

NP PA Meeting

November 16, 2016
-12:00 Noon -

500 Cummings Center
Suite 6500 – Good Harbor Room



Agenda

- Welcome — Alison Gustafson, NP, Population Health Nurse Practitioner
- Back Pain Presentation — Melinda Adam, Director of Rehab Services
- PHO Update:
 - Quality — Liz Isaac, Director Performance Improvement
 - Pharmacy — Carol Freedman, RPh, Clinical Pharmacist

Please RSVP: by November 9, 2016 so we may plan lunch for everyone
jmoleary@nhs-healthlink.org or via telephone at 978-236-1739

Evidence Based Treatment of Low Back Pain

Melinda Adam, PT, DPT, OCS
November 16, 2016

Northeast PHO
NP/PA Meeting

Objectives

Facilitate appropriate management of patients with episodic acute low back pain across practice settings in order to improve patient outcomes and reduce total cost of care.

To review current best practice for physical therapy treatment of LBP.

To provide recent outcome data for patients with LBP treated at BH/AGH outpatient rehabilitation department.

To provide information for emergency access to outpatient physical therapy for patients with acute LBP.

Natural history of LBP

Exact prevalence is unknown – many people with acute symptoms don't seek care.

Most people with acute LBP get better quickly – 50% within 2 weeks, 80% within 8 weeks

Rate of recurrence is very high

Chronic LBP (duration > 3 months) has been estimated between 10-30% in US

45% of patients with initial onset of LBP will become chronic over 3 years if they do not receive early referral to PT

Implications

- Need to educate pts that recovery is likely but recurrence and flare-ups are also common
- Need to educate pts on body mechanics and need to return to normal activity as soon as possible
- Early access to PT is crucial

Contemporary Understanding of LBP

A multidimensional disorder

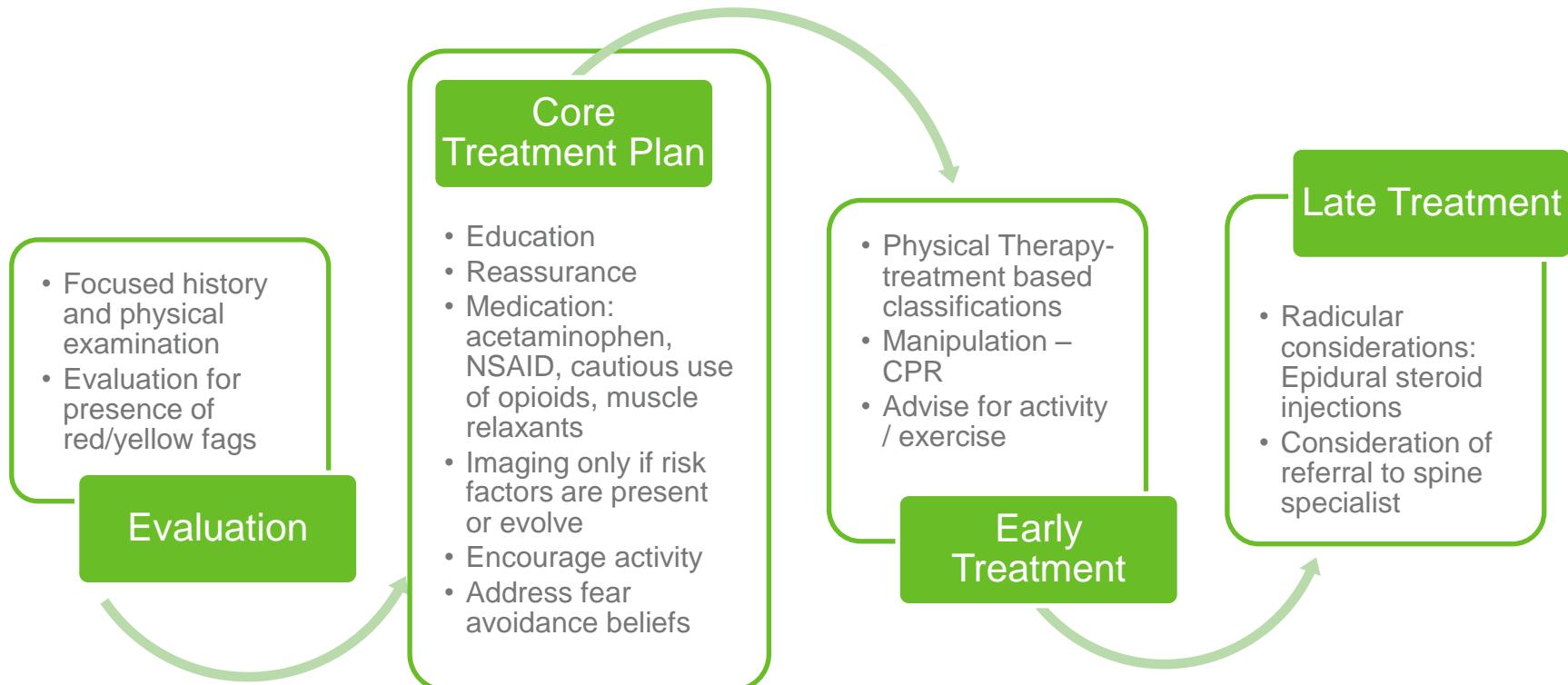
Increasingly clear that persistent and disabling LBP is not an accurate measure of local tissue pathology or damage alone

