

**9<sup>th</sup> Bi-Annual Joyce Niblack Memorial Conference on MPNs**

# What Should We Expect From MPN Therapy?

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# What Should We Expect From MPN Therapy?

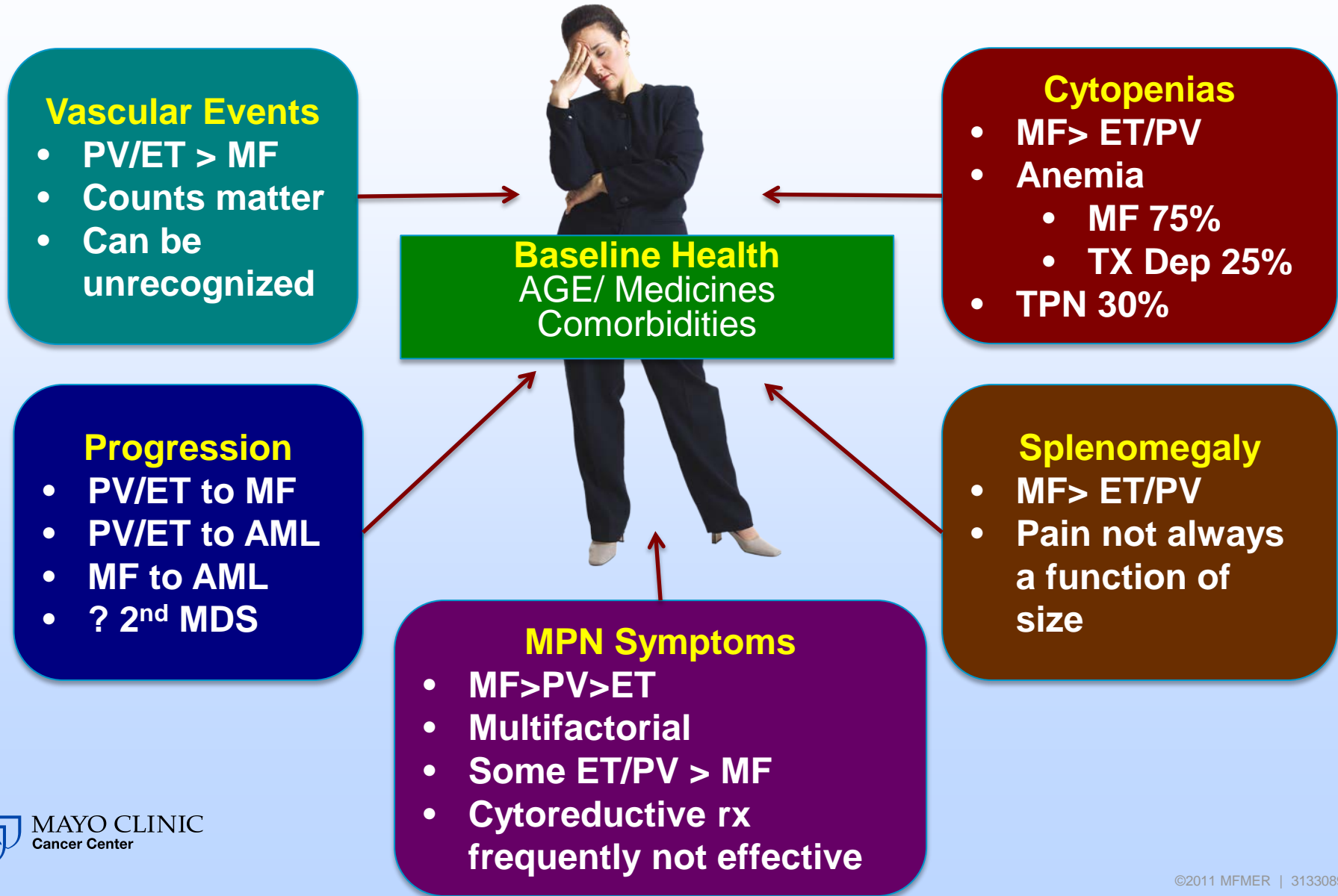
## *Top 10 ways we better match therapy and patients*

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**10. Understand that not all MPN patients are impacted the same**

# Assessing MPN Burden

## *WHO Diagnosis Does Not Tell Whole Story*



# What Should We Expect From MPN Therapy?

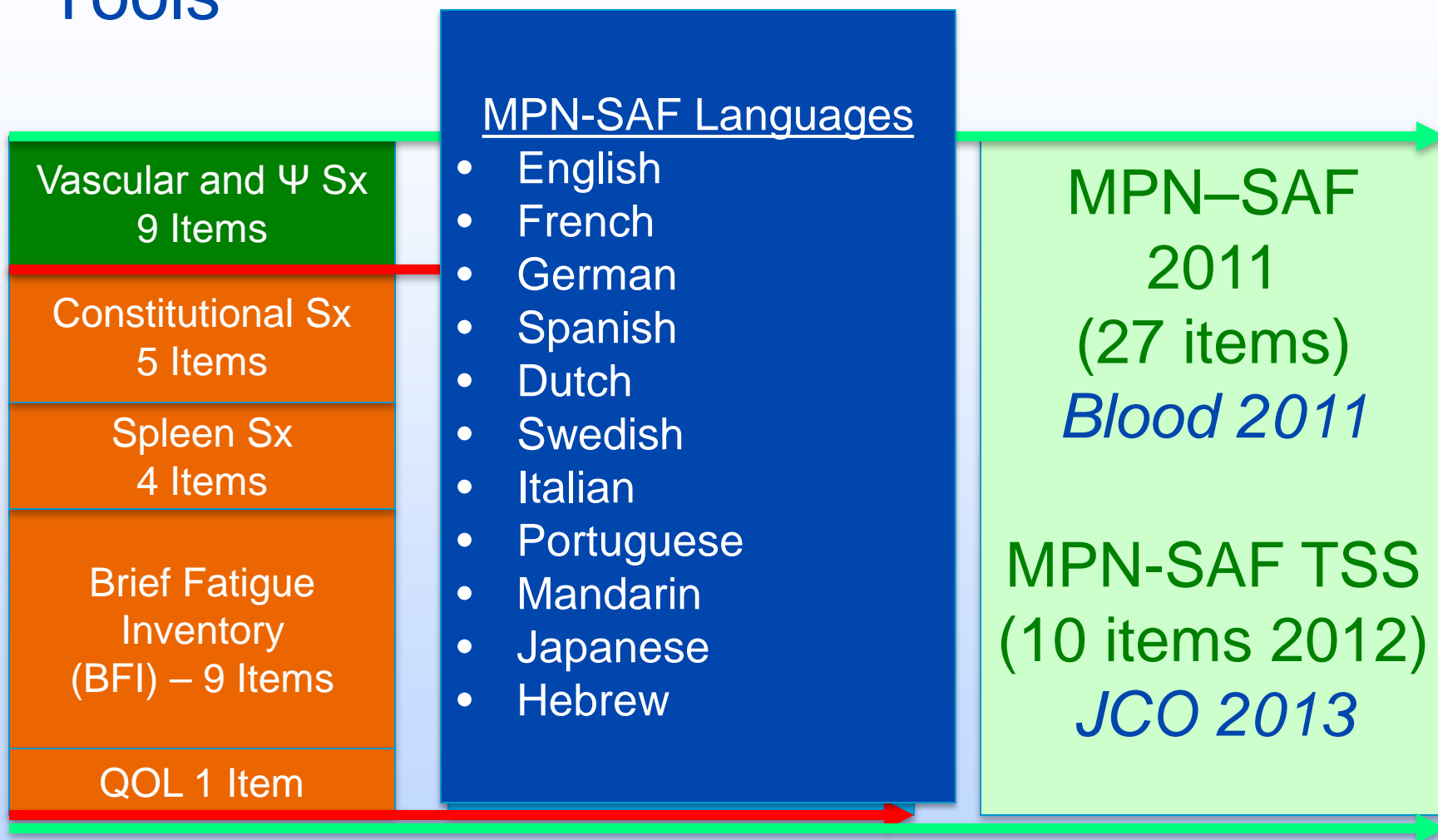
*Top 10 ways we better match therapy and patients*

