Essentials for Policies that Support a Holistic Approach to the Opioid Epidemic

Fourth Annual Interprofessional Forum on Ethics and Religion in Health Care: TRANSFORMING APPROACHES TO SUBSTANCE USE DISORDERS
April 8, 2017

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U.S. Overdose Crisis:
52,404 Deaths in 2015
(33,091 from Prescription and Illicit Opioids)

And preliminary estimates suggest a 20% further increase in OD deaths in 2016.

Source: CDC NCHS 2017.

Overdose Deaths Primarily from Opioids: Prescription Drugs, Heroin and Synthetics (i.e. Fentanyl and similar)

People Misusing Analgesics Obtain them Directly & Indirectly by Prescription

Source: Han, Compton, et al. Annals of Internal Medicine 2017;167(5):293-301
**ENVIRONMENTAL AVAILABILITY:**
Current Opioid Crisis Originated with Prescribing Increases
(W. M. Compton, NIDA, 2017)

Opioid prescriptions
Tripled to MORE THAN 200 MILLION prescriptions in recent years

**HEROIN USE:**
2010 – Now: First Opioid Likely to be Heroin
(W. M. Compton, NIDA, 2017)

**ECONOMICS:**
Heroin Increases Due to Lower Price and Greater Availability
(W. M. Compton, NIDA, 2017)

**Retail Pharmacy Prescriptions for Naloxone Increase Markedly**
(W. M. Compton, NIDA, 2017)

- Retail prescriptions show an increase of 462% from the 4th quarter of 2013 to 2nd quarter 2016.
- Outpatient prescribing of naloxone may complement community-based distribution and first responder access.

**Opioid Use Disorders and Opioid Overdose Epidemic**
FEDERAL HEALTH SYSTEM PRIORITIES
“Treatment Gap”—Needing but not receiving treatment

White House Office of National Drug Control Policy (ONDCP)
National Drug Control Strategy 2016 Priority Areas

- Preventing drug use in communities
- Seeking early intervention in health care
- Integrating treatment for substance use disorders into health care and supporting recovery
  - Breaking the cycle of drug use, crime and incarceration
  - Disrupting domestic drug trafficking and production
  - Strengthening international partnerships
  - Improving information systems to better address drug use and its consequences

“A substance use disorder is not a moral failing but rather a disease of the brain that can be prevented and treated”

Healthy People 2020 [http://www.healthypeople.gov]

- Overarching Goals:
  - High-quality, longer lives free of preventable disease, disability, injury and premature death;
  - Health equity, elimination of disparities;
  - Social & physical environments that promote good health for all;
  - Healthy behaviors across the lifespan.

- Among Top 10 Leading Health Indicators/Focus Areas:
  - Mental Health & Mental Disorders
  - Substance Abuse

Dept. of Health and Human Services:
3 Priority Areas for Opioid-Drug Related Overdoses and Deaths

1. Improved opioid prescribing practices
2. Expanded use and distribution of Naloxone
3. Expansion of Medication-Assisted Treatment (MAT)

DHHS: Agencies in RED = those with most influence on mental health and substance abuse services

- Administration for Children & Families (ACF)
- Administration on Aging (AoA)
- Agency for Healthcare Research & Quality (AHRQ)
- Agency for Toxic Substances & Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid (CMS)
- Food and Drug Administration (FDA)
- Health Resources & Services Administration (HRSA)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Substance Abuse & Mental Health Services Administration (SAMHSA)

NIH Opioid Research Initiative

Using Research to End the Opioid Crisis

(P. M. Compton, MD, 2017)
Safe Opioid Prescribing

Increasing Rates of Chronic Pain & Use of Opioids in U.S. Healthcare

- 35% of American adults (116 million people) in the US suffer with chronic pain
- Annual health care and other related costs estimated to be $635 billion.
- Prior to mid 1980’s—cautious limited role
  - Surgery—managing perioperative pain
  - Pain management following severe injury
  - Pain relief and comfort at end of life, especially for cancer pain

