



# Improving outcome of Inflammatory Bowel Disease in children

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# Yale New Haven Hospital



# Objectives

To discuss

- Features of IBD
- Therapy and Advances in IBD
- Quality Improvement – Multicenter approach
- Quality Improvement at Yale

# IBD in children

- Chronic inflammation of bowel
- Ulcerative colitis
  - Colon involvement only
- Crohn's disease
  - Entire gastrointestinal tract

- Clinical Features

# Crohn's disease – Presentation

## Symptoms\*

- Abdominal pain
- Diarrhea
- Bloody stools
- Weight loss
- Mouth ulcers
- Perianal lesions

# Ulcerative colitis – Presentation

## Symptoms\*

- Diarrhea
- Abdominal pain
- Rectal bleeding
- Nocturnal diarrhea
- Weight loss

# Nutritional deficiency

- Poor weight gain\*

- Anemia

Iron deficiency

- Vitamin deficiency

B vitamins, vitamin D

- Hypoproteinemia



# Impaired Linear Growth\*

<i><b>Patients</b></i>	<i><b>% Occurrence</b></i>
Pediatric IBD	35
Prepubertal CD	60–85
Children with UC	6–12

# IBD course

- Remission \*—  
Lack of clinical symptoms and good growth
- Relapses  
Flare with clinical symptoms and growth failure

Treatment

# Treatment options

- 5 ASA / Mesalamine
- Steroids
- Immunomodulators
- Biologics
- Nutritional therapy
- Surgery

# 5-ASA- Mesalamine

- Topical anti-inflammatory
- Oral /Rectal
- Useful for mild/moderate disease
- Used for long term
- Adverse effects – mild
- Rare – diarrhea, rash, renal toxicity
- Effective dose – 30 to 70 mg/kg/day

# Steroids

## Prednisone

- Oral/ iv
- Strong anti-inflammatory action
- Used for acute relapses
- Taper over few days
- Adverse effects – Acne, cushingoid features, hyperglycemia, growth failure , infection , bone
- Avoid long-term use\*

# Immunomodulators

6-mercaptopurine /Azathioprine

Methotrexate

## Indications

- Moderate/severe disease
- Prevention of loss of response to biologics
- Prevention of post-operative recurrence

# Adverse effects

## 6 –Mercaptopurine

Myelosuppression:(5-10%) severe (< 2%)

Hepatotoxicity (10-15%)

Pancreatitis (< 5%)

Rare malignancy- Rare lymphoma cases reported.

## Methotrexate

Nausea

Hepatotoxicity, Pulmonary toxicity rare

Teratogenic effects

Possible malignancy



# Immunomodulators

Dose and monitoring important

6-Mercaptopurine (6-MP)

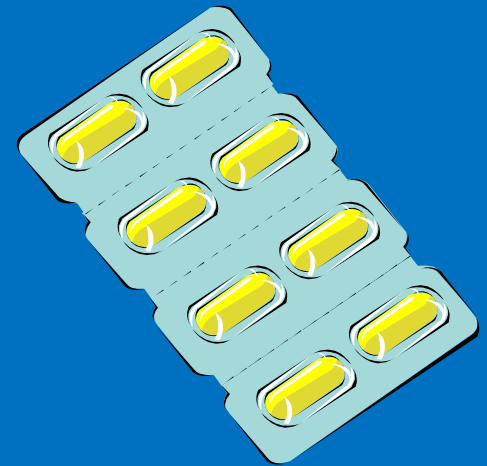
1.0-1.5 mg/kg/day po \*

Azathioprine

2-2.5 mg/kg/day po

Methotrexate

0.4 mg/kg sc/im or po once per week\*



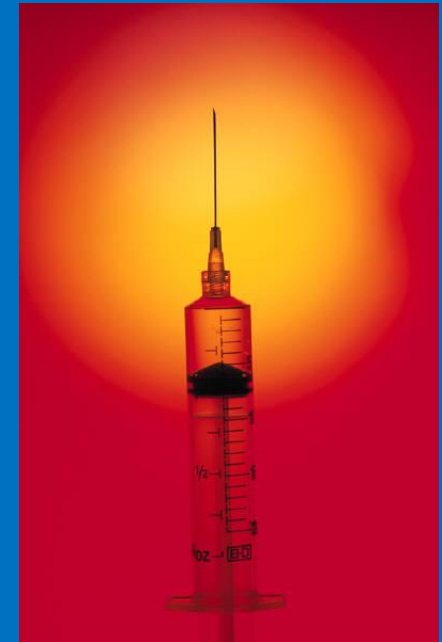
# Biologic Therapy

# Biologic Therapy for Crohn's Disease

- Anti-TNF agents
  - Infliximab (Remicade<sup>®</sup>) – chimeric mab
  - Adalimumab (Humira<sup>®</sup>) – humanized mab
  - Combination (Biologics +immunomodulator) therapy
    - More effective over long-term

# Infliximab (Remicade)

- IV infusion over 2 hours
- Pre-medications
- 5 to 10 mg/kg dose\*
- Given 4 to 8 weekly
- Very effective



# Biologic therapy

## Adverse effects

- Hypersensitivity reactions
- Infection (TB)
- Loss of response
- Testing for TB necessary prior to initiation of biologics\*
- Dosing of doses important

# Improving Outcomes

- Advances in therapy
- QI principles + same therapy

# Advances in IBD therapy

- Combination therapy – high efficacy
- Anti-TNF therapy monitoring
- New agents
- Enteral Nutrition

# Advances in IBD therapy

## Combination therapy

- Sonic study – 508 adults
- Well designed study
- Infliximab, Azathioprine, Combination groups
- Combo > Infliximab > Aza
- Columbel, NEJM 2010
- Recent evidence – addition of methotrexate



# Advances in IBD therapy

## Monitoring Ant-TNF therapy

- Single center Ped study
- 72 patients on infliximab had 191 levels
- 34% - subtherapeutic – intensification
- Adjustment to achieve levels
- Improvement in clinical remission

Minar P, JPGN, 2016

# Advances in IBD therapy

## New Agents

- Vedolizumab – Anti-integrin antibody
- Ustekinumab – Interleukin antibody
- Tofaticinib – JAK inhibitor

# Advances in IBD therapy

## Enteral Nutrition

- Common in Europe, other countries
- Comparison of Exclusive enteral nutrition with steroids
- Similar efficacy
- Less side effects

Day, Dig Dis Sci 2015

- Addition of nutrition beneficial

QI principals

# IBD – Chronic Disease Model

- Life-long disease
- Relapses and Remission
- Growth issues
- Choice of multiple medications
- Adverse effects
- Regular follow up

# IBD Treatment Aim

- Keep patient in remission
- Remission – steroid free and long-term
- Achieve satisfactory nutrition and growth status
- Appropriate use of medications

