

Opioid Regulations and Lung Cancer Patient

Monika Holbein, MD
Oncology Supportive Care
Assistant Professor of Medicine
West Virginia University



pain noun

\ˈpān  \

Definition of *pain* (Entry 1 of 2)

1 : PUNISHMENT

// the *pains* and penalties of crime

2 a : usually localized physical suffering associated with bodily disorder (such as a disease or an injury)

// the *pain* of a twisted ankle

also : a basic bodily sensation induced by a noxious stimulus, received by naked nerve endings, characterized by physical discomfort (such as pricking, throbbing, or aching), and typically leading to evasive action

// the *pain* of bee stings

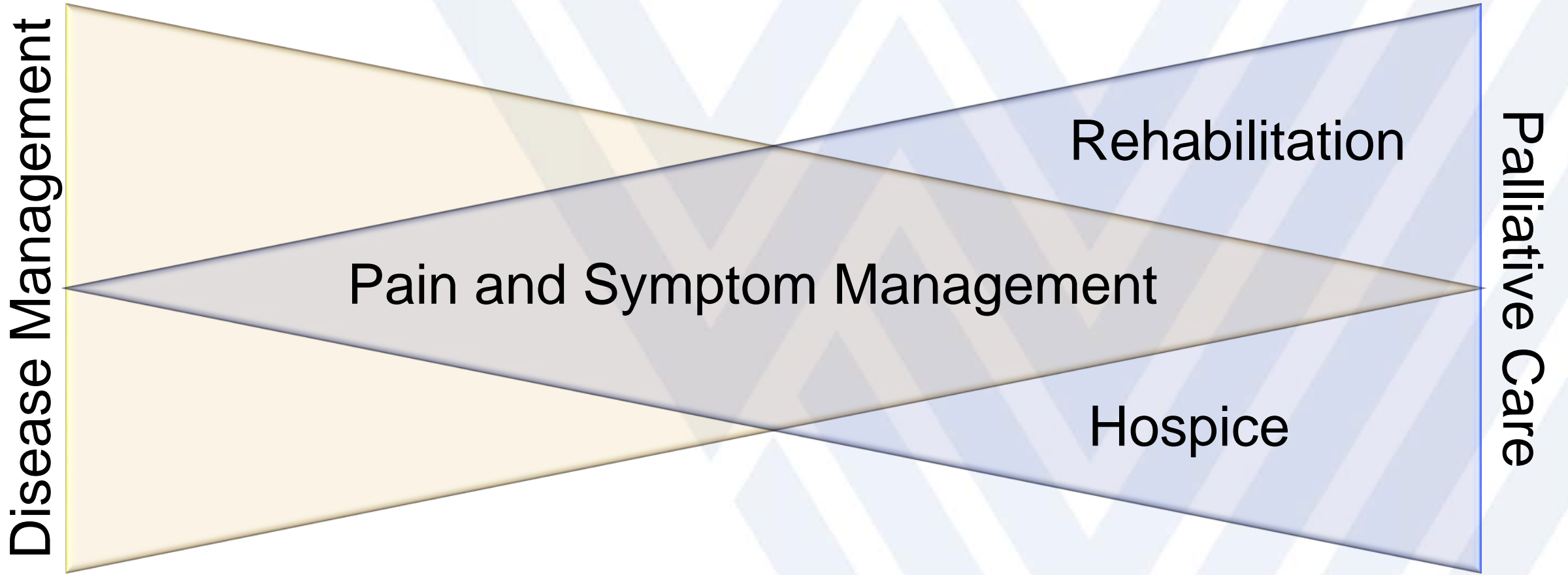
b : acute mental or emotional distress or suffering : GRIEF

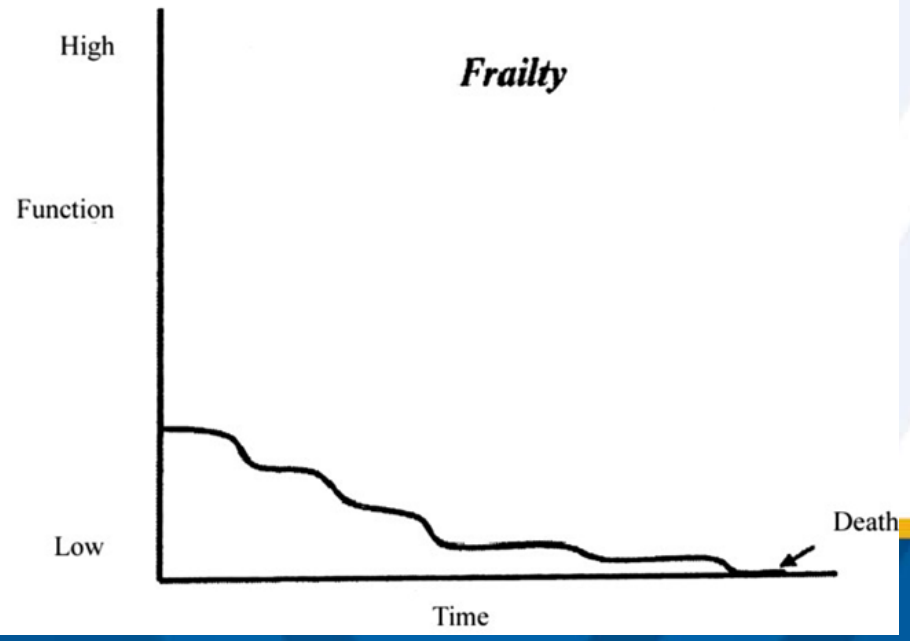
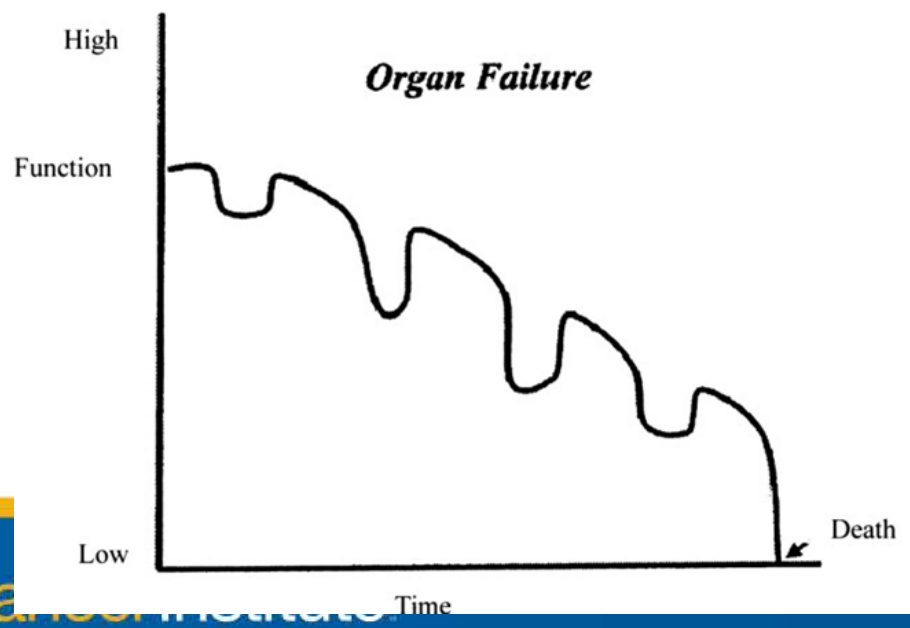
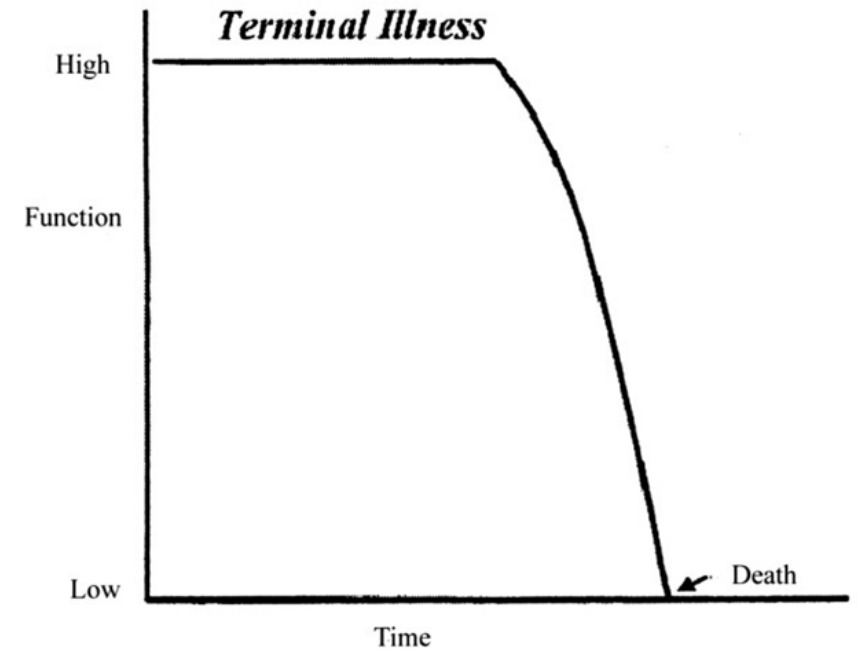
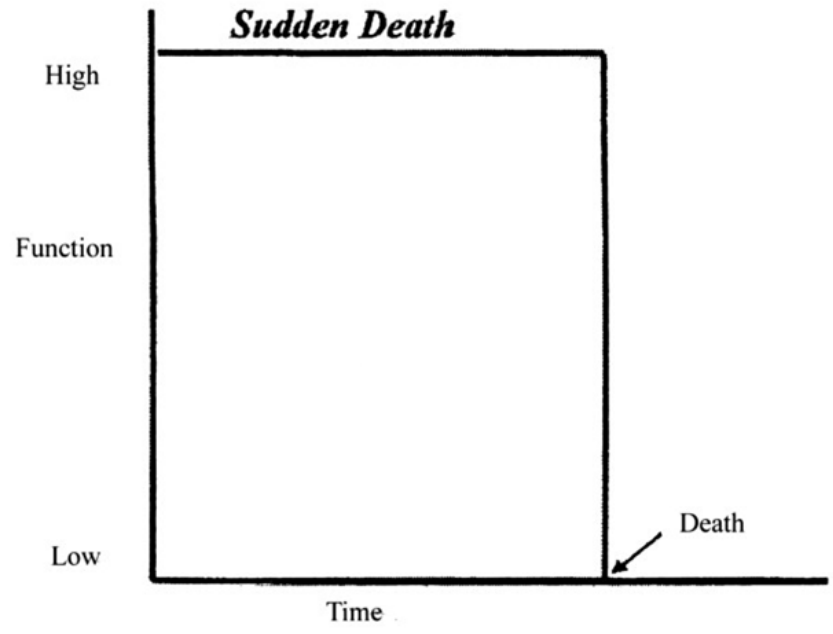
// the *pain* she had felt at those humiliating words

