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TQM for Clinical Audit – Management of Gout Case Study

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Gratia Christian College (GCC) SKM-MTR Exit-C, Kowloon

1. Background & AIM

- Gout is a common condition that we manage in primary care both acutely as well as chronically
- HK Hospital Authority **gout protocol** was last updated in 2015
- Since then, there has been further revised clinical management guidelines for gout
- There has been no audit carried out on gout in my clinic
- Therefore the standard of care of gout is not known

The AIM of this audit is to evaluate whether our management of patients with gout in the General Out-patient Clinic (GOPC) is in accordance with the latest gout best practice guidelines and enhance the standard of care.

2.1 TQM Principles in Clinical Audit

1. Customer Focus

- **Engagement with Patients**: Gather feedback from gout patients regarding their treatment experience.
- **Education and Support**: Provide resources to help patients manage their condition effectively.

2. Leadership Commitment

- **Management Support**: Ensure that clinical leaders advocate for quality improvement initiatives.
- **Staff Training**: Invest in continuous education for healthcare providers on gout management.

2.2 TQM Principles in Clinical Audit

3. Process Approach

- **Standardized Protocols**: Develop clear guidelines for the diagnosis and treatment of gout.
- **Data Collection**: Utilize clinical data to monitor adherence to management protocols.

4. Continuous Improvement

- **Regular Audits**: Conduct periodic reviews of gout management practices.
- **Feedback Loops**: Implement mechanisms for ongoing patient and staff feedback to refine processes.

5. Fact-Based Decision Making

- **Data Analysis**: Use statistical methods to analyze patient outcomes and treatment efficacy.
- **Benchmarking**: Compare local practices with national standards to identify areas for improvement.

3.1 What is GOUT ?

Gout is a common type of **arthritis**

Common sites : foot – big toe, hands, elbows

Symptoms :

intense pain, red, hot and swollen joints

3.2 How does it happen ?

- Gout comes from the build-up of **uric acid** in the bloodstream.

- If uric acid levels become too high, **crystals** begin to form and get deposited in the joints, and tissues of the body.

3.3 Who famously has Gout ?

- Gout was historically seen as a "**disease of kings**" due to the higher purine diet more prevalent in the rich.

- Thought to be a benign condition that was self-inflicted through **alcohol** excess and **over-eating**.

3.4 Infamous Examples

1491 - Invisible Adversary

4. Epidemiology

- HK 2006 to 2016 - crude Incidence of gout increased from 113.05/100,000 person-years (PY) in 2006 to 211.62/100,000 in 2016 (**+88%**).
- The crude prevalence of gout increased from 1.56% in 2006 to 2.92% in 2016 (**+88%**).
- Only 1 in 4 patients with gout prescribed urate lowering therapy (**ULT**)
- The Hong Kong Centre for Health Protection (HKCHP) in 2019 has included gout, alcohol drinking, and obesity among the **target** non-communicable diseases in its campaign programs for primary prevention