# Quality Improvement

- Achieving outcome using consistent evidence based diagnostic and treatment guidelines
- Measuring outcome and ongoing continuous quality improvement to improve outcome

# QI Principal

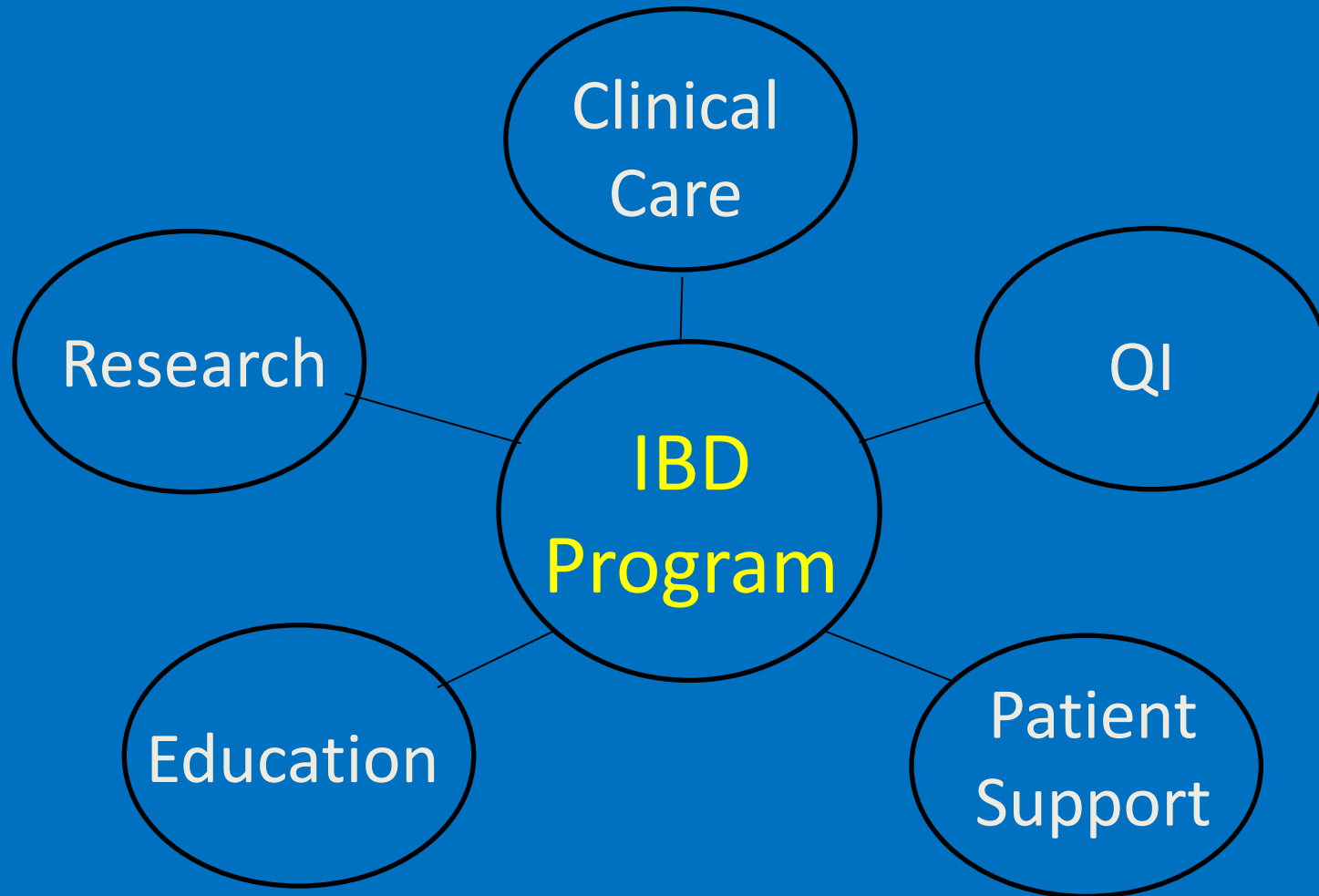
We can not improve

what

we can not measure !



# Yale Pediatric IBD Program

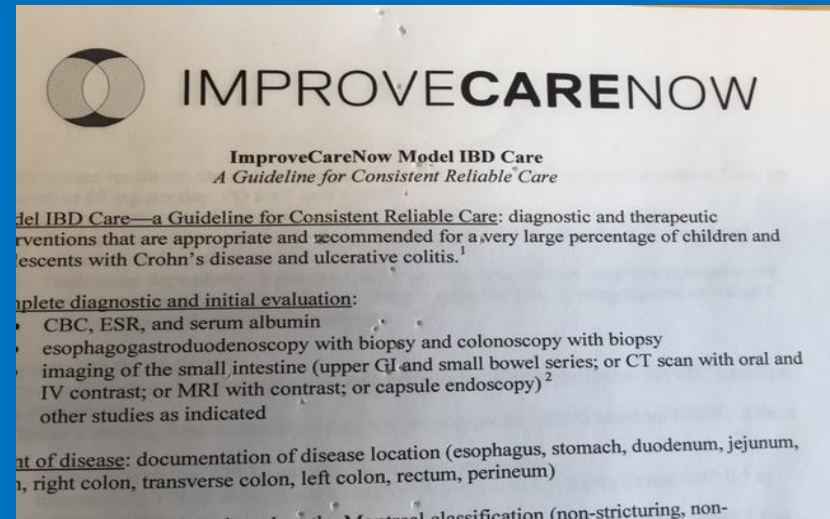


# QI-Improvecarenow

- Multicenter, international QI project
- Improve care for children with IBD
- 87 centers (2 in UK)
- 24,000 IBD patients
- Database in Cincinnati

# What do we do

- Model care guidelines
- Guidelines on diagnosis, therapy, Medication dosing, nutrition and growth monitoring



# What do we do

- Pre-visit Planning –Weekly meeting
- Data entry at every patient visit
- Population Management – monthly meeting
- PDSA cycle

# Data

In God we trust ....

For everything else ...

Show me the data !!!

