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Methadone Pearls and Perils:

A Tool Kit for Safe and Effective Methadone Prescribing in Hospice and Palliative Medicine

Prepared for LeadingAge Ohio's Momentum Conference, August 30, 2022
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Welcome to our presentation!

What brings us here today?

Our ***passion*** for exquisite patient care and a ***commitment*** to safe and effective opioid prescribing

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Methadone and The Opioid Wars

- Since 2008, an epidemic of opioid overdoses in Ohio and in the nation
- Concern for the loss of life to drug overdose or addiction
- The marginalization of "real patients with real pain", and the villainization of their prescribers
- Pain – the new 4 letter word!

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Conundrum for Hospices: "Twin Serpents in the Caduceus"

To assure that we relieve the pain of our patients, but…

…never allow our medications to fall into the hands of those they may harm

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Is Methadone a "pearl" in the opioid epidemic or a "peril"??

- Methadone has the capacity to provide exquisite pain relief with fewer side effects and more comfortable dying for hospice and palliative care patients in a cost-effective way.
- If diverted or prescribed inappropriately by inexperienced prescribers, it is as dangerous or more dangerous than other opioids.

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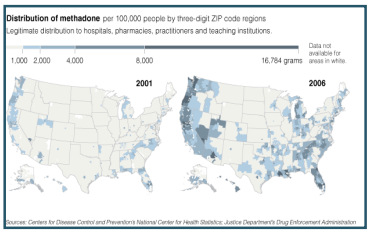

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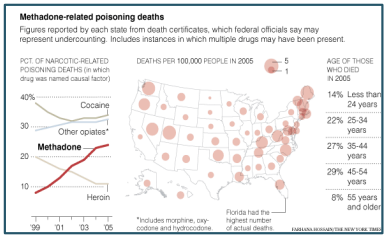

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Objectives:

- Describe the "pearls and perils" of prescribing Methadone for hospice and palliative medicine patients
- Describe policies, procedures, and key resources that must be in place in your organization in order to ensure that Methadone is prescribed and monitored properly and tolerance for diversion is "Zero"

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In order to understand the "Pearls and Perils" of Methadone, we must understand Methadone Pharmacology and Pharmacokinetics.

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History of Methadone – an early "designer drug"

- Synthesized in 1939 by drug manufacturer Farbwerke Hoechst in Frankfurt, Germany after long research into synthetic opioids
- "VA 10820", first known as Methadone around 1947
- No evidence that it was used as a painkiller during WWII – not approved
- Trade name - Dolophine
- Commercial use: 1947 by Eli Lilly & Co - "Dolophine"
- The first and only long-acting opioid for oncologists before the development of MS Contin in the 1980s

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Pharmacokinetics:

Distribution

- Two Phases:
  1. Alpha (A) distribution phase: 2-3 hour
  2. Beta(B) distribution phase: 8-12 hours
- Highly protein bound - mostly to acid glycoprotein (AGG), levels that can fluctuate widely in the body: 60-90% protein bound
- The unbound fraction is pharmacologically active
- Gradually absorbed into fat tissue and protein which serve as a reservoir and then released into the circulation
- The plasma concentration is maintained by this tissue reservoir

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High Lipophilicity:

- Widely distributed in body tissue
  - Helps explain long half-life with repeated doses
- Highest concentration around lungs
- Lowest concentration in the brain, gut, kidney, liver, and muscle

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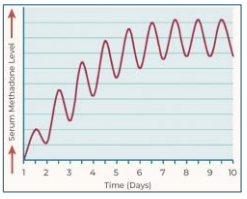
Pharmacology of Methadone – Metabolism:

- Primarily in liver, some in gut
- Significant variation among individuals
- Long half-life of 5-130 hours, mean 20-35
- 4-10 days to achieve steady-state
- Gender variability:
  - Women metabolize faster than men



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Pharmacology of Methadone – Metabolism:

Liver

- Methadone is metabolized by the liver to inactive metabolites
- Liver failure increases the T1/2 of Methadone
- In liver failure, increase the interval between doses

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Metabolism - Liver:

- Metabolized in the liver by the CYP450 enzyme system, mainly the CYP3A4 enzyme
- Other medications influence the metabolism of Methadone by "inducing" an increase in the enzyme system activity, or "inhibiting" the enzyme system, decreasing the enzyme activity
- These drugs are called inducers and inhibitors and can profoundly affect the serum level of Methadone – causing Methadone toxicity or withdrawal if they are added to the medication list of patients on Methadone