— Morley Callaghan

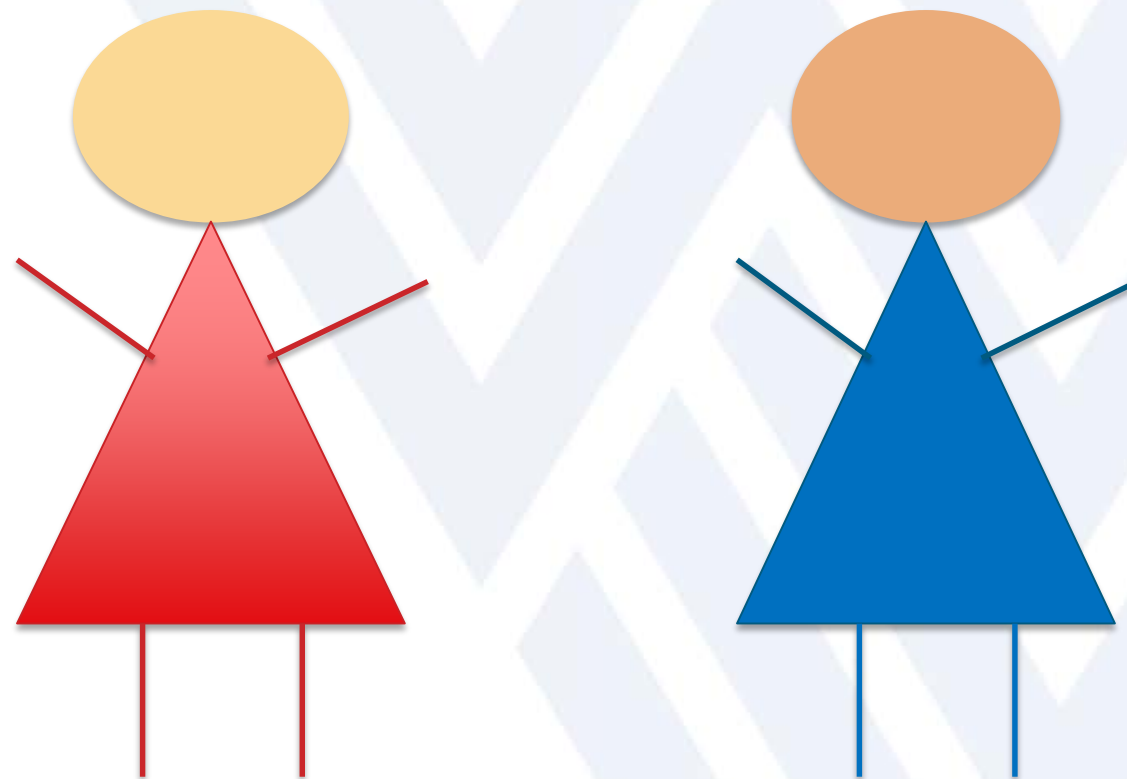
Objectives

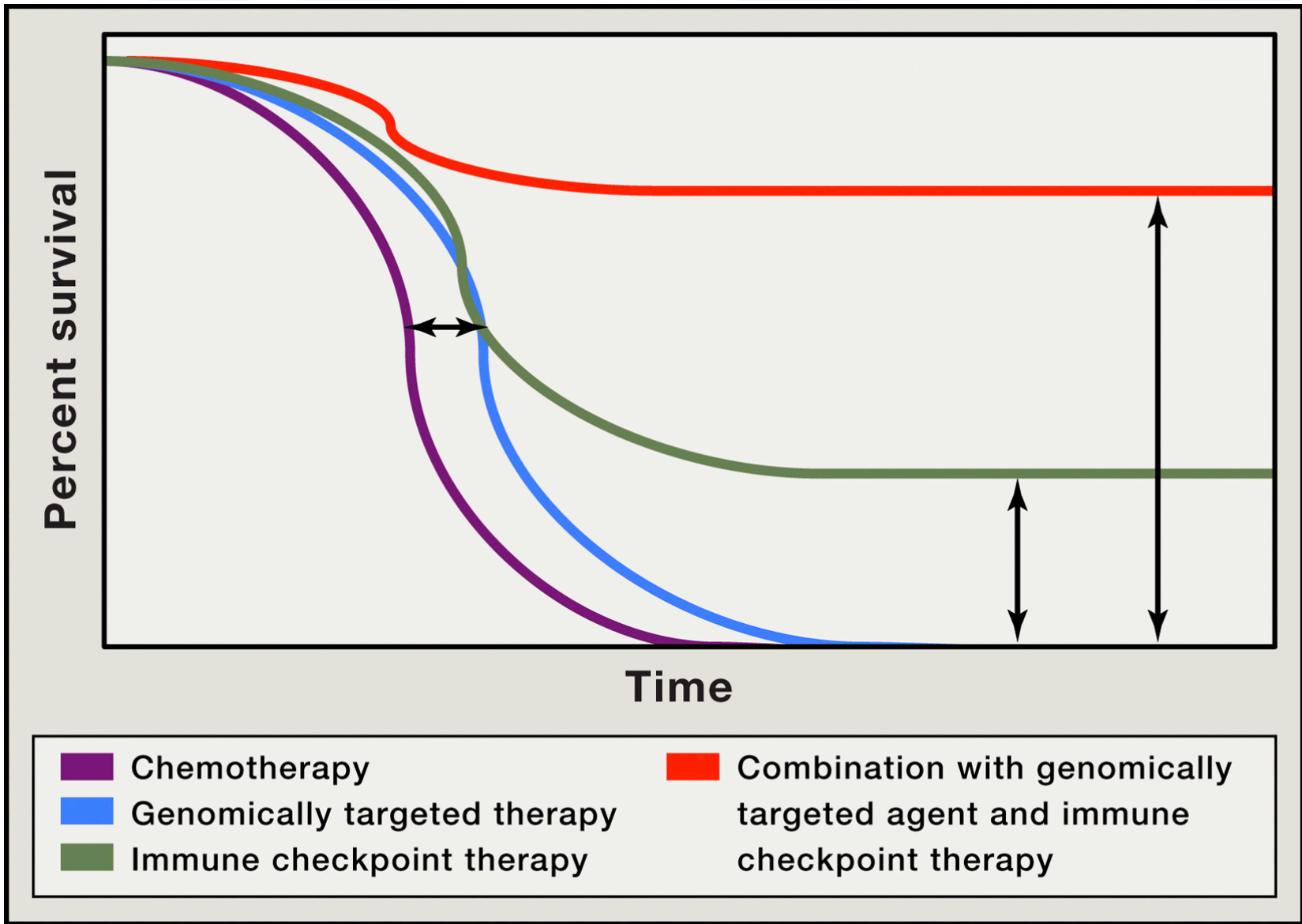
- Review the role of palliative care in lung cancer patients
- Examine current opioid policies international, national and local
- Construct an approach to lung cancer patients who experience pain