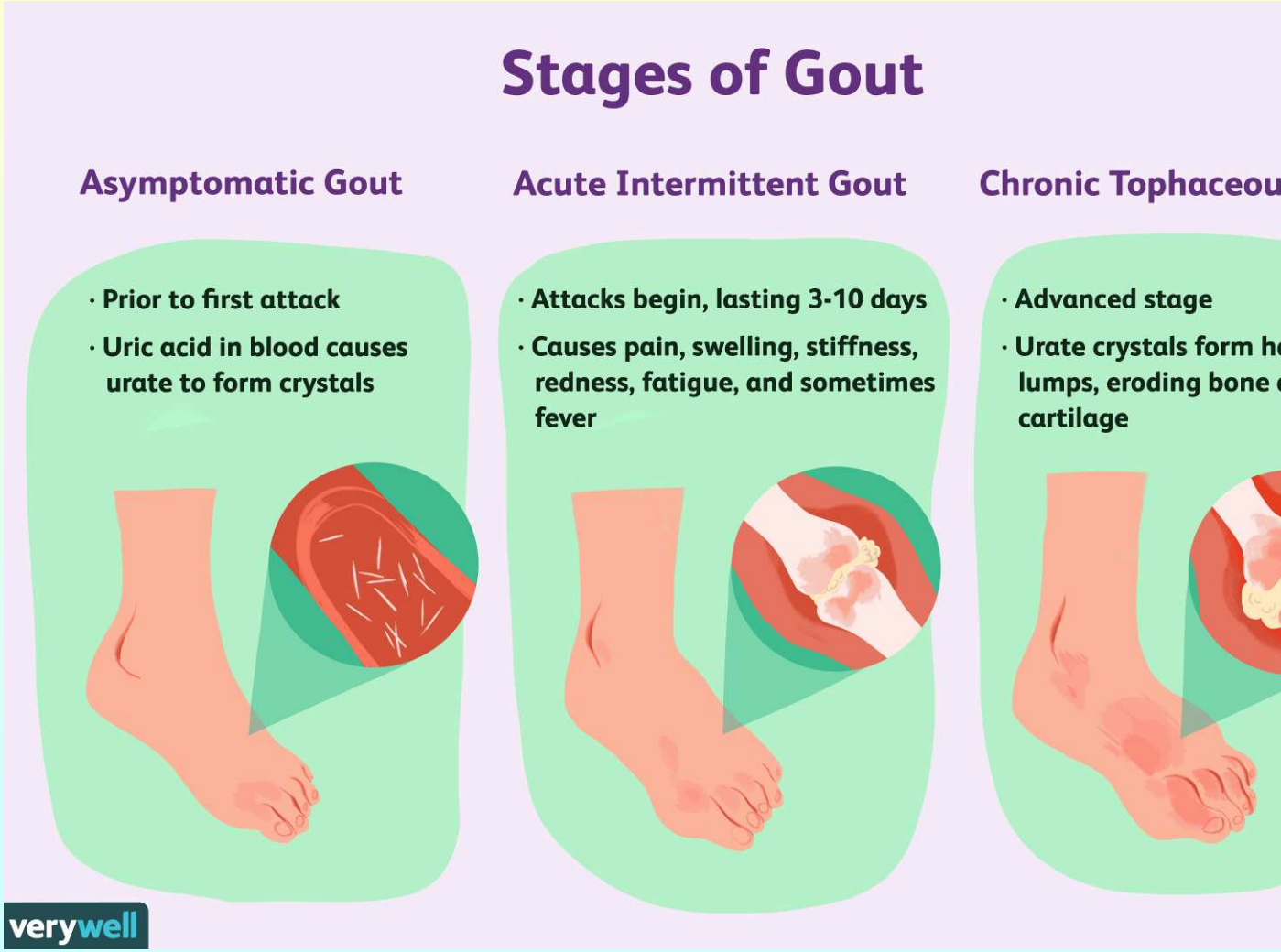
5. Risk Factors for gout include:

- Male
- Diabetic
- A diet rich in seafood, liver, and meat
- Hereditary
- High alcohol intake (beer)
- High Blood Pressure
- Drinking sugar-sweetened beverages
- Kidney Disease

6.1 Phases of Gout

Three main phases of Gout:

- Gout flare
- Inter-critical gout
- Tophaceous gout



6.2 Inter-critical Gout

- The time between gout flares is known as an "**inter-critical**" period.
- A second gout flare typically occurs within **two years**, and additional gout flares may occur thereafter.
- If your gout is untreated for several years, the time between **gout flares** may shorten.
- Your gout flares may involve more joints and become increasingly severe and **prolonged**.

6.3 Tophaceous Gout

- Repeated gout flares or persistent **hyperuricemia** for many years can develop tophaceous gout.
- Develop **tophi** in joints, bursae, bones and cartilage, and under the skin.
- Tophi may cause erosion of the bone and eventually joint damage and **deformity**.