Best seen as a protective mechanism produced by the neuro-immune-endocrine systems in response to the individual's perceive level of danger, threat or disruption of their life.

Involve the interplay of physical, psychological, social, cultural, work, home environment, lifestyle, comorbid health and non-modifiable factors such as genetics, sex, life stage.

The relative contributions from these factors and their interactions with each other is variable, fluctuating and unique to each individual with LBP (1)

What does Best Practice for LBP look like?



Red Flags: Medical Risk Factors



Vertebral Infection

Cancer

Vertebral Fracture

Cauda Equina

Other Non-spine Pain Origins

Imaging becomes indicated in new or evolving presentations within 28 days of onset of low back pain



Vertebral Infection

Immunocompromised
HIV
Diabetes
Tuberculosis
IV drug use



Fever over 100.4° F
Gradual onset of symptoms
Symptoms are unrelated to mechanical movements
Deep, constant pain
General malaise
Spinal rigidity



Metastatic Cancer

Metastatic breast, lung, gut, prostate, renal or thyroid cancer



Gradual onset
Age 50+ or under 17
Personal history of cancer
Constant pain – no relief with bed rest
Failure to reproduce symptoms with examination
Failure of conservative treatment within 1 mo.



Fracture



Over age 70 without trauma
Over age 50 with mild trauma

Prolonged steroid use
Osteoporosis
History of cancer
Female



Cauda Equina



Rapid onset of urinary retention or
fecal incontinence
saddle anesthesia sensory/motor loss
to feet
Decreased DTR's
Severe pain
Urgent surgical consultation



Consider Other Non-Spine Pain Origins

Two percent of low back pain is due to visceral disease including but not limited to the following:

- Disease of pelvic organs (prostatitis, endometriosis, chronic pelvic inflammatory disease)
- Renal disease (nephrolithiasis, pyelonephritis, perinephric abscess)
- Aortic aneurysm
- Gastrointestinal disease
- Pancreatitis
- Cholecystitis
- Penetrating ulcer
- Cardiac or pericardial disease
- Pulmonary or pleural disease

The Bottom Line Regarding Imaging

Serious diseases presenting as LBP are relatively rare. De-emphasize routine ordering of imaging studies in the absence of red flags or neurological compromise due to a lack of clear relationship between anatomical structures, physiological events and pain symptoms.

Most single positive red flags do not significantly increase the likelihood of serious disease. This increase as the number of red flags increases. Clinical decisions should be made based on clusters of findings and clinical judgment

MRI/CT very helpful to identify presence of serious compression of spinal cord, cauda equina or spinal nerves

Yellow Flags: Psychosocial risk factors



Psychosocial aspects of the patient's presentation likely to affect outcome

Emotional distress	High degree of anxiety High degree of depression
Hypervigilance	Excessive pre-occupation with pain
Pain catastrophizing	Overstimulation of the negative impact of pain
Elevated fear-avoidance beliefs	Inappropriate belief that benign activities are harmful to the spine
Low self -efficacy	A patient's belief that he has no control over the pain
Misunderstanding about the nature and likely impact of pain	A combination of factors that lead the patient to believe that he may have a much more serious condition than is actually the case
Misunderstanding about the best strategies for long-term success	The patient may believe that passive, not active treatments are needed (ie. Someone needs to fix my back)