Development of Pain Management as Subspecialty

- Anesthesiology—American Society of Regional Anesthesia and Pain was “reborn” in 1975
- 1998—American Board of Psychiatry and Neurology and American Board of Physical Medicine and Rehabilitation joined American Board of Anesthesiology in recognizing Pain Management as a subspecialty
- 2000—First joint examination was offered for certification by all 3 specialties
- Opioids became a commonly prescribed, low cost management approach to many patients with chronic pain

Regulatory Pressure to Improve Pain Relief and Increase Patient Satisfaction

1996 President of American Pain Society advocated use of pain as “fifth vital sign”
1999 Veterans Administration initiated measurement and documentation of pain as 5th vital sign (PSVS)
Expectation: pain score of 4 or higher would trigger “comprehensive pain assessment and prompt intervention”
2001 the Joint Commission on Accreditation of Hospital Organizations rolled out similar Pain Management Standards for non-VA settings

Promotion & Marketing of Opioids for Non-malignant Pain

- Purdue Pharma introduced Oxycontin in 1996
- Marketed 1996-2001 to >5,000 MDs, nurses & pharmacists at 40 national all-expense-paid pain management and speaker training conferences in CA, AZ and FL
- Targeted MDs who were highest prescribers of opioids (esp. Primary Care)
- Patient starter coupons for free 7 to 30 day supply of Oxycontin (34,000 coupons redeemed)
- Promoted aggressively for use in non-cancer pain, resulting in 10 fold increase in Rx to 6.2 million in 2002
- Reached blockbuster status by 2001 ($3 billion in sales 2001-2002)
- Total profits of >$35 billion

J. Paul Seale, MD; AMERSA, Nov. 2017
**Criminal Misrepresentation of Risk of Addiction by Purdue**

- Trained sales force to describe risk as “< 1%” for patients with chronic pain, based on 2 retrospective studies from 1980s
- Actual risk now known to be 8-12%, based on systematic review & data synthesis (Vowles et al, 2015)
- May 2007 3 Purdue executives pled guilty to claiming Oxycontin was less addictive and less subject to abuse & diversion than other opioids
- Paid $634 million in fines
- Marked increases in abuse, diversion, non-medical use & overdoses in early 2000’s
- 2004 most frequently abused opioid in US

**New Evidence Of Collusion By Congress, Lobbyists And Drug Distribution Industry**

- Reported by 60 Minutes and Washington Post Oct. 17, 2017
- Authored by Bill Whitaker of CBS News
- Based on information provided by Joe Rannazzisi, former head of DEA’s Office of Diversion Control

**Role of Distributors (Middlemen)**

- Cardinal Health, McKesson and Amerisource Bergen are Fortune 500 companies with significant money and influence
- Control distribution of 85-90% of prescription drugs in the retail U.S. market.
- Ship drugs manufactured by companies like Purdue Pharma and Johnson & Johnson to drug stores all over the country.

**Consistent Failure to Report Suspicious Orders**

- Under Controlled Substances Act distributors must report “suspicious orders” to the DEA.
- Consistently failed to report unusually large or frequent shipments
  - In Kermit, West Virginia, a town of 392 ordered 9 million hydrocodone pills over 2 years
  - Mid-sized distributor shipped more than 28 million pills to WV over 5 years, with 11 million sent to Mingo County (population 23,000)
- In 2008 DEA assessed fines of $13.2 million to McKesson and $34 million to Cardinal Health for filling hundreds of suspicious orders for millions of pills
- Total of distributors’ fines >$341 million over the last seven years.

