Opioid Use Disorders: Managing a Chronic Disease

Andrea N. Weber, MD, MME
Medical Director, Chemical Dependency Services
Medical & Psychiatric Hospitalist
UnityPoint Health – St. Luke’s Hospital
October 13, 2017
andrea.weber@unitypoint.org
Disclosures

- I have no conflicts of interest in relation to the content of this lecture.

http://www.yankeepotroast.org/img/soapbox.gif
Objectives

1. Risk stratify and recognize opioid misuse
2. Evaluate and diagnose an individual with an opioid use disorder
3. Recognize and manage opioid withdrawal
4. Compare and contrast available evidence-based treatment
Trends in Opioid Use

Mr. T – October 30, 2013

- 28 year old married, employed Caucasian veteran

- Traumatic motorcycle accident; opioids for pain
- Recreational opioid use with friends for 3-4 weeks

Timeline:
- 2002
- 2007
- 2009
- 2011
- 2013
Mr. T – October 30, 2013

**Other Substance Use History:**
- **Marijuana** – active daily user, self-medication
- **Alcohol use disorder, moderate to severe** – sustained, partial remission since 2007.
  - DUI charge still pending in California
- History of methamphetamine and cocaine use

**Psychiatric History:**
- History of ADHD – diagnosed in childhood
- **Post-traumatic stress disorder (PTSD)** – diagnosed 2004, no active treatment
## Opioids for Chronic Pain: Risk

<table>
<thead>
<tr>
<th></th>
<th>Overdose</th>
<th>Both</th>
<th>Addiction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-acting formulations</td>
<td>Daily dose &gt;100 MME</td>
<td></td>
<td>Adolescence</td>
</tr>
<tr>
<td>Concurrent benzodiazepines</td>
<td>Opioid use &gt;3 months</td>
<td></td>
<td>Genetic vulnerability</td>
</tr>
<tr>
<td>Age &gt;65 years</td>
<td>Depression</td>
<td></td>
<td>Chronic, poorly-defined pain</td>
</tr>
<tr>
<td>Sleep-disordered breathing</td>
<td>Substance-use disorder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal/hepatic impairment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of overdose</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Opioids in Chronic Pain: Risk

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk Screening</strong></td>
<td>• Dose, fill frequency, visits</td>
</tr>
<tr>
<td><strong>Treatment Agreements</strong></td>
<td>• Expectations of both patient and physician</td>
</tr>
<tr>
<td><strong>PMP Monitoring</strong></td>
<td>• Help ensure adherence to agreement</td>
</tr>
<tr>
<td><strong>Urine Drug Screening</strong></td>
<td>• Before and during</td>
</tr>
<tr>
<td></td>
<td>• Confirmatory testing if needed</td>
</tr>
</tbody>
</table>

Opioids for Chronic Pain: Risk
Mr. T – October 30, 2013

2002
Recreational opioid use with friends for 3-4 weeks

2007
Traumatic motorcycle accident; opioids for pain

2009
Continues on OxyContin 30 mg TID, but pain poorly controlled

2011
Supplements prescription with street purchases; crushing/snorting
30 days of OxyContin in 1 week + supplement; avoiding withdrawal and chronic pain

2013
Opioid Use Disorder

- 2 or more within 12 month period:
  - 1. Larger amounts or longer duration than intended
  - 2. Persistent desire or unsuccessful attempt to cut down/control use
  - 3. Significant time spent obtaining, using, or recovering
  - 4. Craving/strong desire/urge to use
  - 5. Failure to fulfill major roles (work, home, school)
  - 6. Continued use despite ongoing social problems
  - 7. Important activities reduced/aborted
  - 8. Recurrent use in hazardous environments
  - 9. Recurrent use despite physical or psychological problems
  - 10. Tolerance
  - 11. Withdrawal

Mild 2-3 symptoms. **Moderate 4-5. Severe ≥6.**
Comprehensive Care

Medical and Psychiatric Stabilization

Physical Evaluation

ASAM National Guidelines

Treatment

Risk Mitigation

Mr. T – October 30, 2013

- Concerns: OxyContin dose, pain control
- Last opioid use (OxyContin) 2 days prior
- Education about buprenorphine-naloxone provided to patient and wife.
- Informed consent documentation reviewed and signed.
Treatment Agreements