Treatment for Yellow Flags

We do need to treat these pts differently

- More education, coaching, behavioral counseling
- Self empowerment
- Likely more active exercise than passive treatment/manual therapy

Treatment Based Classifications

Utilize a classification approach that de-emphasizes the importance of identifying a specific anatomical lesion after red flag screening completed

Treatment based on classifying patients into 1 of 4 separate treatment sub-groups

- Manipulation
- Stabilization
- Exercise – directional preference
- Traction

Treatments which have been shown to prevent recurrence of LBP

A randomized clinical trial of 78 patients with acute, work-related low back pain, reported that patients who received interventions matched with their examination findings had better outcomes than patients who received interventions that were not matched with their examination findings.

Fritz et al, Spine 2003

Manipulation Classification

Criteria	Interventions
No symptoms distal to knee	Mobilization/manipulation of lumbopelvic region
Recent onset of symptoms (<16 days)	Active ROM exercises
Hypomobility of lumbar spine	
Hip IR ROM > 35° for at least one hip	

Stabilization Classification

Criteria	Interventions
Younger age	Stabilization training promoting isolated contraction and co-contraction of deep stabilizing muscles
Greater general flexibility	Strengthening of large spinal stabilizing muscles
Instability “catch”	
Positive prone instability test	

Exercise – Extension Preference

Criteria	Interventions
Symptoms distal to buttock that peripheralizes with lumbar flexion and centralize with extension	End-range extension exercises
Directional preference for extension	Mobilization to promote extension
	Avoidance of flexion



Exercise – Flexion Preference

Criteria	Interventions
Older age	Mobilization or manipulation of the spine and/or hip
Directional preference for flexion	Exercises to address impairment of strength and flexibility
Imaging evidence of lumbar stenosis	Body weight supported treadmill ambulation



Exercise – Lateral Shift

Criteria	Interventions
Visible frontal plane deviation of shoulders relative to pelvis	Exercise to correct lateral shift
Directional preference for lateral translation movements of the pelvis	Mechanical to auto traction

Traction Classification

Criteria	Interventions
Signs and symptoms of nerve root compression	Mechanical or auto traction
No movements centralize symptoms	

Implications of early and guideline adherent PT on utilization and cost

Childs JD, Fritz JM, et al. BMC Health Services Research (2015) 15:150

Background: 753,450 eligible patients presenting to a primary care setting with a new complaint of LBP from January 2007 through December 2009 within the Military Health System (MHS). Descriptive statistics, utilization and costs were examined on the basis of timing of referral to PT and adherence to practice guidelines. Utilization outcomes (advanced imaging, lumbar injections or surgery and opioid use were compared using adjusted odds ratios with 99% CI. Total LBP related health care costs over the 2 year follow up were compared using linear regression models

Results: Early, adherent physical therapy (within 14 days) resulted in 60% less total LBP costs than care that was delayed (14-90 days) but adherent.

Utilization Outcomes	Early Adherent	Early non-adherent	Delayed adherent	Delayed non-adherent
	n=17,175	n=23,993	n=13,742	n=16,649
Mean PT visits	6.3	15.8	6.0	13.9
Advanced imaging	12.8%	17.5%	22.2%	30.2%
Spinal injections	9.2%	11.1%	14.8%	17.6%
Spinal surgery	2.1%	2.4%	3.3%	3.9%
Opioid medication Use	60.4%	62.2%	71.1%	71.6%
Mean Total LBP costs	\$1,914.26	\$2,232.00	\$3,067.57	\$3,456.39

Rehabilitation and Sports Medicine LBP Outcomes



Ortho - Lumbar

Qtr ending	Intakes	% completion	Effectiveness			Efficiency	
			FS change	Predicted	% Rank	# visits	Predicted
9/2016	258	50	13.56	11.83	67	10.75	10.81
6/2016	228	57	14.21	13.15	58	11.14	10.35
3/2016	273	46	12.31	12.79	37	10.33	10.64
12/2015	208	43	12.65	12.4	47	10.4	10.76

How to Refer Your Patients to Us

Addison Gilbert Hospital – 978-381-7141

Beverly Hospital – 978-922-8943

Lahey Outpatient Center Danvers – 978-304-8701

If you have a patient in severe, acute LBP who needs to get into PT within 1-2 days, contact Melinda Adam at 978-729-7010 and I will facilitate getting your patient scheduled.

