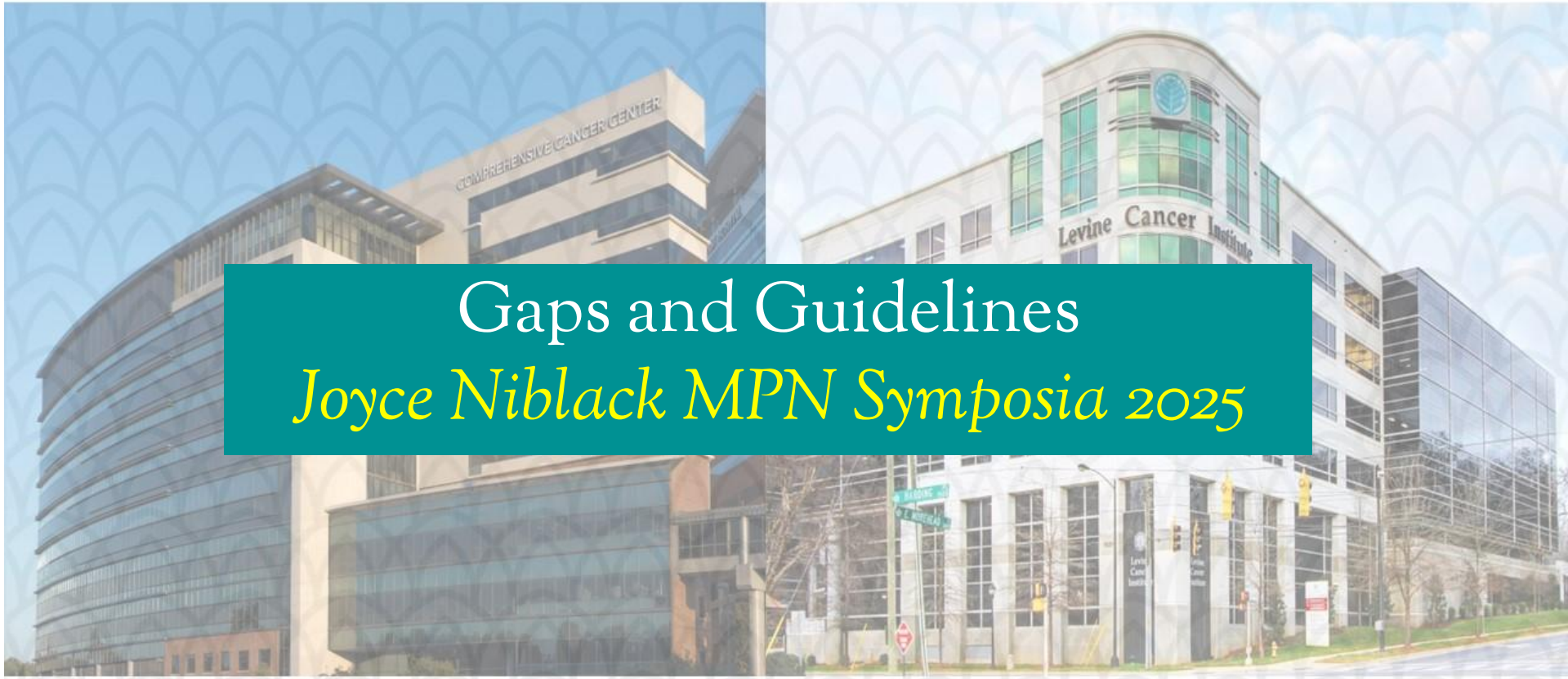
Atrium Health

Wake Forest University School of Medicine

NCI Comprehensive Cancer Center
A Cancer Center Designated by the National Cancer Institute

WE WORK AS ONE



Gaps and Guidelines

Joyce Niblack MPN Symposia 2025

Ruben A. Mesa, MD, FACP
President, Enterprise Cancer Service Line Atrium Health
Executive Director Atrium Health Wake Forest Baptist Comprehensive Cancer Center
Enterprise Senior Vice President Atrium Health
Vice Dean for Cancer Programs – Wake Forest School of Medicine
Professor of Medicine
Ruben.Mesa@Atriumhealth.org

Disclosures – Ruben Mesa, MD

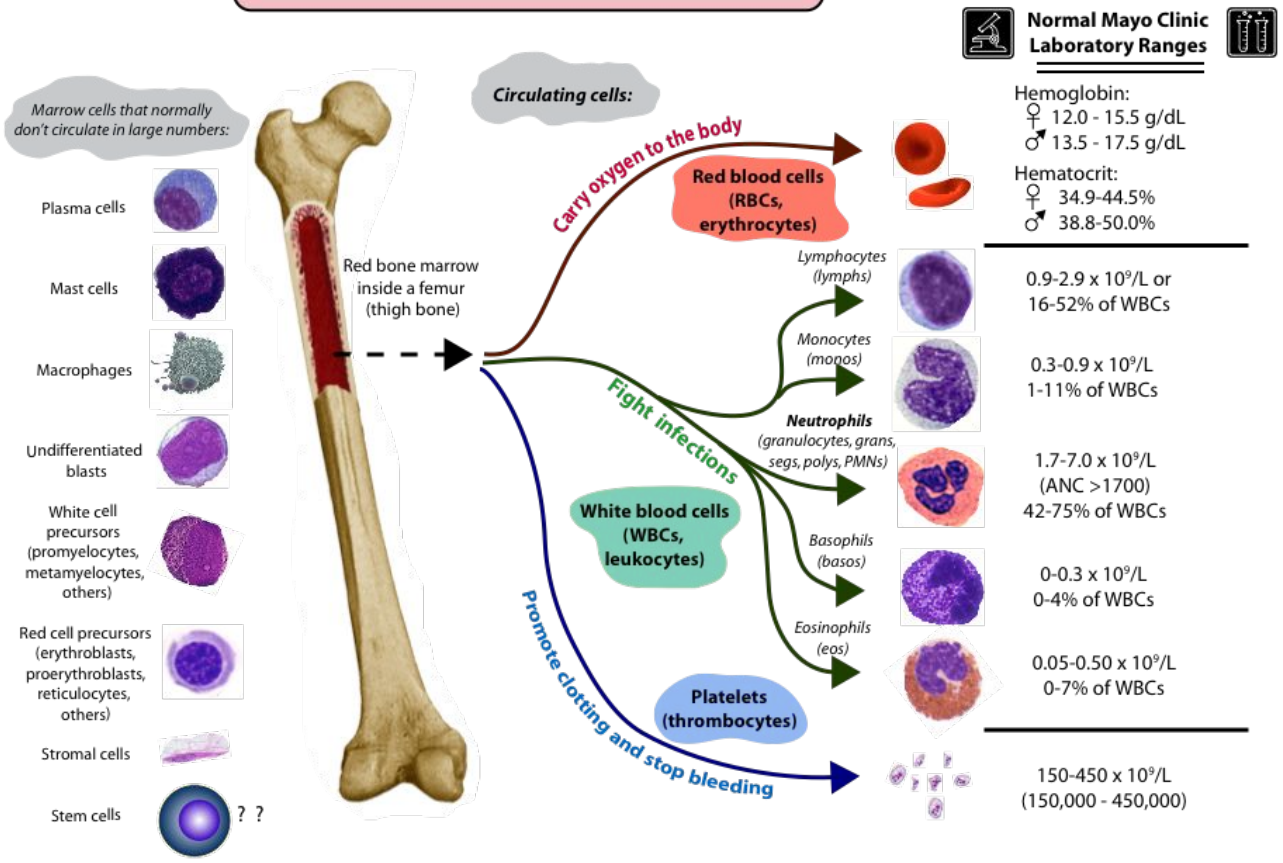
- Consultant (Honoraria) over past 3 years
  - Novartis
  - Sierra Oncology
  - Genentech
  - Sierra
  - Blueprint
  - Geron
  - Telios
  - CTI
  - Incyte
  - BMS
  - Abbvie
  - GSK

- Research Support
  - Incyte

MPNs – How did we get here?

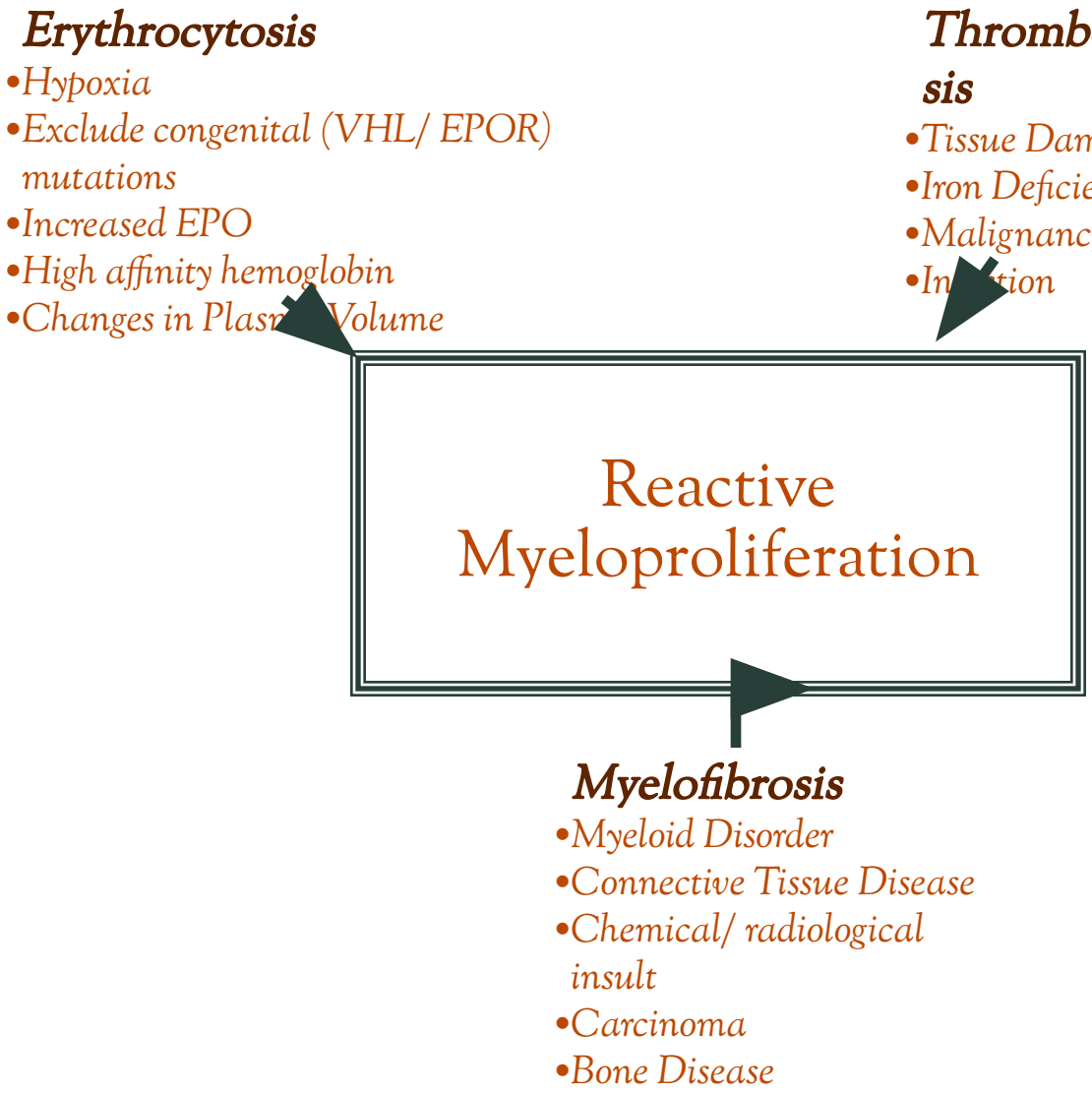
- MPNs pre 2005 – A Brief History
- Learning about MPN Biology
- Goals and Targets
- ET
- PV
- MF
- Putting it all Together

Human Blood and Bone Marrow



Synonyms are in parentheses. Normal laboratory values may differ in other laboratories, hospitals and clinics, even within the Mayo Health System. In some circumstances it may be normal to see a small proportion of bands, myelocytes, or metamyelocytes in the blood (all neutrophil precursors.)

by DP Steensma 2005, for the Mayo Clinic Division of Hematology



Mays Cancer Center
UT Health San Antonio MD Anderson Cancer Center

Myeloproliferative Disorders vs. Syndromes vs. Neoplasm

William Dameshek
1900-1969

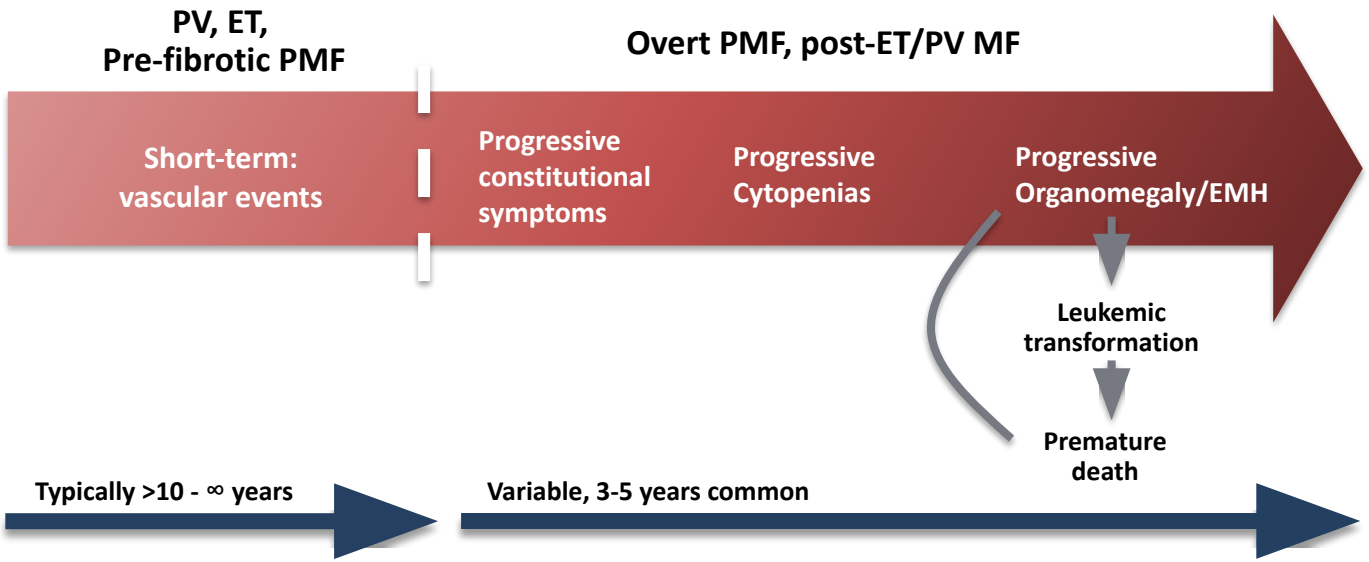
Blood 1951,6:372-375

EDITORIAL

Some Speculations on the Myeloproliferative Syndromes

- *Chronic Granulocytic Leukemia*
- *Polycythemia Vera (PV)*
- *Agnogenic Myeloid Metaplasia*
- *Megakaryocytic Leukemia*
- *Erythroleukemia*
- *?PNH 1969*

Natural History of MPNs



- NCCN Guidelines. Myeloproliferative Neoplasms. V1.2020

History of MPN Therapy

1) Decrease risk of blood clots or bleeding in ET and PV
   - Control hematocrit
   - Use aspirin?
   - Selective use of cytoreductive therapy
     - Hydroxyurea
     - Other cytoreductive – P-32, busulfan, pipobroman, chlorambucil

2) Therapy of myelofibrosis related to disease burden
   - Splenomegaly (surgery, radiation, hydroxyurea, other chemotherapy)
   - Anemia (ESAs, prednisone, thalidomide (and cousins – lenalidomide, pomalidomide), androgens)
   - Symptoms (really nothing)