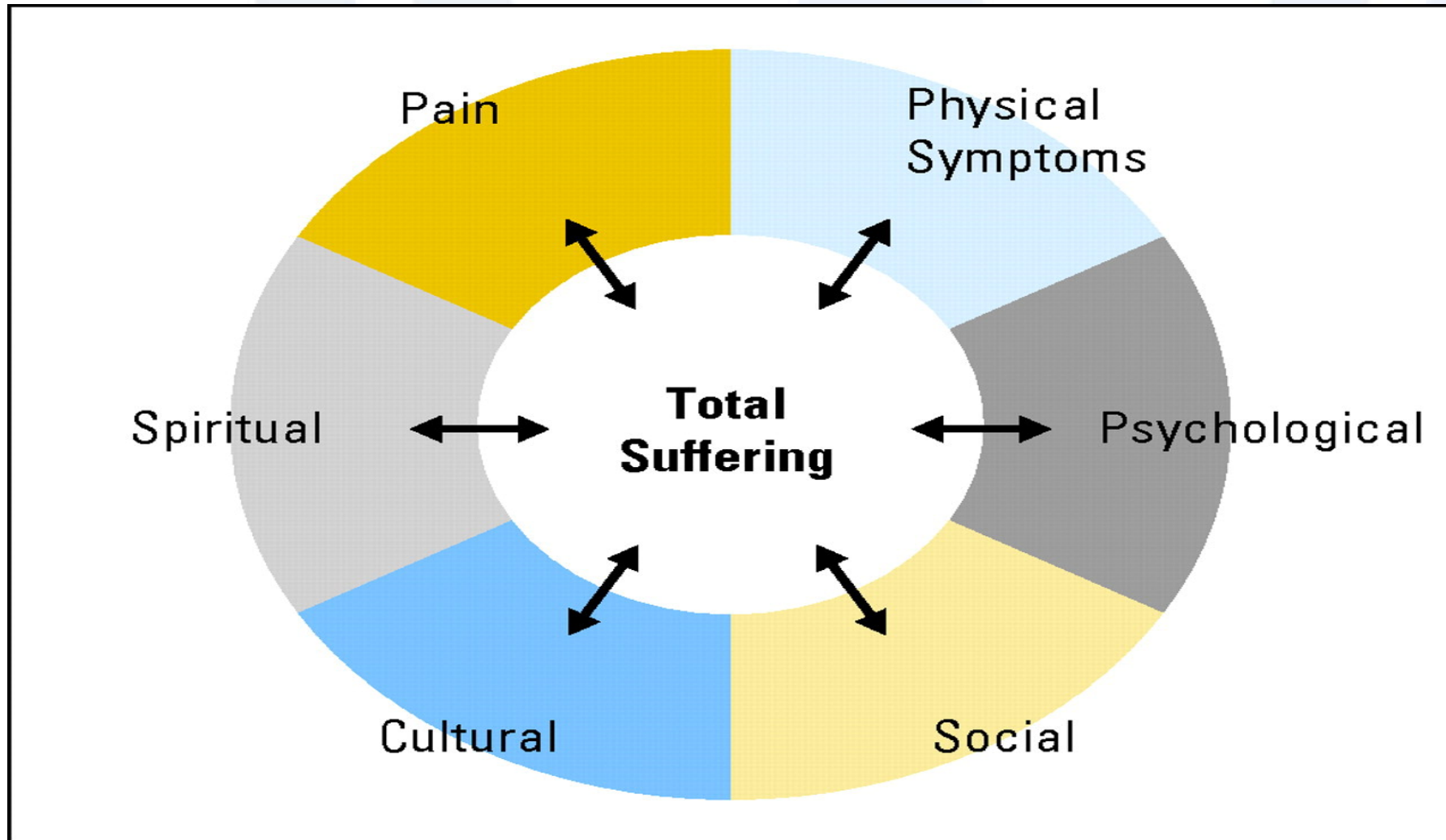




Tale of Two Patients

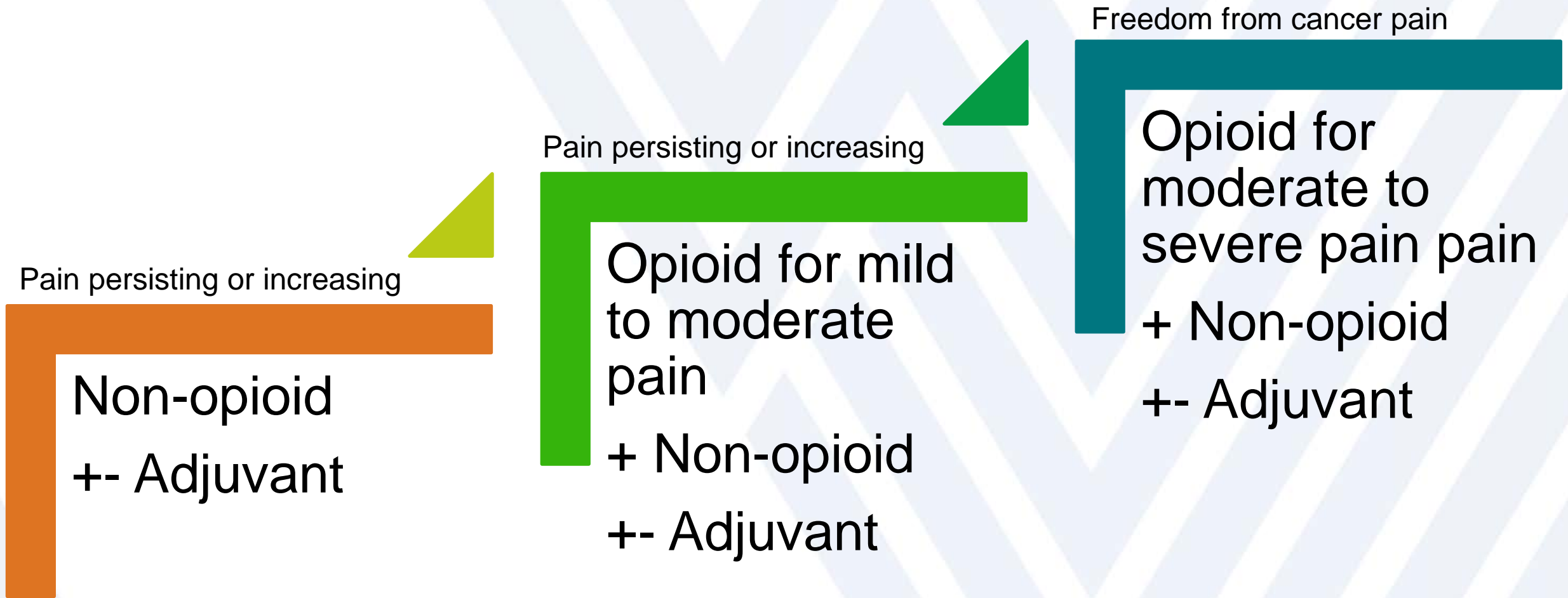






OPIOID POLICIES

World Health Organization



Medicines

- Codeine
- Fentanyl
- Hydromorphone
- Methadone
- Morphine
- Oxycodone
- Pethidine