7. What Tests are Used to Diagnose Gout ?

- Blood Test – serum urate levels
- Joint fluid Analysis
- X-Ray
- Urinalysis

8. What are the Treatment of Gout ?

- **Diet & Lifestyle** - eat foods low in purines and limit consumption of red meat, beer, and soda.
- **Hydration -** drink plenty of water
- **Acute Medication** - Non steriodal anti-inflammatories (NSAID), Corticosteroids, Colchicine may be helpful to decrease the inflammation and reduce the pain from the gout flare-up.
- **Chronic medications** such as Allopurinol , Febuxostat, Probenicid help decrease the uric acid level in the blood.

9. Complications

- **Kidney stones**
- Gout related **joint pain**
- **Irreversible** joint damage or loss of motion
- **Cataracts**
- **Respiratory complications** (as uric acid crystals build in lung tissue)
- New studies shows increased **cardiovascular** risks.

10. Why audit Gout ?

- Gout is one of the **most** prevalent inflammatory arthritis in the Asia-Pacific region.
- **Prevalence** has been steadily increasing.
- **Hyperuricemia** has received increasing attention as a major public health problem.
- The association with long term cardiovascular risks and joint **destructive** tendencies.

11. Gout Audit Objectives

- To evaluate the management of gout in a **GOPC** against recognized international guideline standards.
- To identify the **deficiencies** in care of gout patients.
- To implement **interventions** to improve the standard of care.
- To suggest any **further** improvements after implementing changes.

12. Importance & Relevance of Gout

- Gout is often **misdiagnosed** and its management is suboptimal.
- Focus on the **management** of acute attacks of gout rather than viewing gout as a chronic progressive condition.
- Many patients have inadequate **control** of serum urate level and do not receive adequate lifestyle information.

13. Audit Criterion

My Audit criterion selection will be based on the latest clinical practice **guidelines** by :-

- the Asia-Pacific league of associations for rheumatology (APLAR) 2021,
- the American College of Rheumatology (ACR) 2020,
- the British Society of Rheumatology (BSR) 2017,
- the European League Against Rheumatism (EULAR) 2016.

14. Key elements of gout management identified from the literature:

- Management of acute attacks
- Lifestyle and risk factor modification
- Optimal use of urate-lowering therapies

1451- Uninvited Travel Partner

15. Criterion #1: Clinical diagnosis of gout is acceptable (Standard = 100%)

- 2015 ACR-EULAR Gout Classification Criteria encompassed a **multistep** and data-driven process with the participation of an international group of investigators.
- The gout classification criteria guideline provides a clear **scoring** system in the diagnosis of gout.
- A score of ≥ **8** classifies a patient as having gout and the criteria have high sensitivity and specificity (92% and 89% respectively)

2015 ACR/EULAR Gout Classification Criteria

Criteria		Categories	score
CLINICA	Pattern of joint/bursa involvement	Ankle OR midfoot (mono-/oligo-)	1
		1st MTP (mono-/oligo-)	2
	Characteristics of episode(s) ever	One characteristic	1
		Two characteristic	2
		Three characteristics	3
	Time-course of episode(S) ever	One typical episode	1
		Recurrent typical episodes	2
	Clinical evidence of tophus	Present	4
LAB	Serum Urate	6 - <8 mg/dL	2
		8 - <10 mg/dL	3
		≥ 10 mg/dL	4
IMAGE	Imaging evidence of urate deposition	Present (U/S DCS or DECT)	4
	Imaging evidence of gout-related joint damage	Present (X-ray gouty erosion)	4
SUA<4: -4 / MSU-ve: -2		Maximum Total Score	23

Score ≥ 8 ⇒ High sensitivity (92%) and specificity (89%)