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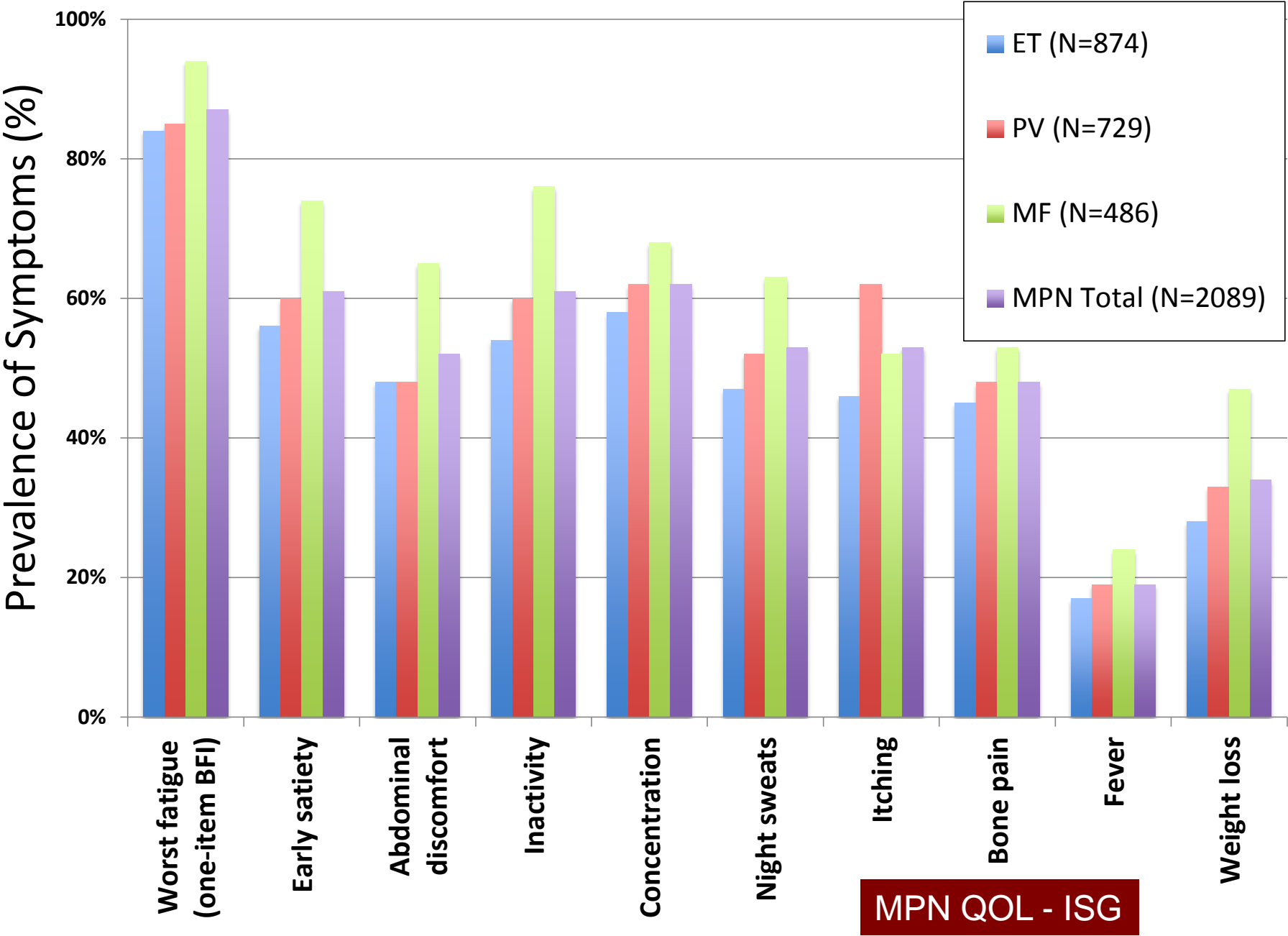
10. Understand that not all MPN patients are impacted the same