Morphine Equivalence (ME)
ME minus Methadone

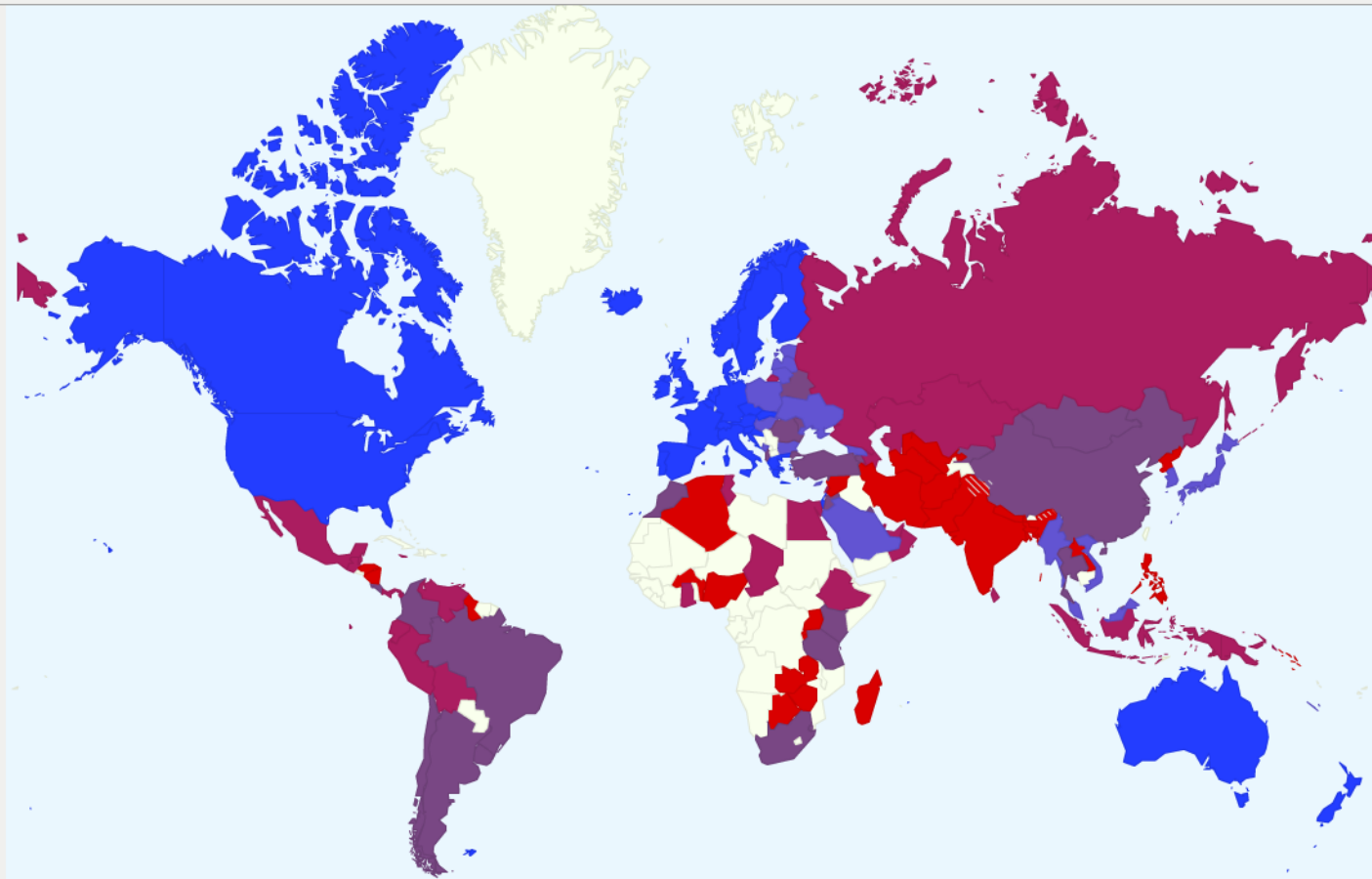
What is Morphine Equivalence?

Regions

- World**
- South America
- Central America
- North America
- All of Africa
- Central Africa
- Northern Africa
- Southern Africa
- Eastern Asia
- Southern Asia
- Asia/Pacific region
- Central Asia
- Middle East
- Northern Asia
- Northern Europe
- Western Europe
- Southern Europe

mg/Capita

- > 100
 - 25 - 100
 - 5 - 25
 - 1 - 5
 - < 1
 - No data
- Important Legend Note



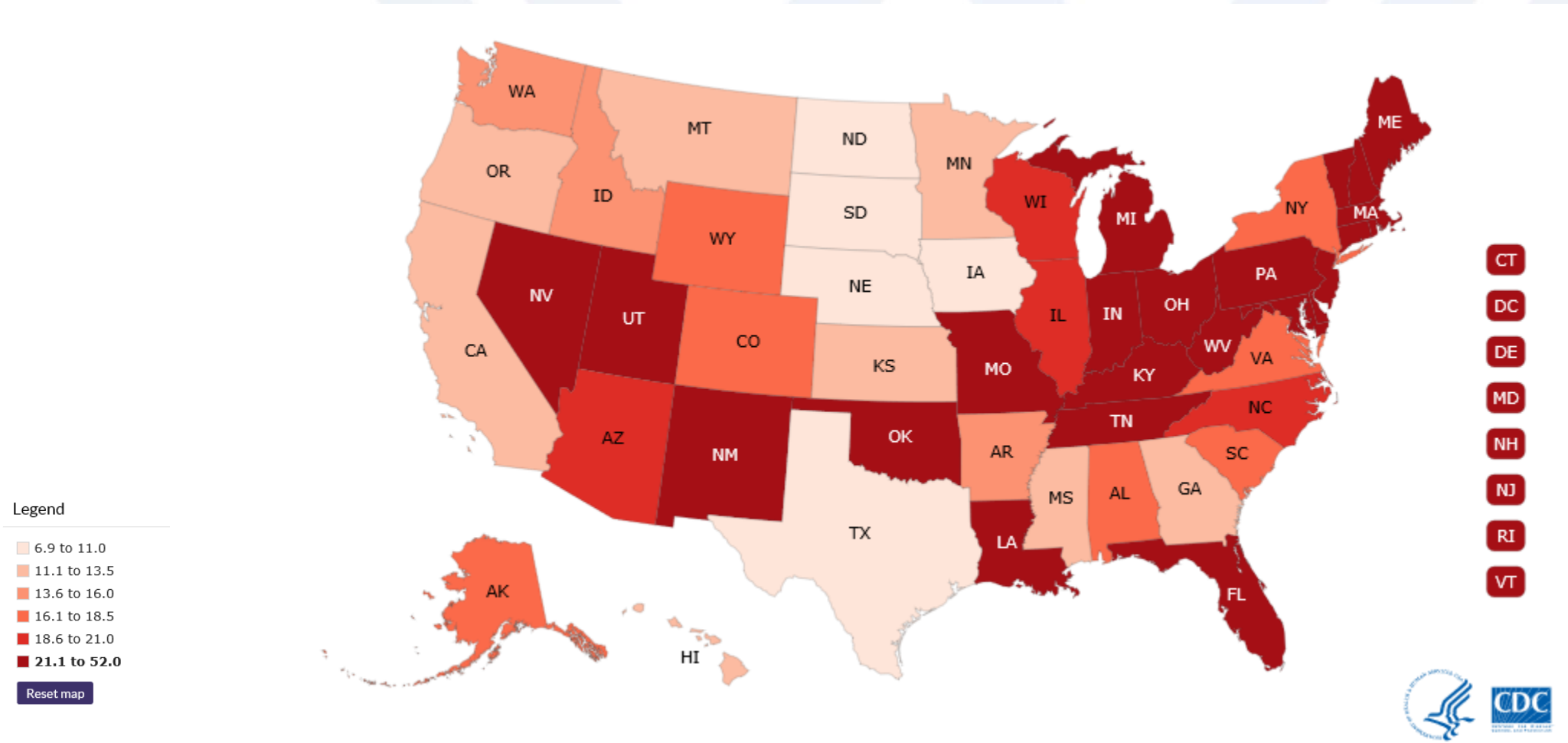
Years

- 2015**
- 2014
- 2013
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- 1972

Table 4 Regional low back pain YLD and DALY rankings in 2010 (out of 291 conditions), GBD 2010

Region	YLD ranking	DALY ranking
Globally	1	6
Central Asia	2	7
East Asia	1	5
Asia-Pacific high income	1	2
South Asia	1	10
Southeast Asia	2	7
Australasia	1	1
Caribbean	4	13
Central Europe	1	3
Eastern Europe	1	3
Western Europe	1	1
Andean Latin America	2	5
Central Latin America	2	7
Southern Latin America	1	2
Tropical Latin America	1	3
North Africa/Middle East	1	2
North America high income	1	3
Oceania	2	14
Central sub-Saharan Africa	3	23
Eastern sub-Saharan Africa	3	17
Southern sub-Saharan Africa	4	15
Western sub-Saharan Africa	2	13