References

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Pharmacy Update

Nurse Practitioner / Physician Assistant

Presentation

November 16, 2016

Carol Freedman, RPh, MAS, BCGP

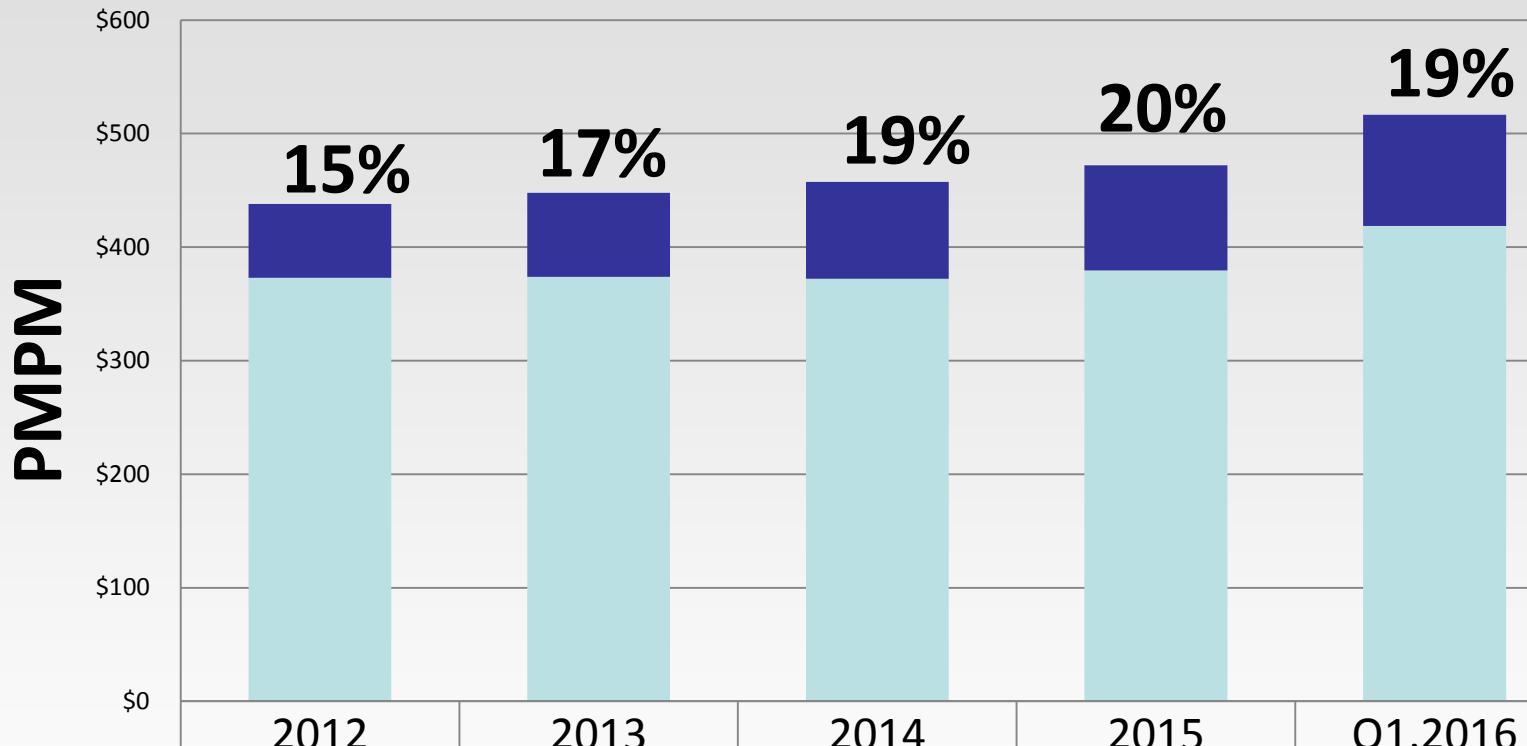
Pharmacy Presentation: Objectives

- Overview of Pharmacy Performance and Trends
 - What are the drivers?
 - What can we do about it?
- Biosimilar Update
 - Share information so that educated decisions can be made regarding benefits, safety and effectiveness of biosimilars.