**9. Understand the spectrum of symptoms MPN patients face**

# Evolution of MPN Symptom Assessment Tools



# Symptoms from 2089 MPN Patients Using the MPN-SAF TSS (MPN10)



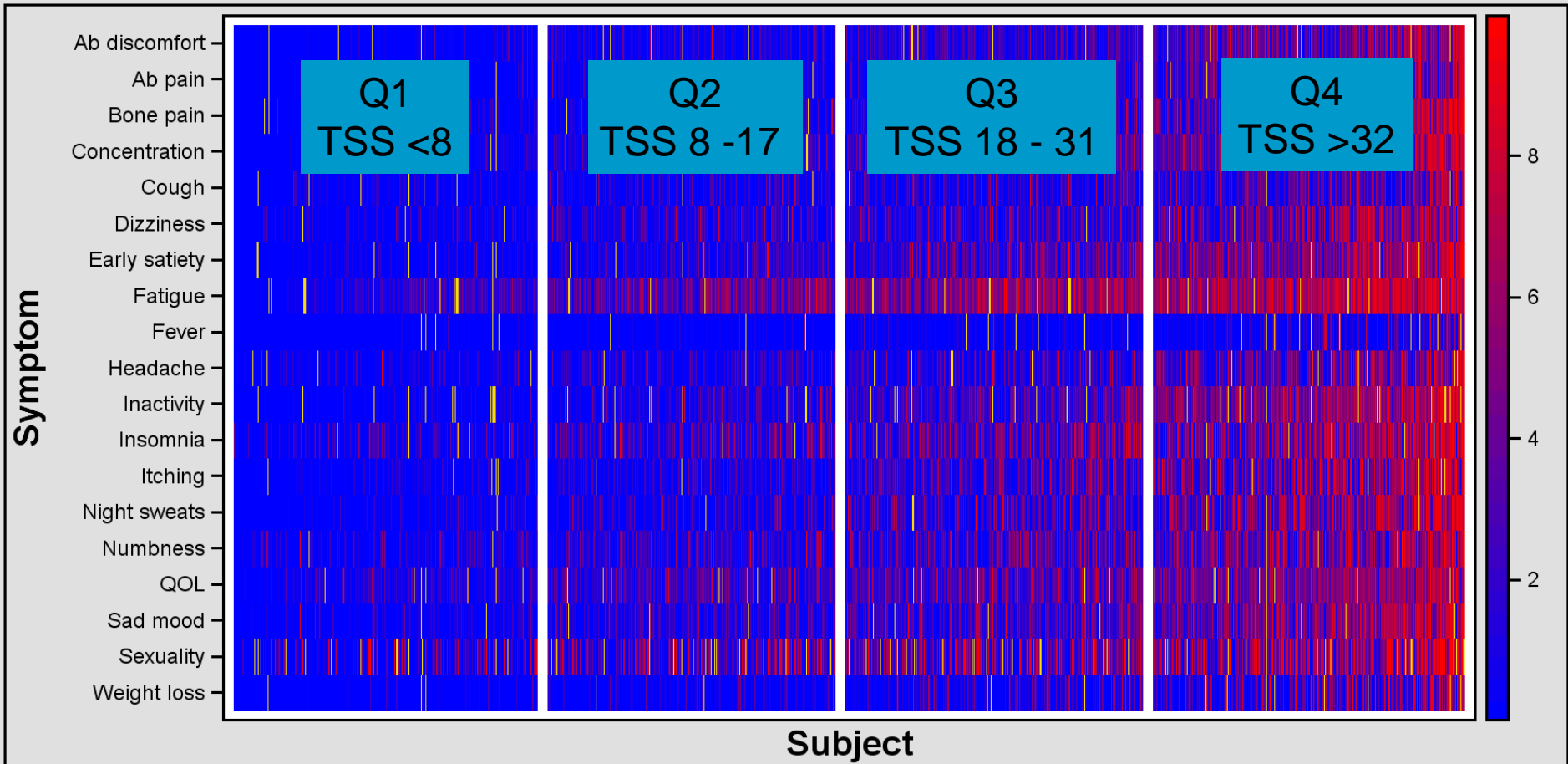
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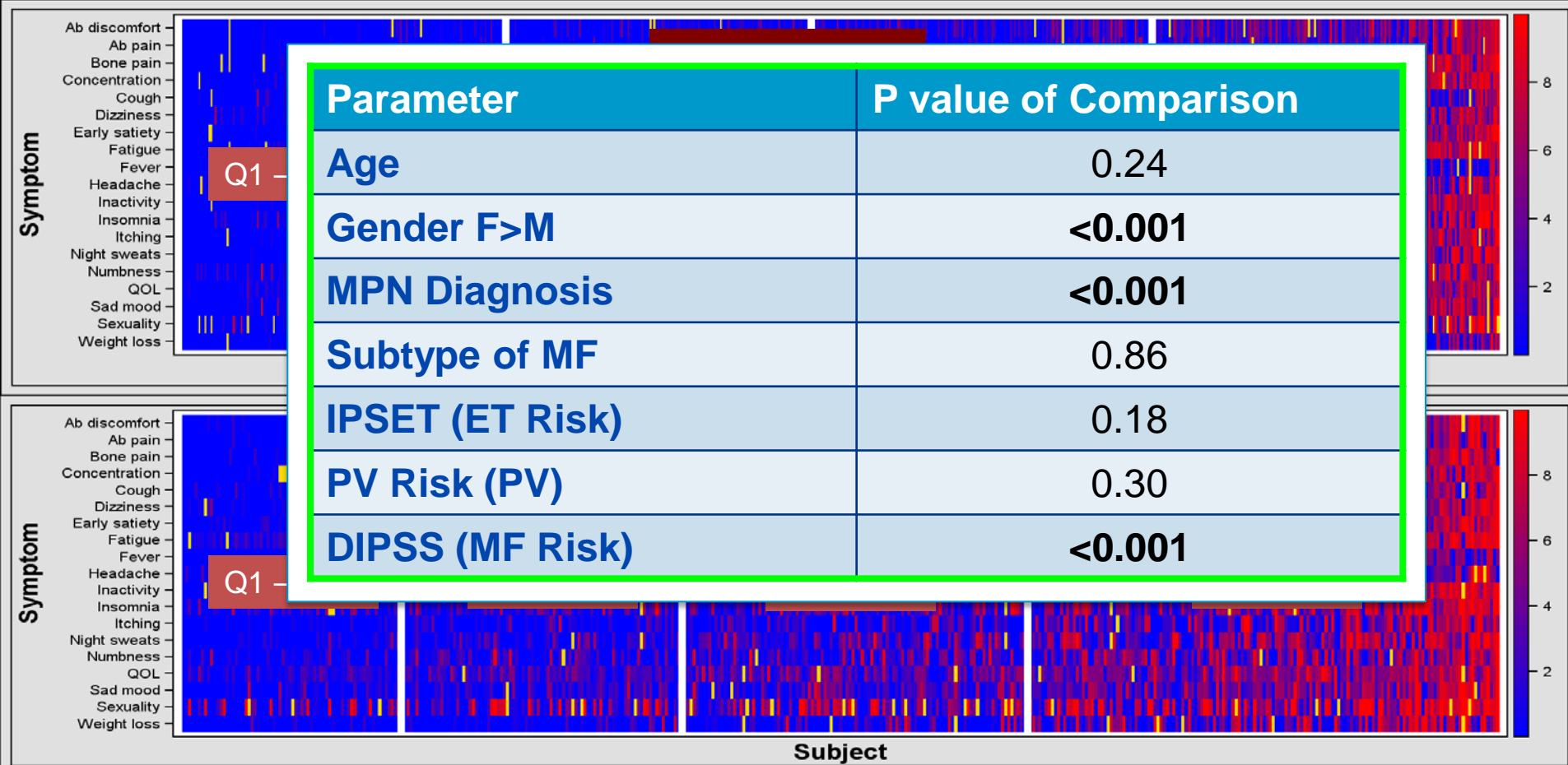
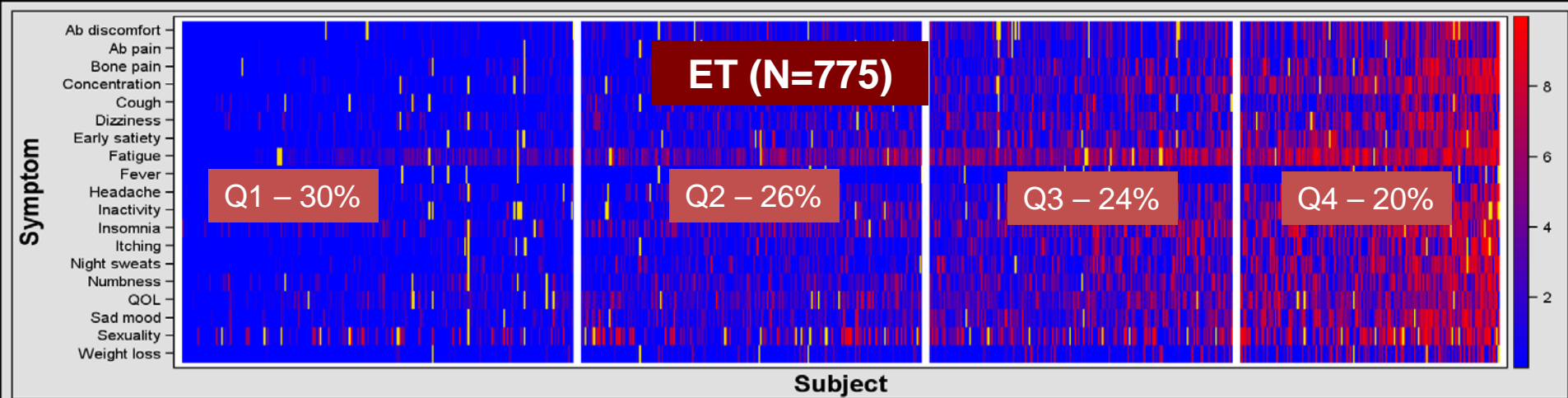
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9. Understand the spectrum of symptoms MPN patients face
- 8. Understand impact of symptom clusters, and gender effect on MPN patients**

# MPN Symptom Burden by Quartiles

## 1858 MPN-SAF Respondents







# Results

## Females

- Lower rate of thrombocytopenia (8% vs 14%,  $p<0.001$ ).
- Higher TSS (adjusted mean 23.9 vs 20.6;  $p<0.001$ )
- Higher symptom scores for 15/18 items
- Prominent symptoms: *fatigue, bone pain, abdominal discomfort, and microvascular related*

## Males

- Higher mean age than females (mean 60.7 yrs [SD 12.6] vs 59.3 yrs [SD 14.4];  $p=0.02$ )
- Higher rate of requirement for red blood cell transfusion (7% vs 5%,  $p=0.02$ )
- Higher mean white blood cell count (mean  $9.5 \times 10^9/L$  [SD  $8.2 \times 10^9/L$ ] vs mean  $8.5 \times 10^9/L$  [SD  $6.1 \times 10^9/L$ ];  $p=0.004$ )

### Females demonstrate...

#### Higher levels of fatigue

- Younger
- Lower red blood counts
- Lower transfusion rates

#### More Abdominal Symptoms

- Male=female abdominal thrombosis rates

#### Microvascular symptoms

- Previous reports show more macrovascular symptoms

#### Higher Symptom Scores

- Individual SS and TSS
- Male=female QOL score

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10. Understand that not all MPN patients are impacted the same
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8. Understand impact of symptom clusters, and gender effect on MPN patients
- 7. Understand the complex issue of MPN fatigue, and possible mood disorders**

# MPN “Fatigue” Project 2014

## *Collaborative Internet Based Trial with MPN Forum*

### ANY MPN Patient

- Survey online
- MPN Forum
- MPN Advocacy
- MPN Research Foundation
- CMPD Ed Foundation

Register/ Online Consent

### Online 70 Item Survey

- Demographics
- MPN History
- MPN-SAF (MPN10)
- Brief fatigue inventory (BFI)
- Profile of mood states (POMS-Short)
- Patient Health Questionnaire (PHQ-2)
- Mental Health Inventory (MHI-5)

### Patients

1788 MPN patients/ 1676 Eval.

ET 33%, PV 39%, MF 25%

68% Female, median age 59.  
MPN10 Score average 28.4  
(range 0-83)

### Psych Comorbidity

23% high likelihood of depression  
( $\geq 3$  on PHQ-2)

Prior diagnosis depression (32%),  
anxiety (29%), stress (26%), grief  
(15%)