CDC



Hospitalizations related to Opioids

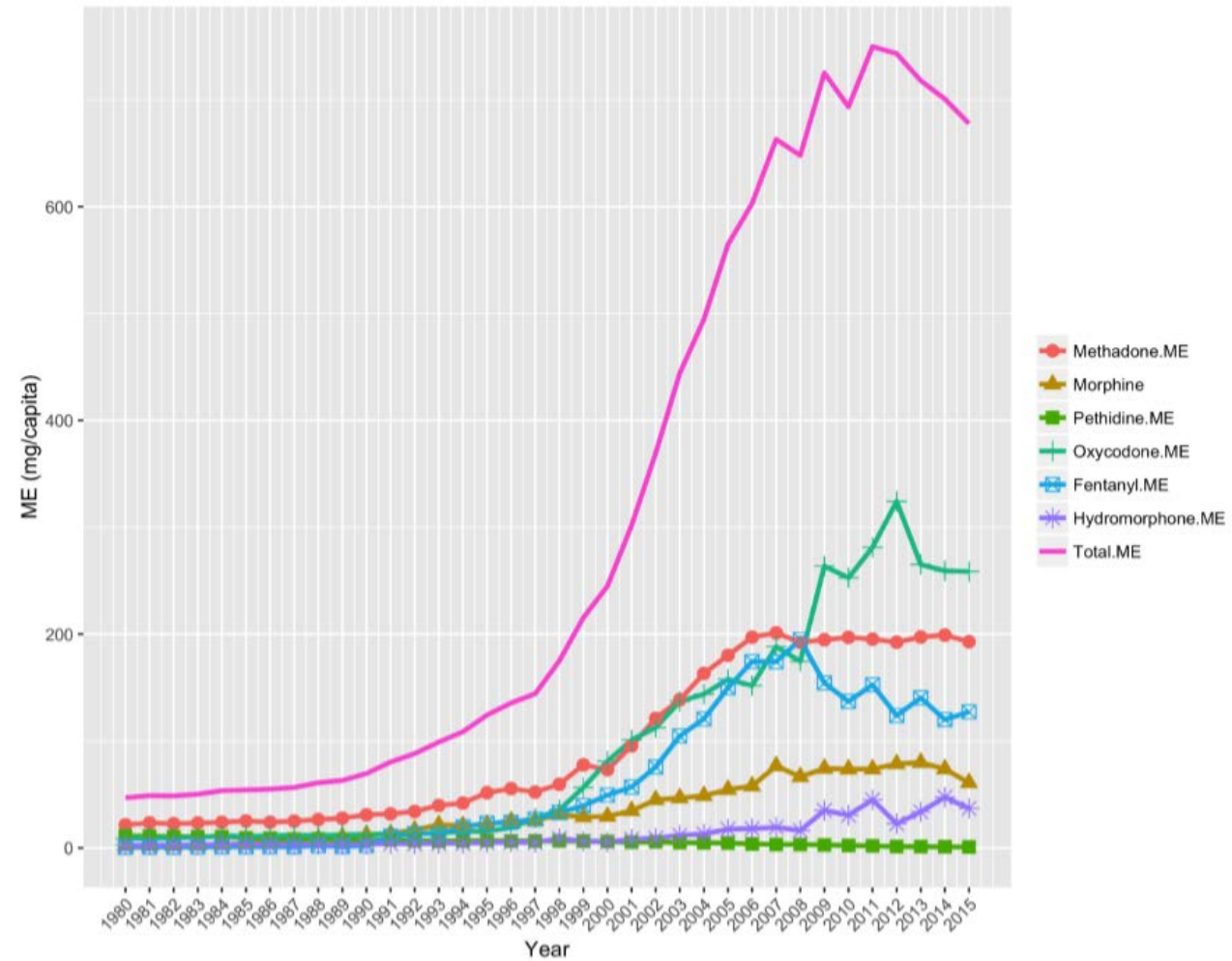
- In 2015, an estimated 78,840 hospitalizations occurred for opioid-related poisonings in the U.S.; the age adjusted rate was 23.2 hospitalizations per 100,000
- By region, hospitalization rates for opioid-related poisonings ranged from 18.9 in the West to 26.1 in the Midwest

Emergency Room Visits

- In 2015, an estimated 140,077 ED visits occurred for opioid-related poisonings in the U.S.; the age adjusted rate was 44.0 visits per 100,000 (Table 3b).
- By region, ED visit rates for opioid-related poisonings ranged from 27.6 in the West to 77.9 in the Northeast (Table 3b).

United States of America

Opioid Consumption in Morphine Equivalence (ME), mg per person



Sources: International Narcotics Control Board; World Health Organization population data
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2015

CDC recommendations

- **Determining When to Initiate or Continue Opioids for Chronic Pain**
 - Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred
 - Establish treatment goals with all patients
 - Discuss risks and realistic benefits of opioid therapy
 - Discuss responsibilities for managing therapy

- **Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation**
 - When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids
 - Prescribe the lowest effective dosage.
 - Three days or less will often be sufficient; more than seven days will rarely be needed.
 - Evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation.
 - Evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.

- **Assessing Risk and Addressing Harms of Opioid Use**

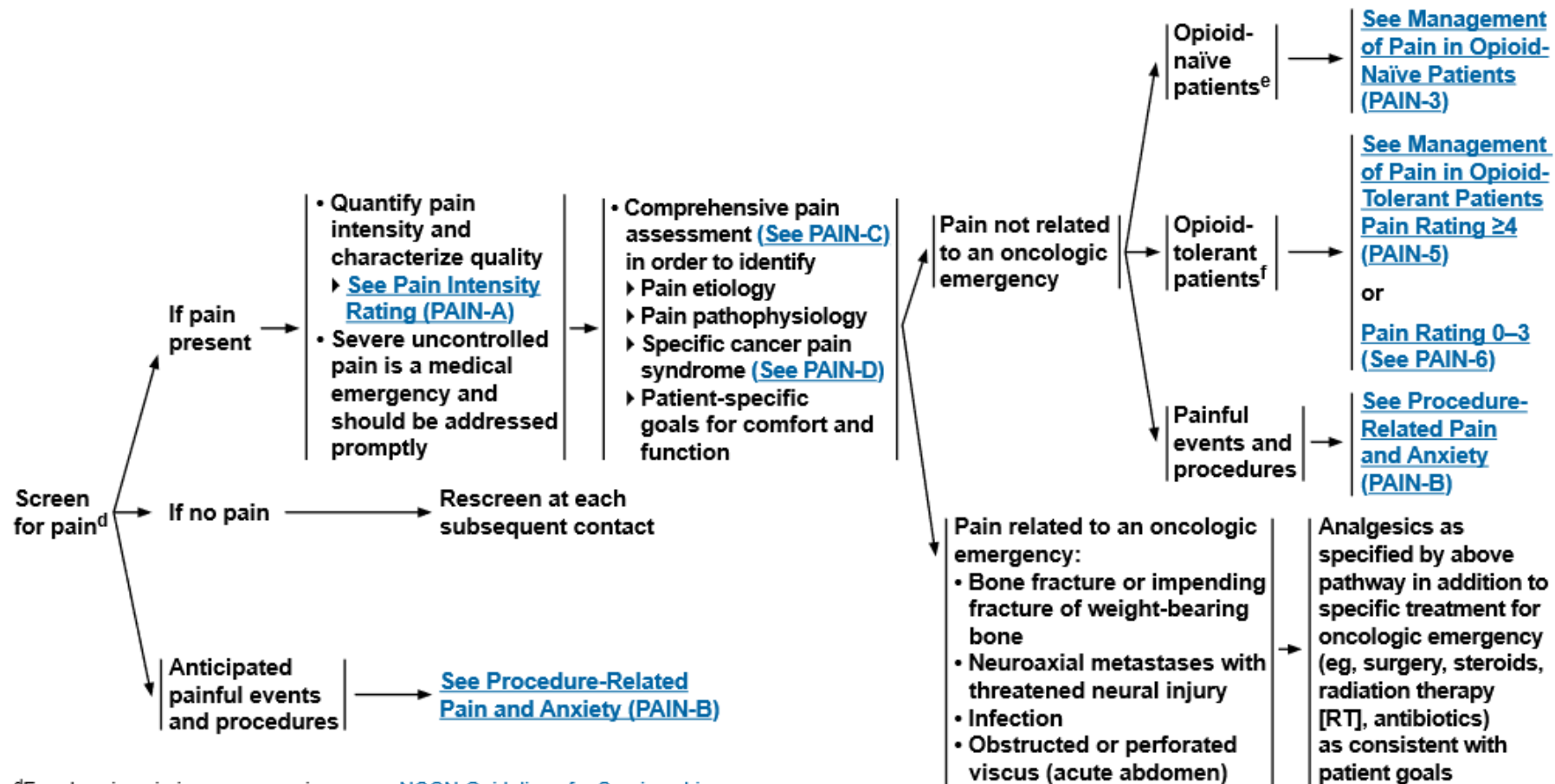
- Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms.
- Review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy
- Use urine drug testing before starting opioid therapy and urine drug testing at least
- Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

NCCN

Pain is defined by the International Association for the Study of Pain (IASP) as an unpleasant, sensory, and emotional experience associated with actual or potential tissue damage, or described in relation to such damage.