Arthritis Rheumatol. 2015;67:2257-68

TABLE 2: Summary of Clinic Audit Measurement Parameters

Para.	Description	Measurement	%
2	BMI recorded; Weight advice Low purine Diet advice Low alcohol consumption advice	APLAR / ACR / NICE	90%
3	Cardiovascular risk assessed - BP - Fasting glucose - Fasting Lipids - Creatinine	BSR	90%
4	In patients on diuretic therapy, this should be stopped unless unavoidable	EULAR	90%
5	Acute gouty arthritis treated with 1st line therapy - Colchicine - NSAID	BSR / EULAR / APLAR / ACR / ACP	90%
6b	Blood UA checked Starting ULT ⩾ 2 gouty attacks / year, gouty tophi, urine renal calculi, radiological damage Number of patient with frequent (2 or more) gout attacks in the past 12 months and are started on allopurinol in	BSR / EULAR / APLAR / ACR	90%
7	Gout mandatory testing of HLA B*5801 prior to initiation of Allopurinol on 1st March 2023 (Phase 2 only)	HK HA	100

8	Colchicine or NSAID should be co-prescribed at ULT initiation	BSR/BHPR and EULAR	**90%**
	Offer to Start ULT during the gout flare over starting ULT after the gout flare has resolved (applicable to Phase 1 only due to HLA B*5801 testing)	ACR	**90%**
9b	Titrated ULT during flare / UA levels raised	ACR	**70%**
	Following allopurinol intolerance or inefficacy patient's treated with: -Probenecid : Patients do not have kidney stones	EULAR	**100%**
10b	-Febuxostat: Patients do not have a history of IHD or CCF	NICE	**100%**
11 **11b**	Blood Monitoring - Renal function (RFT) and UA was checked before the commencement of ULT - All patients with acute gout should have their renal function and UA checked before next follow up during titration with ULT		**90%**
	Treat-to-target Target serum uric acid level is ≤0.36mmol/l (<6mg/dl)	EULAR	**60%**
12b	Target serum uric acid level is < 0.30 mmol/L (<5mg/dl) in High risk patients	BSR/BHPR	**50%**
	UA trend improved from last result		**50%**
13b	Gout in Remission Target UA achieved on Diet alone Target UA achieved on ULT		**60%**
	Refill Clinics secondary to Covid -- Once -- Twice		

15. Data Collection

- Audit design – prospective clinical audit
- Target population – adult patients with ICPC T92 were included in the search
- Pilot – April 2021 (54 cases)
- Sample size ~2500
  -- 95% confidence interval ~300
- Sampling frame
  -- 12 month period
  -- Randomised case selection
- First phase – August 2021 – 2022 (~300 cases)
- Second phase – August 2022 – 2023 (~300 cases)

Table-3: Results of the 1st Phase of Audit Cycle

e 1		Audit Criteria	Standard setting	n / N	Atta nt
nosis	1	Clinical diagnosis of gout is acceptable	**100%**	**284/290**	**98**
netrics		Gender (male) = 75% Mean age = 61.8yr			
tyle fication and factors	2b	BMI recorded Low purine Diet advice Low alcohol consumption advice	**>90%**	**98/284** **82/284** **18/284**	**34** **29** **6**
	3 3b 3d	Cardiovascular risk assessed BP Fasting glucose Fasting Lipids Creatinine : GFR	**>90%**	 **228/284** **167/284** **260/284** **189/284**	 **80** **58** **91** **66**
	4	Patients should NOT be on diuretic therapy unless unavoidable	**>90%**	**274/284**	**96**
agement of e gout	5	>1 Gouty attacks in 4 months Acute gouty arthritis treated with 1st line therapy Total Colchicine prescribed Total NSAID prescribed	 **>90%** **-** **-**	**108/284** **94/108** **164/284** **34/284**	**38** **87** **57** **12**
Monitoring		Blood UA checked Patients w >2 attacks in a year Patient's on ULT	**>90%** **-** **-**	**221/284** **59/284** **154/284**	**77** **20** **54**
/ Chronic	6b	Starting ULT ≥ 2 gouty attacks / year, gouty tophi, urine renal calculi, radiological damage in the past 12 months	**>90%**	**18/39** **3/39 (refused)**	**46** **7**