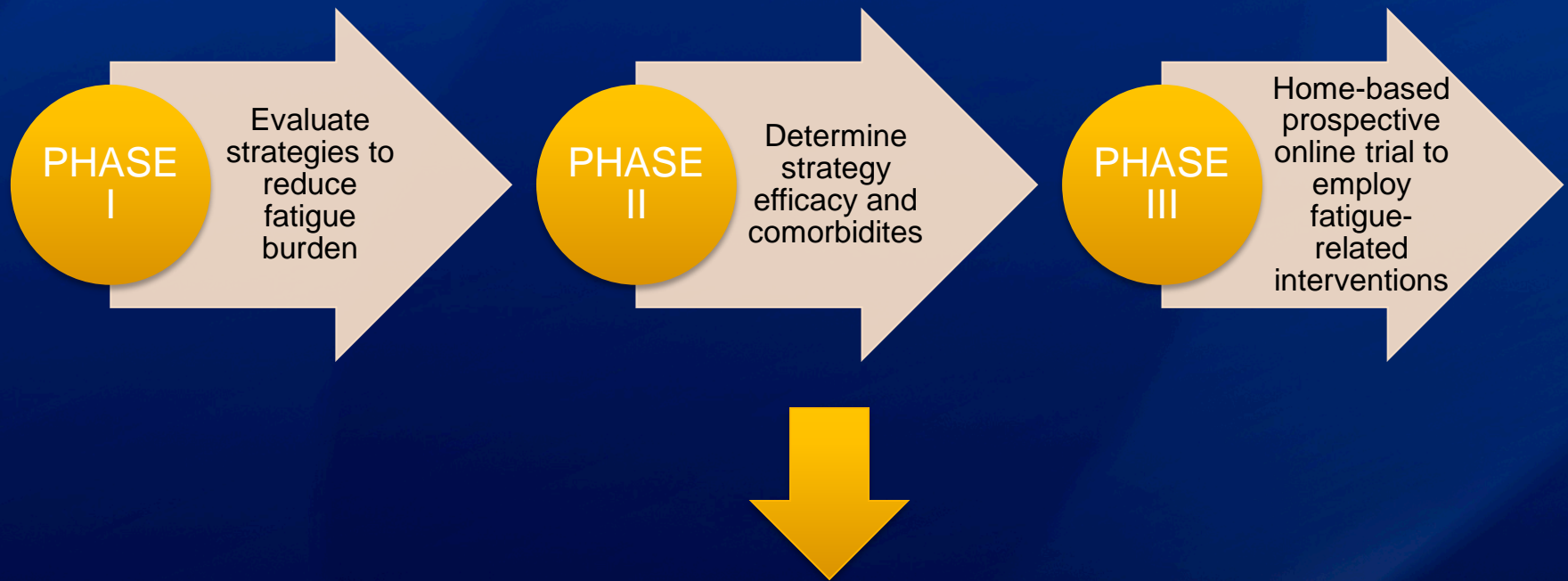
22% on therapy for mood disorder  
in last 6 months

### MPN Correlation

Higher BFI, MPN-SAF,  
MPN10 scores all correlated  
with increased depressive  
symptoms ( $p < 0.0001$ )

# MPN Fatigue Project

- Three part project:



N=1748 MPN pts (718 PV, 625 ET, 420 MF, 29 other)

# Fatigue Project

Strategies To Cope with Fatigue Related to MPN	BFI - Mean (SD), N YES	BFI - Mean (SD), N NO	$\Delta$	95% CI	P
Postponing non-essential activities	5.0 (2.1), 981	3.2 (2.3), 365	1.8	(1.6, 2.1)	<.0001
Setting priorities	4.8 (2.1), 1015	3.2 (2.3), 365	1.6	(1.3, 1.9)	<.0001
Medication psychostimulants	4.2 (2.0), 110	4.1 (2.3), 433	-0.1	(-0.6, 0.4)	<.0001
Antidepressants	4.2 (2.0), 320	4.2 (2.5), 1050	0	(-1.4, 1.6)	<.0001
Delegation	3.9 (2.2), 682	3.9 (2.4), 655	0	(0.8, 1.3)	<.0001
Scheduling of activities to times of peak energy	3.8 (2.1), 827	3.8 (2.4), 928	0	(0.8, 1.3)	<.0001
Naps	3.8 (2.3), 942	3.8 (2.4), 928	0	(0.8, 1.3)	<.0001
Labor-saving devices	3.8 (2.1), 493	4.1 (2.4), 838	-0.3	(0.8, 1.2)	<.0001
Structured daily routines	3.8 (2.2), 706	4.1 (2.4), 838	-0.3	(0.8, 1.2)	<.0001
Socializing with family or friends	4.8 (2.2), 853	3.9 (2.5), 487	0.9	(0.7, 1.2)	<.0001
Support groups	5.3 (2.1), 296	3.9 (2.5), 487	1.4	(0.8, 1.3)	<.0001
Pacing	4.9 (2.1), 772	4.0 (2.4), 580	0.9	(0.7, 1.2)	<.0001
Reading	4.8 (2.2), 820	3.9 (2.4), 523	0.9	(0.6, 1.1)	<.0001
Sleep therapy	5.3 (2.1), 117	4.4 (2.3), 1237	0.9	(0.5, 1.4)	<.0001
Music	4.8 (2.2), 618	4.1 (2.3), 722	0.8	(0.5, 1.0)	<.0001
Church or spiritual activities	4.8 (2.1), 485	4.2 (2.4), 841	0.6	(0.5, 1.0)	<.0001
Nutrition	4.7 (2.2), 876	4.0 (2.4), 499	0.8	(0.5, 1.1)	<.0001
Steroids	4.7 (2.0), 75	4.5 (2.3), 1282	0.2	(0.3, 1.4)	0.003
Meditation, quiet time, or cognitive re-framing	4.7 (2.2), 555	4.2 (2.4), 822	0.5	(0.4, 0.9)	<.0001
New activities/ diversions	4.7 (2.3), 476	4.3 (2.3), 857	0.4	(0.2, 0.7)	0.0003
Relaxation, including yoga	4.7 (2.3), 572	4.3 (2.4), 821	0.4	(0.1, 0.6)	0.005
Walking/sitting in a natural environment	4.6 (2.2), 891	4.3 (2.5), 477	0.3	(-0.02, 0.5)	0.1
Gardening	4.6 (2.3), 585	4.4 (2.4), 788	0.2	(-0.1, 0.4)	0.3
Volunteer activities	4.5 (2.3), 430	4.5 (2.3), 937	0	(-0.2, 0.3)	0.7
Exercise	4.4 (2.3), 1009	4.7 (2.5), 377	-0.4	(-0.6, -0.1)	0.01

Postponing non-essential activities

Setting priorities

Medication

Psychostimulants

Antidepressants

Exercise

# MPN Patient Burden- Disease Impact

## 2014 Landmark Study

### ANY MPN Patient

- Survey online
- MPN Forum
- MPN Advocacy
- MPN Research Foundation
- CMPD Ed Foundation

Register/ Online Consent

### Online Survey

- Demographics
- MPN History
- MPN-SAF (MPN10)
- Impact on QoL
- Impact on Employment
- Impact on ADLs

### Patients

- 813 MPN Patients
  - MF (207)/ PV (380), ET (226)
  - INT/ High Risk
    - MF (94%)
    - PV (78%)
    - ET (74%)

### Symptom Burden

- Anxious about their MPN
  - MF (91%)
  - PV (78%)
  - ET (74%)
- MPN Symptoms decrease my QoL
  - MF (81%)
  - PV (66%)
  - ET (57%)

### Impact

- $\geq 1$  sick day in last month
  - MF (33%), PV (23%), ET (22%)
- $\geq 1$  cancelled activity in last month
  - MF (46%), PV (35%), ET (34%)

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- 6. Understand complex assessment of MPN “risk”, and comorbidities**



# Monitoring MPNs

## Evolving MPN prognostic scales

	IPSET (ET—3 groups) <i>Survival</i> <i>thrombosis risk</i>	PV Risk (4 groups) <i>Survival</i> <i>leukemia rates</i>	DIPSS (PMF—4 groups) <i>Survival</i>
Age, years	≥ 60 (2 pts) vs < 60	≥ 67 (5 pts) 57-66 (2 pts), < 60 (0)	≥ 65 (1 pt) vs < 65
Leukocytes	≥ 11 (1 pt) vs < 11 x 10 <sup>9</sup> /L	≥ 15 (1 point) vs < 15 x 10 <sup>9</sup> /L	> 25 (1 pt) vs ≤ 25 x 10 <sup>9</sup> /L
Hemoglobin			< 10 (2 pts) vs ≥ 10 g/dL
Constitutional symptoms			Present <sup>a</sup> (1pt) vs absent
Blasts			≥ 1% (1pt) vs < 1%
Prior thrombosis	Yes (1 point) vs No	Yes (1 Point) vs No	
Risk group point cutoffs	0; 1-2; 3-4 pts	0; 1-2; 3; 4 pts	0; 1-2; 3-4; ≥ 4 pts

