

# The Development of Gout Treat-To-Target booklet

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## ABSTRACT

**Introduction:** The treat-to-target serum uric acid approach is recommended in local and international guidelines on gout management. Instruction for initiation and dose escalation for urate lowering therapy may cause confusion to the patient. Our aim was to develop and validate Gout Treat-To-Target booklet to aid in patient education.

**Materials and methods:** A content development team which consisted of three consultant rheumatologists developed the booklet. Content validation was performed by a panel of evaluators consisted of eleven physicians (four consultant rheumatologists, two clinical specialists, and five medical officers), who were involved in gout management. Face validation was performed by ten patients with gout.

**Results:** Item-Content Validity Index ranged from 0.9 to 1 with regards to relevancy, clarity, ambiguity and simplicity. Side effects of uricosuric agents were added to the draft based on an evaluator's comment. Item-Face Validity Index was 1, which indicated that all patients were in 100% agreement with all items.

**Conclusion:** We developed and validated our Gout Treat-to-Target booklet. There was high agreement in I-FVI and I-CVI among physicians and patients.

## KEYWORDS:

Gout; content validation; Item-Content Validity Index; face validation; Item-Face Validity Index

## INTRODUCTION

Gout is a spectrum of disorder ranging from asymptomatic hyperuricemia, acute gouty arthritis, inter-critical gout and advanced tophaceous gout.<sup>1</sup> It is a disabling but treatable disease, and when left untreated, complications such as tophi, urate arthropathy and renal stones ensue.<sup>2,3</sup> Most guidelines recommend starting urate lowering therapy (ULT) when there are two or more episodes of gout flare in a year or when patient develop complications.<sup>1,4,5</sup> Maintaining SUA below the saturation point has been shown to reduce flare frequency and facilitate uric acid crystal dissolutions.<sup>6,7</sup> Therefore, a treat-to-target strategy is recommended where the treatment should target SUA level  $\leq 360$   $\mu\text{mol/L}$  in gout without tophi and  $\leq 300$   $\mu\text{mol/L}$  for gout with tophi.<sup>2</sup> The target SUA should be maintained lifelong if the ULT is well tolerated.<sup>1</sup>

Only a small percentage of patients received ULT, ranging from 29% in United States and 34% in United Kingdom.<sup>8,9</sup>

Furthermore, only 10-46% of patients were reported to be adherent to ULT.<sup>10</sup> Inadequate gout education and information from the physicians are among the factors that contribute to non-adherence to therapy.<sup>11-13</sup> Patients perceived gout attacks as an 'inconvenience' which had no negative impact on their overall health, thus they sought solely pain alleviation and dietary management.<sup>14</sup> Patients' belief that gout does not justify long-term treatment and their scepticism over the efficacy of ULT also impede successful gout treatment.<sup>15,16</sup> We conducted this study to develop and validate our Gout Treat-To-Target booklet as a tool to achieve Treat-To-Target strategy.

## MATERIALS AND METHODS

The content development, content validation, and face validation of the Gout Treat-to-Target booklet was conducted from April to June 2022. This study was performed in line with the principles of the Declaration of the Helsinki and the approval was granted by Universiti Teknologi MARA Research Ethics Committee [REF: REC/02/2022(FB/12)].

### Content development

The content of Gout Treat-to-Target booklet was developed over two months by a team of three consultant rheumatologists with eight to twenty years of experience in gout management. A series of discussions were conducted to review relevant literatures and guidelines (both local and international guidelines). The first draft of the content adapted the Malaysian Clinical Practice Guideline (CPG) for the management of Gout and 2016 updated European Alliance of Associations for Rheumatology (EULAR) evidence-based recommendations for gout management.<sup>17,18</sup> The content developer team also decided on the front page and design of Gout Treat-to-Target booklet. This booklet was written in Malay language to suit to the majority of Malaysian patients who can read and understand Malay. The content of Gout Treat-to-Target booklet are summarized in Table I.

### Content validation

The content validation was conducted in May 2022, to assess the relevancy of the items in the booklet. Eleven medical practitioners (four consultant rheumatologists, two clinical specialists, and five medical officers) with experience in gout management were invited to become evaluators and review the content of Gout Treat-to-Target booklet. They rate each item in the booklet from 1 to 4 19, based on:

- relevancy (1: not relevant, 2: need some revision, 3: need minor revision, and 4: very relevant)

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**Table I: The content of Gout Treat-to-Target booklet**