Pharmacy Expenses as % of TME*

(NEPHO, LACU, WIN)

* Total Medical Expenses



	2012	2013	2014	2015	Q1.2016
% Pharmacy of TME	14.86%	16.55%	18.64%	19.61%	19.00%
PHARMACY	\$65.12	\$74.16	\$85.29	\$92.58	\$98.10
MEDICAL	\$373.06	\$373.93	\$372.27	\$379.49	\$418.57

National Trend

COMPONENTS OF TREND

2015

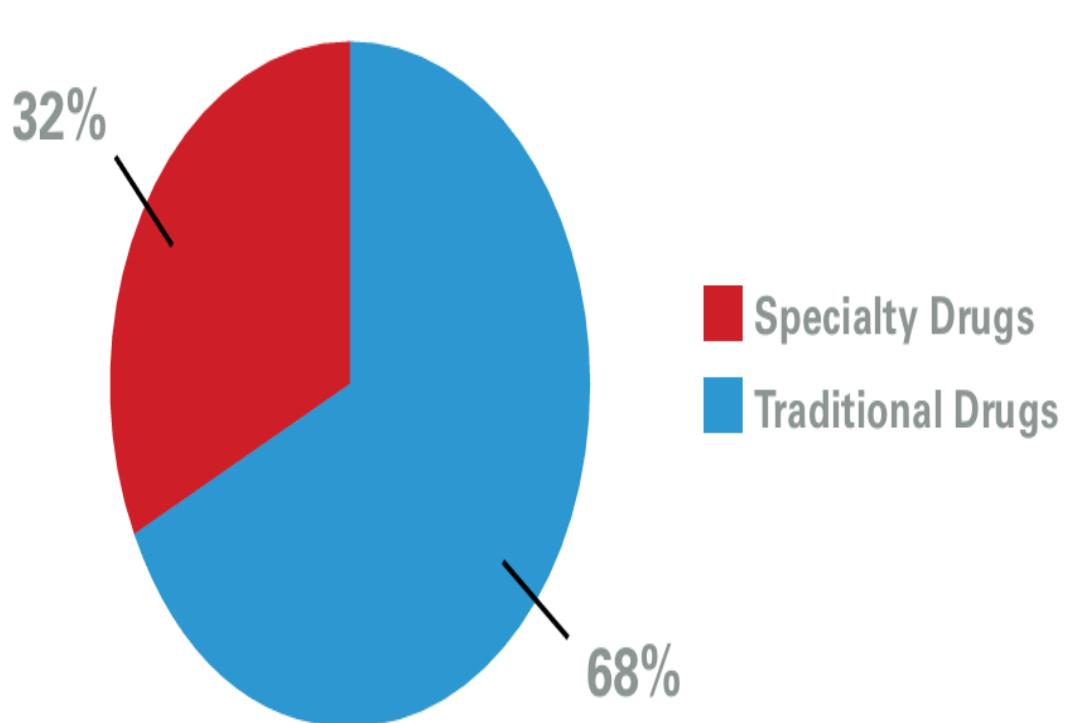
	TREND			
	PMPY* SPEND	UTILIZATION	UNIT COST	TOTAL
Traditional	\$708.09	1.9%	-2.1%	-0.1%
Specialty	\$352.66	6.8%	11.0%	17.8%
TOTAL TREND	\$1,060.75	2.0%	3.2%	5.2%

January-December 2015 compared to same period in 2014, commercially insured.