Passamonti  
Blood 2012

Tefferi  
Leuk 2014

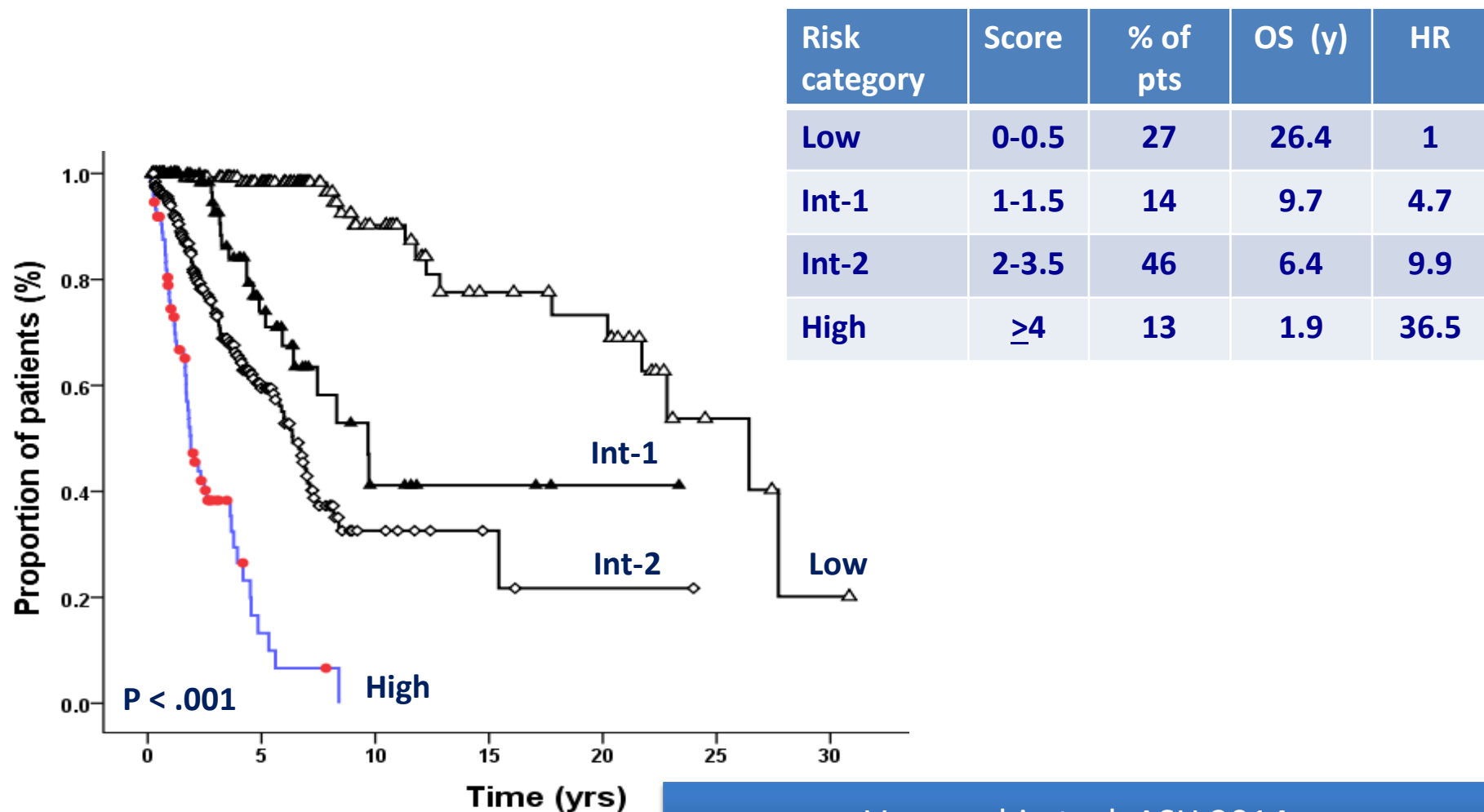
Passamonti  
Blood 2010

<sup>a</sup> 10% weight loss over prior 6 months, night sweats, unexplained fever.

# MIPSS: Molecular International Prognostic Score System

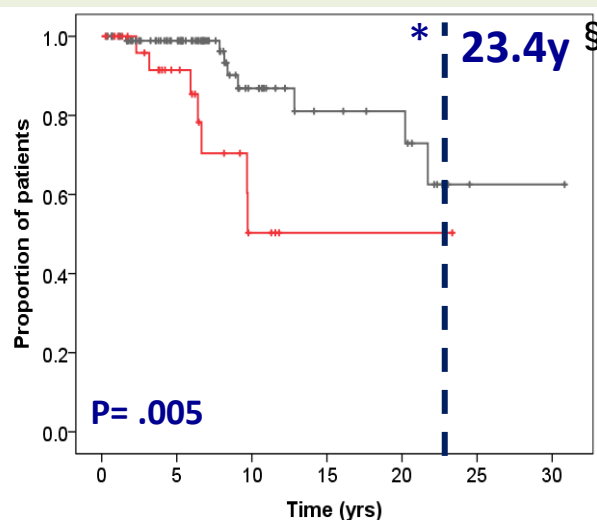
MULTIVARIATE ANALYSIS			Weighted value
Variables	HR (95% CI)	P	
Age >60yrs	3.8 (2.60-5.51)	<0.0001	1.5
Hb <100g/L	1.4 (1.01-1.99)	0.04	0.5
Constitutional Symptoms	1.5 (1.13-2.16)	0.007	0.5
PLT <200x10 <sup>9</sup> /L	2.5 (1.77-3.42)	<0.0001	1.0
Triple Negativity	3.9 (2.20-6.80)	<0.0001	1.5
JAK2/MPL mutation	1.8 (1.11-2.90)	0.016	0.5
ASXL1 mutation	1.4 (1.06-1.99)	0.02	0.5
SRSF2 mutation	1.7 (1.08-2.58)	0.02	0.5

# Development of the MIPSS Score in the Learning Cohort

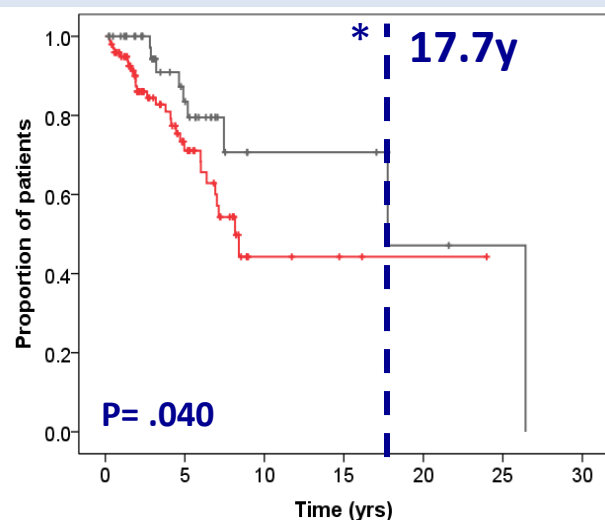


# MIPSS Permits to Refine Prognostic Stratification Within the IPSS Categories

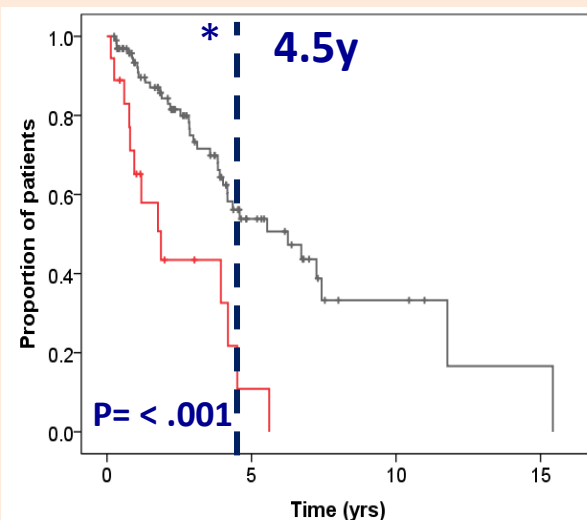
IPSS - LOW



IPSS - INT-1



IPSS - INT-2



Low 24.9y

> Low 15.3y

≤ Int-1 17.7y

> Int-1 8.1y

≤ Int-2 6.2y

> Int-2 1.9y

§ Estimated

**MIPSS**

Vannucchi et. al. ASH 2014

\*, IPSS Median Survival — — — —

# FATIGUE Trial – Co-morbidities in 1676 MPN Patients

Fatigue-related Category	Percent Respondents (N=1676)	Correlation with fatigue score (P-value)
Chronic Illness		
Hypothyroidism	12.9%	
Restless leg syndrome	7.0%	
Heart failure	6.1%	
Obstructive sleep apnea	4.0%	
Rheumatologic disease	3.8%	
Diabetes Mellitus	3.6%	
Fibromyalgia	3.4%	
Chronic lung disease	2.9%	
Chronic fatigue syndrome	1.7%	
Chronic kidney disease	1.6%	
Liver failure	0.6%	
Current Medication Use Categories		
Blood pressure	32.1%	NS*
Antidepressants	16.0%	<0.001
Antihistamines	16.0%	0.0276
Anti-anxiety	10.1%	0.0357
Prescription pain	7.8%	<0.001
Steroids	3.4%	NS*
Cough or cold medications	1.8%	NS*