NCCN Pain Guidelines

- **General**
 - Survival is linked to quality of life
 - Analgesia therapy in conjunction with management of multiple symptoms
 - Psychosocial support
 - Multidimensional impact of suffering
- **Assessment**
 - Screened at each contact
 - Comprehensive pain assessment
 - Evaluate for opioid misuse/abuse
- **Management/Intervention**
 - Optimize Analgesia
 - Optimize ADLs
 - Minimize side effects
 - Avoid Aberrant behaviors
 - Comprehensive management plan



^dFor chronic pain in cancer survivors, see [NCCN Guidelines for Survivorship](#).

^eOpioid naïve includes patients who are not chronically receiving opioid analgesic on a daily basis and therefore have not developed significant tolerance. The FDA identifies tolerance as receiving at least 60 mg of morphine daily, at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.

^fOpioid tolerant includes patients who are chronically receiving opioid analgesic on a daily basis. The FDA identifies tolerance as receiving at least 60 mg of morphine daily, at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

West Virginia

- SEMP Guidelines
- WV Expert Pain Management Panel
- Senate Bill 273

Senate Bill 273

- Initial prescription
 - Must first refer or prescribe treatment alternatives
 - Must not exceed a seven-day supply and explain the associated risks.
 - Must document the patient's medical history, physical examination, treatment plan and PDMP
- For supplies greater than seven days,
 - must sign a opioid contract with the prescribing provider agreeing to
 - only get medication from one doctor
 - same pharmacy each time
- Adults receiving an initial opioid prescription in an emergency room or urgent care facility are limited to a four-day supply of opioid pain medicine.
- Minors are limited to a three-day supply.



Chronic Opioid Prior Authorization Form

The info requested in this form, although extensive, is based on best practice standards and the CDC Chronic Pain Opioid Guidelines. It is intended to facilitate the safe and effective treatment, improve outcomes, and reduce adverse events including opioid use disorder and/or overdose.

Rational Drug Therapy Program
 WVU School of Pharmacy
 PO Box 9511 HSCN
 Morgantown, WV 26506
 Phone: 1-800-847-3859
 Fax: 1-800-531-7787



Today's Date:	Requested Medication & Dose:	Diagnosis:
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PATIENT INFORMATION

Patient's Last Name:	First:	Middle:	Member ID Number:	Date of Birth:
Street Address:			City:	
State:	Zip Code:	Sex: <input type="checkbox"/> M <input type="checkbox"/> F	Race/Ethnicity:	

PRESCRIBER INFORMATION

Prescriber's Last Name:	First:	Middle:	Prescriber's NPI #:	Prescriber's DEA #:
Street Address:			City:	
State:	Zip:	Phone Number:	Fax Number:	

PHARMACY INFORMATION

Name:	Phone Number:
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MEDICAL INFORMATION

Please attach or list patient's current complete treatment list with the medical condition being treated included for each. (Non-Pharmacological, Prescriptions, OTCs, Herbals, Supplements, & Illicit Substances)

<p style="text-align: center;"><u>Current treatments</u></p>	<p style="text-align: center;"><u>Previously failed pain treatments of any/all types</u></p>
--------------------------------------------------------------	----------------------------------------------------------------------------------------------

Is the patient pregnant?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the patient allergic to any opioid medications? (If yes, please list and describe reactions in 2 to 3 words)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the patient have normal renal or hepatic function? (If No, please provide GFR, CrCl, and/or Hepatic Panel respectively)	<input type="checkbox"/> Yes <input type="checkbox"/> No

Confidentiality Notice: The documents accompany this telecopy contain legally confidential information belonging to the sender. This information is intended

Physical exam findings relevant to pain diagnosis (Please briefly describe after Height, Weight, & Vital Signs)				
Height:	Weight:	Blood Pressure:	Heart Rate:	Respiratory Rate:
Laboratory findings relevant to pain diagnosis (Please attach and/or briefly describe)				
Radiological findings (MRI, X-Ray, or Ultrasound) relevant to the pain diagnosis (Please briefly describe)				
Has the patient experienced a decrease in his/her daily function (i.e. ability to climb stairs, complete house work, perform tasks, etc.) beyond a subjective increase in daily pain?				<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the patient been screened for risk of substance-use disorder? (Please indicate risk screening tool & result)				<input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> Opioid Risk Tool (ORT)		<input type="checkbox"/> Current Opioid Misuse Measure (COMM)		
<input type="checkbox"/> Drug Abuse Screening Test (DAST)		<input type="checkbox"/> Prescription Drug Use Questionnaire (PDUQ)		
<input type="checkbox"/> Diagnosis, Intractability, Risk, & Efficacy Score (DIRE)		<input type="checkbox"/> Pain Medication Questionnaire (PMQ)		
What was the patient's risk of substance abuse based on the above screening tool?				<input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High
Does the patient currently have an up-to-date & signed Patient & Provider Agreement (Please Attach) including:				
<ul style="list-style-type: none"> • Therapeutic goals of reducing pain and improving functional outcomes • Treatment time frame with a planned end point as appropriate • Review of the associated risks of opioid therapy 				<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the patient been educated on the proper storage/disposal of controlled substances?				<input type="checkbox"/> Yes <input type="checkbox"/> No
Patient's opioid daily dose is >50MME/day. The CDC Opioid guidelines recommend education & utilization of naloxone.				
Has the patient been educated on being a candidate for carrying naloxone?				<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the patient been prescribed naloxone?				<input type="checkbox"/> Yes <input type="checkbox"/> No
WV Code §60A-9-5a requires initial and at least annual review of the Prescription Drug Monitoring Program (PDMP).				
Has the PDMP been reviewed immediately prior to the prescribing of the requested opioid medication? (If any unexpected results existed, please attach a copy to this request or briefly explain)				<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>This confirmatory information will be shared with the WV PDMP administration.</i>				
Has a Urine Drug Screening been completed prior to the prescribing of the requested opioid medication?				<input type="checkbox"/> Yes <input type="checkbox"/> No
Were the results consistent with current treatment and devoid of illicit substance? (If No, please state results)				<input type="checkbox"/> Yes <input type="checkbox"/> No
Practitioner Signature: _____				
<small>(If a signature stamp is used, then the prescribing practitioner must initial the signature, signatures by agents of the practitioner are not acceptable)</small>				

Confidentiality Notice: The documents accompany this telecopy contain legally confidential information belonging to the sender. This information is intended only for the use of the intended recipient. If you are not the intended recipient, please do not disseminate, distribute, or copy this information. If you have received this information in error, please notify the sender immediately by telephone or email.



West Virginia Controlled Substance Last Name with DOB Report						Report Date	10/16/2018
From	1/1/2010	To	10/16/2018	Date of Birth	1/1/1970	Prescription Count	33
Last Name	Galaxy						

Patient Name & Address	Sex	Prescriber Name	Prescriber DEA & Zip	Dispenser Name	Dispenser DEA & Zip	Rx Written Date	Rx Dispense Date & Date Sold	Rx Number	Product Name	Strength	Qty	Days	# of Refill	Sched	FOP
Ford , 123 Any Street, Anytown, 25301	U	Doctor Five	BC3461833 25130	BestestRx1	ARC297381 25301	01/04/2017	1/5/2017	1116347	Zolpidem Tartrate	10 MG	30.000	30	1/5	CIV	Medicare
Ford , 123 Any Street, Anytown, 25301	U	Doctor Three	AW2017615 25314	BestestRx1	ARC297381 25301	09/13/2016	9/13/2016	1093194	Clonazepam	0.5 MG	90.000	30	1/5	CIV	Medicare
Ford , 123 Any Street, Anytown, 25301	U	MEADE, ANDIE E PA-C	FH4566696 23061	BestestRx5	ACC297381 25301		11/4/2015	629179	Morphine Sulfate	60 MG	60.000	30		CII	Insurance
Ford , 123 Any Street, Anytown, 25301	U	SHAPAKA, SHERICA	AW2017615 25314	BestestRx5	ACC297381 25301		1/29/2015	600811	TRAMADOL ACETAMINO PHN	37.5/325 MG	12.000	2		CIV	Insurance
Ford , 123 Any Street, Anytown, 25301	U	Doctor TEN	BP5337161 25301	BestestRx5	ACC297381 25301		10/10/2012 10/10/2012	511179	APAP/HYDROCODONE BITARTRATE	500 MG-7.5 MG	20.000	3		CII	N/A
Ford , 123 Any Street, Anytown, 25301	U	Doctor Seventeen	BK4207494 25301	BestestRx5	ACC297381 25301		8/14/2012 8/14/2012	505333	Morphine Sulfate	15 MG	75.000	18		CII	N/A
Ford , 123 Any Street, Anytown, 25301	U	Doctor Seventeen	BK4207494 25301	BestestRx5	ACC297381 25301		8/14/2012 8/14/2012	505330	Morphine Sulfate	60 MG	60.000	30		CII	N/A
Ford , 123 Any Street, Anytown, 25301	U	Doctor Six	BH6775021 25557	BestestRx1	ARC297381 25301		7/11/2012	808548	Clonazepam	0.5 MG	90.000	30		CIV	Medicare
Ford , 123 Any Street, Anytown, 25301	U	Doctor Six	BH6775021 25557	BestestRx1	ARC297381 25301		6/11/2012	808548	ESZOPICLONE	2 MG	30.000	30		CIV	Medicare