**Industry Struck Back at DEA**

- Over the past decade recruited and hired at least 46 investigators, attorneys and supervisors from DEA into high-paying jobs with drug industry and law firms representing them
- Pressured top DEA lawyers to take a softer approach
- DEA bosses demanded more and more evidence
- Key leaders in DEA enforcement were reassigned to other duties
- By 2013 caseloads slowed down dramatically and success against suspicious shipments virtually stopped

**Industry Appealed to Congress**

- In 2013 began working with members of Congress to create legislation that would strip the DEA of its most potent tool in fighting opioid distribution
- “Marino Bill” promoted as way to ensure that patients had access to pain medication they needed
- Spent $102 million lobbying Congress, claiming DEA was out of control
Impact of Industry Influence on Legislation

- The “Marino Bill”
  - written by Linden Barber, ex-Director of DEA litigation and now Sr. VP with Cardinal Health
  - Introduced by Congressman Tom Marino and Congresswoman Marsha Blackburn
  - Presented to Senate in March 2016 & passed by unanimous consent by House and Senate with no objections and no recorded votes
  - Actual impact: has prevented the DEA from freezing suspicious shipments of opioids
  - No distributor shipments of narcotics have been frozen now for almost 2 years

Pharmaceutical Ties of Nominees for Major Washington Posts

- Nomination of Senator Marino as Head of ONDCP (“Drug Czar”) was announced Sept. 2, 2017 by White House
- Marino withdrew his name from consideration October 18, one day after the airing of the “60 Minutes” investigation
- Former pharma executive is now reported to be under consideration for nomination as head of Health and Human Services

Medication-Assisted Treatment (MAT)

- MAT includes opioid treatment programs (OTPs) and office-based opioid treatment (OBOT);
- MAT combines behavioral therapy and medications to treat substance use disorders;
- MAT for opioid addiction is subject to federal legislation, regulations, and guidelines, including DATA 2000 and federal regulation (42 CFR Part 8)

Center for Substance Abuse Treatment (CSAT)

Substance Abuse Treatment Facility Locator

- Searchable directory of drug and alcohol treatment programs that shows the location of facilities around the country;
- More than 11,000 addiction treatment programs, including:
  - Residential treatment centers,
  - Outpatient treatment programs,
  - Hospital inpatient programs,
  - Treatment programs for marijuana, cocaine, and heroin addiction,
  - Programs for adolescents, and adults.

Buprenorphine Prescribing

- Comprehensive Addiction Treatment Act of 2016 (“CARA 2016”)

- Designed to provide increased access to treatment in primary care and other office-based settings.
- The Act would allow patients to receive opioid replacement treatment (ORT) in their primary care provider’s office, thus decreasing the burden and shame of seeking treatment.
- However, when the law was enacted, only physicians who took a specialized class and request this designation could legally prescribe the medication.
- Each physician was limited to 30 patients per practice.
- Nurse practitioners/Physician Assistants were not included.

Comprehensive Addiction Recovery Act (CARA 2016): 3 Pillars

1. Supports expansion of diversion programs that channel individual caught in low-level drug law violation away from the criminal justice system and into evidenced based treatment instead.
2. Supports the expansion of medication assisted treatment (MAT) using methadone, buprenorphine and other forms of MAT. Includes those incarcerated in facilities not currently providing MAT for opioid use disorder.
3. Supports the expanded use of naloxone for first responders, who can quickly administer the medication and reverse the effects of the life threatening opiate overdose. The act authorizes grants which help to defray the cost.

CARA: Not funded

- Reauthorizes the funding for the National all Schedule Prescription Electronic Reporting Act for state prescription drug monitoring programs.
- Increases education to providers concerning opioid abuse, pain management and safe opioid prescribing.
- Expands use of MAT in conjunction with behavioral interventions.
- One section of the Act is dedicated to addressing care for the treatment for pregnant and postpartum women.
- The bill reauthorizes a grant program for residential opioid addiction treatment and creates a pilot program for agencies to address identified gaps in the continuum of care. This includes non-residential treatment services.

Patient Limits

- CARA allows states to lower the patient practice limit and allows states to require practitioners to comply with additional practice setting, education or reporting requirements. States cannot lower the patient limit below 30.
- CARA raised the per patient limit that restricted the number of patients a MD can treat with buprenorphine from 100 to 275 in an effort to improve patient access to care.