Scherber  
et. al.  
ASH 2014

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9. Understand the spectrum of symptoms MPN patients face
8. Understand impact of symptom clusters, and gender effect on MPN patients
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6. Understand complex assessment of MPN “risk”, and comorbidities
- 5. Understand new response criteria, and need for their validation**

# Response Criteria for MPNs 2014 (All $\geq 12$ Weeks)

ET/PV – ELN (Barosi et. al. *Blood* 2013)

MF – IWG-MRT (Tefferi et. al. *Blood* 2013)

	Complete Remission	Partial Remission	Clinical Improvement	Other
ET	<ul style="list-style-type: none"> <li>Resolve ET Signs</li> <li><math>\geq 10</math> pt. MPN10 ↓</li> <li>Near normal counts</li> <li>No Prog. or Vascular</li> <li>BM rem &amp; <math>\leq</math>Gr 1 MF</li> </ul>	<ul style="list-style-type: none"> <li>Resolve ET Signs</li> <li><math>\geq 10</math> pt. MPN10 ↓</li> <li>Near normal counts</li> <li>No Prog. or Vascular</li> </ul>		Peripheral Blood Granulocytes <ul style="list-style-type: none"> <li>CR – Eradicated mutation</li> <li>PR - <math>\geq 50\%</math> ↓, <math>\geq 20\%</math> baseline</li> </ul>
PV	<ul style="list-style-type: none"> <li>Resolve PV Signs</li> <li><math>\geq 10</math> pt. MPN10 ↓</li> <li>Near normal counts</li> <li>No Prog. or Vascular</li> <li>BM rem &amp; <math>\leq</math>Gr 1 MF</li> </ul>	<ul style="list-style-type: none"> <li>Resolve PV Signs</li> <li><math>\geq 10</math> pt. MPN10 ↓</li> <li>Near normal counts</li> <li>No Prog. or Vascular</li> </ul>		Peripheral Blood Granulocytes <ul style="list-style-type: none"> <li>CR – Eradicated mutation</li> <li>PR - <math>\geq 50\%</math> ↓, <math>\geq 20\%</math> baseline</li> </ul>
MF	<ul style="list-style-type: none"> <li>Resolve MF Signs</li> <li>Resolve MF sympts</li> <li>Near normal counts</li> <li>BM rem &amp; <math>\leq</math>Gr 1 MF</li> </ul>	Like MF CR but <ul style="list-style-type: none"> <li>Hb (between 85 and 100 g/L)</li> <li>PLT (between 50-100 x 10<sup>9</sup>/L)</li> </ul>	<ul style="list-style-type: none"> <li>Anemia (2g/dl or T.I.)</li> <li>Spleen (Based on BL)</li> <li>Symptoms (<math>\geq 50\%</math> ↓)</li> </ul>	<ul style="list-style-type: none"> <li>Molecular (ET/PV Criteria)</li> <li>Cytogenetic               <ul style="list-style-type: none"> <li>CR – Normal</li> <li>PR - <math>\geq 50\%</math> ↓</li> </ul> </li> </ul>

N.B. ET/PV – Progression is MF/MDS/ or AML  
MF – Progression based on spleen growth or AML

# “Clinically Meaningful” – What is Valid? *(Example – Spleen Reduction)*

> 50% reduction of Palpable Length

IWG-MRT  
2006  
Blood 2006

> 35% Volume Reduction by MRI

COMFORT  
1 & 2  
NEJM 2012

> 10% Volume Reduction by MRI  
- Better Survival and PGIC

Pooled  
CI/CII  
Blood 2013



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9. Understand the spectrum of symptoms MPN patients face
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7. Understand the complex issue of MPN fatigue, and possible mood disorders
6. Understand complex assessment of MPN “risk”, and comorbidities
5. Understand new response criteria, and need for their validation
- 4. Optimizing the timing and utilization of stem cell transplant**

# Stem Cell Transplant Use in MPNs

## Baseline Assumptions/ Caveats

- SCT *almost* exclusively for MF/ MPN-BP
- In MF evolving risk/benefit analysis for use

### Question 2

#### Pre Transplant Therapy?

- JAK Inhibition?
- Cytoreduction?
- Iron chelation?

“Problematic”  
MF  
& SCT  
Eligible

Allo SCT

### Question 1

#### Timing?

- Urgent
- Delayed
- Never

### Question 3

#### Post Transplant Therapy?

- JAK Inhibition?
- Interferon?
- other?

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5. Understand new response criteria, and need for their validation
4. Optimizing the timing and utilization of stem cell transplant
- 3. Optimizing the utilization of current available agents**

# Primary Commercially Available MPN Drugs 2015

	Hydroxyurea	Interferon/ Peg -INF	Anagrelide	Ruxolitinib
ET	XXX	XX	XX	X
PV	XX	XX	X	XXX
MF	X	X	X	XXX

# Proposed Algorithm of Therapy of ET/PV in 2015

## Assess Symptom Quartile by MPN 10

Q1:TSS <8  
Q2:TSS 8-17  
Q3:TSS 18-31  
Q4:TSS ≥32

Diagnosis of PV or ET

## JAK2 Inhibitor (Experimental Indication)

- Ruxolitinib
- Other Clinical Trial JAK2 Inhib

Assess MPN Risk Score (Table 1) &  
Assess MPN Symptoms (MPN 10)  
Control of Hematocrit (<45%) in PV (? In ET)  
Low dose aspirin in appropriate patients

Decide on need for concurrent cytoreduction based on Risk and Symptoms

NO

Monitor for symptom  
burden, vascular events,  
progression

Worsening symptom burden  
Vascular event, progression  
Phlebotomy intolerance

YES

Front Line Cytoreduction  
HU, or HU vs INF Clinical Trial

Worsening symptom burden  
Vascular event, progression  
HU Resistance/ Intolerance

**Consider Ruxolitinib (PV)/ ET ( 2<sup>nd</sup> line or Trial) or  
INF (Trial)/HU if not previously received**

# Proposed Algorithm of Therapy of MPN-MF in 2015

## **N.B.**

Consider Rx for Prevention of Vascular Events in Appropriate Patients (Aspirin & Cyto-reduction)

## **Symptom Quartiles by MPN 10**

**Q1:TSS <8**      **Q3:TSS 18-31**  
**Q2:TSS 8-17**    **Q4:TSS ≥32**

Diagnosis of MPN-MF (Primary, Post ET or Post PV Myelofibrosis)

Calculate DIPSS MF Score & Assess MPN Symptoms (MPN 10)

## **JAK2 Inhibitors**

- Ruxolitinib (Jakafi/Jakavi) (Approved for MF)
- Clinical Trial JAK2 Inhib

## **Anemia Rx**

- Clinical Trials
- IMiD/ Androgens/ EPO
- Splenectomy

Low Risk  
Med S = 185m  
**Symptom Q1-Q2**

Low Risk  
Med S <185m  
**Symptom Q3-Q4**

Intermediate to High Risk  
Med S = 16m (H), 35m (Int 2), 78 (Int 1)  
*Assess role and timing of ALLO SCT (Donor, Risk, Candidate)*  
*ALLO – Urgent, Delayed, Never*

Urgent ALLO

Delayed/Never ALLO

Possible Role Of JAK2 Inhib (Trial) or INF (Trial)

Proceed to ALLO (Possible JAK2 Inhib Prior) (Trial)

JAK2 Inhibitor\*  
\*Unless anemia/cytopenias main problem

JAK2 Single Agent Failure  
Refractory Cytopenias

Observation vs INF (Trial)