	8	Colchicine or NSAID should be co-prescribed at ULT initiation	**>90%**	**17/18**	**94%**
	9a 9b	- Offer to Start ULT during the gout flare over starting ULT after the gout flare has resolved - Titrated ULT during flare / UA levels raised	**>90%** **>70%**	**18/18** **23/154**	**100%** **15%**
	10a 10b	Following allopurinol intolerance or inefficacy Patient's treated with:- - Probenecid : Patients do not have kidney stones - Febuxostat: Patients do not have a history of IHD or CCF (Phase 1: only available as Self-Financed Item)	**100%** **100%**	**7/7** **8/8**	**100%** **100%**
itoring and agement of rrent gout	11a 11b	Blood Monitoring - Renal function (RFT) and UA was checked before the commencement of ULT - All patients started ULT should have their RFTs and UA checked before next follow up during titration with ULT	**>90%** **>90%**	**17/18** **17/18**	**94%** **94%**
ssment of Gout ents' Outcome	12a	Treat-to-target Target serum uric acid level is ≤0.36mmol/l (<6mg/dl	**>60%**	**76/273**	**27%**
	12b	Target serum uric acid level is <0.3mmol/l (<5mg/dl) in High risk patients	**>50%**	**0/11**	**0%**
	12c	UA trend improved from last result	**>50%**	**40/284**	**14%**
ome	13 13a 13b	Gout in Remission Target UA achieved on Diet alone Target UA achieved on ULT	**>60%**	 **13/122** **50/154**	 **10%** **32%**
ounders		Refill Clinics secondary to Covid Once Twice	-	 **74/284** **8/284**	 **26%** **3%**

16. Evaluation of Phase-1 Data

- Only 4 out of the 13 criteria met the set standard which included not being on diuretic (Criterion 4, >90%)

- Areas for improvement:-
  - *Assessment of Chronic Gout Management (15%)*
  - *Lifestyle Advice (18 – 34%)*
  - *Outcome targets for SUA*

17. Identification of Deficiency

- Lack of Knowledge in Latest Guidelines
- Lack of Time
- Lack of Proper Documentation
- Lack of Reminder System
- Lack of Patient Information Leaflets
- Patient's Lack of Education

