trained observer*
- Scored as negative or not done
- *If it was positive, then the subject would have met the sufficient criterion and would not need to be further assessed with the criteria scoring





Imaging Domains





7. Imaging Evidence of Urate Deposition

- Imaging evidence of urate deposition in symptomatic (ever) joint or bursa:
 - Ultrasound evidence of double contour sign (A)
 - DECT demonstrating urate deposition (B)



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Score as present (either modality) or absent/not done



8. Imaging Evidence of Gout-related Joint Damage

- Conventional radiography of hands and/or feet demonstrate at least one erosion
 - Erosion: cortical break with sclerotic margin and overhanging edge
 - <u>Excludes</u>: DIP joints, gull
 wing appearance (to exclude
 OA-related findings)
- Score as present or absent/not done



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Threshold for Classifying Gout

- The *total* possible score is 23
- The *threshold* for classifying as gout is ≥8
 - Balance of Sensitivity and Specificity
 - Performance tested in independent dataset (N=330):
 - Sensitivity: 0.92
 - Specificity: 0.89
 - AUC: 0.95





Comparison with Existing Criteria

Criteria	AUC	Sensitivity	Specificity
2015 ACR/EULAR Criteria	0.95	0.92	0.89
Clinical only (no synovial fluid or imaging information)	0.89	0.85	0.78
ARA 1977 (full)	0.83	1.00*	0.51
ARA 1977 (survey)	0.83	0.84	0.62
Rome	0.95	0.97	0.78
Rome (clinical)	NA	0.77	0.78
New York	0.83	1.00*	0.79
New York (clinical)	NA	0.79	0.78
Mexico	0.84	1.00*	0.44
Mexico (clinical)	NA	0.95	0.44
Netherlands	0.87	0.95	0.59
100% sensitive by definition with MSI	I nositivity si	ich individuals wou	uld meet sufficient

criterion for 2015 ACR/EULAR criteria



ACR-EULAR 2015 Gout Classification Criteria







2015 ACR-EULAR Gout Classification Criteria (1)

Criteria (to be used if Sufficient Criterion not met): Score ≥8 required for classification as gout		Categories	Score
	Pattern of joint/bursa involvement during symptomatic* episode(s) ever	Joint(s) or bursa(e) other than ankle, midfoot or 1 st MTP (or their involvement only as part of a polyarticular presentation)	0
		Ankle OR midfoot (as part of monoarticular or oligoarticular episode without MTP1 involvement)	1
		MTP1 (as part of monoarticular or oligoarticular episode)	2
	 Characteristics of symptomatic episode(s) ever: i) Erythema overlying affected joint (patient-reported or physician-observed) ii) can't bear touch or pressure to affected joint iii) great difficulty with walking or inability to use affected joint 	No characteristics	0
AL		One characteristic	1
LINIC		Two characteristics	2
D		Three characteristics	3
l	 Time-course of episode(s) ever: Presence (ever) of ≥2, irrespective of anti-inflammatory treatment: i) Time to maximal pain <24 hours ii) Resolution of symptoms in ≤14 days iii) Complete resolution (to baseline level) between symptomatic episodes 	No typical episodes	0
		One typical episode	1
		Recurrent typical episodes	2
	Clinical evidence of tophus: Draining or chalk-like subcutaneous nodule under transparent skin, often with overlying vascularity, located in typical locations: joints, ears, olecranon bursae, finger pads, tendons (e.g., Achilles).	Absent	0
		Present	4





2015 ACR-EULAR Gout Classification Criteria (2)

		<4mg/dL [<0.24mM] ⁺	-4
LAB	Serum urate: Measured by uricase method. Ideally should be scored at a time when the patient was not taking urate-lowering treatment and patient was beyond 4 weeks of the start of an episode (i.e., during intercritical period); <i>if</i> practicable, retest under those conditions. The highest value irrespective of timing should be scored.	4-<6mg/dL [0.24-<0.36mM]	0
		6-<8mg/dL [0.36-<0.48mM]	2
		8-<10mg/dL [0.48-<0.60mM]	3
	Synovial fluid analysis of a symptomatic (ever) joint or bursa:**	≥10mg/dL [≥0.60mM]	4
		Not done	0
	Should be assessed by a trained observer.	MSU negative	-2
	Imaging evidence of urate deposition in symptomatic (ever) joint	Absent OR Not done	0
GING [‡]	or bursa: Ultrasound evidence of double-contour sign ¹ <u>or</u> DECT demonstrating urate deposition [§] .	Present (either modality)	4
IMAG	Imaging evidence of gout-related joint damage: Conventional radiography of the hands and/or feet demonstrate at least one erosion.**	Absent OR Not done	0
		Present	4

Maximum score is 23. Threshold to classify as gout is ≥8.