Provider Requirements

- Agrees to fully participate in the Prescription Drug Monitoring Program (PDMP) of the State in which the qualifying practitioner is licensed.
- Must complete 24 or more hours of training in the treatment and management of opiate-dependent patients provided by:
  - American Society of Addiction Medicine
  - American Academy of Addiction Psychiatry
  - American Medical Association
  - American Psychiatric Association
  - Or other organizations that the Secretary determines appropriate

CARA 2016: Waiver Requirements

- Waiver Notification to SAMHSA
- Submission of Training Certificate
- Special DEA Identification Number

https://www.samhsa.gov/medication-assisted-treatment/qualify-nps-pas-waivers
CARA: Nurse Practitioners
(Prescriptive Authority for Advanced Practice Nurses)

• Includes a provision that expands office-based treatment—
  – Permits Nurse Practitioners and Physician Assistants to
    prescribe buprenorphine for the first time.
  – Expands prescribing privileges for 5 years until 2021.
  – NPs and PA must complete 24 hours of training to be
    eligible for the waiver to prescribe buprenorphine.
  – If the NP resides in a state which requires MD
    collaboration or supervision, the MD must be supervised by a
    qualifying physician.
  – The HHS secretary has 18 months to provide guidance
    through updated regulations on office based opioid
    addiction treatment.

Nurse Practitioner/Physician Assistant
Requirements:

• 1. Licensed under state law to prescribe schedule III, IV or V
  medications for pain
• 2. Completed 24 or more hours of training in the treatment and
  management of opioid-dependent patients provided by previously
  named groups
• 3. Other training or experience that will demonstrate the ability of
  the NP or PA to treat and manage
  opioid-dependence
• 4. The NP/PA practices under the supervision of a
  licensed physician who holds an active waiver to prescribe
  Schedule III, IV, or V narcotic medication for opioid addiction
  therapy
• IF REQUIRED BY STATE LAW, practices in collaboration
  with a physician who holds an active waiver to prescribe
  medication for opioid addiction treatment

American Association Nurse Practitioners (AANP)
Nurse Practitioner State Practice Environment

RACE, EDUCATION & POVERTY

SOCIAL DETERMINANTS OF HEALTH

• Resources (Safe housing and local food markets)
• Educational, economic, and job opportunities
• Health care services
• Recreational and leisure-time opportunities
• Transportation options
• Public safety
• Social support
• Social disorder
• Culture
• Language/Literacy
• Residential segregation
• Crime & Violence
• Social norms and attitudes
  (Discrimination, racism, and distrust of government)
• Socioeconomic conditions
  (Concentrated poverty & stressful conditions that accompany it)
• Access to mass media and emerging technologies
  (Cell phones, Internet, and social media)

PLACE MATTERS:
THE RAT PARK EXPERIMENT (1970s)

https://www.youtube.com/watch?v=PKH8BOSLMQY

BRUCE ALEXANDER’S HYPOTHESIS: DRUGS DO NOT CAUSE ADDICTION;
ADDITION TO OPIATE DRUGS COMMONLY OBSERVED IN LABORATORY RATS
EXPOSED TO IT IS ATTRIBUTABLE TO THEIR LIVING CONDITIONS, AND NOT TO
ANY ADDICTIVE PROPERTY OF THE DRUG ITSELF.[1]

He told the Canadian Senate in 2001 that prior experiments in which
laboratory rats were kept isolated in cramped metal cages, tethered
to a self-injection apparatus, show only that “SEVERELY DISTRESSED
ANIMALS, LIKE SEVERELY DISTRESSED PEOPLE, WILL RELIEVE THEIR DISTRESS
PHARMACOLOGICALLY IF THEY CAN.”[2]

addiction
Baltimore City: Poverty Levels

RED: 40% to 100% of Population Earning <= $25,000

Baltimore City: Educational Attainment

BROWN: Lowest Education Opportunity

Baltimore City: Resident of Public Housing

RED: Public Housing Communities

Baltimore City: Violence

RED = Most Violence

Homicide Victims by Race: Baltimore, 2013

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http://data.baltimoresun.com/bing-maps/homicides/
Race and Illicit Drug Use:

![Graph showing drug use by race, ages 12 and older](Image)

Race and Heroin Use:

![Graph showing racial distribution of heroin users](Image)

Actual & Perceived Racism:

“May be cutting black men down before their time”

- Black men in America
  - Lower life expectancy
  - Increased risk for almost every health problem known
- UCLA Minority Health Study:
  - Gap persists when controlling for poverty & lifestyle
  - Possibly related to Stress Response (release of cortisol = "Toxic Cocktail" → BP ↑ blood sugar & ↓ immune sx)
  - Cumulative Stress Response compounds effects

Baltimore Sun, Susan Brink (10/4/07): Racism may affect black men’s health

Inequality and African-American Men in Baltimore, MD

Inequality and African-American Men in Baltimore, MD

Vicious Multi-Directional, Multi-Generational Cycle

Race, Education & Poverty

Access & Other Health Disparities

Criminal Justice Involvement

MASS INCARCERATION OF AFRICAN-AMERICAN MEN
“The New Jim Crow: Mass Incarceration in an Age of Colorblindness”

“A primary function of any racial caste system is to define the meaning of race in its time. Slavery defined what it meant to be black (a slave), and Jim Crow defined what it meant to be black (a second-class citizen). Today mass incarceration defines the meaning of blackness in America: black people, especially black men, are criminals. That is what it means to be black.”

Racial Inequality in the U.S. Justice System
(American Prospect, Sophia Kerby, March 17, 2012)

- **People of color**: 30% of US population; 60% of imprisoned
- **Incarceration Rates**: 1 in 15 African American men, 1 in 36 Hispanic men, 1 in 106 White men
- **Bureau of Justice Statistics**: 1 in 3 black men can expect to go to prison in their lifetimes
- **Human Rights Watch**: African-Americans
  - 14% of regular drug users
  - 37% of those arrested for drugs (1980-2007 > 25 million adult Afr Amer)

Baltimore Drug Arrest Data

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<td>Drug Arrests as Proportion of All Arrests</td>
<td>9.8%</td>
<td>28.6%</td>
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<td>Change in Rate of Drug Arrests per 100,000 (405% growth)</td>
<td>2,231</td>
<td>11,276</td>
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<td>White Change in Rate of Drug Arrests per 100,000 (185% growth)</td>
<td>573</td>
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<td>Black Change in Rate of Drug Arrests per 100,000 (759% growth)</td>
<td>832</td>
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<td>Black/White Ratio of Drug Arrests (Change = 3.01)</td>
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Ryan King (May 2008). Disparity by Geography: The War on Drugs in America’s Cities

“The Critical Link Between Health Care and Jails”
James Marks & Nicholas Turner, Health Affairs, March 10, 2014

- **Jail involved individuals** (people with a history of arrest and jail admission), carry a heavy illness burden, with high rates of infectious and chronic disease, mental illness, and substance abuse. Because these people tend to also be uninsured, jail frequently has been their only regular source of health care
- **30% of local corrections budget allocated for inmate health care costs**: “This investment is largely lost when people are released back into the community, where they typically do not get treatment”

“The Critical Link Between Health Care and Jails”
James Marks & Nicholas Turner, Health Affairs, March 10, 2014

- **People with untreated substance use or mental illness are at heightened risk of cycling in and out of jail** for low-level, non-violent offenses
- **The expansion of Medicaid eligibility under the Affordable Care Act is a critical opportunity to bring the jail-involved population into the mainstream healthcare system**
CURRENT POLITICAL ENVIRONMENT

“Public Health Emergency”
NOT “National State of Emergency”
(SO NO NEW FUNDING)

“The Commission blew an opportunity to share with the public what is well-known and understood by public health and addictions experts on the frontlines of the opioid epidemic—that there are proven harm reduction and treatment interventions that will be far more effective at curbing overdose fatalities than any supply reduction or enforcement strategy.”