1. Introducing the treatment agreement
   1. Safety, Universal precaution

2. Defines behavioral expectations to ensure safe treatment
   1. One prescriber, One pharmacy
   2. Use medication only as prescribed only; don’t change dose
   3. Not using drugs or medications dangerous in combination
   4. Drug testing
   5. Pill counts
   6. Medication security (from theft, loss, children)
   7. Don’t share, give away, or sell medication
   8. Conditions under which treatment will be stopped

3. Responding to the breach in the agreement – more later…
Opioid Effects

Volkow, McLellan. NEJM 2016.
Opioid Withdrawal

**Vital Signs:**
- Fever
- Tachycardia
- Hypertension
- Tachypnea

**Neuropsychiatric:**
- Headache
- Tremor
- Yawning
- Anxiety/Agitation
- Irritability
- Insomnia

**Ears, Nose, Skin:**
- Mydriasis
- Lacrimation
- Rhinorrhea
- Sneezing
- Sweating
- Flushing
- Piloerection

**Gastrointestinal:**
- Nausea
- Emesis
- Diarrhea

**Genitourinary:**
- Urinary frequency
- Incontinence

**Musculoskeletal:**
- Myalgias
- Arthralgias
- Hyperalgesia
- Shivering
**Clinical Opioid Withdrawal Scale (COWS)**

<table>
<thead>
<tr>
<th>Score</th>
<th>Symptoms</th>
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<tbody>
<tr>
<td>0</td>
<td>Resting Pulse Rate: &lt;80 to &gt;120</td>
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<tr>
<td></td>
<td>Sweating: subjective vs obvious</td>
</tr>
<tr>
<td>1</td>
<td>Restlessness</td>
</tr>
<tr>
<td>2</td>
<td>Pupil size</td>
</tr>
<tr>
<td>3</td>
<td>Bone/joint aches</td>
</tr>
<tr>
<td></td>
<td>Runny nose or tearing</td>
</tr>
<tr>
<td></td>
<td>GI upset: cramps, nausea, emesis, diarrhea</td>
</tr>
<tr>
<td>4-5</td>
<td>Tremor</td>
</tr>
<tr>
<td></td>
<td>Yawning</td>
</tr>
<tr>
<td></td>
<td>Anxiety or irritability</td>
</tr>
<tr>
<td></td>
<td>Gooseflesh skin</td>
</tr>
</tbody>
</table>

Score 5-12 mild, 13-24 moderate, 25-36 mod severe, 36-48 severe

*Wesson DR, Ling W. J Psychoactive Drugs 2003.*
Mr. T – October 30, 2013

Induction

- COWS: 12
  - 2/0.5 mg
- COWS: 7
  - 4/1 mg
- COWS: 6
  - 8/2 mg BID

Time (hours):
- 0
- 1
- 2
Mr. T – Follow-up

**November-December**
- Weekly visits
- Took home OxyContin on 2 occasions
- Increased to 20/5 mg for pain
- No counseling yet

**January**
- Cancellation of appointment without reason
- Requests refill
- Iowa PMP: OxyContin from PCP
<table>
<thead>
<tr>
<th>Date</th>
<th>Buprenorphine</th>
<th>Other positives</th>
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<tbody>
<tr>
<td>October 30</td>
<td>NA</td>
<td>Oxycodone, THC</td>
</tr>
<tr>
<td>November 6</td>
<td>+</td>
<td>Oxycodone, benzo</td>
</tr>
<tr>
<td>November 13</td>
<td>+</td>
<td>None</td>
</tr>
<tr>
<td>November 20</td>
<td>+</td>
<td>Oxycodone</td>
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<tr>
<td>November 29</td>
<td>+</td>
<td>THC</td>
</tr>
<tr>
<td>December 30</td>
<td>+</td>
<td>THC</td>
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</table>
I am sorry that you were not able to make it to your appointment with me today.

The treatment agreement that you signed on October 30, 2013 includes the following items:

"I agree not to get prescription opioids from any other doctor." You did fill an Oxycontin prescription on January 9.

"I agree to participate in counseling and other recovery activities as recommended by my doctor and other members of my treatment team." You have not yet made and kept an appointment with your counselor.