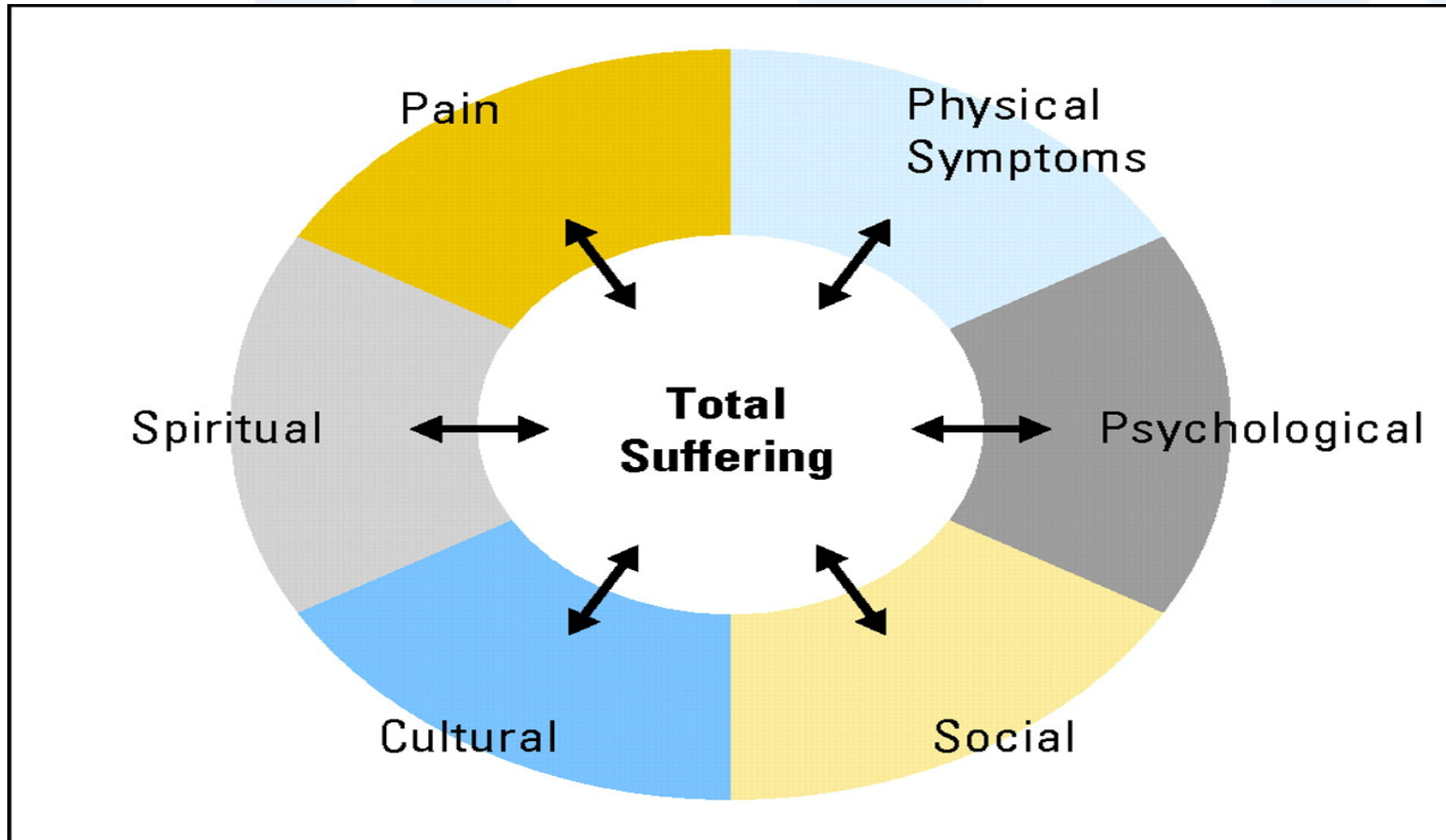
* Form of Payment

Page: 1 of 4

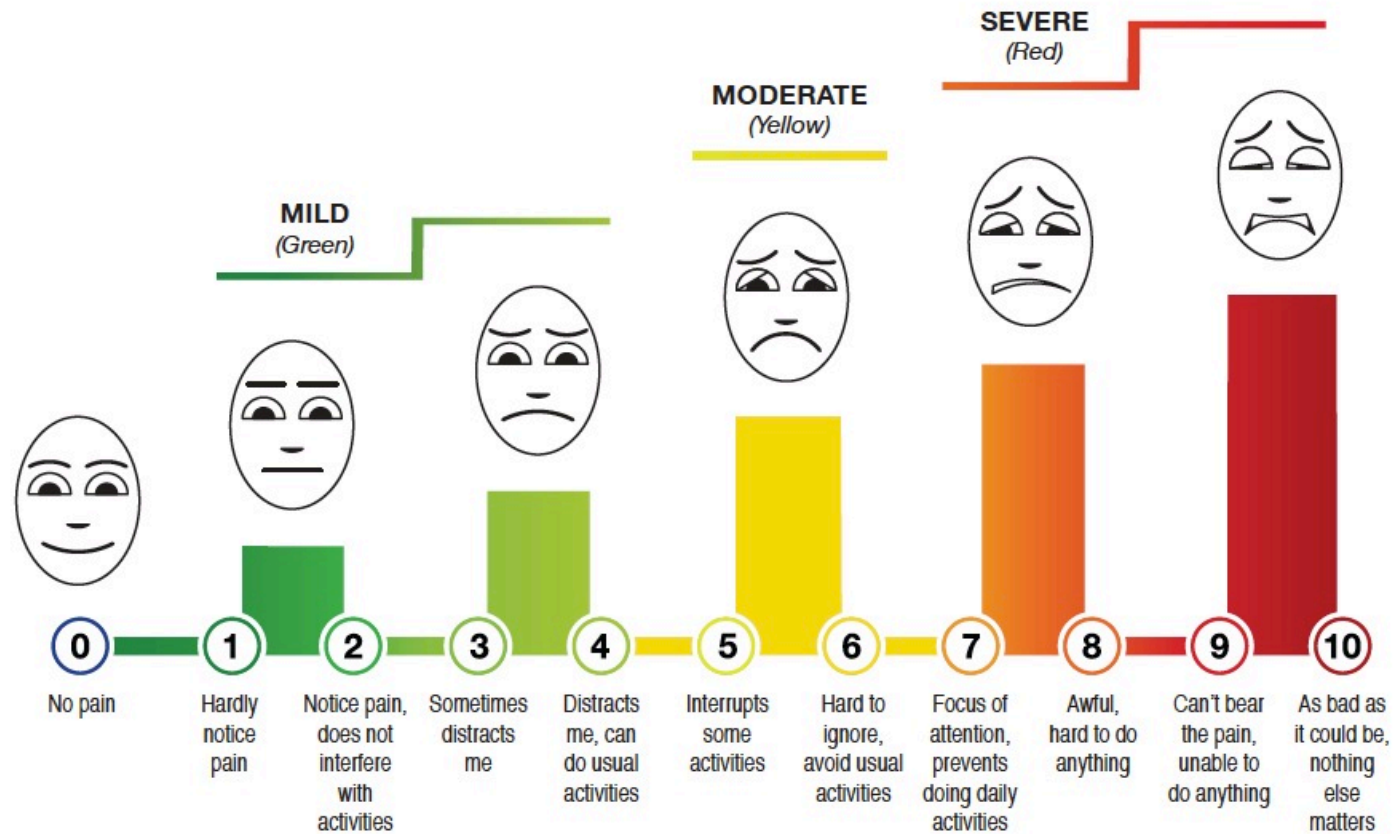
of Refill 0: Original Script 1/2 : 1st of 2 refills

Note : The State of West Virginia does not guarantee the above information to be complete/accurate. All reports are subject to search criteria entered by User and data provided by Dispensers. For information relating to a specific prescription, please contact the dispensing pharmacy or prescriber.