# Results

[Export Center Data To Excel](#)

[All Center Measures - Small Multiples Graphs](#)

[All Centers Performance Report](#)

[All Graphs Per Center Report](#)

[Dashboard With Sparkline](#)

[All Measures Per Center - Small Multiples Graphs](#)

[Gap Analysis Report](#)

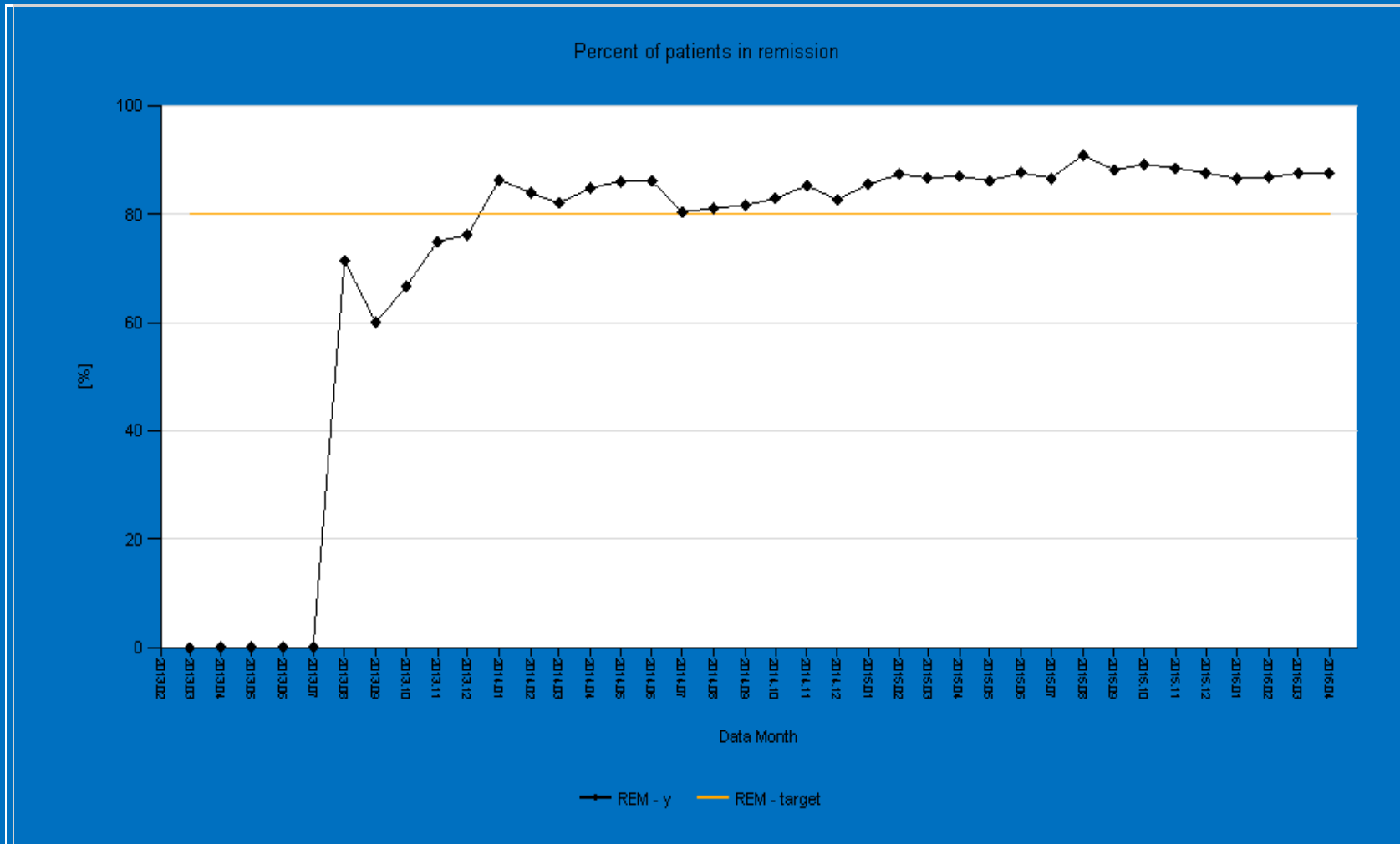
Measure Group	Sub Group	Measure Title	Network Target	>=75% cohort Teams' Performance	Team's Performance
Clinical Measures	Clinical Remission	<a href="#">Percent of patients in remission</a>	80	81	88
		<a href="#">Percent of patients with prednisone-free remission</a>	76	79	88
		<a href="#">Percent of patients with sustained remission</a>	45	51	54
		<a href="#">Percent of patients not taking prednisone</a>	95	95	97
	Adequate Nutrition and Growth	<a href="#">Percent of patients with satisfactory nutritional status</a>	90	90	89
		<a href="#">Percent of patients with at risk of nutritional failure</a>		8	10
		<a href="#">Percent of patients in nutritional failure</a>		1	1
		<a href="#">Percent of patients with satisfactory growth status</a>	90	94	87
		<a href="#">Percent of patients with at risk of growth failure</a>		5	14
	<a href="#">Percent of patients in growth failure</a>		2	0	
	Model Classification	<a href="#">Percent of visits with a complete bundle</a>	95	90	100
	Model Treatment	<a href="#">Percent of patients with a documented visit within the last 200 days</a>	80	74	76
		<a href="#">Percent of patients whose dose of thiopurine is at least the dose recommended in the ICN Model Care Guidelines</a>	80	64	25
		<a href="#">Percent of Patients where the dose of infliximab is at least 4.5 mg/kg</a>	95	97	98
<a href="#">Percent of Patients where the dose of methotrexate is at least 10 mg/m2 or 15 mg/wk</a>		95	90	100	
Data Quality	<a href="#">Percent of population registered AND active in registry</a>		82	93	
	<a href="#">Percent of actual visits recorded in registry</a>		74	0	
	<a href="#">Percent of visits with all critical data recorded</a>		84	100	
	<a href="#">Percent of visits meeting the consistency bundle</a>		86	100	
	<a href="#">Percent of active patients in registry with visit recorded in last 13 months</a>		93	99	
	<a href="#">Was there at least one hospital discharge within the last 90 days?</a>		78	100	