If you are interested in continuing buprenorphine treatment, we will need to meet and discuss these discrepancies and come up with a plan that satisfactorily addresses them. This might include:
- scheduling and keeping appointments with Outpatient Substance Abuse Counselor
- executing a consent for release of information so that I can communicate directly with other prescribers
- increased frequency of monitoring visits and drug screening
Mr. T – Treatment Course

<table>
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<tr>
<th>Year</th>
<th>Total daily dose (mg)</th>
<th>UDS for other opioids</th>
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<tbody>
<tr>
<td>2013</td>
<td>0</td>
<td>Negative</td>
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<tr>
<td>2014</td>
<td>8</td>
<td>Positive</td>
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<td>2015</td>
<td>16</td>
<td>Negative</td>
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<td>2016</td>
<td>24</td>
<td>Positive</td>
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</table>
Natural History

Euphoria

Normal

Withdrawal

Tolerance & Physical Dependence

Acute use

Chronic use
Pharmacotherapies: Overview

1. Non-opioid therapy
2. Detoxification
3. Opioid-antagonists
4. Opioid-agonists
# Non-Opioid Therapies

<table>
<thead>
<tr>
<th>Medication</th>
<th>Symptom</th>
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</thead>
<tbody>
<tr>
<td>Clonidine</td>
<td>Diaphoresis, tachycardia</td>
</tr>
<tr>
<td>Ondansetron</td>
<td>Nausea</td>
</tr>
<tr>
<td>Benzodiazepine</td>
<td>Anxiety, Insomnia</td>
</tr>
<tr>
<td>Loperamide</td>
<td>Diarrhea</td>
</tr>
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</table>
Detoxification

- Low rates of retention in treatment
- High rates of relapse post-treatment
  - < 50% abstinent at 6 months
  - < 15% abstinent at 12 months
  - Increased rates of overdose due to decreased tolerance

Oral Naltrexone

- Well-tolerated, safe
- Duration of action 24-48 hours
- FDA approved 1984

- Benefit limited to highly motivated patients
  - > 80% of impaired physicians abstinent at 18 months

Cochrane Database of Systematic Reviews 2006.
Injectable Naltrexone (Vivitrol ®)

- IM injection (w/ customized needle) once a month
- FDA approved 2010
- Opioid-free for 7-10 days before treatment

- IM vs placebo for 24 weeks
- Weeks of confirmed abstinence (90% vs 35%)
- Patients with confirmed abstinence (36% vs 23%)
- Reduced cravings

Detoxification to Naltrexone

<table>
<thead>
<tr>
<th>Protocol Day</th>
<th>Naltrexone-Assisted Detoxification</th>
<th>Buprenorphine-Assisted Detoxification</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Ancillary medications(^a) to support abstinence</td>
<td>Buprenorphine, 6 mg</td>
</tr>
<tr>
<td>2</td>
<td>Buprenorphine, 2 mg sublingually every 1–2 hours, up to 8 mg</td>
<td>Buprenorphine, 4 mg</td>
</tr>
<tr>
<td>3 (Washout)</td>
<td>Naltrexone, 1 mg</td>
<td>Buprenorphine, 4 mg</td>
</tr>
<tr>
<td>4</td>
<td>Naltrexone, 3 mg</td>
<td>Buprenorphine, 4 mg</td>
</tr>
<tr>
<td>5</td>
<td>Naltrexone, 12 mg</td>
<td>Buprenorphine, 2 mg</td>
</tr>
<tr>
<td>6</td>
<td>Naltrexone, 25 mg</td>
<td>Buprenorphine, 1 mg</td>
</tr>
<tr>
<td>8</td>
<td>Extended-release injectable naltrexone, 380 mg i.m.</td>
<td>Extended-release injectable naltrexone, 380 mg i.m.</td>
</tr>
<tr>
<td>15</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- More likely to successfully start XR-naltrexone (56% to 32%)
- More likely to received 2\(^{nd}\) injection at week 5 (50% to 27%)
- Severity of withdrawal and depressive symptoms similar for both groups.

Naloxone

- Full opioid antagonist
- Intranasal (atomization, nasal spray), Intramuscular
- Standard-of-care
- Iowa 2016 standing order

- Pharmacies:
  - CVS
  - Walgreens
  - Hy-Vee
  - U of Iowa Pharmacies
  - Many more…
What is naloxone?
Naloxone (such as Narcan™) is a prescription medication that can reverse an overdose that is caused by an opioid drug. When administered during an overdose, naloxone blocks the effects of opioids on the brain and restores breathing. It can be given as an injection into a muscle or as a nasal spray.

Naloxone has no potential for abuse. If it is given to a person who is not experiencing an opioid overdose, side effects are rare. If naloxone is administered to a person who is experiencing an opioid overdose, it can produce withdrawal symptoms. Naloxone does not reverse overdoses that are caused by non-opioid drugs.

Naloxone should be stored at room temperature and away from light. The shelf life of naloxone is one to two years.

How to give naloxone:
There are four ways to give naloxone. Follow the instructions for the type you have.