Page	Content	Purpose
1	Name, registration number and name of the hospital.	Identification
2	Gout history and complications (tophi, erosion, urate stone) Cardiovascular co-morbidities SUA target	Documentation
3-4	Initiation of allopurinol: Table to document date, SUA, creatinine clearance, dose of allopurinol, and dose of colchicine.	Documentation
5	Initiation of febuxostat: Table to document date, SUA, creatinine clearance, dose of febuxostat, and dose of colchicine.	Documentation
6-10	Continuation of ULT: Table to document date, SUA, creatinine clearance, dose of ULT, and dose of colchicine.	Documentation
11	Appendix A: Gout treatment	Education
12	Appendix B: Information on ULT and colchicine	Education
13	Appendix C: Gout Diet	Education
14	Appendix D: Healthy Lifestyle	Education

**Table II: Content Validity ratings by eleven evaluators and Item-Content Validity Index values**

Items	Relevancy		Clarity		Ambiguity		Simplicity	
	Panels in agreement, n (%)	Item-Content Validity Index	Panels in agreement n (%)	Item-Content Validity Index	Panels in agreement n (%)	Item-Content Validity Index	Panels in agreement, n (%)	Item-Content Validity Index
Gout								
History	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Comorbidities	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Complications	10 (91)	0.9	11 (100)	1	11 (100)	1	11 (100)	1
Target SUA	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Allopurinol: Treatment initiation								
SUA level	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Creatinine clearance	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Colchicine dose	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Allopurinol dose	10 (91)	0.9	10 (91)	0.9	11 (100)	1	11 (100)	1
Febuxostat: Treatment initiation								
Indication	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
SUA level	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Creatinine clearance	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Dose	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
ULT continuation								
SUA level	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Creatinine clearance	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Dose	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Colchicine dose	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Appendix A: Gout treatment								
Reduce swelling	10 (91)	0.9	11 (100)	1	10 (91)	0.9	11 (100)	1
Urate lowering therapy	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Appendix B: Information on ULT and colchicine								
Allopurinol/febuxostat	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Benzbromarone/ Probenecid	10 (91)	0.9	10 (91)	0.9	11 (100)	1	11 (100)	1
Colchicine	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Appendix C: Gout diet								
Should be avoided	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Encouraged	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
No restriction	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1
Appendix D: Healthy lifestyle	11 (100)	1	11 (100)	1	11 (100)	1	11 (100)	1

Table III: Face Validity ratings by ten patients and Item Face Validity Index values

Items	Assessment (No of patient in agreement)				Item Face Validity Index
	1 (Not relevant)	2 (Need some revision)	3 (Need minor revision)	4 (Very relevant)	
Gout					
History				10	1
Comorbidities				10	1
Complications				10	1
Target SUA				10	1
Allopurinol: treatment initiation					
SUA level				10	1
Creatinine clearance				10	1
Colchicine dose				10	1
Allopurinol dose				10	1
Febuxostat: treatment initiation					
Indication				10	1
SUA level				10	1
Creatinine clearance				10	1
Dose				10	1
ULT continuation					
SUA level				10	1
Creatinine clearance				10	1
Dose				10	1
Colchicine dose				10	1
Appendix A: Gout treatment					
Reduce swelling				10	1
Urate lowering therapy				10	1
Appendix B: Information on					
ULT and colchicine				10	1
Allopurinol/Febuxostat					
Benzbromarone/ Probenecid				10	1
Colchicine				10	1
Appendix C: Gout diet					
Should be avoided				10	1
Encouraged				10	1
No restriction				10	1
Appendix D: Healthy lifestyle				10	1

- b) clarity (1: not clear, 2: need some revision, 3: need minor revision, and 4: very clear)
- c) simplicity (1: not simple, 2: need some revision, 3: need minor revision, and 4: simple)
- d) ambiguity (1: doubtful, 2: need some revision, 3: need minor revision, 4: no doubt).

#### Face validation

The face validation was conducted in June 2022, to assess the simplicity and comprehensiveness of each item in the Gout Treat-To-Target booklet. Ten patients with gout were selected via purposive sampling. The patients were asked to give a rating score from 1 to 4 based on simplicity and comprehension of each item; (1: the item is not clear and understandable, 2: the item is somewhat clear and understandable, 3: the item is clear and understandable, and 4: the item is very clear and understandable). Rating 1 and 2 represent invalid content or not relevant, while rating 3 and 4 represent valid content or relevance. The patients were also asked to comment on the clarity of the module content, report any the confusing word or sentences, and inform any words that were not acceptable and suggest an alternative word that is commonly used. The comments were taken into consideration to refine the domain and its content to produce the final version of the Gout 'Treat-to-Target' booklet.