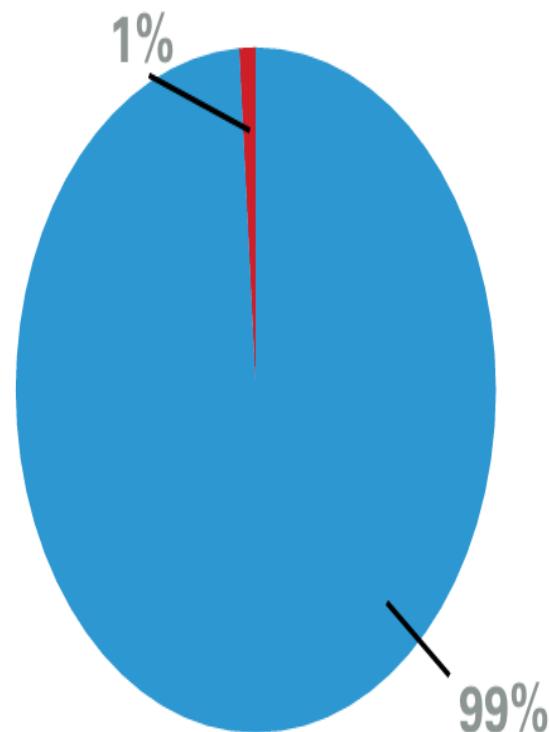
Reflects total cost for both payers and patients.

*Per Member Per Year

Prescription Drug Spending in 2014



Prescriptions Written in 2014



Source: The Express Scripts 2014 Drug Trend Report. March 2015. Available at: <http://lab.express-scripts.com/drug-trend-report/>

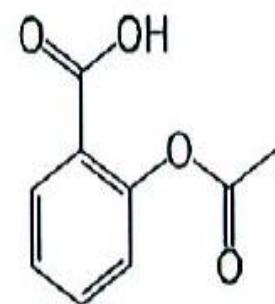
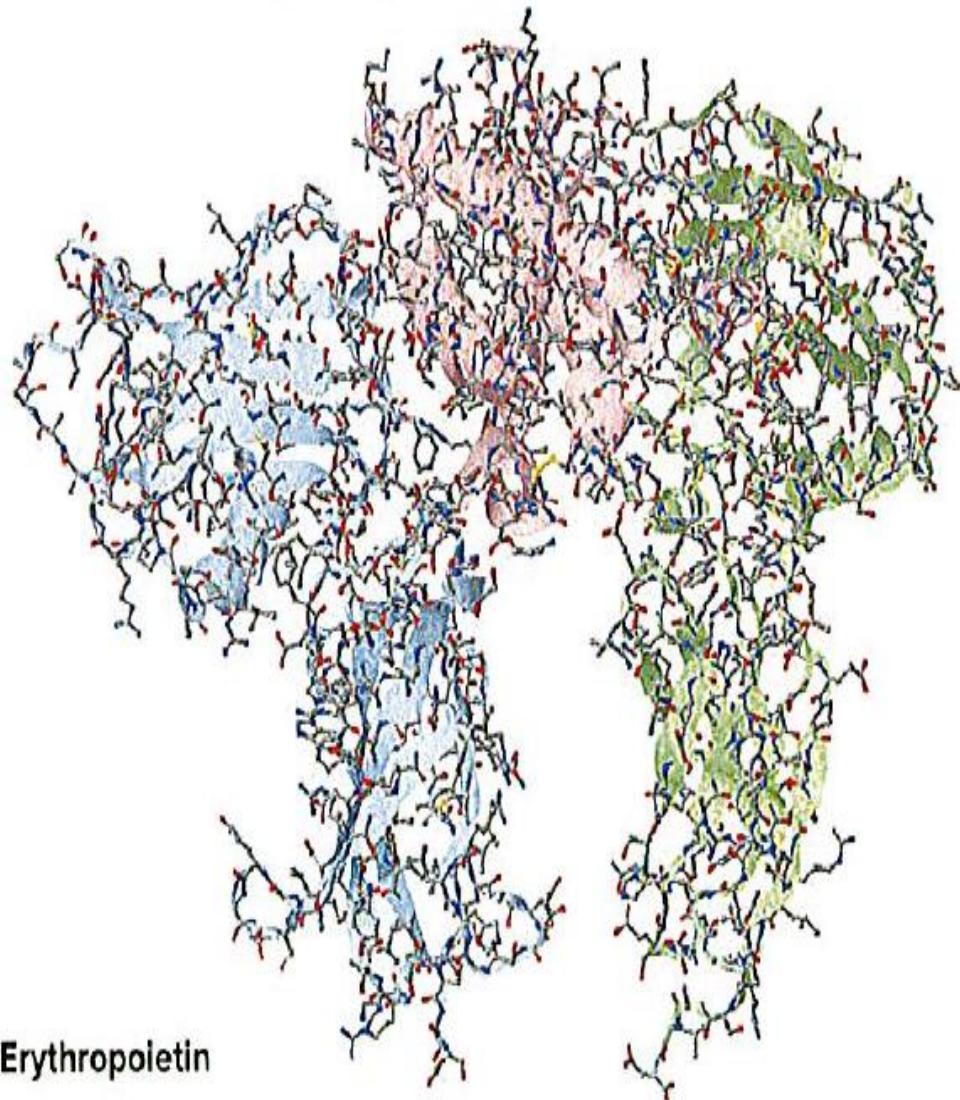
What can we do about pharmacy costs?