Key: At or above Network Target

Scoring below the Cohort Team Performance and Network Target

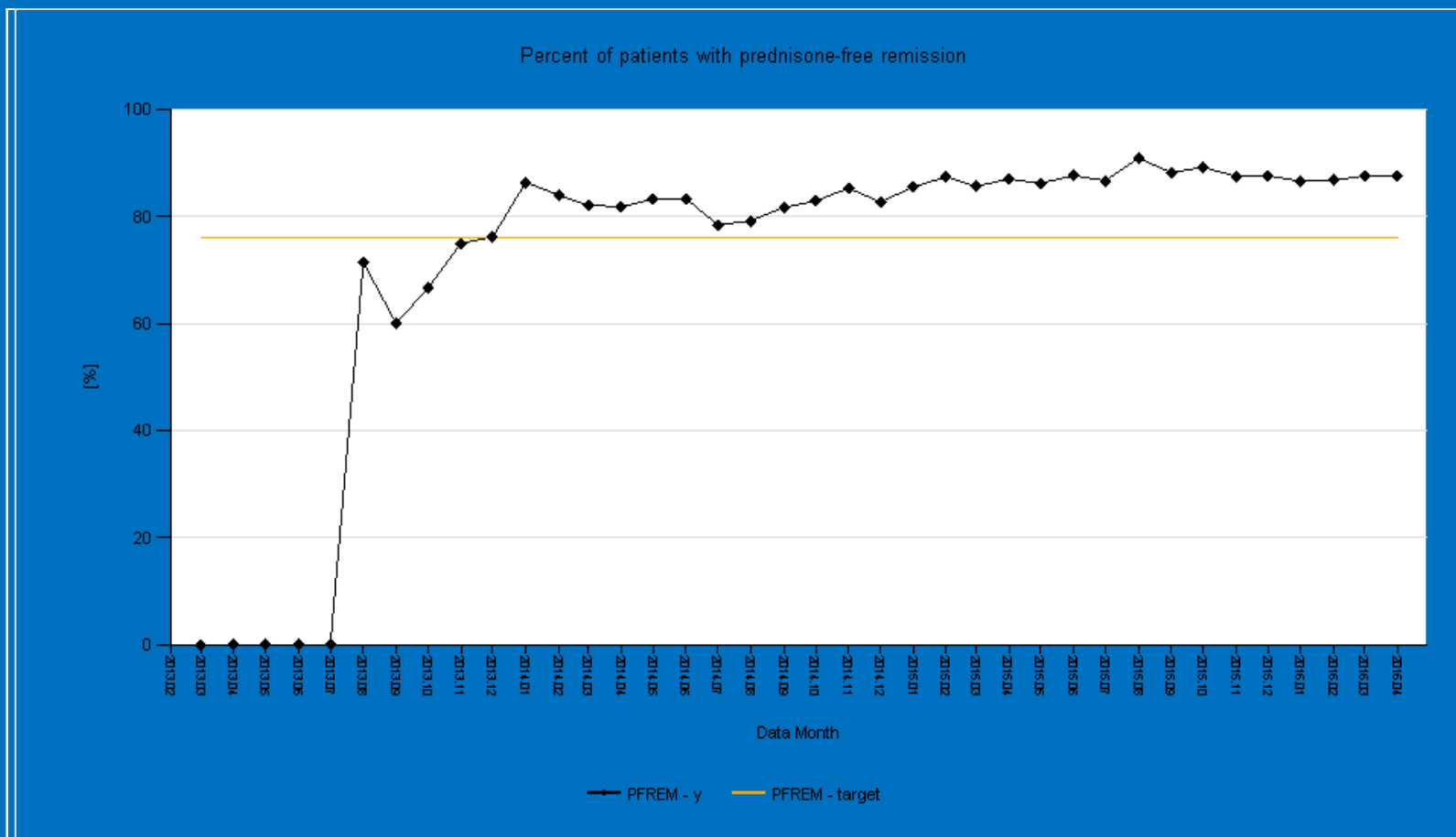
# Clinical remission

## Clinical Measures



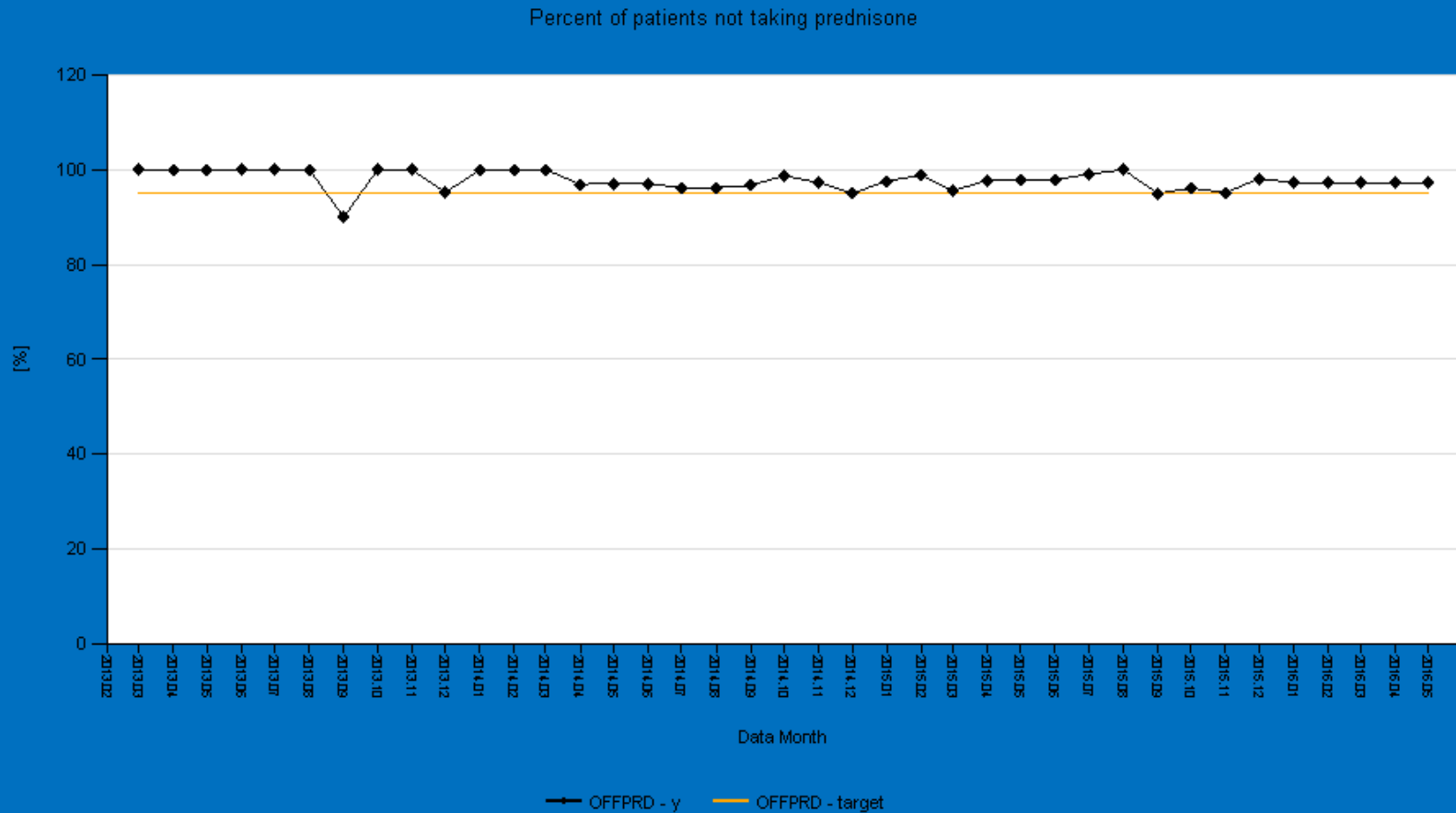