Clinical Trials

- Ruxo Combination
- Non Ruxo JAK2
- New Targets

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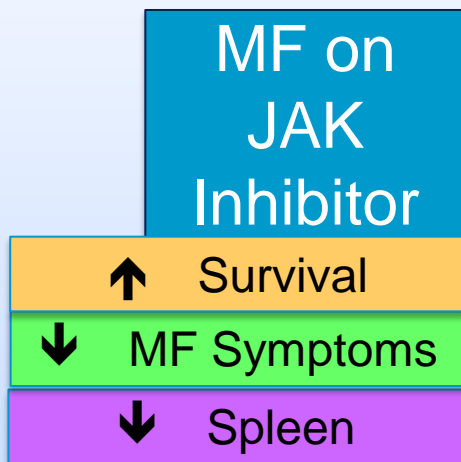
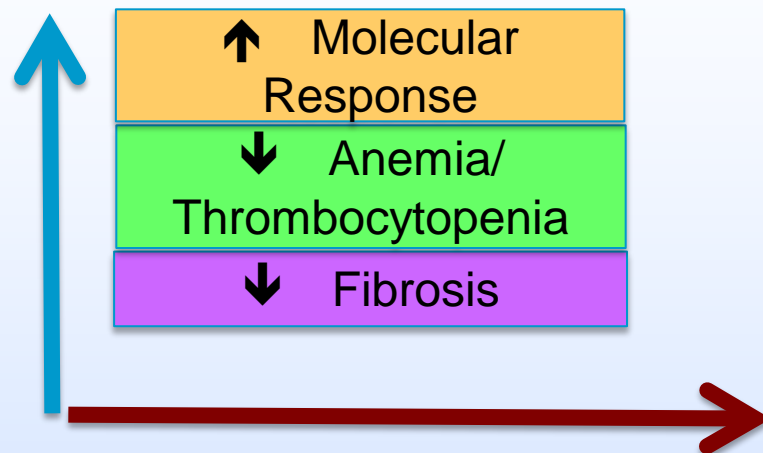
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6. Understand complex assessment of MPN “risk”, and comorbidities
5. Understand new response criteria, and need for their validation
4. Optimizing the timing and utilization of stem cell transplant
3. Optimizing the utilization of current available agents
- 2. Thoughtful analysis of combination MPN therapeutic approaches**

Clinical Status



# Myelofibrosis – Rx Opportunities



MF on  
JAK  
Inhibitor

Dx of MF



# Interferons in MPNs – Evolving Footprint

Peginterferon alpha-2a

**MPD – RC 112**  
***PEG IFN vs HU***  
***(Front Line)***  
High Risk ET/PV  
NCT01258856

**MPD-RC 111**  
***PEG IFN***  
***(2<sup>nd</sup> Line)***  
High Risk ET/PV - SVT  
NCT01259817

Pegylated P Interferon alpha-2b  
*AOP 2014 P1101*

**PROUD - PV**  
***AOP2014/P1101 vs HU***  
***(Front Line)***  
High Risk PV  
NCT01949805

# LANDSCAPE MPN Clinical Trials 2015

## ET/PV

PEG INF vs HU  
MPD-RC 112  
NCT01258856

PEG INF (2<sup>nd</sup> Line)  
NCT01259817

P1101 vs HU (PV)  
AOP  
NCT01949805

Ruxolitinib (PV)  
Response 1,2  
Relief Trials

Momelotinib  
NCT01998828

Givinostat (HDAC)  
NCT0190432

## Single Agent MF

Pacritinib v BAT  
(PERSIST1-PH III)  
NCT01773187

Pacritinib v. BAT  
(PERSIST2- PH III)  
NCT02055781

Momelotinib v. Rux  
(PH III)  
NCT01969838

Momelotinib vs.  
BAT (PH III)  
NCT012101268

NS-018 (PH II)  
NCT01423851

Imetelstat

PF04449913 (Smo)  
NCT02226172

## Combination MF Rux Plus -

Lenalidomide  
NCT013575140

Pomalidomide  
NCT01644110

Danazol  
NCT01732445

Azacitidine  
NCT01787487

Decitabine  
NCT02076191

PRM-151  
NCT01981850

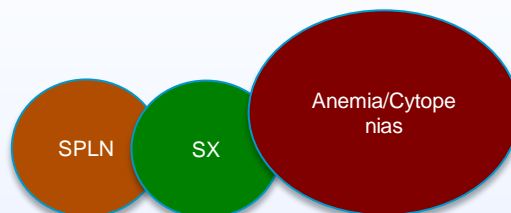
Panobinostat  
NCT01693601  
NCT01433445