**Nasal spray (assembly required)**
1. Remove the two colored caps from the delivery syringe.
2. Screw the white atomizer cone onto the top of the delivery syringe.
3. Remove the cap off the capsule of naloxone.
4. Gently screw the capsule of naloxone into the barrel of syringe.
5. Insert white cone into nostril; give a short, strong push on the end of capsule to spray naloxone into nose: one half (1 ml) of the capsule into each nostril.
6. If no response in 3 minutes, give a 2nd dose.

**Nasal spray (ready-to-use)**
1. Peel back the package to remove the device.
2. Place the tip of the nozzle in either nostril until your fingers touch the bottom of the patient’s nose.
3. Press the plunger firmly to release the dose into the patient’s nose.
4. If there is no response after 3 minutes, give 2nd dose in other nostril.

**Auto-injector (ready-to-use)**
1. Pull auto-injector from outer case.
2. Pull off red safety guard.
3. Place the black end of the auto-injector against the outer thigh, through clothing if needed, press firmly and hold in place for 5 seconds.
4. Repeat if there is no response after 3 minutes.

**Injectable naloxone**
(Recommended administration by trained EMS)
1. Remove cap from naloxone vial and uncover the needle.
2. Insert needle through rubber plug with vial upside down.

   Pull back on plunger and draw up 1 ml of naloxone.
3. Insert the needle into the muscle of the upper arm or thigh, through clothing if needed, and push on the plunger to inject the naloxone.
4. Repeat the injection if no response after 3 minutes.

Iowa Board of Pharmacy. 2016.
Opioid-Agonist Therapy (OAT)

Euphoria

Normal

Withdrawal

Tolerance & Physical Dependence

Acute use

Chronic use

OAT Maintenance
Methadone

- Synthetic opioid antagonist
- Long-acting
- Better pain control

- Side effects:
  - Prolonged QTc
  - Respiratory depression
  - Abuse potential

- Difficult to obtain
- Stigma

Methadone - Example

Reassess: 5-10 mg every 2-3 hours, up to 40 mg

Withdrawal: 20 mg

Give total dose every 24 hours

Cessation

0 6 24 48

Hours

Alford, D. Opioids: Research to Practice. CRIT 2016.
Opioid Treatment Program (OTP)

SAMSHA 2017.
Figure 1 - Heroin Use in Past 30 Days

407 MM Patients by Current Methadone Dose

Percentage Heroin Use

* Adapted from a study of 407 methadone maintenance patients.

Buprenorphine

- Partial opioid agonist
- High affinity
- Sublingual tablets, film, implant
- Slow receptor dissociation

- Available as monotherapy or combined with naloxone to prevent diversion.
# Buprenorphine – Available Options

<table>
<thead>
<tr>
<th>Name</th>
<th>Formulation</th>
<th>Available Doses</th>
<th>Target Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Buprenorphine</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generic</td>
<td>Sublingual tab</td>
<td>2, 8 mg</td>
<td>16 mg daily</td>
</tr>
<tr>
<td>Probuphine</td>
<td>Subdermal implant</td>
<td>74.2 mg</td>
<td>4 implants for 6 months</td>
</tr>
<tr>
<td><strong>Buprenorphine naloxone</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generic</td>
<td>Sublingual tab</td>
<td>2/0.5 mg, 8/2 mg</td>
<td>16/4 mg daily</td>
</tr>
<tr>
<td>Bunavail</td>
<td>Buccal film</td>
<td>2.1/0.3 mg, 4.2/0.7 mg, 6.3/1 mg</td>
<td>11.4/2.8 mg daily</td>
</tr>
<tr>
<td>Suboxone</td>
<td>Sublingual films</td>
<td>2/0.5 mg, 4/1 mg, 8/2 mg, 12/3 mg</td>
<td>16/4 mg daily</td>
</tr>
<tr>
<td>Zubsolv</td>
<td>Sublingual tab</td>
<td>1.4/0.36 mg, 5.7/1.4 mg</td>
<td>11.4/2.8 mg daily</td>
</tr>
</tbody>
</table>

Buprenorphine Taper vs Maintenance

Results:
- Completed 52 week trial
  - taper 0%
  - maintenance 75%
- Mean % urine negative
  - maintenance 75%
- Mortality
  - taper 20%

Buprenorphine

Drug Addiction Treatment Act (DATA)

FDA approval

Limit 30 patients per physician

Limit 100 patients per physician after 1 year

Limit 275 patients per physician after 2 years
PA/NP can waive with 24 hr training