3) Stem Cell transplant for "young" and "high risk" myelofibrosis

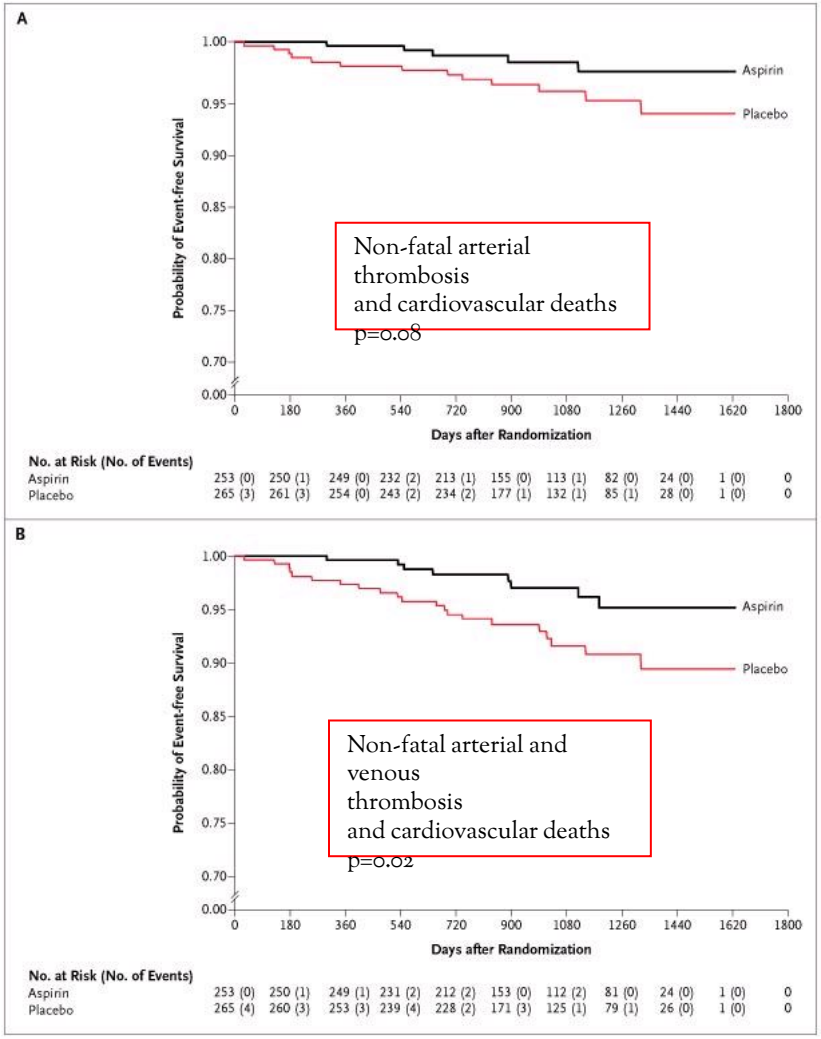
Efficacy and Safety of Low Dose Aspirin In PV

Landolfi et al.

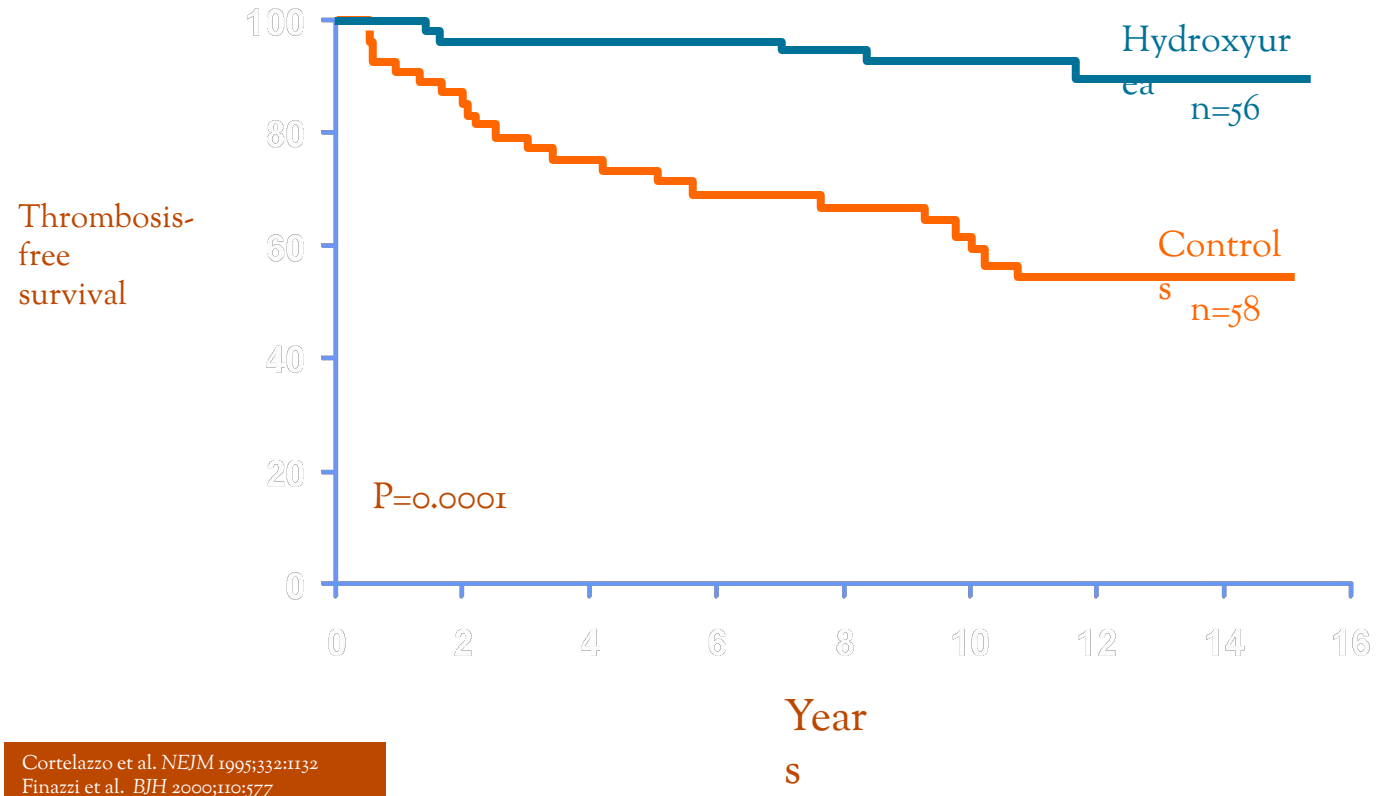
Multicenter European study.

NEJM 2004;350:114

- 518 patients
- mean f/u 3 years
- more smokers in the ASA arm
- ASA 100 mg enteric-coated
- Overall mortality not different
- NS reduction in major thrombosis
- Major bleeding episodes not different



HU-Treatment Effect in High-Risk ET



Cortelazzo et al. *NEJM* 1995;332:1132
Finazzi et al. *BJH* 2000;110:577

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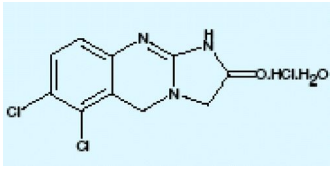
Published Anagrelide Experience



Study	N	ET	PV	CML	Other	Impact
Silverstein 1988	*20*	*17*	*2*	*1*	*0*	Initial Trial
ASG 1992	*577*	*355*	*68*	*114*	*60*	Response rate 79%
Petit 1997	*942*	*546*	*113*	*179*	*108*	Basis for FDA Approval
Storen 2001	*35*	*35*	*0*	*0*	*0*	Long Term Safety
Fruchtman 2005	*3590*	*2425*	*506*	*561*	*458*	Basis for EMEA License
Harrison 2005	*805*	*809*	*0*	*0*	*0*	PT 1 Trial

PT 1 Study: HU vs Anagrelide in High Risk ET

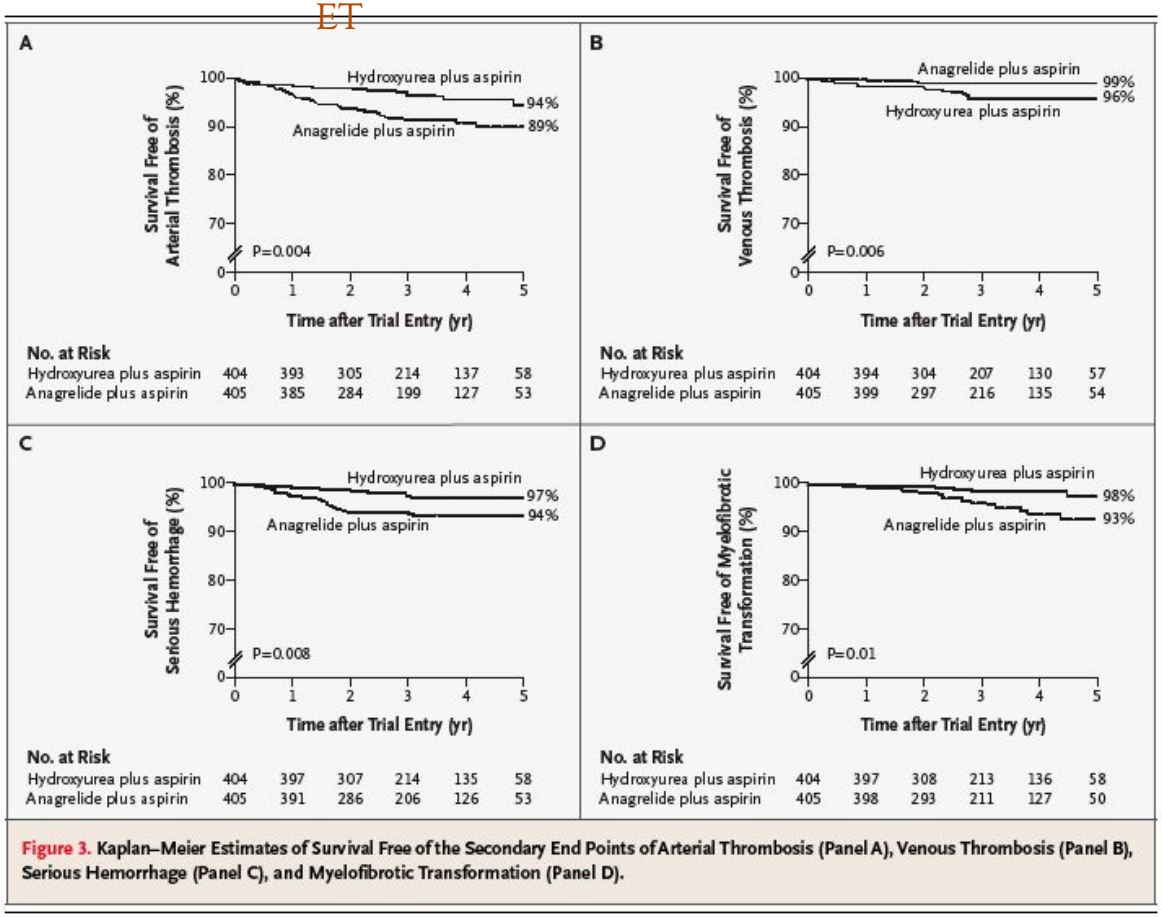


Figure 3. Kaplan–Meier Estimates of Survival Free of the Secondary End Points of Arterial Thrombosis (Panel A), Venous Thrombosis (Panel B), Serious Hemorrhage (Panel C), and Myelofibrotic Transformation (Panel D).

Harrison et. al. NEJM 2005;353:33-45

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MPN Patient Meetings

1999 - Present

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- MPNs pre 2005 – A Brief History
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JAK2^{V617F}

letters to nature

Jam

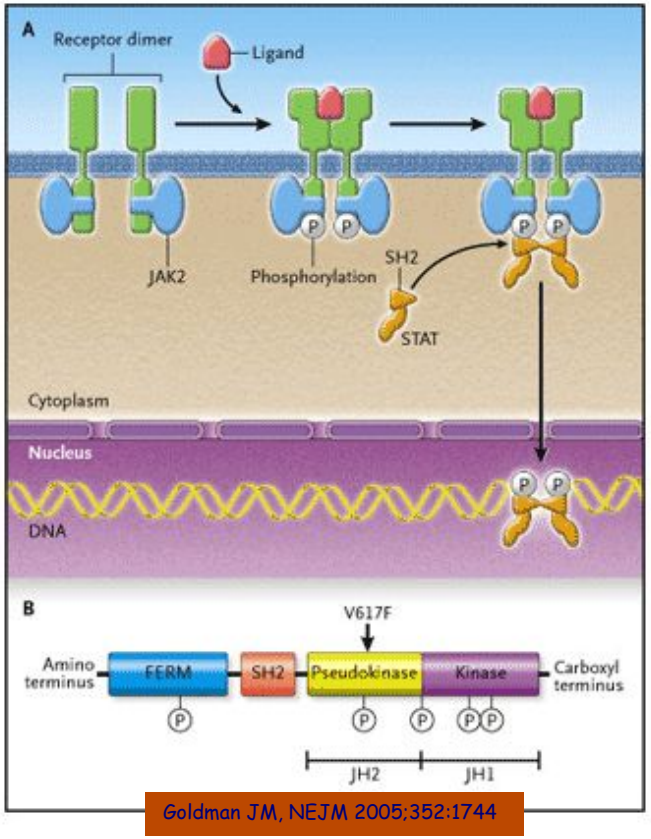
A unique clonal *JAK2* m
leading to constitutive s
causes polycythaemia v