#### Statistical analysis

The qualitative content validity method was employed where the panel of evaluators observed the grammar, the usage of appropriate and correct words, and the application of the correct and proper order of sentences. Content validity was also quantified using Item-Content Validity Index (I-CVI) which was calculated by dividing the number of evaluators that score 3 and 4 for each item by the total number of evaluators. The I-CVI values can range from 0 to 1. With more than five experts, the acceptable value for I-CVI is 0.78. The calculated I-CVI of  $\geq 0.79$  indicates relevant items, I-CVI 0.70 to 0.79 indicates items which need revision, and I-CVI of  $\leq 0.70$  indicates items which need to be eliminated. The Item Face Validity Index (I-FVI) were obtained by dividing the number of patients that score 3 and 4 for each item by the total number of patients. I-FVI values can range from 0 to 1. Rating 1 and 2 represent invalid content or are not relevant, while ratings 3 and 4 represent valid content or relevance. The value of I-FVI of  $\geq 0.79$  for each item is considered relevant.

#### RESULTS

Table II shows the number of evaluators in agreement and I-CVI on each item in the gout Treat-To-Target booklet. More than 90% level of agreement was achieved among the panel of evaluators. I-CVI of all components ranged between 0.9 to

1 with regards to relevancy, clarity, ambiguity and simplicity. Two evaluators suggested to change the word joint 'kerusakan sendi' (damaged joint) to joint erosions and to add side effect for uricosuric agents. The suggestion to add side effects for uricosuric agents were updated to the expert panels and incorporated into the final version of gout Treat-To-Target booklet. In face validity, all patients indicated 100% agreement with all items (I-FVI equal to 1) and the findings are shown in Table III.

## DISCUSSION

This study was conducted to develop and validate our Treat-To-Target booklet as a tool to achieve Treat-To-Target strategy in gout management. Other interventions which were shown to be effective in achieving this strategy were nurse-led gout care in general practices, nurse-led rheumatologist-assisted telemedicine intervention and ambulatory care pharmacist-led intervention.<sup>21-23</sup> All these interventions have been shown to aid in gout management in various populations.

We invited eleven physicians to validate the content of Gout Treat-to-Target booklet. There were more than 90% level of agreement achieved among the panel of evaluators with regards to relevancy, clarity, ambiguity and simplicity of the content, and 100% agreement were indicated by all ten patients involved in face validity. The reason for such high agreement is that the booklet only include the most important aspects of gout management, which were expressed in short sentences. Apart from avoiding the use of long sentences, figures and diagrams were used instead. Layman's terms were used as much as possible.

Local and international guidelines recommend allopurinol as the first-line ULT.<sup>4,24</sup> It should be started at a lower dose and up-titrated according to SUA levels. The up-titration can be confusing and can result in patients taking the wrong dose of medications. In pages of three to ten of Gout Treat-to-Target booklet contains tables which allows physicians to document the dose of ULT and the specific dates for ULT up-titration, as well as the SUA and creatinine clearance. Thus, patients can always refer to the booklet.

Limited gout knowledge among patients is an important barrier to successful gout treatment. Patients were not aware of the potentially progressive features of the disease such as tophi development and joint damage, the fact that gout could be controlled with medications to lower SUA, and the paradoxical gout attacks can occur with ULT initiation, which resulted in patients subsequently stopped taking their ULT.<sup>25</sup> Personal health literacy, according to Healthy People 2030, is defined as the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.<sup>26</sup> Gout Treat-to-Target booklet contains information on gout medications, diet restrictions and suggested lifestyle, which would allow patients to understand and inform their decisions to the physicians. It is a tool which can be used in clinical practice to empower patient's health literacy in gout.

Physician factor is the other important barriers of successful gout treatment. Many were not aware of or did not follow gout management guidelines. Although allopurinol was the most commonly prescribed ULT, the starting dose ranged 50 mg to 300 mg. Only half of the physicians reported up-titrating allopurinol, and some non-rheumatologists were hesitant to exceed allopurinol dose of 300 mg.<sup>25</sup> Booklets had been used as education tools not only for patients but also for healthcare providers. An example is a patient-education booklet which was created to overcome identified barriers to the delivery of recommended care. The booklet reminded the professionals of the guidelines and made it easier to follow them.<sup>27</sup> Similarly, Gout Treat-to-Target booklet can serve as a guide for non-rheumatologists during consultation with patients to ensure that to the key points in gout management are relayed.

One of the limitations of our study was that Gout Booklet is only available in Malay. Our reason for doing this was because most Malaysians, regardless of their ethnicities are well-versed in Malay language. Moving forward, future study should include translating Gout Treat-to-Target booklet to other languages, so that it can be used for other ethnicities locally and internationally. A study should be conducted to investigate the effectiveness of Gout Treat-to-Target booklet in clinical practice. Lastly, in the era of digital and technology, Gout Treat-to-Target booklet should be developed as online application.

## CONCLUSION

The Gout Treat-to-Target booklet had been successfully developed. We conducted content and face validity, with very good agreement among the evaluators and patients, respectively.

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