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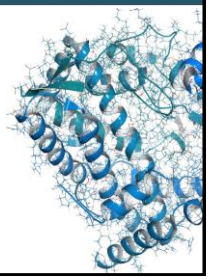
Metabolism - CYP450 System:

- Methadone itself inhibits certain CYP450 enzymes and affects metabolism of other drugs
- Approximately 50-60% of drugs (non-opioids) are metabolized by the CYP3A4 (shown at right)
- This has huge implications for the safe prescribing of Methadone – especially in a world where so many of our patients are on so many medications



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Metabolism of Opium-Based (natural/plant-based) Opioids:

- Opioids undergo hepatic metabolism (glucuronidation or demethylation, dealkylation - depending on the specific opioid) followed by renal clearance
- Morphine is glucuronidated to M-3-G and M-6-G as well as demethylated to normorphine
- Hydromorphone is glucuronidated to H-3-G

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Natural (opium-based) Opioid Metabolites:

- M-3-G and H-3-G have no analgesic effects but are neuroexcitatory in the nervous system
- In the CSF, [M-3-G] > [morphine] by 2-fold
- As the CNS [M-3-G] or [H-3-G] levels increase, neuroexcitatory behaviors increase: Hyperalgesia Syndrome
- As Methadone has no active metabolites, much lower risk of Opioid Hyperalgesia Syndrome - common cause of terminal agitation / delirium

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Pharmacology of Methadone – Elimination:

- Urine (primary), biliary, and feces
- Metabolites are inactive (useful with renal failure but cautious approach with severe renal impairment)
- pH of the urine can change elimination curve of the Methadone
- As renal insufficiency increases, elimination of Methadone by feces increases

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Elimination:

Long and variable elimination

- Two phases:
  - Alpha 6-8 hours
  - Beta(elimination distribution) 15-60 hours
- Plasma concentration maintained by slow release from tissue reservoirs

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Pharmacology of Methadone - How it works:

- Affects the Mu-opioid receptors
  - Similar to morphine, hydromorphone, oxycodone
  - Analgesia, euphoria, physical dependence, respiratory depression, miosis, decreased GI motility
- Affects the Kappa-opioid receptor
  - Analgesia, sedation, respiratory depression
- Delta-opioid receptor
  - Analgesia, dysphoria, hallucinations

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Pharmacology of Methadone - How it works:

- Inhibit reuptake serotonin and norepinephrine - **therefore can contribute to serotonin syndrome!**
- NMDA receptor antagonist
  - Prevent central sensitization: complex regional pain syndromes, chronic pain
  - Reduce opioid tolerance
  - Treats neuropathic pain
  - Reverse Opioid Hyperalgesia Syndrome

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Pharmacology:

- Methadone prolongs the phase of electrical transmission thru the A-V node leading to Q-T prolongation
  - increases risk of ventricular arrythmias

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How does the fascinating pharmacology and pharmacokinetics of Methadone make it the opioid with Pearls and Perils??

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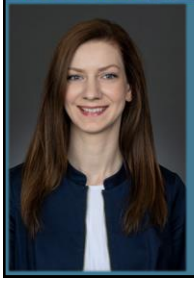

Ellen Ji, DO

2022 - 2023 Fellow
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Methadone Pearls:

Methadone is a **great** drug for hospice and palliative care!

- Variety of routes: PO, PR, IV, sub-Q, PEG tube, sublingual, buccal
- The only LIQUID long-acting opioid
- Short-acting: Immediate release when medication is ingested
- Long-acting: slow release once at steady state
- Lower pill burden

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Methadone Pearls:

Affects Nociceptive and Neuropathic Pain Receptors

- Hospice patients have both acute and chronic pain
  - acute pain is perceived as nociceptive
  - chronic pain is neuropathic
- Methadone is the only opioid with significant affect on the NMDA K and delta receptors and other neuropathic pain receptors in the brain as well as mu and kappa

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Methadone Pearls:

No active metabolites = improved safety in renal and hepatic disease, and at end of life!