The NEW ENGL

ORIG

Kralovics et. al.,

A Gain-of-Fun
in Myeloprc



Goldman JM, NEJM 2005;352:1744

ARTICLE

ase JAK2 in polycythemia
myeloid metaplasia

65:1054

ine kinase JAK2 in human

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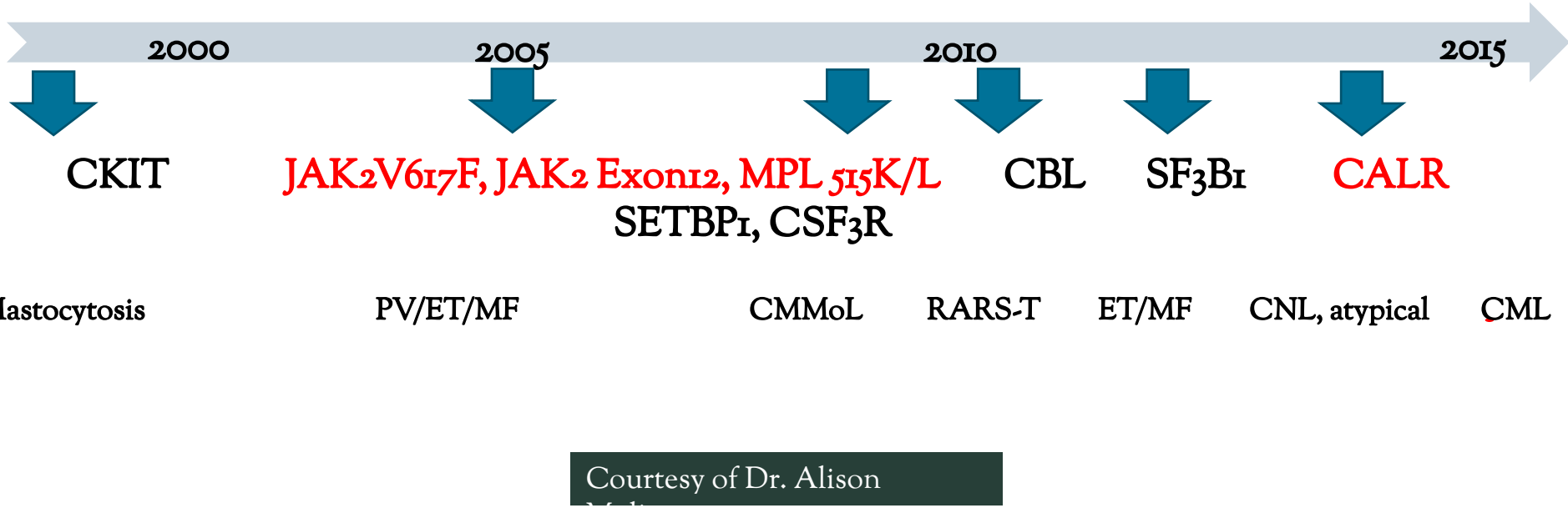
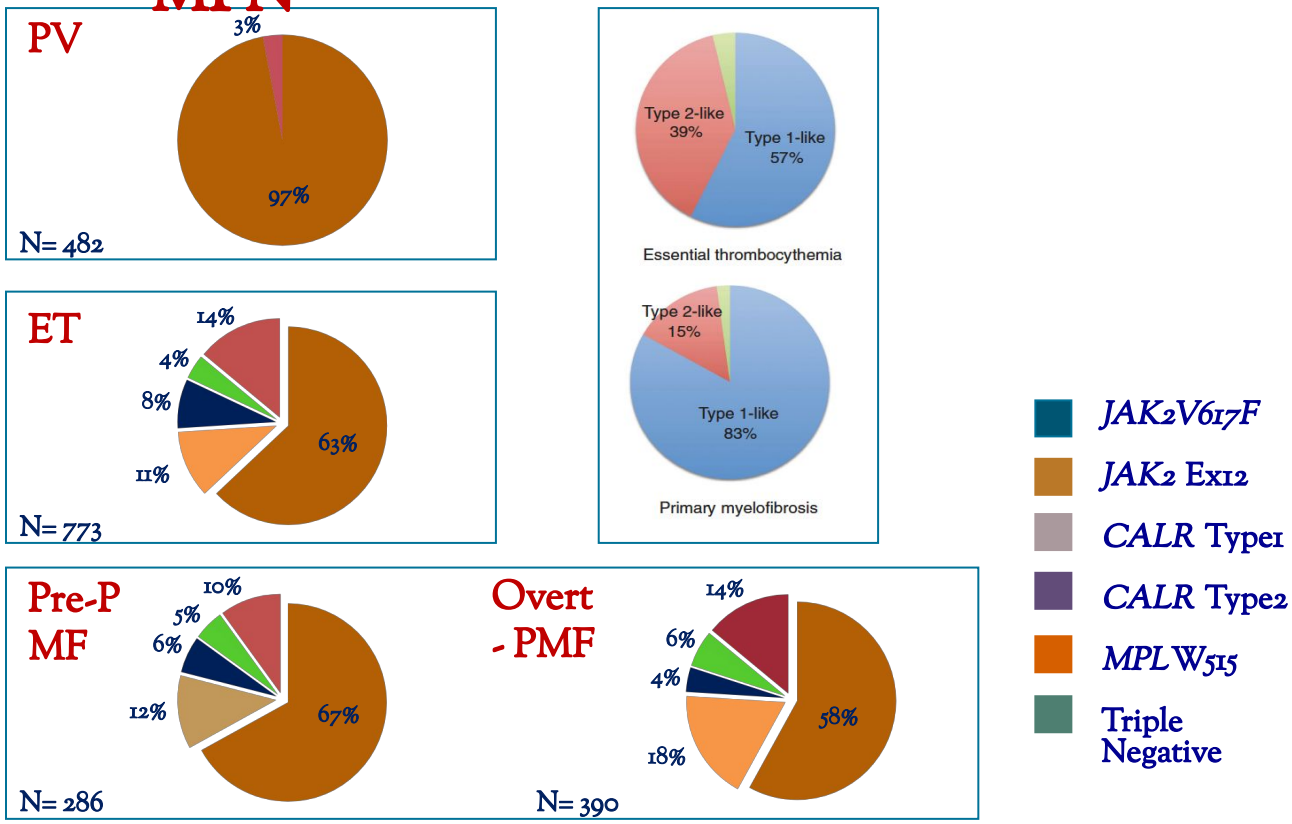
Timeline of MPN Driver Mutation Discoveries

Driver Mutations and Disease Phenotypes



Courtesy of Dr. Alison

Spectrum of Driver Mutations in MPN



Pietra D et al, Leukemia 2016; 30:1431-8;

PV, ET: Database of CRIMM; Florence; PMF: Database AGIMM; Guglielmelli P et al, Blood 2017; 129:3227-36.

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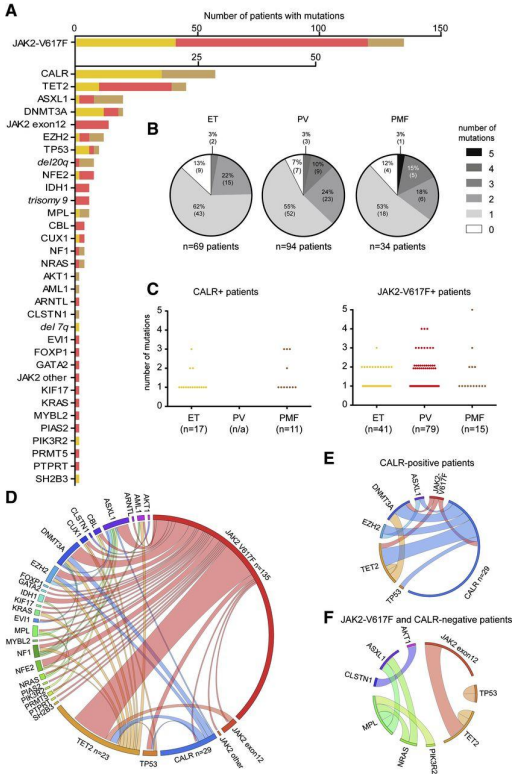
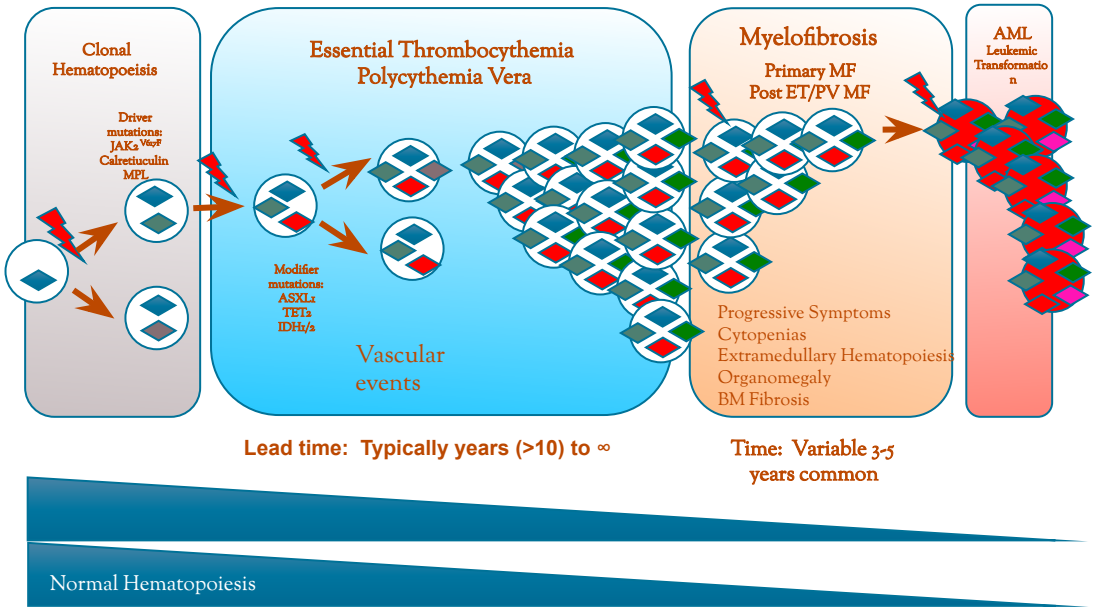
Frequency and distribution of mutations in patients with MPN. (A) Number of patients with mutations in the genes is indicated.



Pontus Lundberg et al. Blood 2014;123:2220-2228

©2014 by American Society of Hematology

Natural History of MPNs



MPNs – How did we get here?

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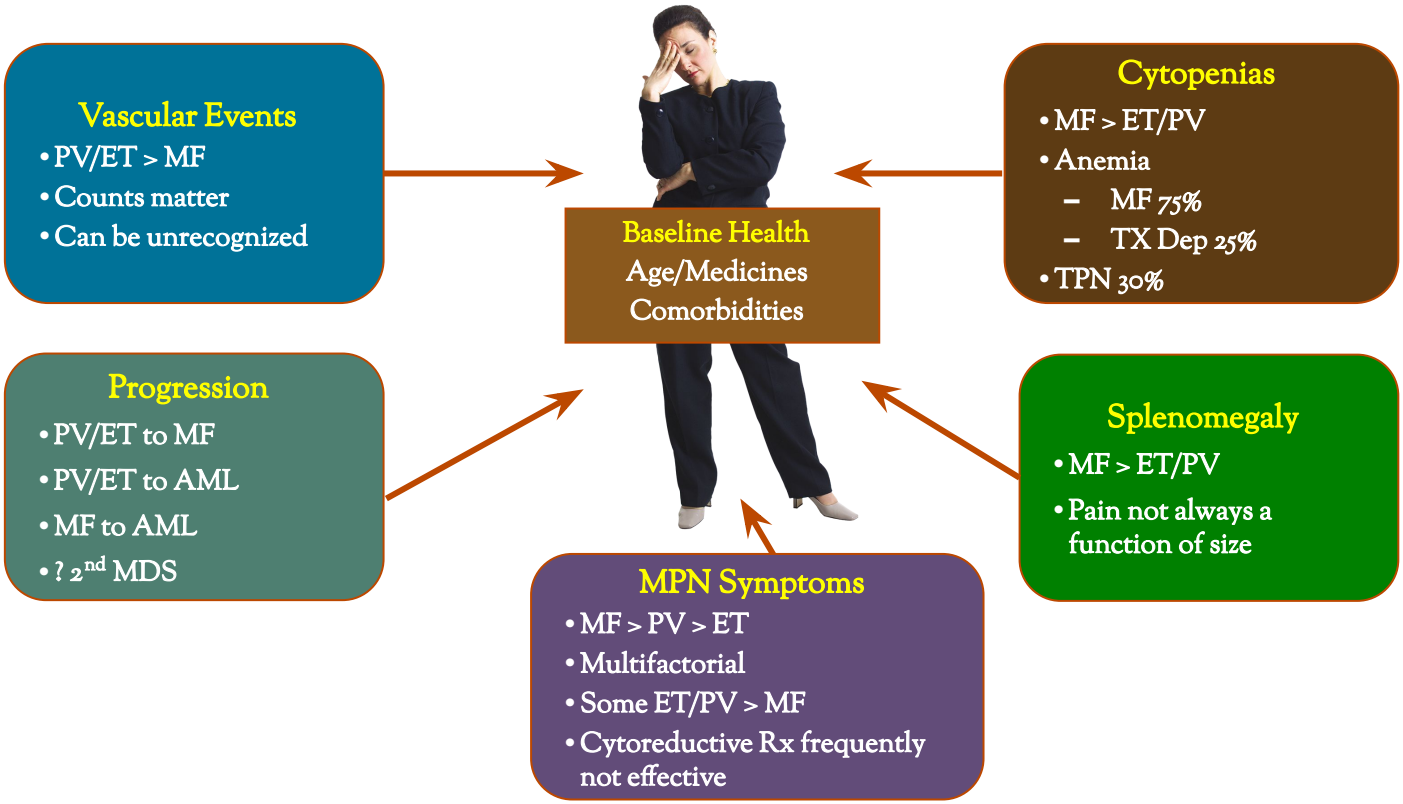
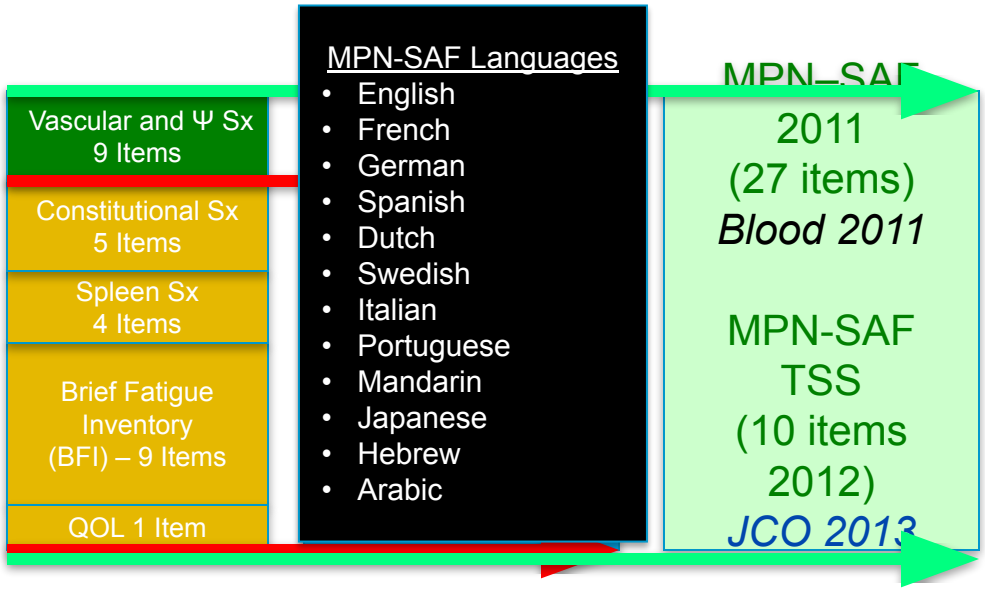
Assessing MPN Burden

WHO Diagnosis Does Not Tell Whole Story

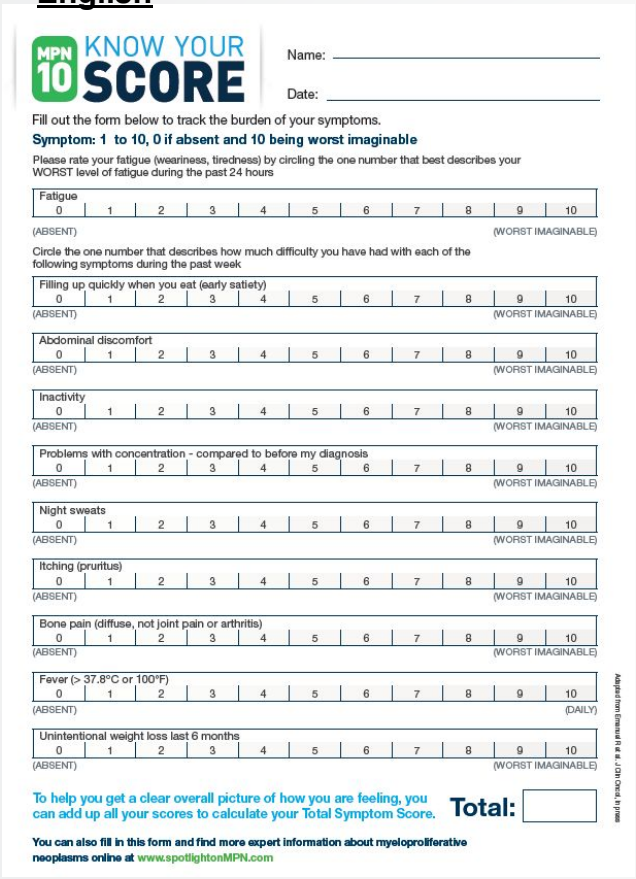


Evolution of MPN Symptom Assessment Tools



MPN SAF TSS "MPN10" in Many Languages

English



MPN 10 KNOW YOUR SCORE

Name: _____

Date: _____

Fill out the form below to track the burden of your symptoms.