Commission
Established March 2017
Final Draft Report
November 1, 2017

The White House Commission on Opioid Addiction released its final report on Nov. 1. The report contained a range of recommendations including increasing the number of drug courts and launching a public campaign to prevent abuse of opioids and to challenge the stigma associated with its use.

While much of the focus on the Commission’s final report is understandable in cataloging the recommendations, there is a bigger issue at play—what is absent.
We cannot incarcerate our way out of drug use and the opioid epidemic

Historically speaking.....

- Addiction treatment has always been segregated from the rest of healthcare, and almost always provided in separate specialty care addiction treatment programs.
- Financing for addiction treatment was also separated from other healthcare coverage, typically “carved out” and managed separately from the larger healthcare plan.
- Many private insurance plans have not covered addiction treatment at all. Over 80% of addiction treatment financing has come from government sources (Block grants, VA, etc.)
- Whether public or private, coverage has always been restricted to only the most advanced and severe form of substance use problem: addiction. Coverage for less severe but far more common forms of substance use disorders has never been included.

Affordable Care Act - ACA

- Uninsured people with substance use disorders (SUDs): Est. 1.6 million
- Medicaid Expansion: to cover SUD treatment in alternative benefit plans
- Mental Health Parity & Addiction Equity Act of 2008:
  - Enrollees in alternative benefit plans, Medicaid managed care plans, and the Children's Health Insurance Program.
  - All state Medicaid programs must ensure that coverage and limits on the use of treatment for SUD are no more restrictive than those placed on other medical and surgical services.

IOM Consensus Recommendations for Essential Health Benefits (EHB)

1. Ambulatory Patient Services
2. Emergency Services
3. Hospitalization
4. Maternity & Newborn Care
5. Mental Health & Substance Use Disorder Services, including Behavioral Health Treatment
6. Prescription Drugs
7. Rehabilitative and Habilitative Services
8. Laboratory Services
9. Preventive and Wellness Services & Chronic Disease Management
10. Pediatric Services, including Oral and Vision Care

6 Ways “Obamacare” is Already Changing Behavioral Health Coverage

1. Pre-existing conditions are now covered.
2. Insurance plans must offer parity of mental and physical health coverage.
3. There are limits on out-of-pocket spending.
4. Insurers must cover prescription drugs.
5. More people are getting treatment.
6. The already strained system isn’t keeping up.
Substance Use and Mental Health Disorders: Impact of Potential Repeal of the ACA

- Medicaid is single largest source of care for people with mental health and substance use disorders (SUDs)
- Approx. 25% of people with insurance coverage through Medicaid expansion have one or both disorders (Buck, 2011; Day, et al., 2016; Miller, 2013; Paradise, 2017; Toledo, 2017; Fornili, 2017)
- Medicaid-eligible individuals with SUDs more likely to experience:
  - Higher levels of medical & psychiatric comorbidity
  - Greater problem severity
  - Have more need for higher-complexity treatment (Bailey, 2017)
- About 30 million more people will lose insurance coverage (CBO, 2017)
- Increase "Treatment Gap" by over 50% (Frank & Glied, 2017)
- Approx. 217,000 additional deaths over next decade (Roberts et al., 2017)

In Closing: We are morally and ethically bound to address this drug addiction crisis, and the time is now.

- “We do not have a crisis of pills needing management, although pills are part of a picture we must address.
- We do have a crisis of people who need care responsive to who they are and the communities where they live.”
  
  **Stefan Kertesz, MD, MSc, Professor, Univ. of Alabama School of Medicine**

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"Knowing is not enough; we must apply. Willing is not enough, we must do.” Goethe