1. Follow clinical guidelines / lowest cost agent
2. Deprescribe / Deintensify when appropriate
 - Polypharmacy, PPIs, BP meds, opioids, statins (e.g elderly)
3. Improve patient medication adherence
 - 50 % of meds prescribed not taken appropriately
 - Non-adherence responsible for ~50% of > \$200 BILLION in avoidable health care costs (2014)
4. Encourage formulary integration in Epic
5. Stay educated on biosimilars
6. Gather reliable evidence-based information

Biosimilars - Update

- Lack of understanding of generics in 1970's & 80's resulted in slow adoption
- Copies of complex therapeutic proteins (biologics)
- Usually not developed by original manufacturer
- Approved through SLOW and COMPLICATED regulatory process
- NOT GENERICS

Figure 1 The Differing Complexity of Biologics and Chemical Drugs²⁹



This illustration depicts the markedly greater structural complexity of the biologic agent, erythropoietin, compared with aspirin, a conventional, small-molecule chemical drug.

Status of Biosimilars in US

REFERENCE DRUG	BIOSIMILAR	APPROVAL DATE	CURRENTLY AVAILABLE
Neupogen (filgrastim)	Zarixio (filgrastim-sndz) (filgrastim-jcwp) (filgrastim-vkzt)	March 2015	Yes
Remicade (infliximab)	Inflectra (infliximab-dyyb)	April 2016	No
Enbrel (etanercept)	Erelzi (entanercept-szzs)	August 2016	No
Humira (adalimumab)	Amjevita (adalimumab-atto) ABP 501	September 2016	No
Lantus (insulin glargine)	Basaglar (insulin glargine)	Winter 2016/ 2017	No

Differences between Biosimilar & Generic

PARAMETER	BIOSIMILAR	GENERIC
Synthesis	Living systems; recombinant DNA technology	Chemical synthesis
Structure in comparison to reference product	Designed to be <u>similar</u> ; cannot be 100% identical	Designed to be <u>almost completely identical</u>
Structural complexity	Complex	Simple molecular structure
Potential for immunogenicity	Immunogenicity possible; requires testing & pharmacovigilance monitoring	Less likely to be immunogenic through allergic reactions can occur
Interchangeability with reference product	<u>NOT interchangeable</u>	Legislations <u>allows for interchange</u>
Automatic substitution	<u>Not currently allowed</u>	<u>Generally allowed</u>

Differences continued

PARAMETER	BIOSIMILAR	GENERIC
Nomenclature	Draft guidance proposes unique INN - reference product with 4-letter suffix	INN generally same as reference product
Indications	Extrapolation / <u>approval for each indication</u> ; 351(k) approval	<u>Approved for all indications</u> ; ANDA approval
Clinical Trials	Required	Disease state trials NOT required
Governance	Purple Book	Orange Book
Approval	BPCI Act "patent dance" litigation process	180-day exclusivity for 1st generic ANDA approved
Research Costs	High	Lower
Cost	\$\$\$\$ > \$600	< \$600

INN, International Nonproprietary Name (generic),

ANDA = abbreviated new drug application; BPCI = Biologics Price Competition & Innovation