# Prednisone-free remission

## Clinical Measures



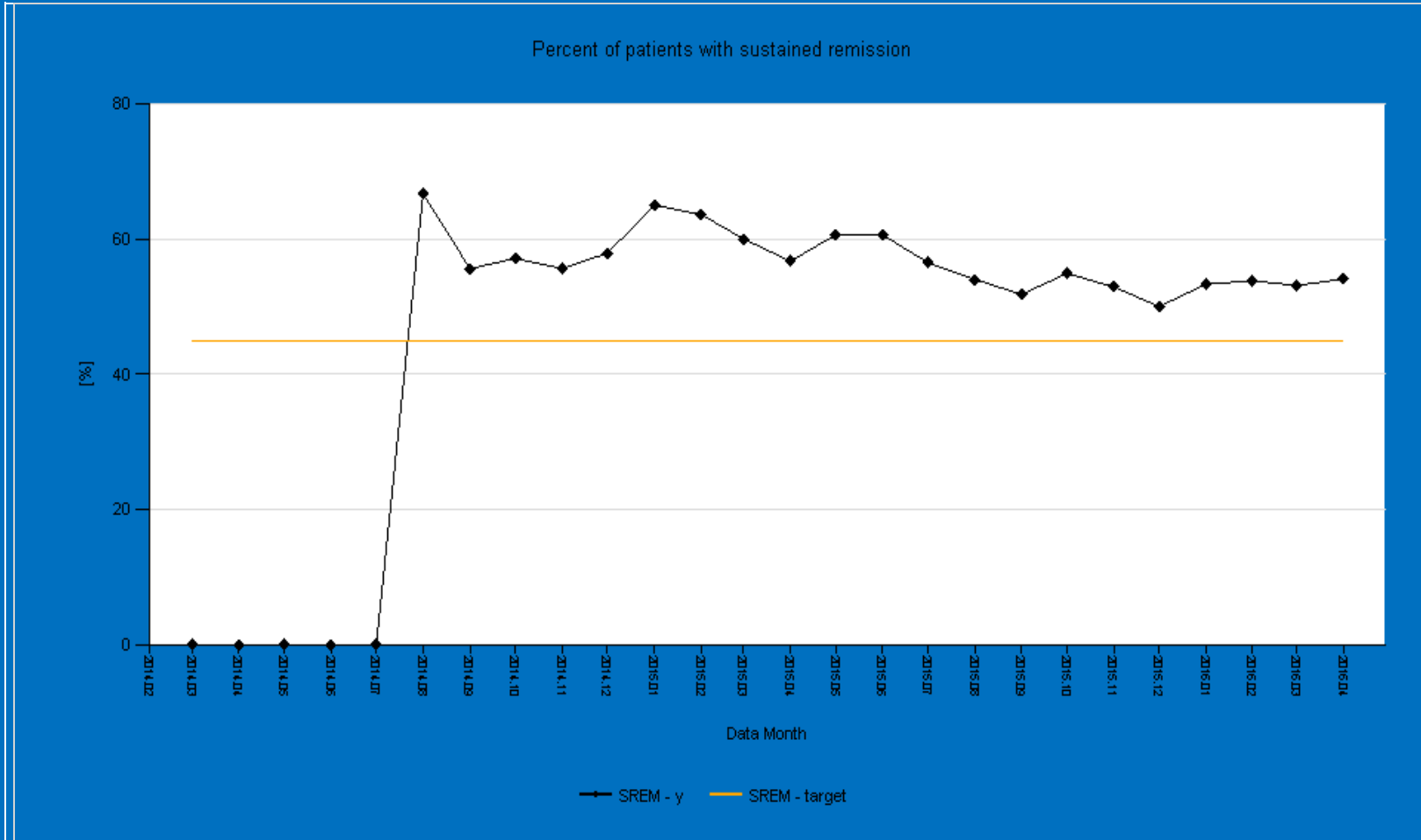


# Not taking prednisone



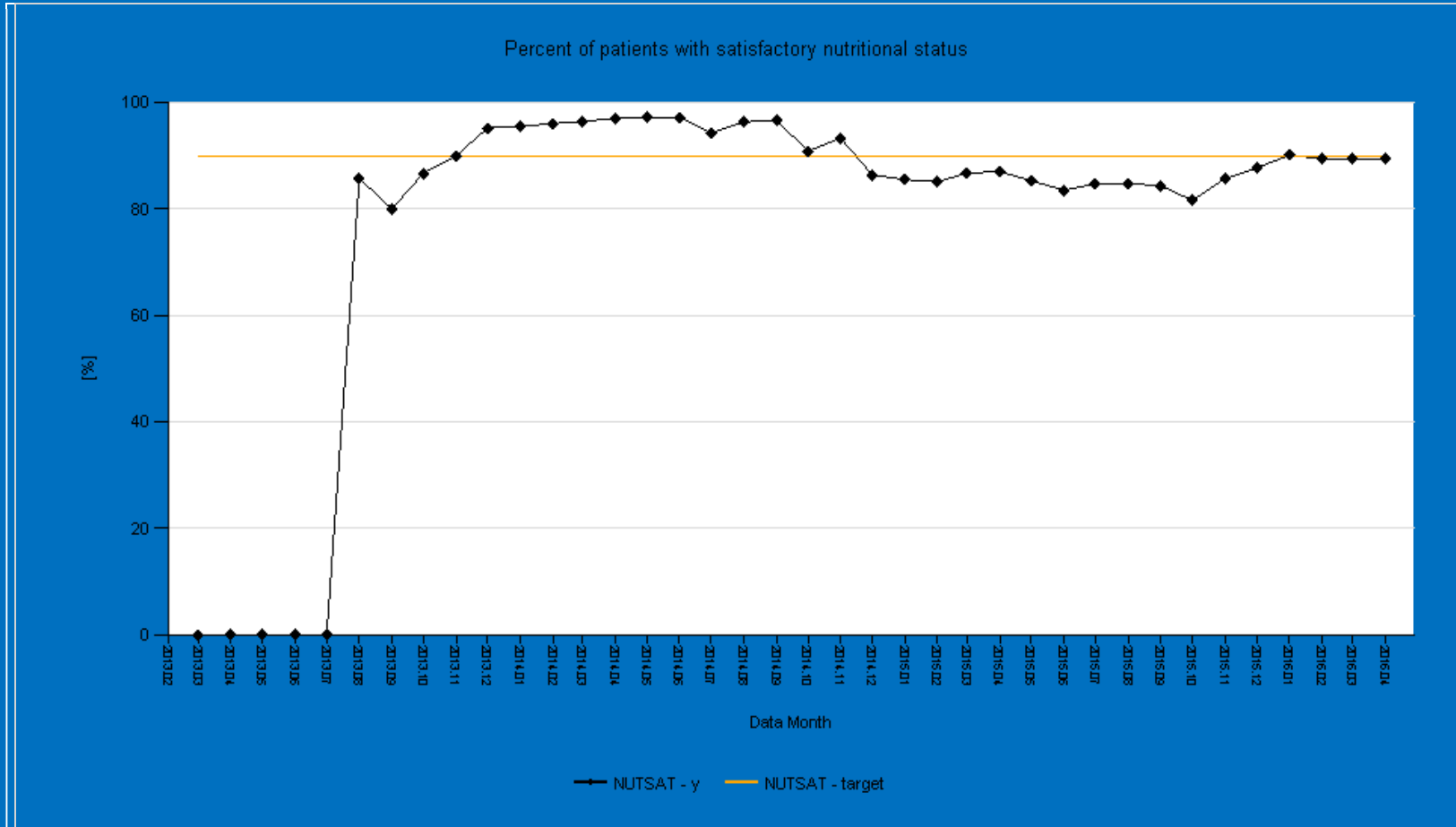
# Sustained Remission

## Clinical