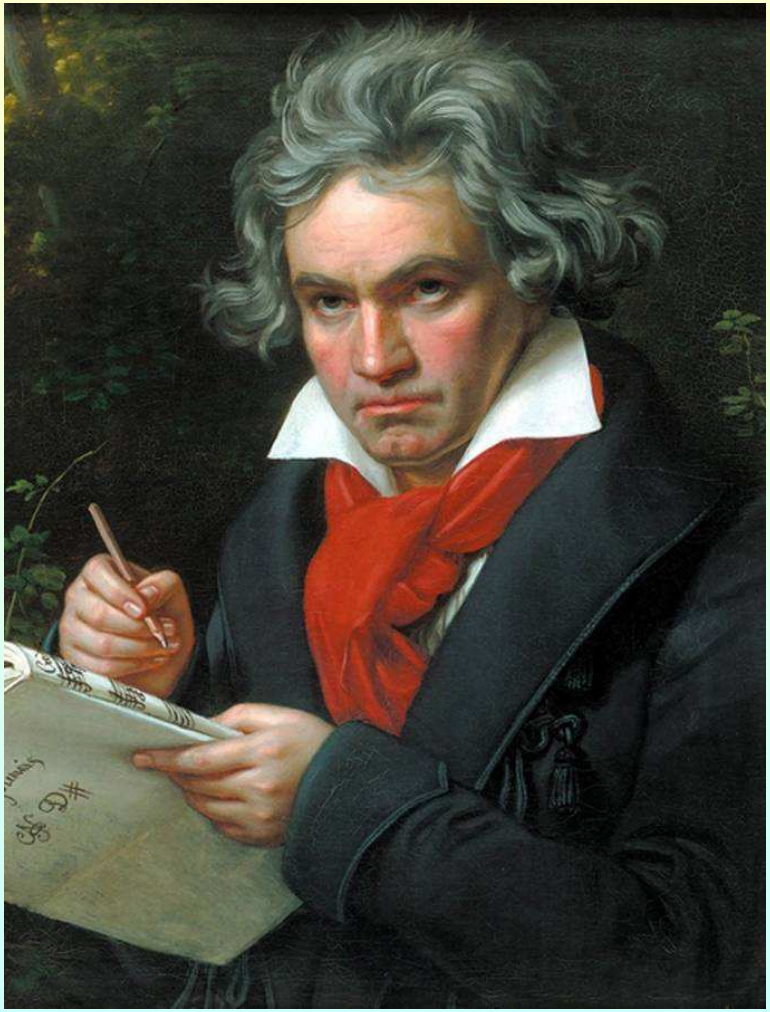
18.1 Continuous Improvements

- Departmental meetings to update old and new colleague on the current guidelines on the management of gout
- Recent changes to department guidelines on performing HLA 58:01 before starting Allopurinol
- May not be an auditable criterion as this was not available prior to November 2022
- Febuxostat is also available at GOPC since November 2022, reducing the need to refer to specialist clinic.

18.2 Continuous Improvements

- Leaflets to be available in all consulting rooms for easier access
- Reminders posted on opening computer case files, for target aims and blood test request.
- Perform random case checks during the implementation phase
- Discussed and identify poor compliance issues and ways to educate patient's on the importance of "Treat to Target"

1770 - Maestro’s Symphony of Suffering



Comparison of Data between 1st & 2nd Phase of Audit Cycle

parison		Audit Criteria	Standard	Phase 1	Phase 2	p-value
nosis	1	Clinical diagnosis of gout is acceptable	100%	98%	99%	N/A
etrics		Gender (male)		75%	76.5%	0.847
		Mean age		67yr	66yr	0.759
yle modification and actors	**2a**	BMI recorded	>90%	34%	85%	**0.001**
	2b	Low purine Diet advice		29%	89%	**0.000**
	2c	Low alcohol consumption advice		6%	43%	**0.001**
		Cardiovascular risk assessed	>90%			
	3a	BP		80%	97.5%	0.786
	3b	Fasting glucose		58%	89%	**0.000**
	3c	Fasting Lipids		91%	89%	0.094
	3d	Creatinine : GFR		66%	95%	**0.000**
	4	Patients should NOT be on diuretic therapy unless unavoidable	>90%	96%	97%	0.637
gement of Acute gout	5	≥1 Gouty attacks in 4 months		38%	49%	0.887
	5a	Acute gouty arthritis treated with 1st line therapy	>90%	87%	97%	**0.025**
	5b	Total Colchicine prescribed	-	57%	75%	**0.000**
		Total NSAID prescribed	-	12%	10%	0.276
Monitoring	**6a**	Blood UA checked	>90%	78%	89%	**0.002**
		Patients w >2 attacks in a year	-	21%	30%	0.894
		Patient's on ULT	-	54%	68%	
Chronic Gout gement	6b	Starting ULT	>90%	46%	55%	0.228
		≥ 2 gouty attacks / year, gouty tophi, urine renal calculi, radiological damage in the past 12 months		7%	8%	N/A
		-Refused		N/A	25%	N/A
		*-Intended to but delayed due to HLA*B5801 test*				
testing from March	7	HLA*B5801 Tested		N/A	82%	N/A
		HLA*B5801 Positive		N/A	13%	N/A