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Cri	teria	Categories	Score
	Dettern of igint/human in all servers	Ankle OR midfoot (mono-/oligo-)	1
C	Pattern of joint/bursa involvement	MTP1 (mono-/oligo-)	2
L		One characteristic	1
I N	Characteristics of episode(s) ever	Two characteristics	2
I C		Three characteristics	3
A	Time course of epicodo(s) over	One typical episode	1
L	Time-course of episode(s) ever	Recurrent typical episodes	2
	Clinical evidence of tophus	Present	4
	Serum Urate	<4mg/dL [<0.24mM]	-4
		6-<8mg/dL [0.36-<0.48mM]	2
A		8-<10mg/dL [0.48-<0.60mM]	3
В		≥10mg/dL [≥0.60mM]	4
	Synovial Fluid examination for MSU crystals	negative	-2
I M A	Imaging evidence of urate deposition	Present	4
G E	Imaging evidence of gout-related joint damage	Present	4
		Maximum Possible Total Score	23
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A web-based calculator can be accessed at:

http://goutclassificationcalculator.auckland.ac.nz



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Illustrative Examples





- 68 y.o. F
- MTP1 ≥1 monoarticular episode (plus other patterns)
- Erythema, can't bear pressure, great difficulty
- Recurrent 'typical' episodes
 - Maximal pain within 12 hrs
 - Resolution within 7 days
 - Complete resolution between episodes
- Clinical tophus (pinnae of ears)
- SUA 0.71mM (~11.8mg/dL)
- No SF/tophus aspiration
- U/S: +double contour sign
- No x-ray performed





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Case Examples – #1, cont'd

- MTP1 monoarticular
- Erythema, can't bear pressure, great difficulty
- Recurrent 'typical' episodes
 - Max pain within 12 hours
 - Resolution within 7 days
 - Complete resolution between episodes
- Clinical tophus (ears)
- SUA 0.71mM (~11.8mg/dL)
- No SF/tophus aspiration
- U/S: +double contour sign
- X-ray not done



С	riteria	Categories	Score
	Pattern of joint/bursa	Ankle/midfoot	1
C	involvement	MTP1	2
L I		One	1
N	Characteristics of episode(s) ever	Two	2
Т		Three	3
C	Time-course of	One typical	1
A	episode(s) ever	Recurrent	2
L	Clinical tophus	Present	(4)
	Serum Urate	<4mg/dL	-4
L		6-<8mg/dL	2
Α		8-<10mg/dL	3
В		≥10mg/dL	(4)
	Synovial fluid MSU	negative	-2
I M A -	U/S or DECT +	Present	4
A – G E	X-ray gout erosion	Present	4

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- 25 y.o. M, multiple episodes
- MTP1 monoarticular
- Characteristics: can't bear touch, great difficulty walking
- Time-course: maximal pain within 12 hrs; resolves by 14 days; never complete resolution to baseline
- No tophus
- SUA: 0.49 mM (~8.2 mg/dL)
- MSU: negative
- U/S: + DCS
- X-ray: negative



С	riteria	Categories	Score
	Pattern of joint/bursa	Ankle/midfoot	1
C	involvement	MTP1	(2)
L L		One	1
N	Characteristics of episode(s) ever	Two	2
Т		Three	3
С	Time-course of	One typical	1
A	episode(s) ever	Recurrent	2
-	Clinical tophus	Present	4
	Serum Urate	<4mg/dL	-4
L		6-<8mg/dL	2
Α		8-<10mg/dL	(3)
В		≥10mg/dL	4
	Synovial fluid MSU	negative	-2
I M A - G E	U/S or DECT +	Present	4
	X-ray gout erosion	Present	4
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- 46 y.o. M, multiple episodes
- Ankle/midfoot mono (no MTP1 monoarticular episodes)
- Characteristics: erythema, can't bear touch, great difficulty walking
- Time-course: maximal pain within 12 hrs; no resolution by 14 days; complete resolution to baseline between episodes
- No tophus
- SUA: 0.43mM (~7.2 mg/dL)
- MSU: not done
- U/S, DECT: not done
- X-ray: negative