Measures



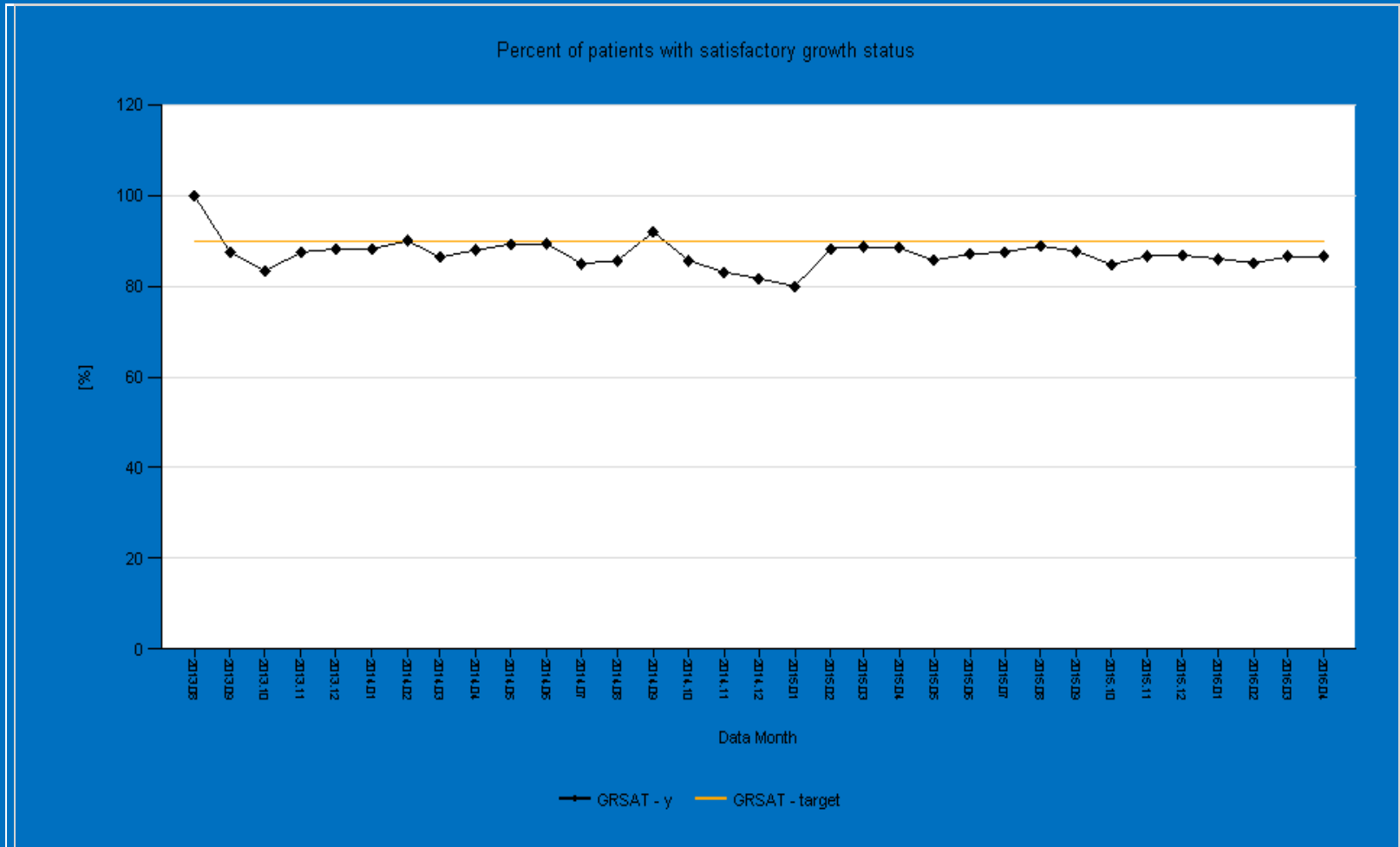
# Nutritional status

## Clinical Measures



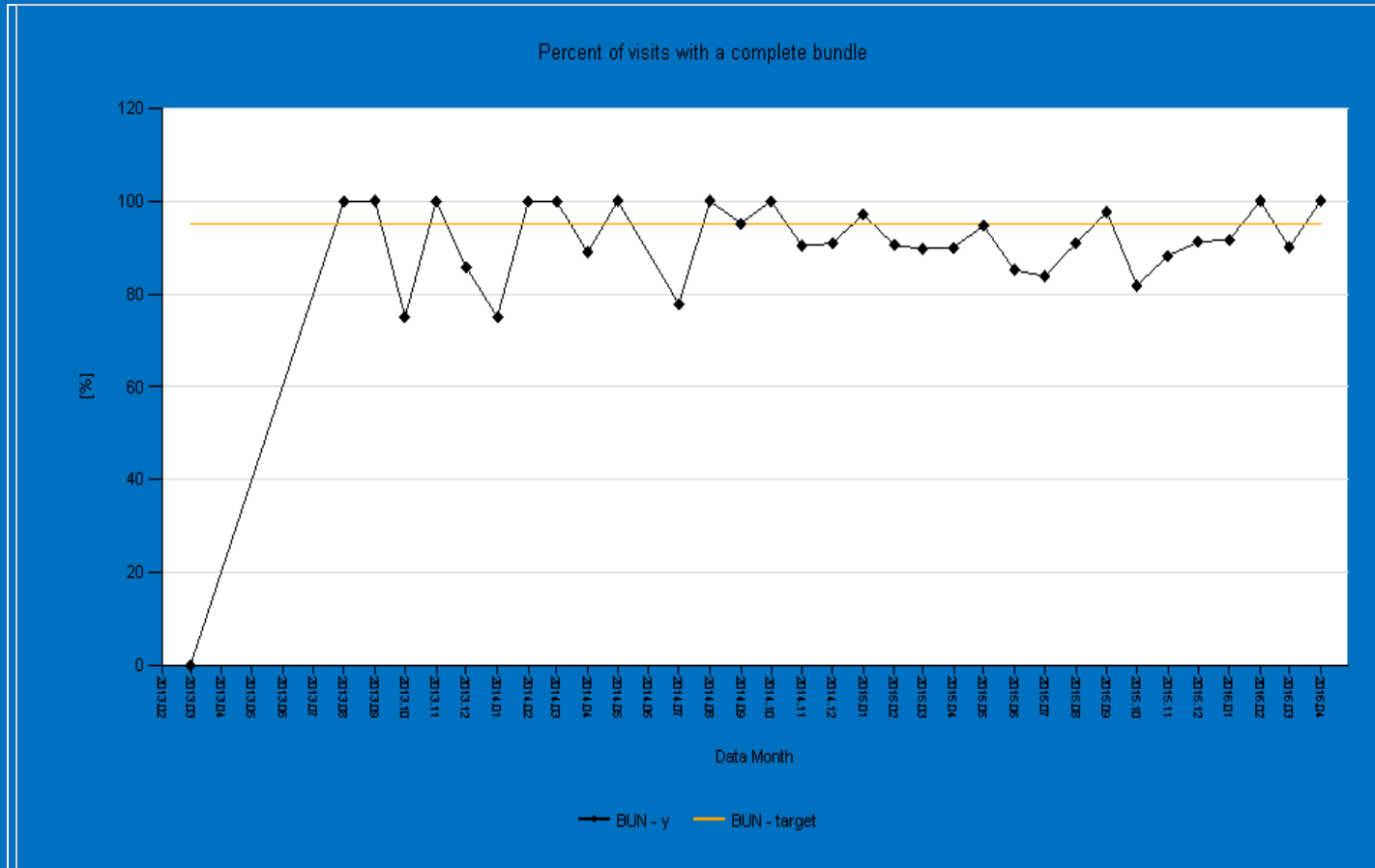
# Growth status

## Clinical Measures



# Completeness of bundle

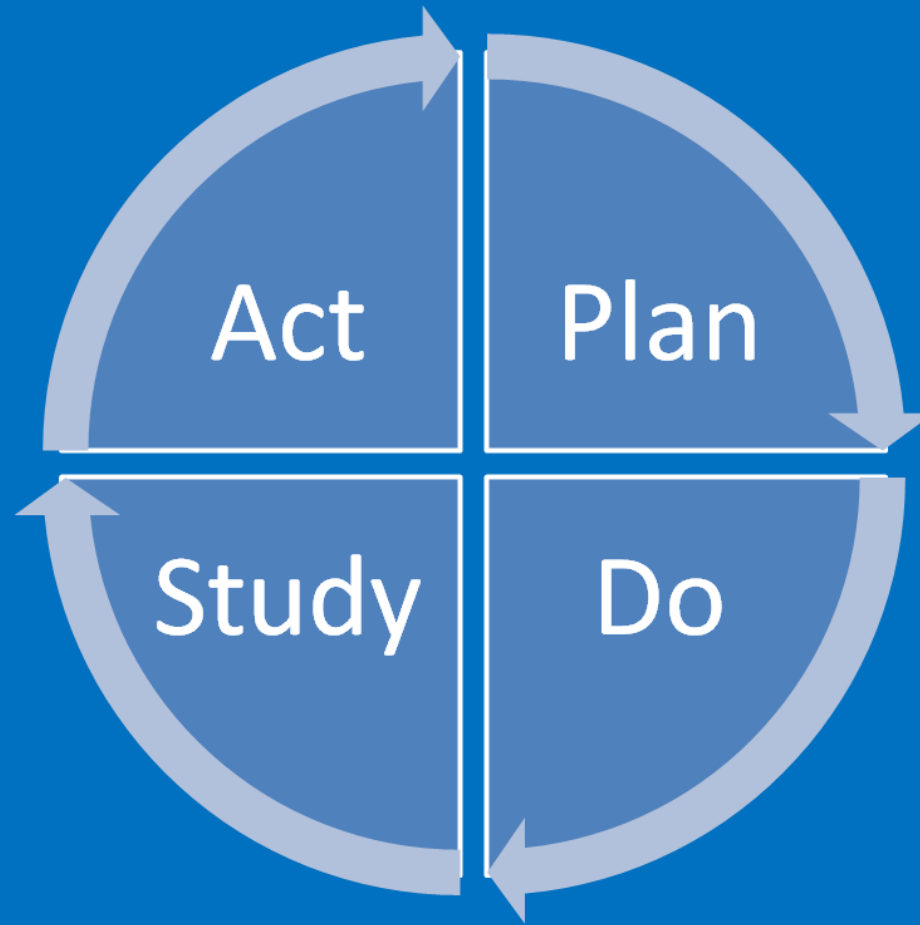