	8	Colchicine or NSAID should be co-prescribed at ULT initiation	>90%	94%	93%	0.223
pplicable to Phase 1 due to Mandatory HLA g from March 2023)	9a 9b	Offer to Start ULT during the gout flare over starting ULT after the gout flare has Titrated ULT during flare / UA levels raised Refused Titration	>90% >70%	100% 15%	81% 37% 14%	0.102 0.317
e 1 only available as Financed Item)	10a 10b	Following allopurinol intolerance or inefficacy patient's treated with: - -Probenecid : Patients do not have kidney stones -Febuxostat: Patients do not have a history of IHD or CCF	100% 100%	100% 88%	100% 100%	*Note-1* *Note-1*
toring and management urrent gout	**11a** **11b**	Blood Monitoring - RFT and SUA was checked before the commencement of ULT - All patients started ULT should have their RFT and SUA checked before next follow up during titration with ULT	>90% >90%	94% 94%	100% 100%	**0.001** **0.000**
ssment of Gout nts' Outcome	**12a**	Treat-to-target Target serum uric acid level is ≤0.36mmol/l (<6mg/dl)	>60%	27%	40%	**0.001**
	12b	Target serum uric acid level is ≤0.3mmol/l (<5mg/dl) in High risk patients	>50%	0%	27%	*Note-1*
	12c	UA trend improved from last result	>50%	14%	50%	**0.000**
	13a **13b**	Gout in Remission Target UA achieved on Diet alone Target UA achieved on ULT	>60%	**10%** 32%	**9%** 53%	**0.001** **0.000**
ounders		Refill Clinics secondary to Covid Once Twice	-	26% 3%	16% 11%	N/A N/A

Summary Table x Improvements

8 out of 13 of the criteria reaching the set standards, most criteria were improved upon.

	Audit Criteria	Phase-1	Phase-2	p-Value
2a	BMI Recorded	34%	85%	0.001
2b	Low purine Diet advice	29%	89%	0.000
2c	Low alcohol consumption advice	6%	43%	0.001
3a	BP	80%	97.5%	0.000
3b	Fasting Glucose	58%	89%	0.000
3d	Creatinine : GFR	66%	95%	0.000
5a	Acute gouty arthritis treated with 1st line therapy	87%	97%	0.025
5b	Total Colchicine prescribed	57%	75%	0.000
6a	Blood UA checked	77%	89%	0.002
11a	RFT and UA was checked before the commencement of ULT	94%	100%	0.001
11b	ULT - All patients started ULT should have their RFT and UA checked before next follow up during titration with ULT	94%	100%	0.000
12a	Treat-to-target Target serum uric acid level is $\leq$ 0.36mmol/l (<6mg/dl)	14%	50%	0.001
13a	Target UA achieved on Diet alone	10%	9%	0.001
13b	Target UA achieved on ULT	32%	52%	0.000

19. Improvements in Standards of Care

- **Impact on Patient Care**

-- enhance the standard of care

- **Impact on Doctors**

-- strengthened the doctors' knowledge in gout and reinforced their ability to keep up to date with evidence based care and management

- **Impact on Clinic**

-- engaging the multi-disciplinary team

20. Limitations

- Covid-19
- Mandatory changes- HLA:5801 testing
- Sampling bias
- Data Collection
- Time Limitation

21. The Future: Improvement Strategies

- *Education*
  - Strengthening patient education on gout may enhance their acceptance and adherence to treatment, compliance to medication, **lifestyle** modification and motivate change
- *Newer therapies*
  - Interleukin-1 (IL-1) inhibitors
- *Referral*
  - Refractory symptoms and signs and difficulty in reaching target SUA, multiple serious events from pharmacologic ULT and considering **surgical** intervention

22. Conclusions

- Ultimately, a **paradigm shift** is needed to educate patients from the onset to manage gout as a potential chronic disease, and have a higher threshold aim to treat-to-target.

- **Lifestyle modification** is a cornerstone in the management of hyperuricemia and gout.

- **Continuous audit** cycles are needed to maintain the standards and continuously enhance the quality of care.

23. Utube Case Study from Singapore below (7 min.)

https://www.youtube.com/watch?v=tu8a9HWAG5M

For the FULL Conf. Paper, please read App. 6-4