Cı	riteria	Categories	Score
	Pattern of joint/bursa involvement	Ankle/midfoot	
C		MTP1	2
L I	Characteristics of	One	1
Ν		Two	2
Т		Three	(3)
C	Time-course of episode(s) ever	One typical	1
A		Recurrent	(2)
L '	Clinical tophus	Present	4
	Serum Urate	<4mg/dL	-4
L		6-<8mg/dL	2
Α		8-<10mg/dL	3
В		≥10mg/dL	4
	Synovial fluid MSU	negative	-2
I M A	U/S or DECT +	Present	4
G E	X-ray gout erosion	Present	4

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- 47 y.o. M, multiple episodes
- Oligoarticular MTPs (other)
- Characteristics: can't bear touch, great difficulty walking, erythema
- Time-course: maximal pain within 12 hrs; no resolution by 14 days; never complete resolution to baseline
- No tophus
- SUA: 0.43 mM (~7.2 mg/dL)
- MSU: negative
- U/S: DCS, DECT not done
- X-ray: +erosion



Criteria		Categories	Score
	Pattern of joint/bursa involvement	Ankle/midfoot	1
C		MTP1	2
L I		One	1
N	Characteristics of episode(s) ever	Two	2
Т		Three	3
C	Time-course of	One typical	1
A	episode(s) ever	Recurrent	2
-	Clinical tophus	Present	4
	Serum Urate	<4mg/dL	-4
L		6-<8mg/dL	2
Α		8-<10mg/dL	3
В		≥10mg/dL	4
	Synovial fluid MSU	negative	-2
I M A	U/S or DECT +	Present	4
G E	X-ray gout erosion	Present	4
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- 62 y.o. F, multiple episodes
- Oligo- upper extremity; polyarticular with lower
- Characteristics: erythema, can't bear pressure
- Time-course: max pain
 >24hrs, resolution >14 days, never complete resolution
- No tophus
- SUA 5.2mg/dL, during joint pain
- MSU negative
- U/S or DECT not done
- X-ray negative



Criteria		Categories	Score
	Pattern of joint/bursa	Ankle/midfoot	1
C	involvement	MTP1	2
L I	Characteristics of	One	1
N		Two	(2)
T.		Three	3
С	Time-course of	One typical	1
A	episode(s) ever	Recurrent	2
	Clinical tophus	Present	4
	Serum Urate	<4mg/dL	-4
L		6-<8mg/dL	2
Α		8-<10mg/dL	3
B		≥10mg/dL	4
	Synovial fluid MSU	negative	-2
I M A	U/S or DECT +	Present	4
G E	X-ray gout erosion	Present	4
		-	\frown

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Summary of Steps for Classification of Gout:





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Summary

 New classification criteria for gout have been developed and validated through an international collaborative effort





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<u>Steering committee</u>: Nicola Dalbeth, Jaap Fransen, Tim L. Jansen (EULAR PI), Tuhina Neogi (ACR PI), H. Ralph Schumacher, William Taylor

Fellows: Dianne Berendsen (EULAR), Alexis Ogdie (ACR)

<u>SUGAR investigators</u>: Melanie Brown, Worawit Louthrenoo, Janitzia Vazquez-Mellado, Maxim Eliseev, Geraldine McCarthy, Lisa K. Stamp, Fernando Perez-Ruiz, Francisca Sivera, Hang-Korng Ea , Martijn Gerritsen, Carlo Scire, Lorenzo Cavagna, Chingtsai Lin, Yin-Yi Chou, Anne-Kathrin Tausche, Ana Beatriz Vargas dos Santos, Matthijs Janssen, Jiunn-Horng Chen, Ole Slot, Marco Cimmino, Till Uhlig We gratefully acknowledge the help of Eduardo Aranda-Arreola, Dianne Berendsen, Giovanni Cagnotto, Su-Ting Chang, Jiunn-Horng Chen, Yi-Hsing Chen, Yin-Yi Chou, Viktoria Fana, Angelo Gaffo, Chien-Chung Huang, Po-Hao Huang, Kanon Jatuworapruk, Fatima Kudaeva, Femke Lamers-Karnebeek, Joung-Liang Lan, Juris Lazovskis, Panomkorn Lhakum, Hui-Ju Lin, Anne Madigan, Olivier Peyr, Geraldo da Rocha Castelar-Pinheiro, Alain Sanchez-Rodríguez, and Douglas White with data collection, crystal examination or patient referral for SUGAR. We are also grateful to Eliseo Pascual (Alicante, Spain) for help with MSU observer certification.

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