## Clinical Measures



# Our QI projects

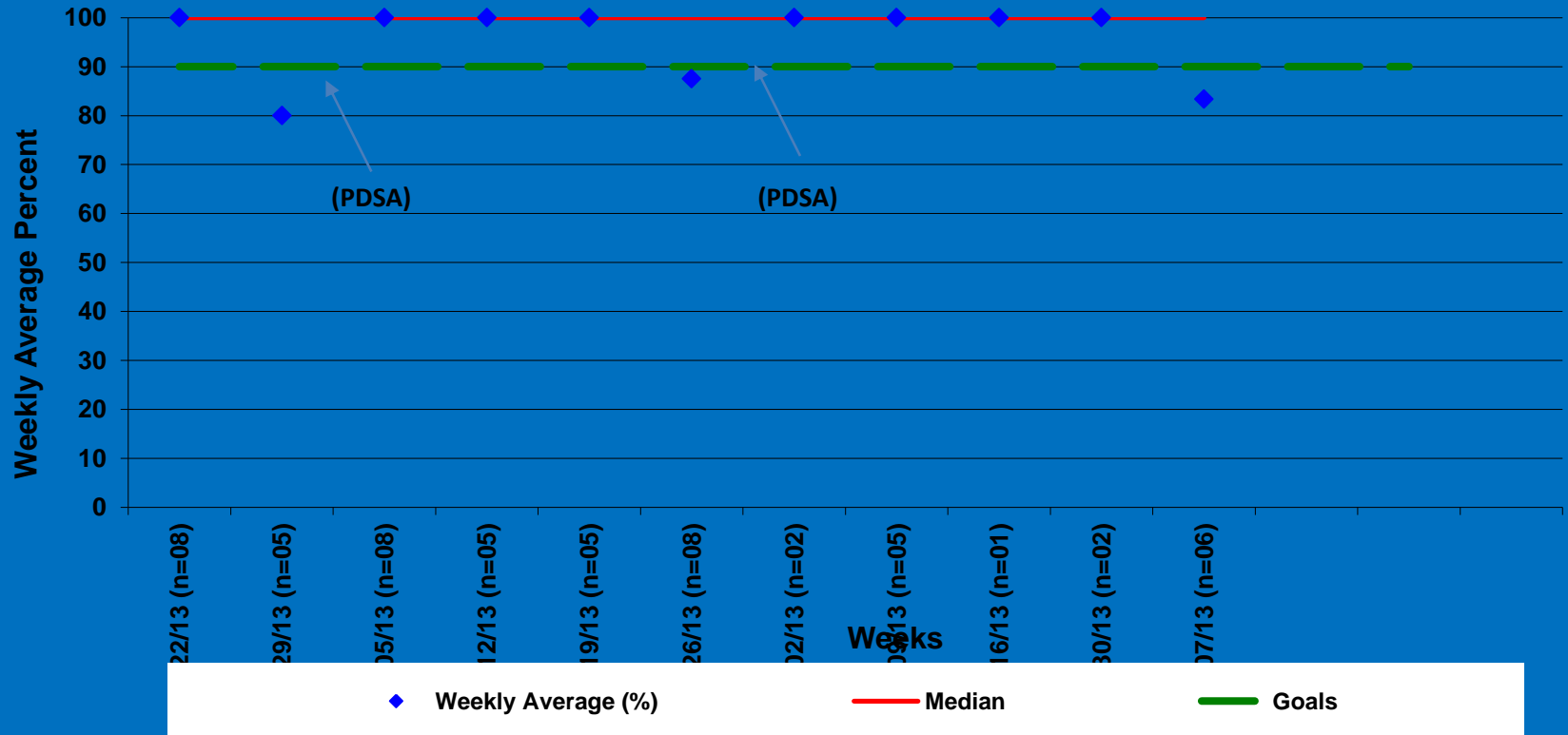
- Optimal dose of mesalamine in children with IBD
- Checking vitamin D status in children with IBD