Symptom: 1 to 10, 0 if absent and 10 being worst imaginable

Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your WORST level of fatigue during the past 24 hours

Fatigue											
0	1	2	3	4	5	6	7	8	9	10
(ABSENT)										(WORST IMAGINABLE)

Circle the one number that describes how much difficulty you have had with each of the following symptoms during the past week

Filling up quickly when you eat (early satiety)										
0	1	2	3	4	5	6	7	8	9	10
(ABSENT)										(WORST IMAGINABLE)

Abdominal discomfort										
0	1	2	3	4	5	6	7	8	9	10
(ABSENT)										(WORST IMAGINABLE)

Inactivity										
0	1	2	3	4	5	6	7	8	9	10
(ABSENT)										(WORST IMAGINABLE)

Problems with concentration - compared to before my diagnosis										
0	1	2	3	4	5	6	7	8	9	10
(ABSENT)										(WORST IMAGINABLE)

Night sweats										
0	1	2	3	4	5	6	7	8	9	10
(ABSENT)										(WORST IMAGINABLE)

Itching (pruritus)										
0	1	2	3	4	5	6	7	8	9	10
(ABSENT)										(WORST IMAGINABLE)

Bone pain (diffuse, not joint pain or arthritis)										
0	1	2	3	4	5	6	7	8	9	10
(ABSENT)										(WORST IMAGINABLE)

Fever (> 37.8°C or 100°F)										
0	1	2	3	4	5	6	7	8	9	10
(ABSENT)										(DAILY)

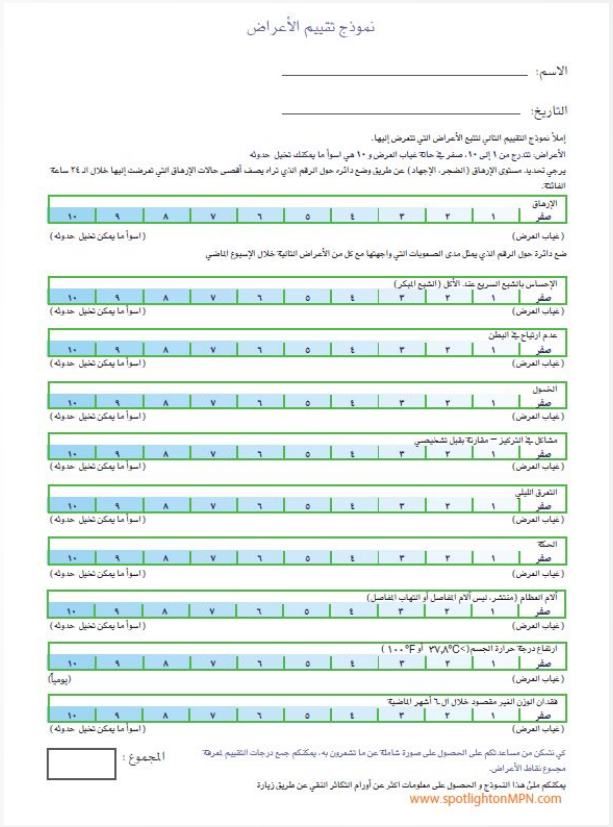
Unintentional weight loss last 6 months										
0	1	2	3	4	5	6	7	8	9	10
(ABSENT)										(WORST IMAGINABLE)

To help you get a clear overall picture of how you are feeling, you can add up all your scores to calculate your Total Symptom Score. **Total:** ☐

You can also fill in this form and find more expert information about myeloproliferative neoplasms online at www.spotlightonMPN.com

Adapted from Emanuel PJ et al. J Clin Oncol. In press

Arabic



نموذج تقييم الأعراض

الاسم: _____

التاريخ: _____

إملأ نموذج التقييم التالي لتتبع الأعراض التي تتعرض إليها.

الأعراض، تتدرج من ١ إلى ١٠، صفر= حالة غياب العرض و ١٠ هي أسوأ ما يمكنك تخيل حدوثه

يرجى تحديد مستوى الإرهاق (الضجر، الإجهاد) عن طريق وضع دائرة حول الرقم الذي تراه يصف أقصى حالات الإرهاق التي تعرضت إليها خلال الـ ٢٤ ساعة الفائتة:

الإرهاق										
صفر	١	٢	٣	٤	٥	٦	٧	٨	٩	١٠
(غياب العرض)										(أسوأ ما يمكن تخيل حدوثه)

ضع دائرة حول الرقم الذي يمثل مدى الصعوبات التي واجهتها مع كل من الأعراض التالية خلال الإسبوع الماضي.

الإحساس بالشبع السريع عند الأكل (الشبع المبكر)										
صفر	١	٢	٣	٤	٥	٦	٧	٨	٩	١٠
(غياب العرض)										(أسوأ ما يمكن تخيل حدوثه)

عدم ارتياح في البطن										
صفر	١	٢	٣	٤	٥	٦	٧	٨	٩	١٠
(غياب العرض)										(أسوأ ما يمكن تخيل حدوثه)

الخمول										
صفر	١	٢	٣	٤	٥	٦	٧	٨	٩	١٠
(غياب العرض)										(أسوأ ما يمكن تخيل حدوثه)

مشاكل في التركيز – مقارنة بقبل تشخيصي										
صفر	١	٢	٣	٤	٥	٦	٧	٨	٩	١٠
(غياب العرض)										(أسوأ ما يمكن تخيل حدوثه)

التعرق الليلي										
صفر	١	٢	٣	٤	٥	٦	٧	٨	٩	١٠
(غياب العرض)										(أسوأ ما يمكن تخيل حدوثه)

الحكة										
صفر	١	٢	٣	٤	٥	٦	٧	٨	٩	١٠
(غياب العرض)										(أسوأ ما يمكن تخيل حدوثه)

آلام العظام (منتشر، ليس آلام المفاصل أو التهاب المفاصل)										
صفر	١	٢	٣	٤	٥	٦	٧	٨	٩	١٠
(غياب العرض)										(أسوأ ما يمكن تخيل حدوثه)

ارتفاع درجة حرارة الجسم(<٣٧,٨°C أو ١٠٠°F)										
صفر	١	٢	٣	٤	٥	٦	٧	٨	٩	١٠
(غياب العرض)										(يومياً)

فقدان الوزن الغير مقصود خلال الـ٦ أشهر الماضية										
صفر	١	٢	٣	٤	٥	٦	٧	٨	٩	١٠
(غياب العرض)										(أسوأ ما يمكن تخيل حدوثه)

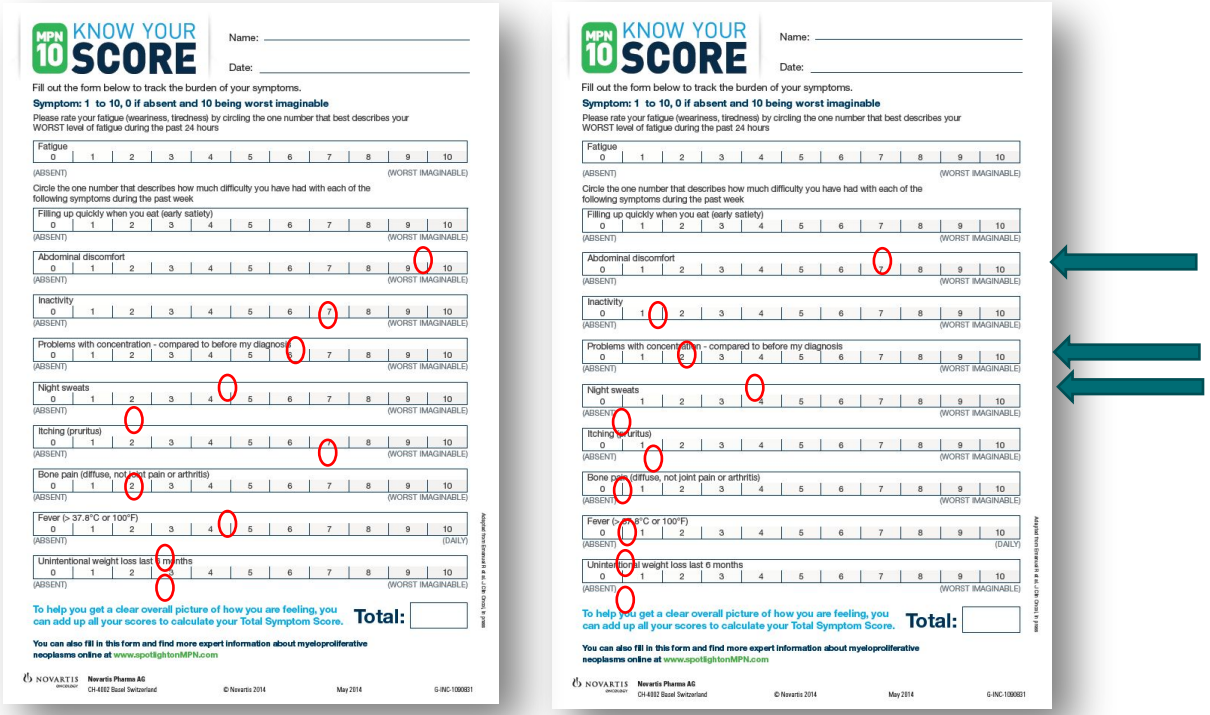
كي نتمكن من مساعدتكم على الحصول على صورة شاملة عن ما تشعرون به، يمكنكم جمع درجات التقييم لمعرفة مجموع تفاقم الأعراض.

المجموع: ☐

يمكنكم ملئ هذا النموذج و الحصول على معلومات اكثر عن أورام النكاثر النقي عن طريق زيارة

www.spotlightonMPN.com

MPN10: allows visual assessment



KNOW YOUR MPN10 SCORE

Name: _____

Date: _____

Fill out the form below to track the burden of your symptoms.

Symptom: 1 to 10, 0 if absent and 10 being worst imaginable

Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your WORST level of fatigue during the past 24 hours

Fatigue 0 1 2 3 4 5 6 7 8 9 10 (ABSENT) (WORST IMAGINABLE)

Circle the one number that describes how much difficulty you have had with each of the following symptoms during the past week

Filling up quickly when you eat (early satiety) 0 1 2 3 4 5 6 7 8 9 10 (ABSENT) (WORST IMAGINABLE)

Abdominal discomfort 0 1 2 3 4 5 6 7 8 9 10 (ABSENT) (WORST IMAGINABLE)

Inactivity 0 1 2 3 4 5 6 7 8 9 10 (ABSENT) (WORST IMAGINABLE)

Problems with concentration - compared to before my diagnosis 0 1 2 3 4 5 6 7 8 9 10 (ABSENT) (WORST IMAGINABLE)

Night sweats 0 1 2 3 4 5 6 7 8 9 10 (ABSENT) (WORST IMAGINABLE)

Itching (pruritus) 0 1 2 3 4 5 6 7 8 9 10 (ABSENT) (WORST IMAGINABLE)

Bone pain (diffuse, not joint pain or arthritis) 0 1 2 3 4 5 6 7 8 9 10 (ABSENT) (WORST IMAGINABLE)

Fever (> 37.8°C or 100°F) 0 1 2 3 4 5 6 7 8 9 10 (ABSENT) (DAILY)

Unintentional weight loss last 6 months 0 1 2 3 4 5 6 7 8 9 10 (ABSENT) (WORST IMAGINABLE)

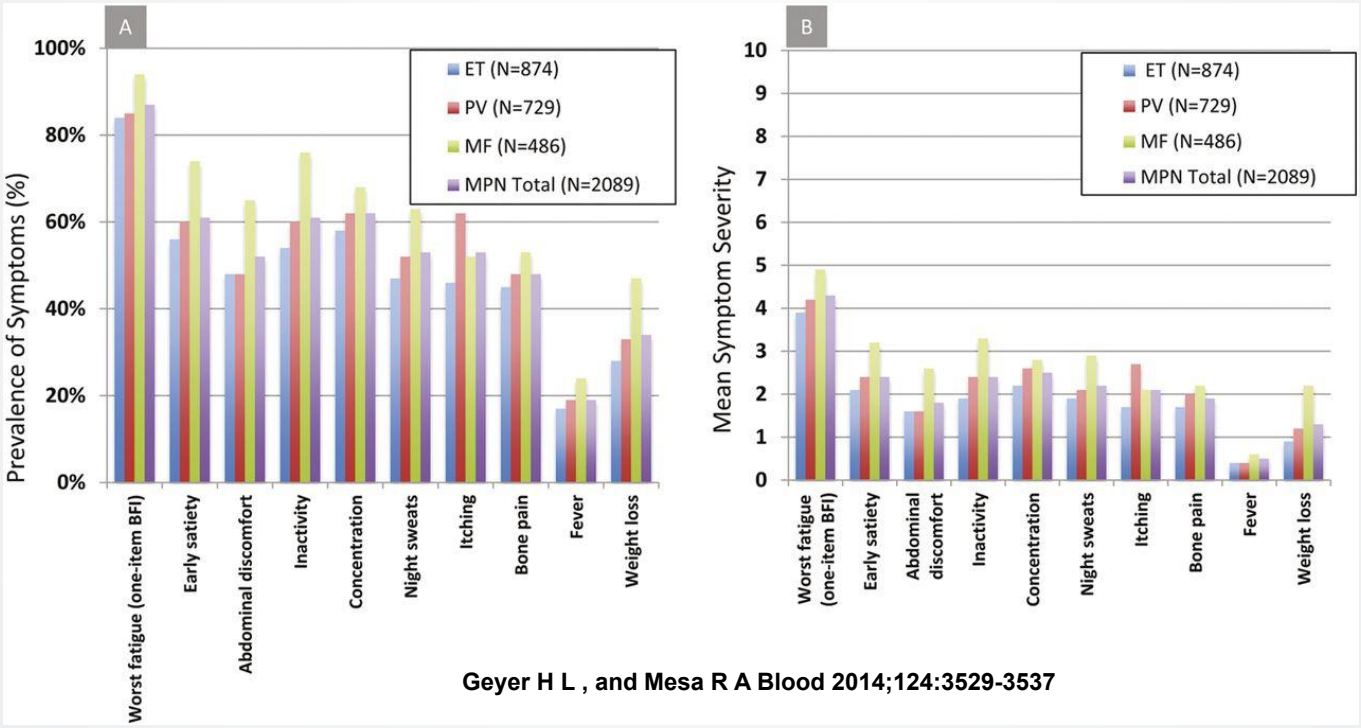
To help you get a clear overall picture of how you are feeling, you can add up all your scores to calculate your Total Symptom Score. **Total:**

You can also fill in this form and find more expert information about myeloproliferative neoplasms online at www.spotlightonMPN.com

NOVARTIS Novartis Pharma AG CH-4002 Basel Switzerland © Novartis 2014 May 2014 G-INC-1006931

1. Emanuel RM, et al. *J Clin Oncol.* 2012;30:4098-4103.

Classic Signs and Symptoms of MPNs



Geyer H L , and Mesa R A Blood 2014;124:3529-3537

What is MPN Symptom Burden in Patients vs. General Population?
MOSAICC Population Vs. Controls

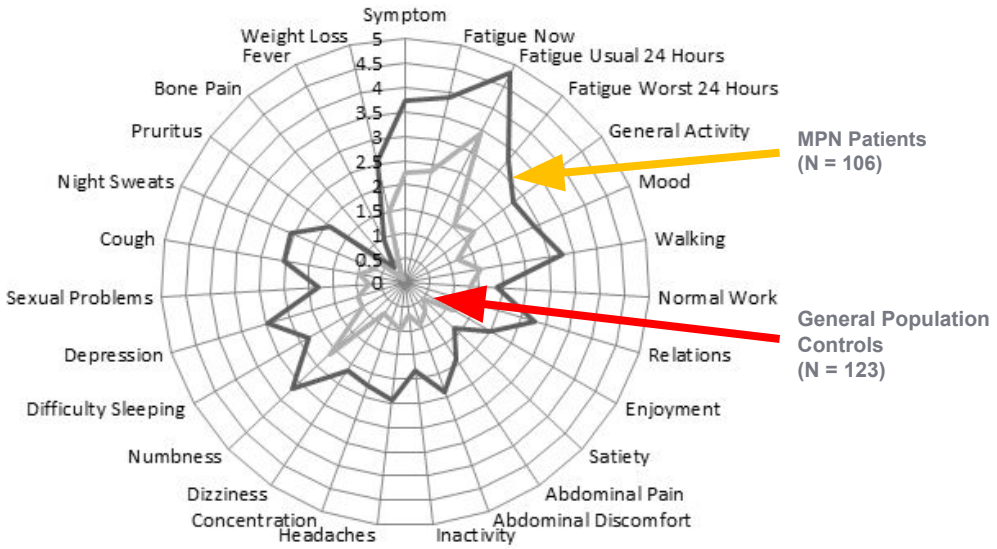
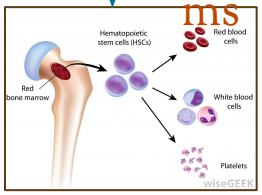


Image courtesy of Ruben A. Mesa, MD

Anderson et. al. ASH 2015

What do symptoms tell us about MPN Biology?