BKM 120 (Pi3K)  
NCT01730248

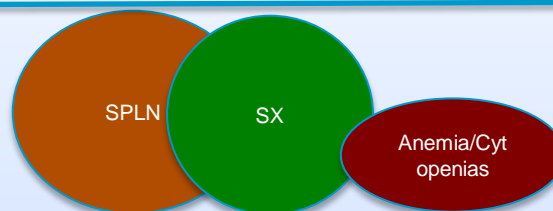
LDE 225 (HH)  
NCT01787552

# Different phenotypes in setting of JAK inhibition

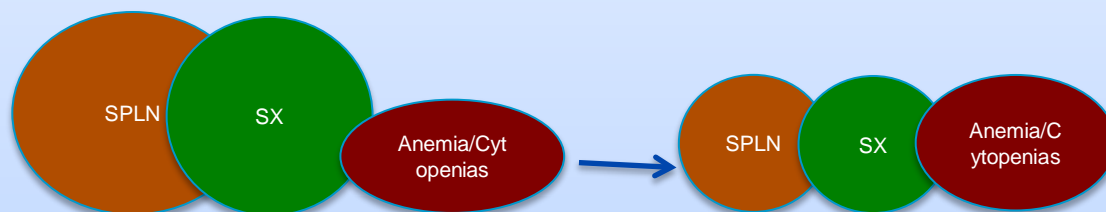
**Primary anemia phenotype**



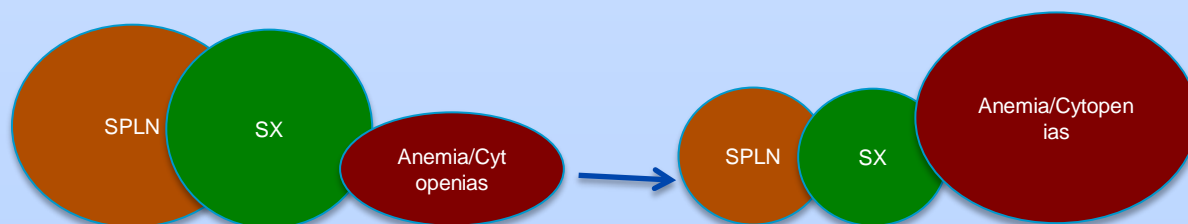
**Proliferative phenotype**



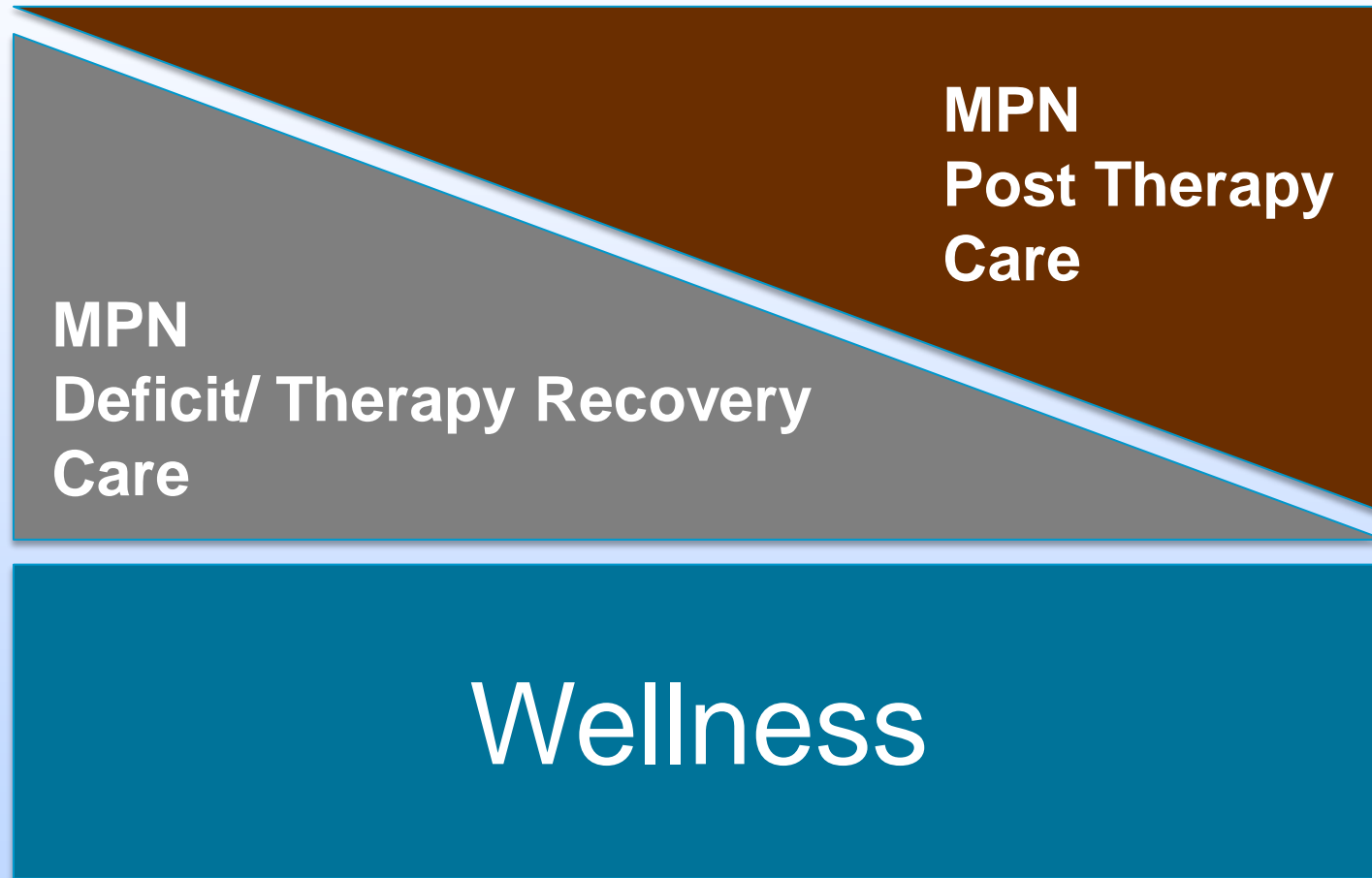
**Good ruxolitinib response**



**Ruxolitinib response with anemia a problem**



# MPN Patient Supportive and Survivorship Care

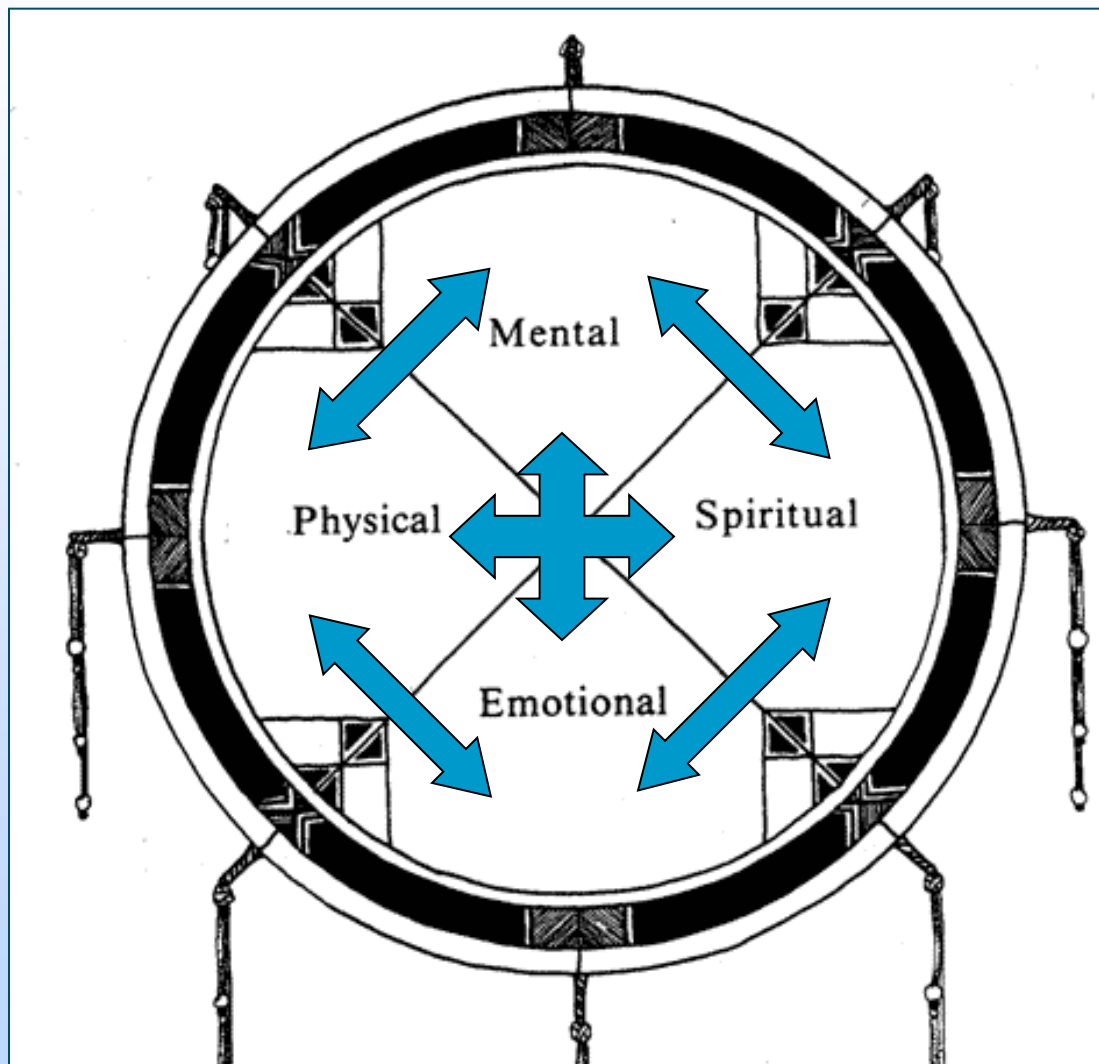


# What Should We Expect From MPN Therapy?

## *Top 10 ways we better match therapy and patients*

10. Understand that not all MPN patients are impacted the same
9. Understand the spectrum of symptoms MPN patients face
8. Understand impact of symptom clusters, and gender effect on MPN patients
7. Understand the complex issue of MPN fatigue, and possible mood disorders
6. Understand complex assessment of MPN “risk”, and comorbidities
5. Understand new response criteria, and need for their validation
4. Optimizing the timing and utilization of stem cell transplant
3. Optimizing the utilization of current available agents
2. Thoughtful analysis of combination MPN therapeutic approaches
- 1. Never lose the forest through the trees**

# Medicine Wheel of Health “Integrative Medicine”



# Being a Blood Disease Survivor

## *Top 10 List*

---

10. Learn about your disease
9. Make friends with facing a similar challenge
8. Be your own best advocate
7. Capture what is discussed at doctors visits (friends/ recorder)
6. Take care of your caregiver
5. Take care of the rest of your health
4. Eat in a healthy way (most of the time😊)
3. Exercise
2. Live every moment
1. Focus on relationships

# Quotes from Erma Bombeck

## Written as she was dying from Cancer

- If I had my life to live over I would...
- Have gone to bed when I was sick instead of pretending the earth would go into a holding pattern if I weren't there for a day



I would have...

- Burned the pink candle sculpted like a rose before it melted in storage

I would have...

- Sat on the lawn with my grass stains

I would have...

- Talked less and listened more

I would have...

- Invited friends over to dinner even if the carpet was stained or the sofa faded

I would have...

- Shared more of the responsibility carried by my husband

I would have...

- Never have insisted the car windows be rolled up on a summer day because my hair had just been teased and sprayed

I would have...

- Don't worry about who doesn't like you, who has more or who is doing what. Instead, cherish the relationships we have with those who do love us.

I would have...

- Never have bought anything just because it was practical, wouldn't show soil, or was guaranteed to last a lifetime



I would have...

- Instead of wishing away nine months of pregnancy, I'd have cherished every moment and realized that the wonderment growing inside me was the only chance in life to assist God in a miracle

I would have...

- Taken the time to listen to my grandfather ramble about his youth

I would have...

- Cried and laughed less while watching TV and more while watching life

I would have...

- But mostly, given another shot at life, I would seize every minute... look at it and really see it... live it and never give it back. Stop sweating the small stuff.





# MAYO CLINIC

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