Methadone vs Buprenorphine

Psychosocial Services - Methadone

McLellan, AT et.al , JAMA 1993
Psychosocial Services - Buprenorphine

**Mixed studies regarding the benefit of behavioral interventions**
- Research protocols vs real-life.

**What probably works (as a minimum):**
- Weekly interaction with a physician/health care provider
- Promotion of simple messages regarding abstinence and coping
- Regular urine screens at similar frequency

**More intensive behavioral interventions more likely to help:**
- Heroin use
- Chronic pain
- Poor psychosocial system

DATA Waivered Providers

SAMSHA 2017.
Now PCSS-MAT is offering No Cost 8 Hour MAT waiver trainings at times and days that are more convenient for you.

Take the MAT waiver course at a time that’s right for you.

Pajamas Optional

The American Osteopathic Academy of Addiction Medicine holds two online MAT waiver trainings per month. On weekends or during the week. At different times. Designed for you whether you live on the West or East Coast.

Go to pcssmat.org and see which sessions best suit your needs.
Prescription Monitoring Program (PMP)


If first time user:
1. Click “Register”
2. Will need DEA #
3. Request will be sent to Iowa Board of Pharmacy
4. When approved, you will receive notification.
5. Username: DEA number
6. Password: created at registration
Prescription Monitoring Program (PMP)

Please review your 'My Account' section to ensure that this information is accurate. After you login, go to 'My Account' to review and update all necessary information, especially your email address.


Prescription Monitoring Program (PMP)
### Request

<table>
<thead>
<tr>
<th>User Name</th>
<th>Response</th>
<th>Sent On</th>
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<tbody>
<tr>
<td>Andrea Weber</td>
<td>No results were found for the request criteria specified.</td>
<td>9/28/2017 2:29:00 PM</td>
<td>Patient Rx History Report.PDF</td>
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</table>

**Current Response**

Andrea Weber on Thu 9/28/2017 2:29 PM

No results were found for the request criteria specified.

Attachment: *Patient Rx History Report.PDF*
Prescription Monitoring Program (PMP)

Iowa Prescription Monitoring Program
Iowa Board of Pharmacy, Des Moines, IA 50309
Phone: (515) 281-5944 Email: terry.witkowski@iowa.gov Fax: (515) 281-4609

Patient RX History Report

This report may contain more than one patient's prescription information. Please review the "Patients that Match Search Criteria" section below to ensure all prescriptions belong to the requested patient.

Search Criteria: 

Date: 09-28-2017

Page: 1 of 2

<table>
<thead>
<tr>
<th>Patients that match search criteria</th>
<th>DOB</th>
<th>Address</th>
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<tbody>
<tr>
<td>Pt ID</td>
<td>Name</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Prescriptions</th>
<th>Fill Date</th>
<th>Product, Str, Form</th>
<th>Quantity</th>
<th>Days</th>
<th>Pt ID</th>
<th>Prescriber</th>
<th>Written</th>
<th>Rx #</th>
<th>N/R</th>
<th>Pharm</th>
<th>Pay</th>
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<tbody>
<tr>
<td>08/31/2017</td>
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<td>7256</td>
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</tbody>
</table>
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**Iowa Prescription Monitoring Program**  
Iowa Board of Pharmacy, Des Moines, IA 50309  
Phone: (515) 281-5944 Email: terry.witkowski@iowa.gov Fax: (515) 281-4609

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#### Search Criteria

<table>
<thead>
<tr>
<th>Fill Date</th>
<th>Product, Str, Form</th>
<th>Quantity</th>
<th>Days</th>
<th>Pt ID</th>
<th>Prescriber</th>
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**N/R:** N=New R=Refill  
**Pay:** 01=Private Pay 02=Medicaid 03=Medicare 04=Commercial Ins. 05=Military Inst. and VA 06=Workers Comp 07=Indian Nations 99=Other  
**Prescribers for prescriptions listed:**  
BER DA50  
VAN D161

**Pharmacies that dispensed prescriptions listed:**  
A84102961  UNIV OF IA HOSP & CLINICS: PHARMACY DEPARTMENT, 200 HAWKINS DRIVE, IOWA CITY, IA 52242  
BH9569851  HUMANA PHARMACY INC DBA RIGHTSOURCE, 4302 WEST BUCKEYE ROAD, PHOENIX, AZ 85043  
BW6312742  WAL-MART PHARMACY 10-2710, 3601 29TH AVENUE S.W., CEDAR RAPIDS, IA 52404

Date: 09-28-2017  
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