MPN Symptoms



?

Mood Disorders
Anxiety over Uncertainty

Cytokine Driven Symptoms
Spleen/ Inflammation

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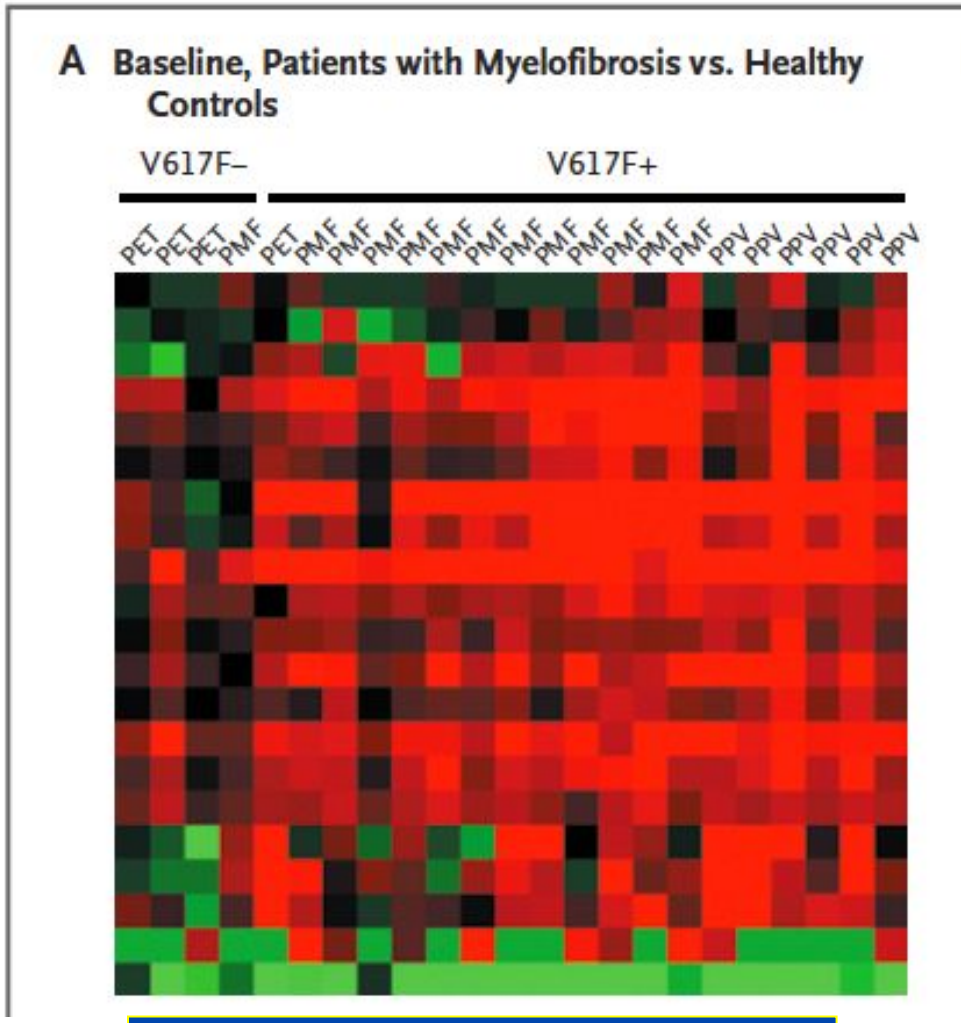
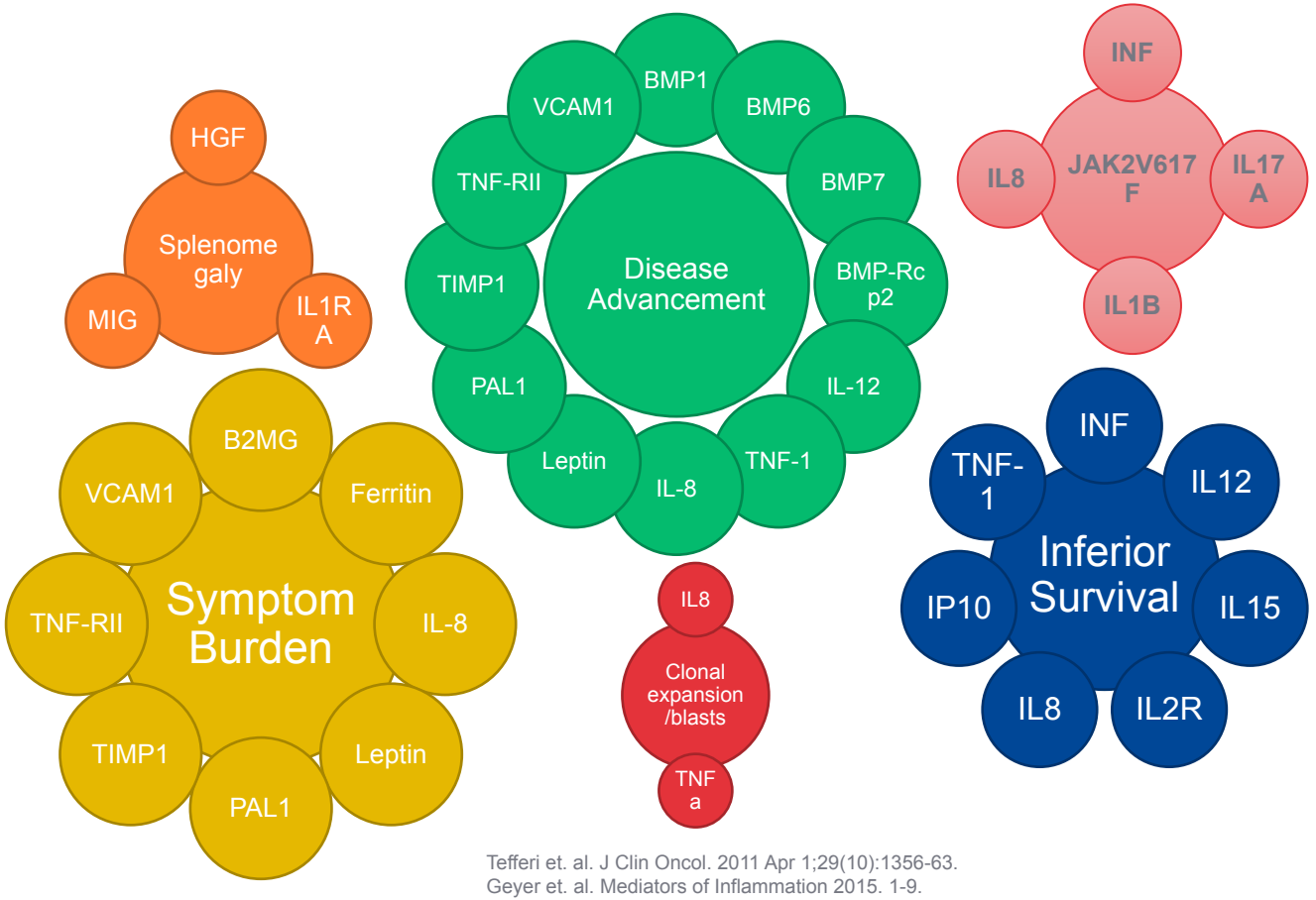


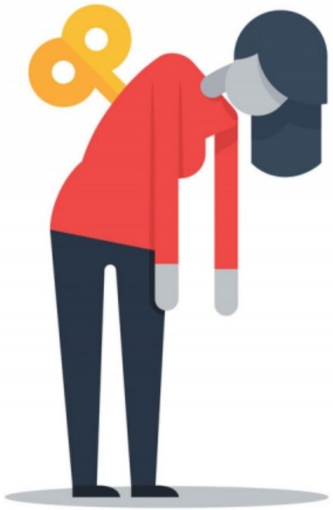
S. Verstovsek, H. Kantarjian, R. Mesa, et. al. NEJM 2010;363:1117-27

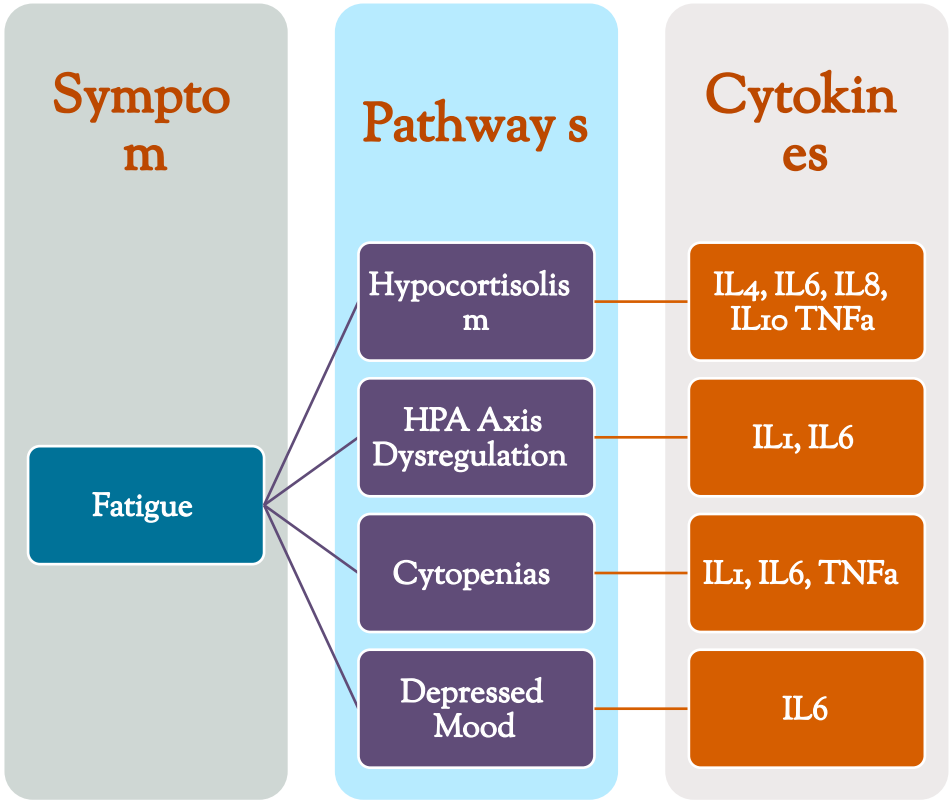
Inflammatory Cytokines and Chemokines in the MPNs



Tefferi et. al. J Clin Oncol. 2011 Apr 1;29(10):1356-63.
Geyer et. al. Mediators of Inflammation 2015. 1-9.