APPROACH TO LUNG CANCER PATIENTS EXPERIENCING PAIN



Defense and Veterans Pain Rating Scale



v 2.0

DoD/VA PAIN SUPPLEMENTAL QUESTIONS

For clinicians to evaluate the biopsychosocial impact of pain

1. Circle the one number that describes how, during the past 24 hours, pain has interfered with your usual **ACTIVITY**:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Does not interfere Completely interferes

2. Circle the one number that describes how, during the past 24 hours, pain has interfered with your **SLEEP**:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Does not interfere Completely interferes

3. Circle the one number that describes how, during the past 24 hours, pain has affected your **MOOD**:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Does not affect Completely affects

4. Circle the one number that describes how, during the past 24 hours, pain has contributed to your **STRESS**:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10
Does not contribute Contributes a great deal

*Reference for pain interference: Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. Ann Acad Med Singapore 23(2): 129-138, 1994.

v 2.0

Please circle the number that best describes:

No pain	0	1	2	3	4	5	6	7	8	9	10	Worst possible pain
Not tired	0	1	2	3	4	5	6	7	8	9	10	Worst possible tiredness
Not nauseated	0	1	2	3	4	5	6	7	8	9	10	Worst possible nausea
Not depressed	0	1	2	3	4	5	6	7	8	9	10	Worst possible depression
Not anxious	0	1	2	3	4	5	6	7	8	9	10	Worst possible anxiety
Not drowsy	0	1	2	3	4	5	6	7	8	9	10	Worst possible drowsiness
Best appetite	0	1	2	3	4	5	6	7	8	9	10	Worst possible appetite
Best feeling of wellbeing	0	1	2	3	4	5	6	7	8	9	10	Worst possible feeling of wellbeing
No shortness of breath	0	1	2	3	4	5	6	7	8	9	10	Worst possible shortness of breath
Other problem	0	1	2	3	4	5	6	7	8	9	10	

Patient's Name _____

Date _____ Time _____

Complete by (check one)

- Patient
- Caregiver
- Caregiver assisted

Sample Opiate/Pain Management Agreement*

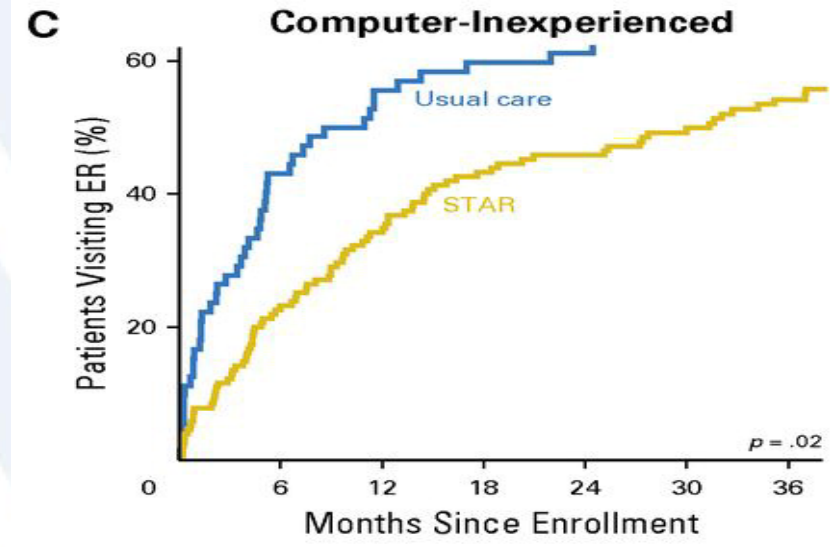
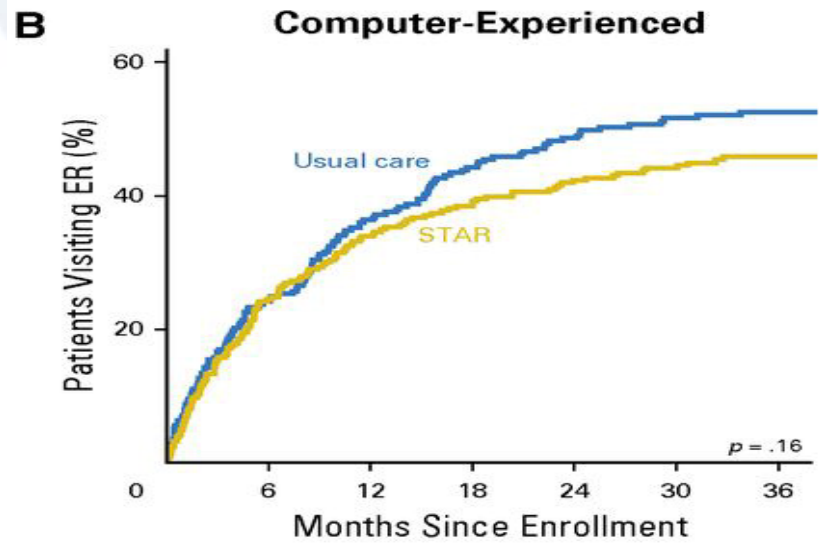
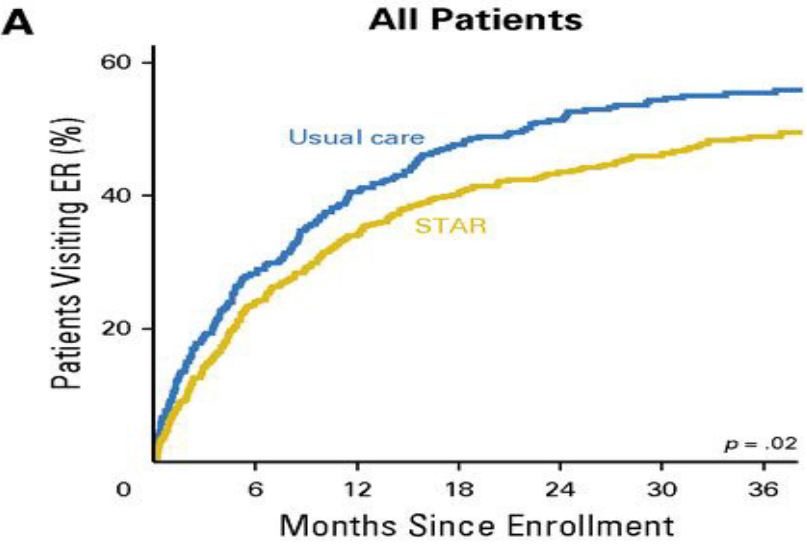
The purpose of this Agreement is to prevent misunderstandings about certain medications you will be taking for pain management. This Agreement is to help you and your provider to comply with the law regarding controlled pharmaceuticals.

- _____ I understand that there is a risk of psychological and/or physical dependence and addiction associated with chronic use of controlled substances.
- _____ I understand that this Agreement is essential to the trust and confidence necessary in a provider/patient relationship and that my provider undertakes to treat me based on this Agreement.
- _____ I understand that if I break this Agreement, my provider will stop prescribing these pain control medicines.
- _____ In this case, my provider will taper off the medicine over a period of several days, as necessary, to avoid withdrawal symptoms. Also, a drug-dependence treatment program may be recommended.
- _____ I would also be amenable to seek psychiatric treatment, psychotherapy, and/or psychological treatment if my provider deems necessary.
- _____ I will communicate fully with my provider about the character and intensity of my pain, the effect of the pain on my daily life, and how well the medicine is helping to relieve the pain.
- _____ I will not use any illegal controlled substances, including marijuana, cocaine, etc., nor will I misuse or self-prescribe/medicate with legal controlled substances. Use of alcohol will be limited to times when I am not driving or operating machinery and will be infrequent.
- _____ I will not share my medication with anyone.
- _____ I will not attempt to obtain any controlled medications, including opioid pain medications, controlled stimulants, or anti-anxiety medications from any other provider.
- _____ I will safeguard my pain medication from loss, theft, or unintentional use by others, including youth. Lost or stolen medications will not be replaced.
- _____ I agree that refills of my prescriptions for pain medications will be made only at the time of an office visit or during regular office hours. No refills will be available during evenings or on weekends.
- _____ I agree to use this pharmacy _____ located at this address _____ with the telephone number of _____ for filling my prescriptions for all of my pain medicine.

K:\Shrd\Prescription Monitoring Program\Resources

Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial

Ethan Basch, Allison M. Deal, Mark G. Kris, Howard I. Scher, Clifford A. Hudis, Paul Sabbatini, Lauren Rogak, Antonia V. Bennett, Amylou C. Dueck, Thomas M. Atkinson, Joanne F. Chou, Dorothy Dulko, Laura Sit, Allison Barz, Paul Novotny, Michael Fruscione, Jeff A. Sloan, and Deborah Schrag



No. At Risk								
Total	766	533	412	337	289	228	182	
STAR	441	323	254	209	179	144	109	
Usual Care	325	210	158	128	110	84	73	

Take Home

- Palliative care in lung cancer patients has been proven to decrease symptoms and increase survival
- Opioid policies are focus on population health, with special provisions for cancer patients
- Pain in cancer patients needs a multimodal approach



Questions?

Monika Holbein, MD

Monika.holbein@hsc.wvu.edu