# QI principal - PDCA



# Mesalamine- dosing

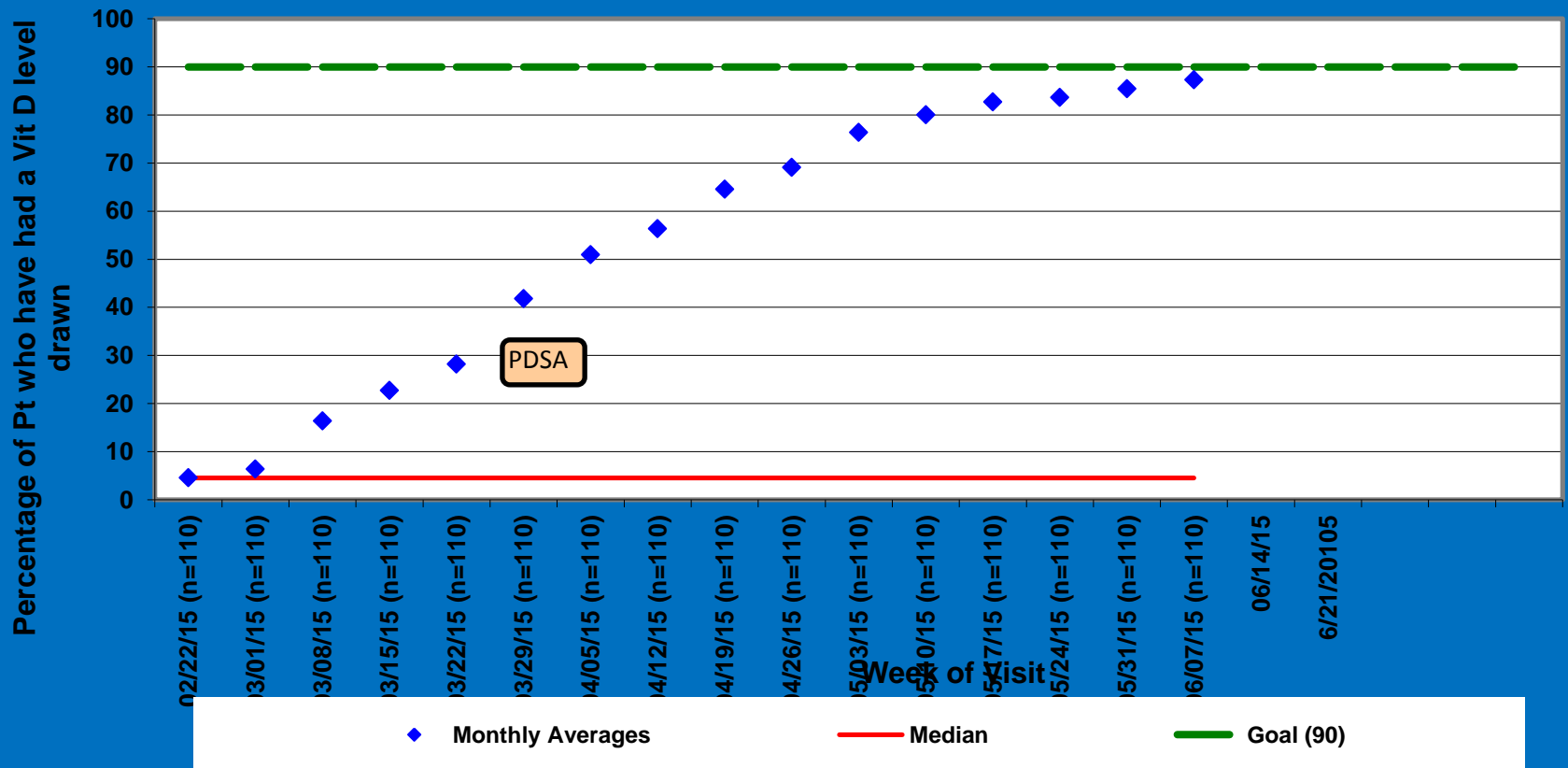
By September 2013, 90% of IBD patients will be on an adequate dose of mesalamine (>30 mg/kg/day).





# Vitamin D level check

In Spring 2015, 90% of patients will have Vitamin D levels checked



# Quality Improvement

- Quality Patient Care
- Benefits patients
- Improving outcome
- Integral part of health care
- Govt programs and insurers demand
- P4P Pay for performance

# Acknowledgement

- YNHCH & Yale Pediatrics
- 
- Yale Pediatric IBD Team
- Patients and families



# Yale Pediatric IBD Team



- Director- Michael Caty & Dinesh Pashankar
- Nurse – Alicia Tirloni
- Dietician – Susann Boroczky
- Social Worker – Ellen Doram
- Gastroenterologists- Uma Phatak, Anthony Porto, Arik Alper
- Fellows- Jazmin Foglio, Madhura Phadke ,Leina Alrabadi



Thank You