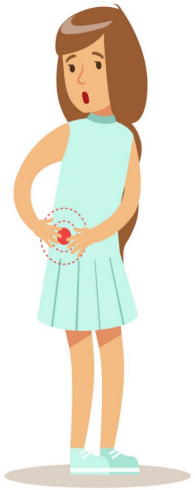
Fatigue

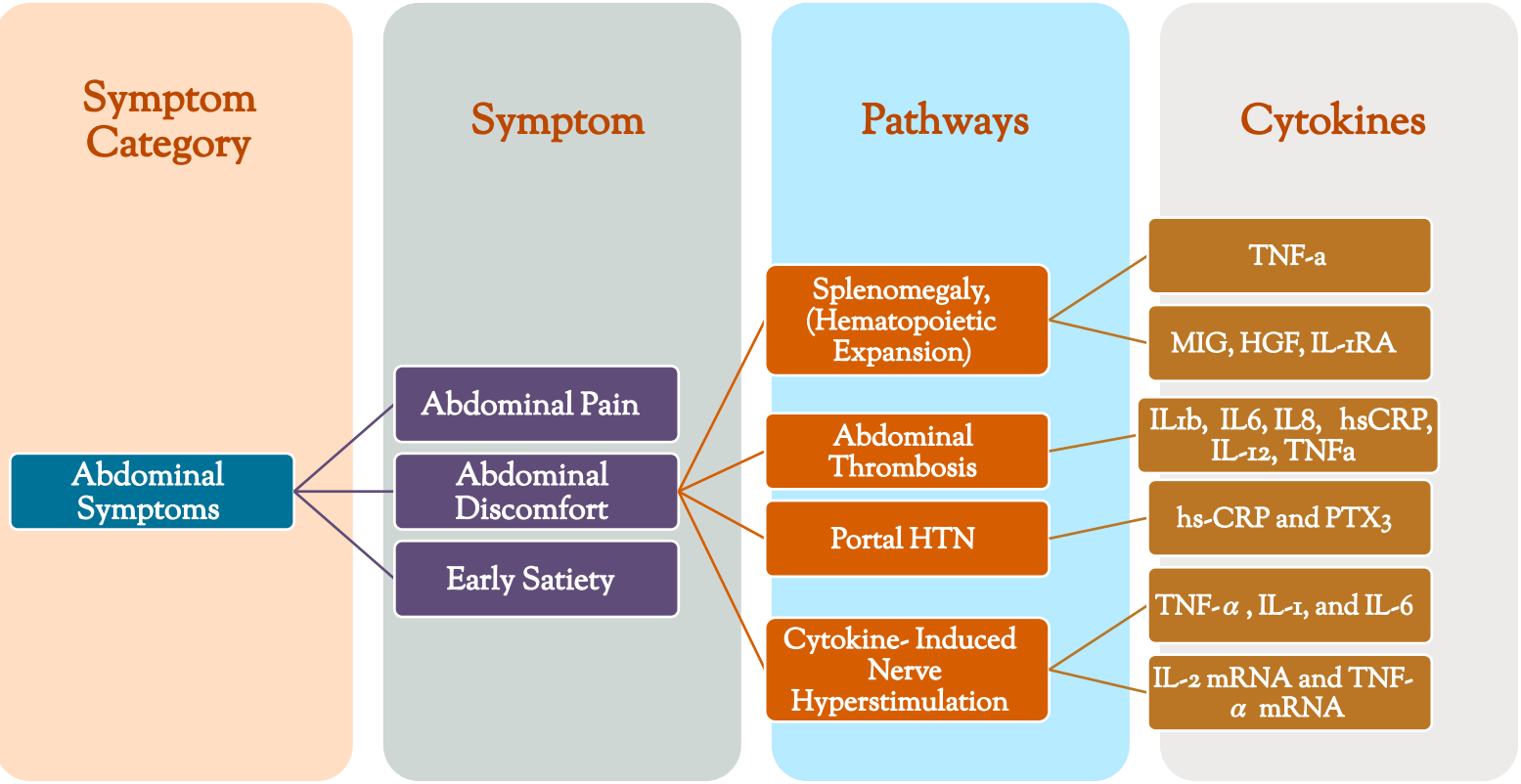




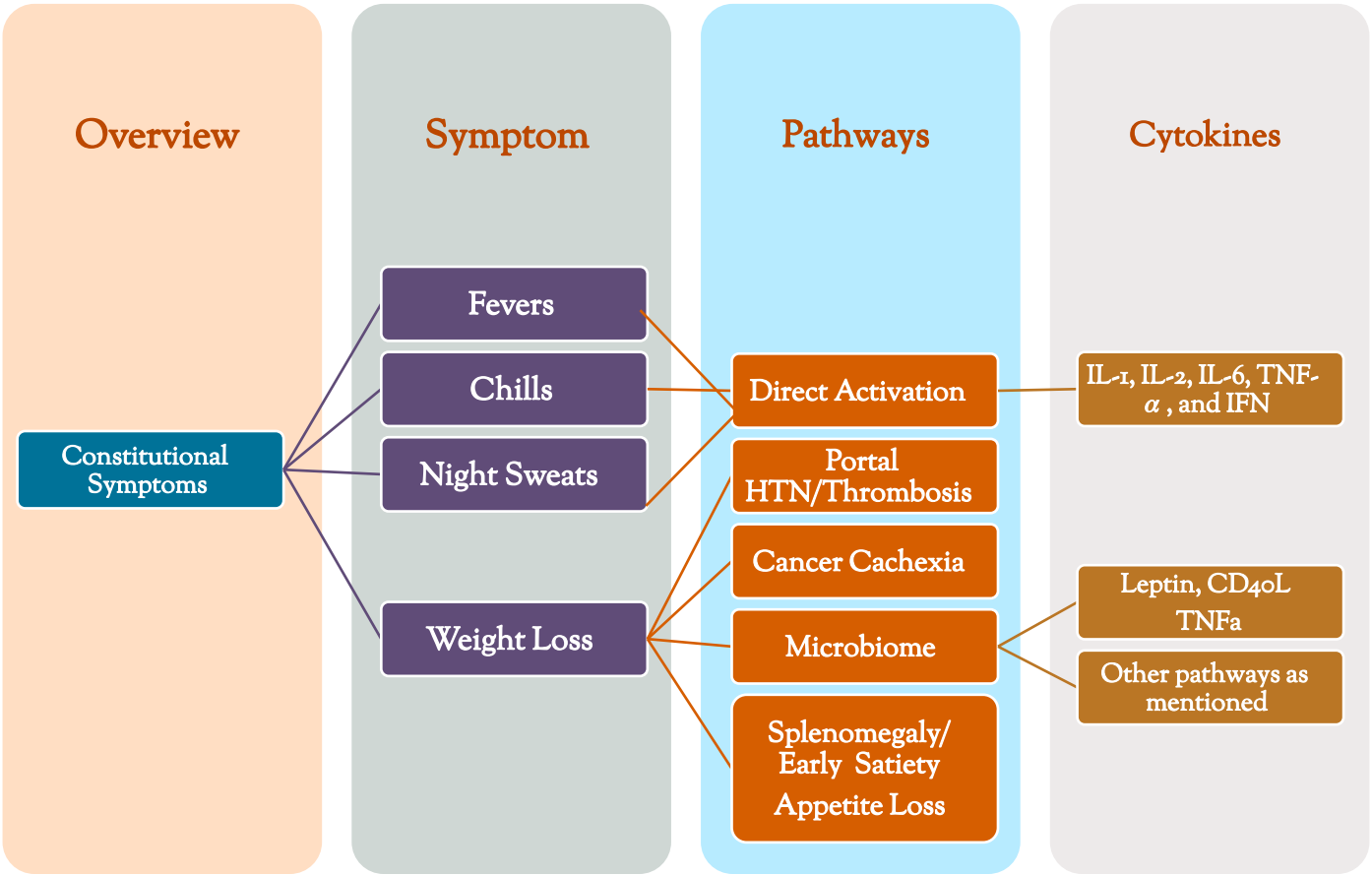
Cancer, vol. 92, no. 6, pp. 1684–1688, 2001.
Cancer, vol. 104, no. 4,pp. 788–793, 2005.
Brain, Behavior, and Immunity, vol. 21,no. 3, pp. 251–258, 2007.
Cancer, vol. 106, no. 4, pp. 751–758, 2006.
[American Journal ofPsychiatry, vol. 158, no. 8, pp. 1252–1257, 2001.

Abdominal Symptoms

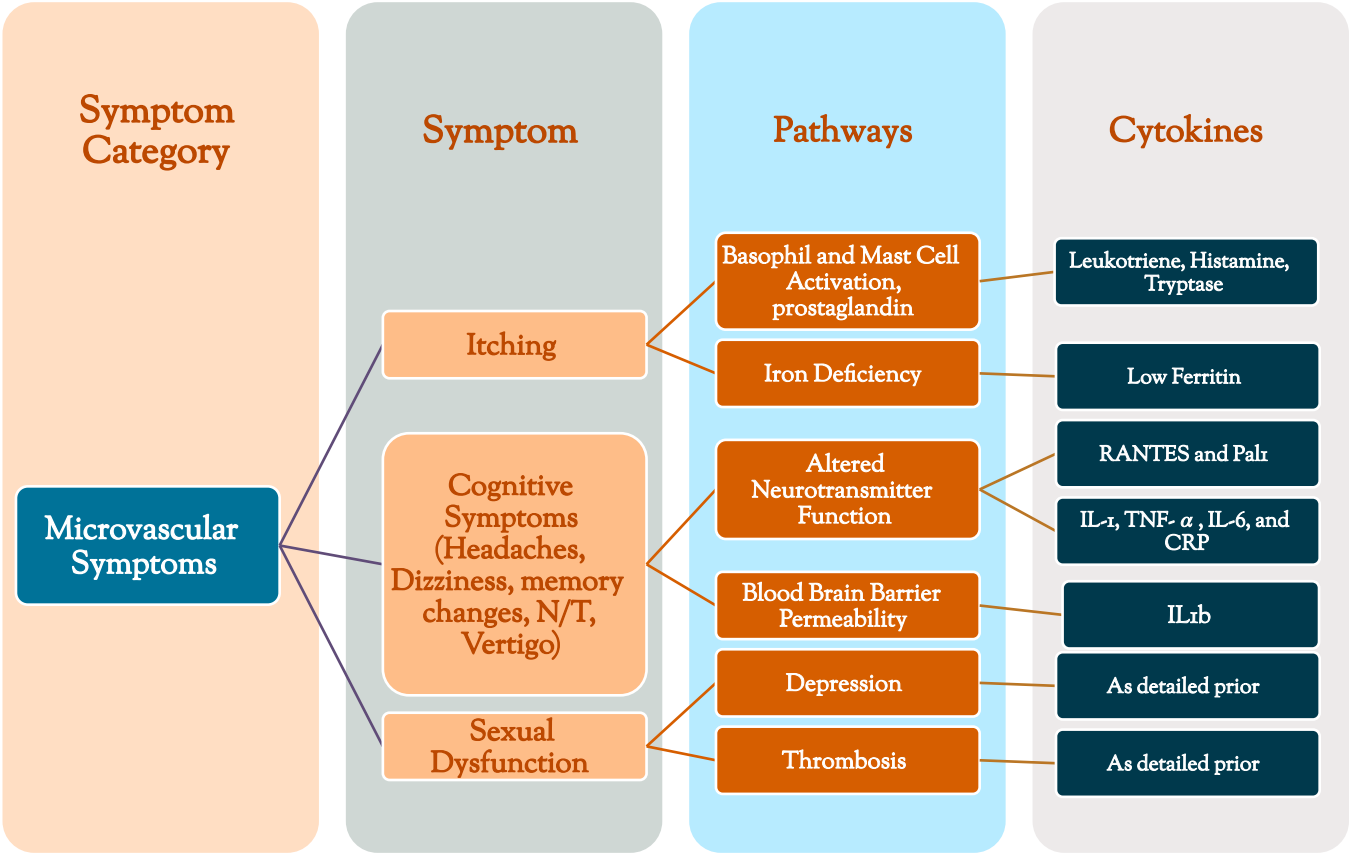




Constitutional Symptoms



Microvascular Symptoms



What is Precise and Personalized Cancer Care?

Communicatio
n
Social DOH

Molecular Features
of

Individual Health
Factors
In Treatment

Geography
Employment
Financial

Individualized
Supportive

Individual
Cultural
Value Factors
In Treatment

Individualized

Disease
impact
Symptoms

Atrium Health

Wake Forest University
School of Medicine

MPNs – How did we get here?

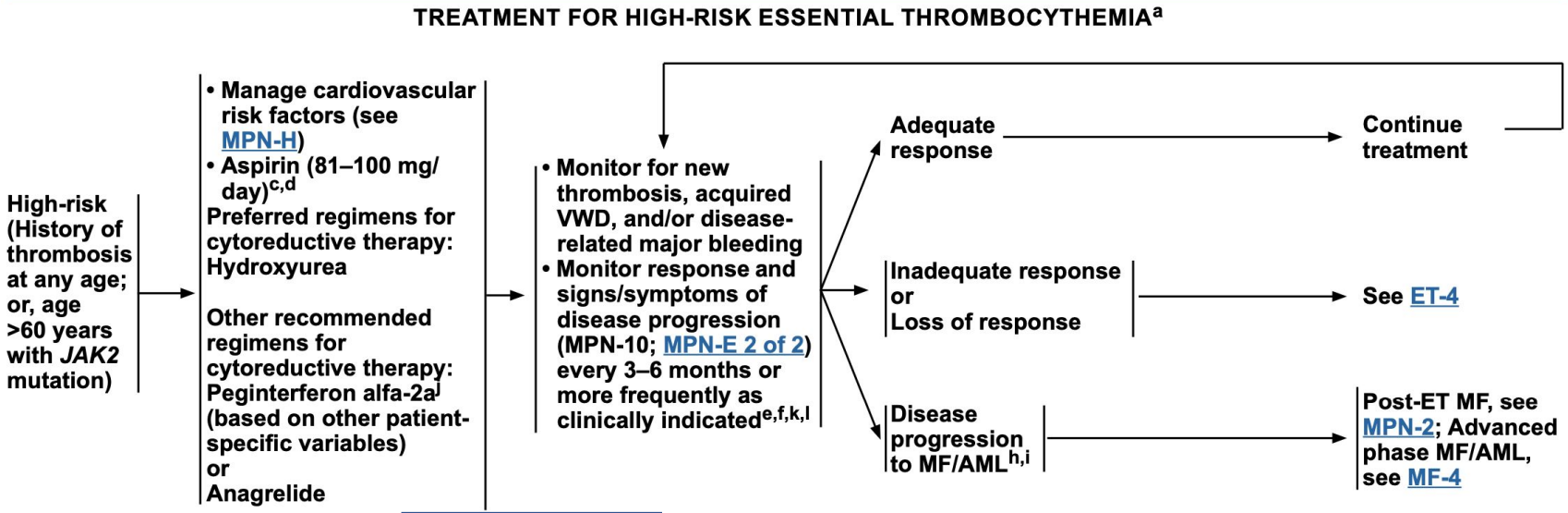
- MPNs pre 2005 – A Brief History
- Learning about MPN Biology
- Goals and Targets
- ET
- PV
- MF
- Putting it all Together

Gap 2
Do we manage CV risk well?

Gap 4
Predicting Progression and what is adequate response?

National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2022
Essential Thrombocythemia



Gap 1
Who needs treatment vs Risk?

Gap 3
We need more and better treatments for ET?

Gerds, AT et al. J Natl Compr Canc Netw. 2022 Sep;20(9):1033-1062.

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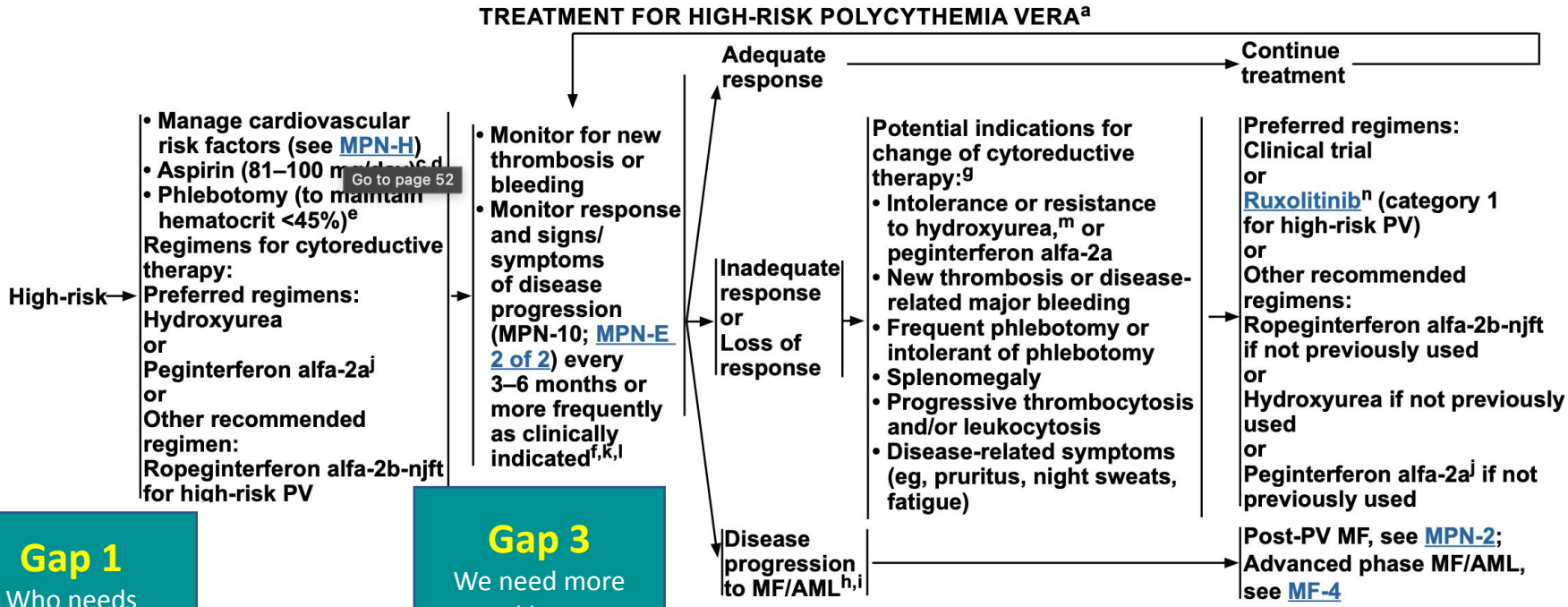
Gap 2
Do we manage CV risk well?

Gap 4
Predicting Progression and what is adequate response?

National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2022
Polycythemia Vera



Gap 1
Who needs treatment vs Risk?

Gap 3
We need more and better treatments for ET?

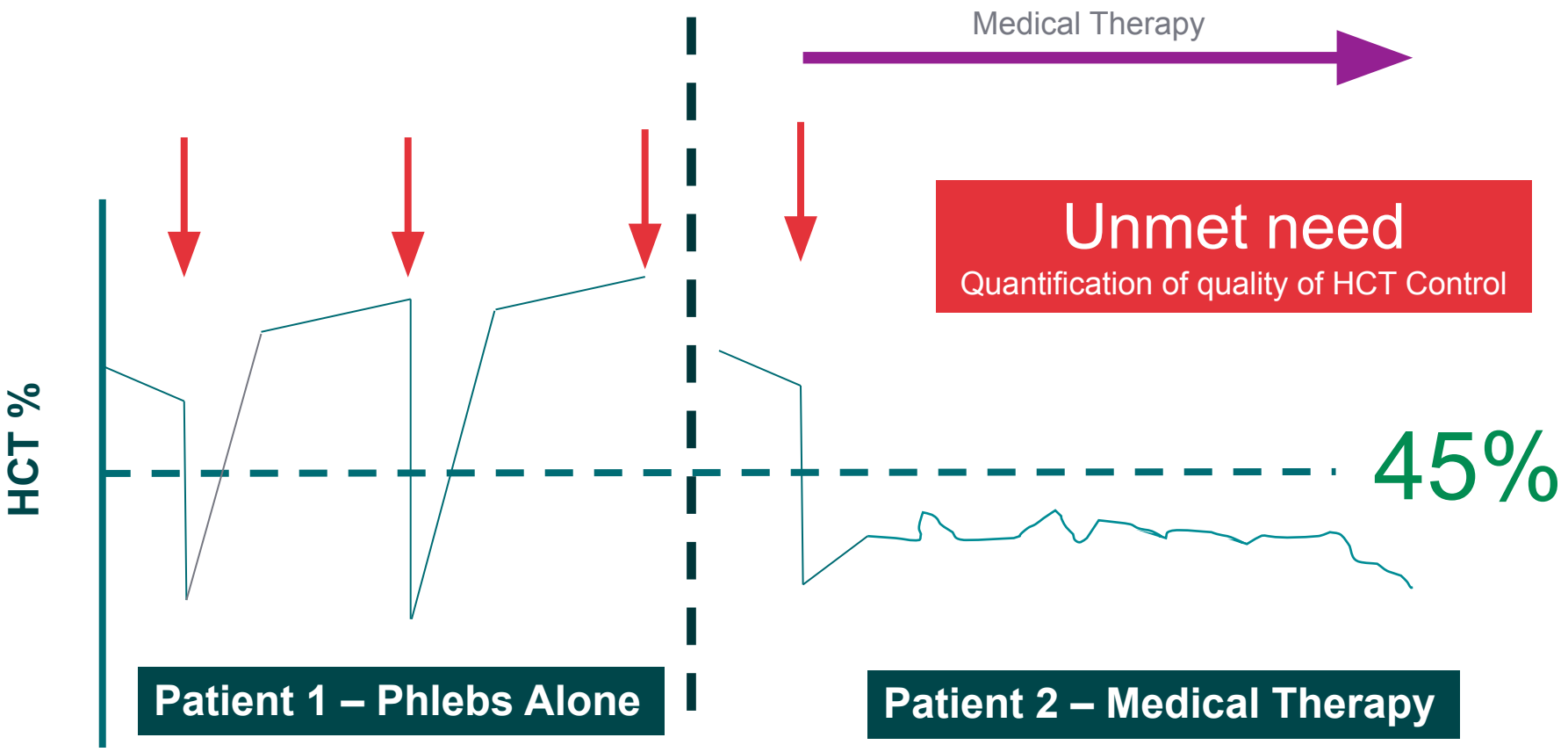
Gerds, AT et al. J Natl Compr Canc Netw. 2022 Sep;20(9):1033-1062.

What is risk in PV?

- Risk of vascular event (Age >60, prior thrombosis)?
- Risk of progression to Post PV MF or AML?
- Risk of Death?

- How do we factor in symptomatic? Low risk but requiring persistent phlebs? Not tolerating Phlebs?

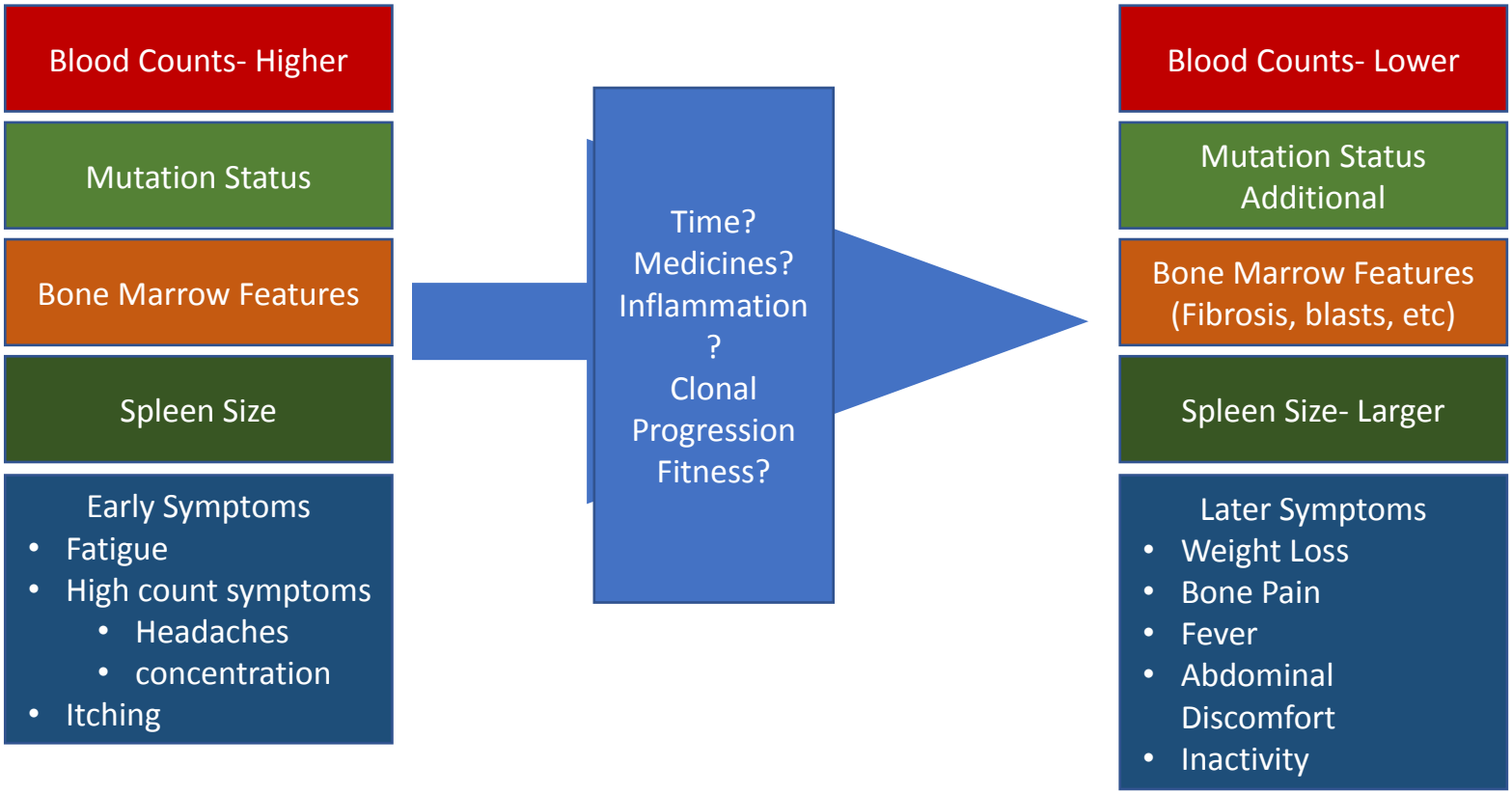
HCT Control



*Self-tested case

Atrium Health
Levine Cancer

MPN Progression



Prepared by the speaker

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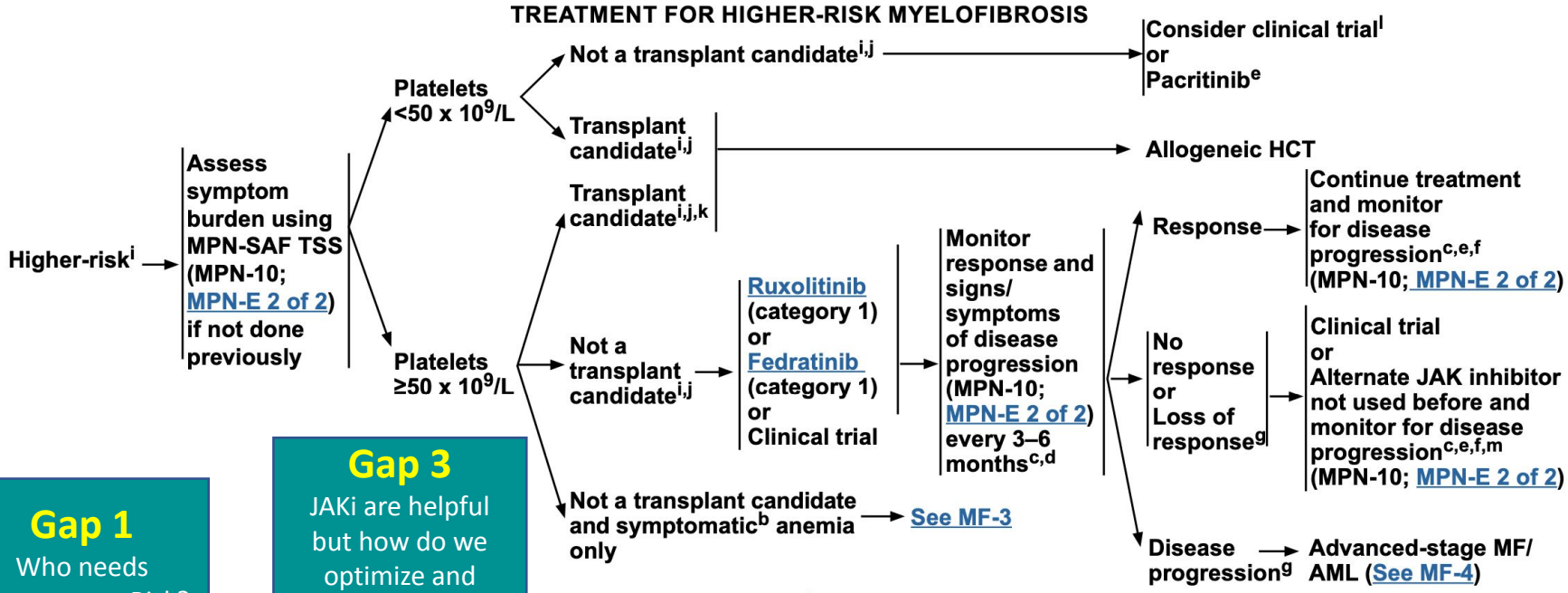
JAK Inhibitor Landscape 2024

Gap 2
We still likely do transplant too late in too many

Gap 4
Predicting Progression and what is adequate response?

National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2022
Myelofibrosis



Gap 1
Who needs treatment vs Risk?

Gap 3
JAKi are helpful but how do we optimize and which agent when?

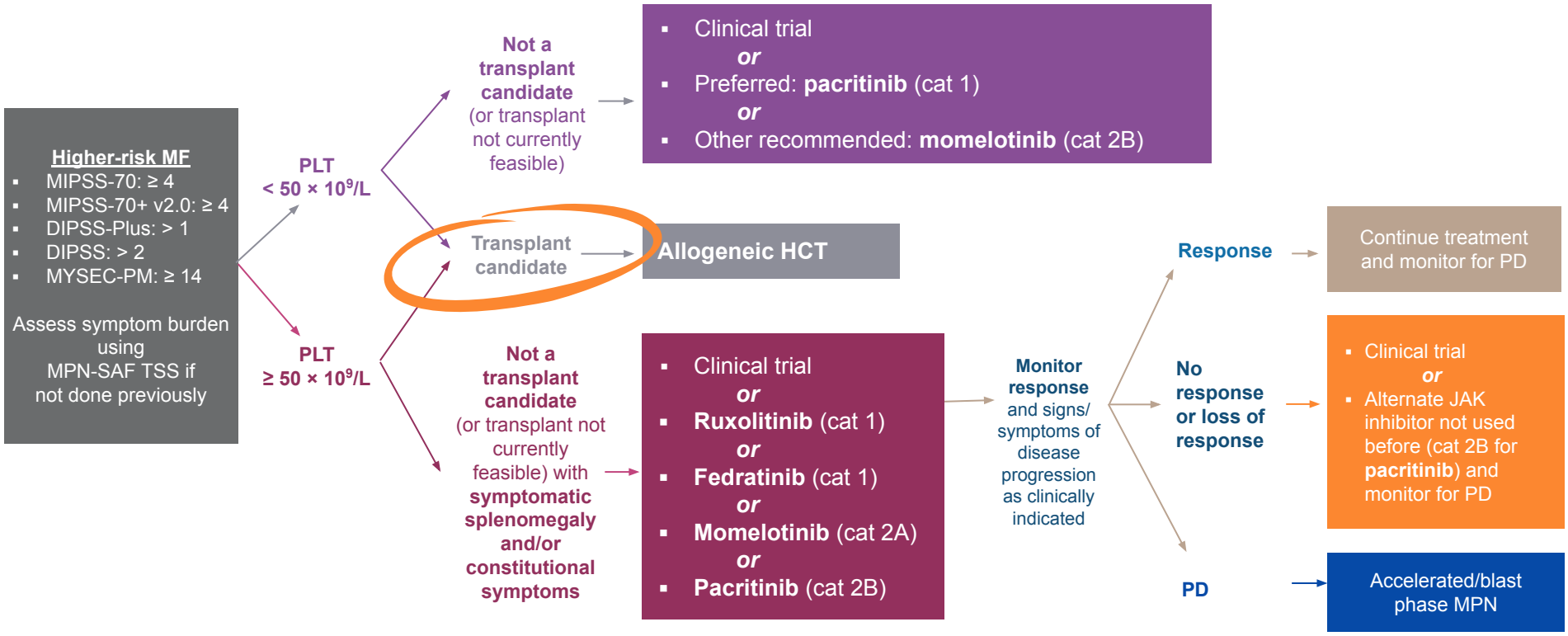
Gerds, AT et al. J Natl Compr Canc Netw. 2022 Sep;20(9):1033-1062.

Gap 5
How do we get to deeper and broader impact?

@AaronGerds

Cleveland Clinic

NCCN Guidelines
Treatment for Higher-Risk Myelofibrosis



Cat, category; HCT, hematopoietic cell transplantation; MYSEC-PM, Mysec Prognostic Model; NCCN, National Comprehensive Cancer Network; PD, progressive disease; PLT, platelet.

NCCN. Myeloproliferative neoplasms (v1.2024). 2023. Accessed May 30, 2024. https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf

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Case for Transplanting Earlier in Myelofibrosis

1. **FACT 1:** Ideal time for transplant is probably pre-progression
2. **FACT 2:** Medical therapy both pre-transplant and post-transplant likely future state
3. **FACT 3:** Delaying transplant likely increases transplant risks and poor outcomes
4. **FACT 4:** The patient's medical wishes are crucially important in this decision

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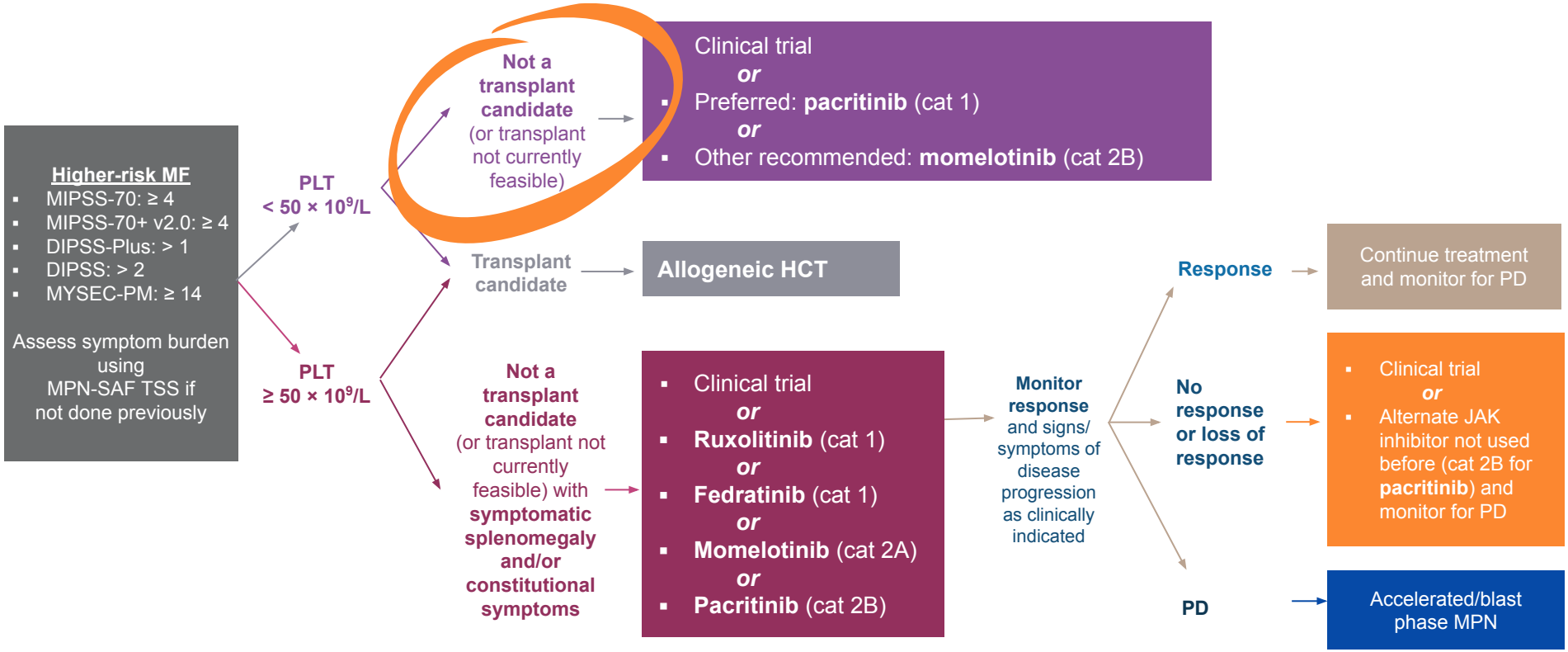
NCCN Guidelines
Treatment for Higher-Risk Myelofibrosis



NCCN. Myeloproliferative neoplasms (v1.2024). 2023. Accessed May 30, 2024. https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf

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JAK Kinase Inhibition for Myelofibrosis

JAK Inhibitor	Ruxolitinib[1,2]	Fedratinib[3,4]	Pacritinib[5]	Momelotinib[6,7]
Approval date	2011 (FDA); 2012 (EMA)	2019 (FDA); 2021 (EMA)	2022 (FDA)	2023 (FDA); 2024 (EMA)
Indication	**FDA:** Intermediate- or high-risk MF, including PMF, post-PV MF, and post-ET MF in adults **EMA:** Disease-related splenomegaly or symptoms in adults with PMF, post-PV MF, or post-ET MF	**FDA:** Adults with intermediate-2 or high-risk primary or secondary (post-PV or post-ET) MF **EMA:** Disease-related splenomegaly or symptoms in adults with PMF, post-PV MF, or post-ET MF who are JAK inhibitor-naive or have been treated with ruxolitinib	**FDA:** Adults with intermediate- or high-risk primary or secondary (post-PV or post-ET) MF with a platelet count < 50 × 10^9/L	**FDA:** Intermediate- or high-risk MF, including PMF or secondary (post-PV and post-ET) MF in adults with anemia **EMA:** Disease-related splenomegaly or symptoms in adults with moderate to severe anemia who have PMF, post-PV MF, or post-ET MF who are JAK inhibitor-naive or have been treated with ruxolitinib
Targets	*JAK1*, *JAK2*	*JAK2*, *JAK1*, *FLT3*, *BRD4*, *TYK2*	*JAK2*, *IRAK1*, *FLT3*, *ACVR1*	*JAK1*, *JAK2*, *ACVR1*
Interactions	Avoid CYP3A4 inhibitors; dose adjustments may be needed	Avoid CYP3A4 inducers; reduce dose 50% with strong CYP3A4 inhibitors	Avoid CYP3A4 inducers	Avoid OATP1B1 inhibitors; dose adjustments may be necessary; rosuvastatin (BCRP substrate) start at 5 mg and do not increase to > 10 mg once daily
Unique concerns	Avoid abrupt discontinuation	Wernicke encephalopathy in early studies	Cardiovascular events and bleeding in early studies	Dose adjustment needed if severe hepatic impairment

BCRP, breast cancer resistance protein.

1. Ruxolitinib [PI]. Approved 2011. Revised January 2023; 2. Ruxolitinib [PI]. EMA. Published October 4, 2012. Updated April 15, 2024; 3. Fedratinib [PI]. Approved 2019. Revised May 2023; 4. Fedratinib [PI]. EMA. Published March 3, 2021. Updated January 12, 2024; 5. Pacritinib [PI]. Approved 2022. Revised August 2023; 6. Momelotinib [PI]. Approved 2023. Revised September 2023; 7. Momelotinib [PI]. EMA. Published February 8, 2024.

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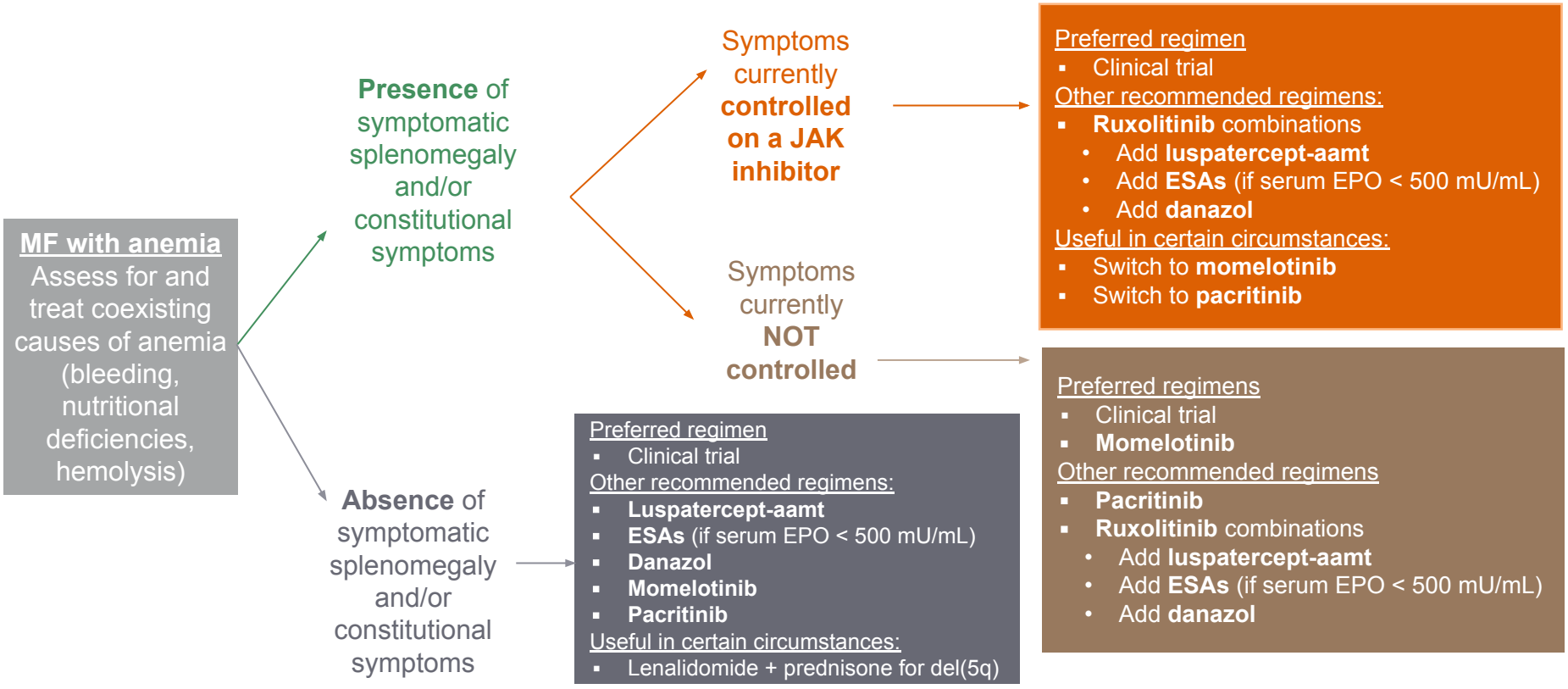
NCCN Guidelines
Management of Myelofibrosis-Associated Anemia



del, deletion; EPO, erythropoietin; ESA, erythropoiesis-stimulating agent.

NCCN. Myeloproliferative neoplasms (v1.2024). 2023. Accessed January 2, 2024. https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf

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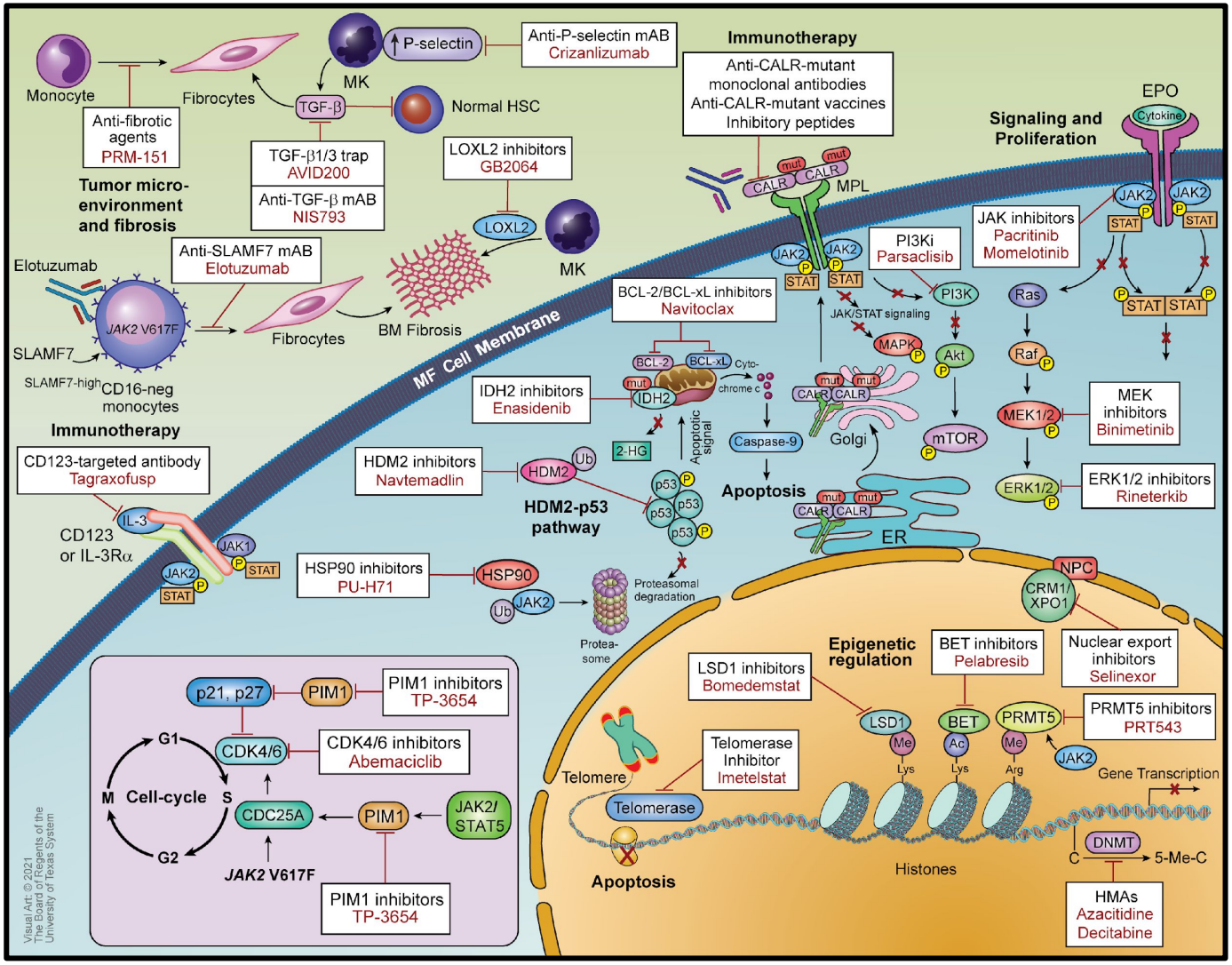
Targets of Novel Therapeutic Agents in Development for Myelofibrosis



Chifotides HT, Bose P, Masarova L. Pemmaraju N, Verstovsek S. *Clin.Lymph. Myeloma Leuk.* 2022; 22(4):210-223.

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Cancer as we know it today

We lack effective early detection approaches to diagnose many types of cancer.

We have curative therapies that come at the cost of serious side effects.

We have too few methods to prevent cancer.

We leave too many patients and families to navigate the disease on their own.

We have stark inequities in diagnosis, treatment and trial access, and patient outcomes, based on race, region and resources.

Cancer kills 600,000 people per year in the United States, including close to 1,800 aged 19 and under.

We have limited success in some of the toughest to treat and rare cancers.

A Team Based Approach for Care

Helping Cancer Patients RISE Beyond Their Cancer!

CANCER MEDICAL SPECIALTIES

- Cardio-Oncology
- Onco-Nephrology
- Optho-Oncology
- Palliative Medicine
- Survivorship Clinics
- Endocrine
- Medical Management Clinic

PATIENT & CAREGIVER SERVICES

- Nutrition
- Genetic Counseling
- Psycho-Social Support
- Social Work
- Transportation
- Holistic Support Programs
- Financial Counseling

Standardizing MPN Data Collection

Pre-MPN History
- Complete Demographics
- Co-morbidities
- Meds
- Fam Hx
- Prior Events/ Symptoms

MPN Presentation
- Labs/ Exam
- MPN SAF
- Marrow and NGS

MPN Course
- Meds/ Toxicities (inc $)
- Events
- Serial Labs/ MPN SAF
- Repeat Marrow NGS

Outcomes
- Events
- Progression
- Co-Morbidities
- Mortality

What is Precise and Personalized Cancer Care?

Molecular Features of Disease
-Multi-Omic
-Dx, treatment, survivorship

Communication
Social DOH
Health Literacy

Individual Health Factors In Treatment Planning?

Geography
Employment
Financial Pressures

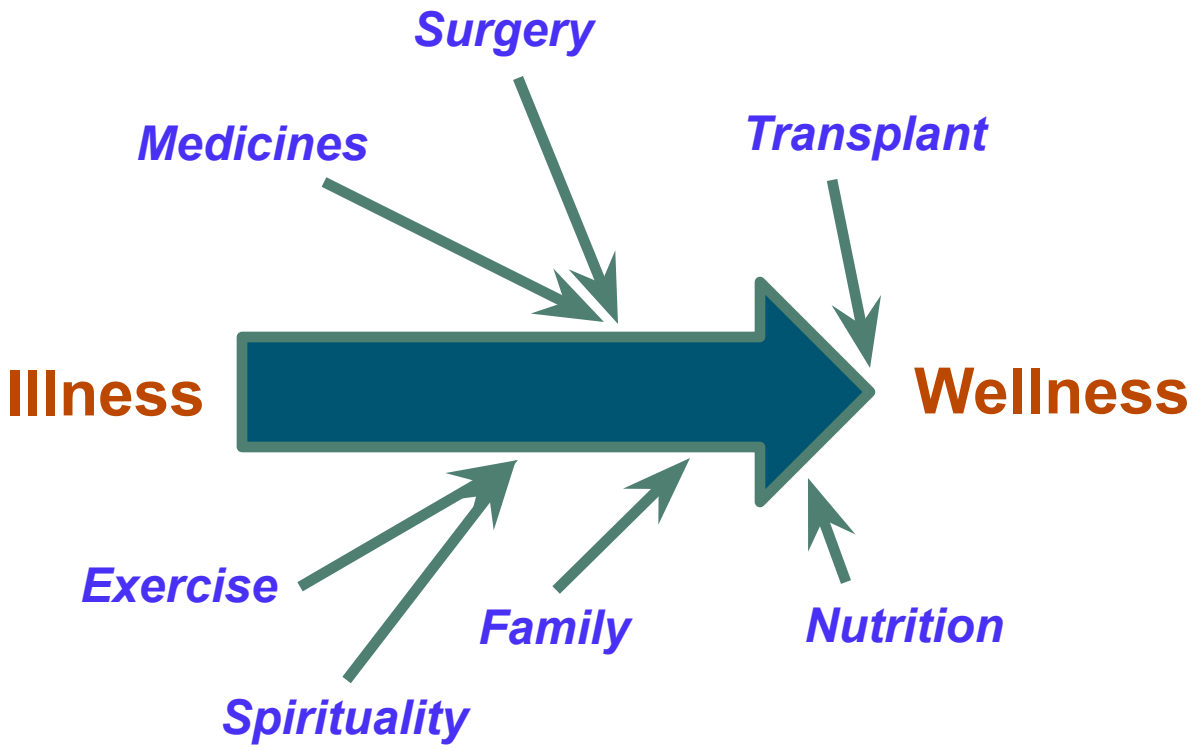
Individualized Supportive Care Needs?

Individual Cultural Value Factors In Treatment Planning?

Individualized Survivorship?

Disease impact
Symptoms
QoL?

The Race (with No Finish Line)



MPN Patient Community

MPN Group	Focus	Website
MPN Research Foundation	RES-ED-ADV	www.Mpnresearchfoundation.org
Leukemia and Lymphoma Society*	RES-ED-ADV	www.lls.org
MPN Advocacy & Education International*	ED-ADV	www.mpnadvocacy.com
MPN Education Foundation*	ED-COMM	www.mpninfo.org
AAMDS Foundation	ED	www.aamds.org
MPN Voice	ED	www.mpnvoice.org.uk
MPN HUB*	ED	www.mpn-hub.com
MPN Advocates Network	ED-ADV	www.mpn-advocates.net
Global MPN Scientific Foundation*	RES-ED-ADV	www.gmpnsf.org
MPN Forum Facebook Group	ED-COMM	https://www.facebook.com/groups/ourmpnforum/

Questions?

Atrium Health
Levine Cancer