- Perhaps the most important aspect of Methadone's profile
- The only opioid other than fentanyl with no active metabolites
- No active metabolites: if hepatic metabolism or renal clearance is decreased, Methadone doesn't accumulate dangerously in the body
- **Active metabolites from other opioids are the cause of opioid hyperalgesia syndrome - a leading cause of agitation and delirium at the end of life, so more peaceful dying- rotate to Methadone to treat Opioid hyperalgesia syndrome**

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Methadone Pearls:

- Safe in elderly, debilitated patients with proper dose reduction recommendations
- Safe for patients with true allergy to other opioids: no plant-based allergens as in natural (poppy-based) opioids

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Methadone Pearls:

- Very cost effective, especially for large population distribution

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Methadone	Generic	10mg q8h	$152/yr
MS-ER	Generic	60mg q12h	$2381/yr
MS-ER	MS-Contin	60mg q12h	$6500/yr
MS-ER	Kadian	120mg qd	$15000/yr
Fentanyl-p	Duragesic Generic	50mcg q72h	$10536/yr $3600/yr
Oxycodone -ER	Oxycontin	40mg q12h	$9768/yr

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Methadone Pearls:

Tolerance resistant

- Patients on Methadone do not develop drug resistance/tolerance like they do to other opioids
- Means fewer dosing changes and potential errors
- Patients maintain comfort and pain control for longer intervals

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Methadone Pearls:

Favorable side-effect profile

- Antidotally less constipation
- Antidotally less nausea and vomiting
- Dizziness may be noted, particularly early in therapy
- Sweating may be more than with other opioids

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Methadone Perils:

Complex pharmacometrics require prescriber expertise

- Variable half-life: 5-150 hours, average is 24 hours
- Long onset of action when first administered: Initiation of therapy may require the patient to take frequent doses of breakthrough pain (BTP) medication to maintain comfort for several days until Methadone takes affect – usually 3-4 days before onset of effectiveness is noted
- Very difficult to rotate to other opioids from Methadone

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Methadone Perils:

Multiple conversion calculations

- New learners are challenged to understand the pharmacokinetics, the myriad of methods of prescribing, and the vast difference between Methadone and other opioids

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Methadone Perils:

- Risk for prolonged sedation/somnolence due to the long half-life
- Patients with a Methadone overdose may require a Naloxone drip rather than a one-time administration – will require admission to the hospital or hospice IPU for the drip and monitoring
- Amount of Naloxone needed to reverse the somnolence is given as an hourly drip: example - 0.2mg of Naloxone revives consciousness, then give 0.2 mg / hour IV

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Methadone Perils: Drug Interactions

	Inducers	Inhibitors
The Impact:	Increase metabolism (breakdown) of methadone	Decrease metabolism (breakdown) of methadone
The Result:	Decrease methadone concentration	Increase methadone concentration
The Risk:	Methadone dose may be inadequate	Methadone dose can become toxic
The Fix:	Encourage use of rescue opioid	Decrease TDD by 25%
The Meds:	Carbamazepine	Amiodarone
	Anti-retrovirals	Amitriptyline
	Anti-convulsants: Phenobarbital, Phenytoin	Antibiotics: ciprofloxacin, clarithromycin, erythromycin
	Anti-TB: Rifampin	Antifungals: -azoles
	St. John's Wort	SSRIs
	Spironolactone	Antacids: omeprazole (Gelfman)

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Methadone Perils:

Potential for cardiac toxicity

- QTC prolongation
  - Risk of life-threatening arrythmia: Torsades de Pointes
  - Increased if patient is on other medications that also cause QT prolongation
  - Cardiac screening required prior to initiation of Methadone for palliative care patients, generally hospices do not do EKGs or worry about the QT risk

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Methadone Perils: Drug Interactions

QTC prolonging Rx classes	Some examples:
Anti-arrhythmics	Amiodarone, sotalol
Anti-psychotics	Haloperidol, chlorpromazine, risperidone, quetiapine
Quinolone antibiotics	Ciprofloxacin, levofloxacin, moxifloxacin
Macrolide antibiotics	Clarithromycin, erythromycin
Anti-emetics	Prochlorperazine, ondansetron
Tricyclic antidepressants	Amitriptyline, nortriptyline
Muscle relaxant	cyclobenzaprine

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Methadone Perils:

- Patient with hypokalemia
- Patient has low prothrombin
- Caution in patients with liver failure: concern increases as the degree of liver failure increases- results in reduced metabolism of active Methadone – longer half-life of Methadone

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Methadone Perils:

- Zero tolerance for diversion and abuse
- Methadone of little interest to drug abusers, but it may be diverted and sold or exchanged for drugs with greater street value
- A street purchaser of Methadone frequently unsophisticated users and "opioid naïve"
- Methadone sold on the middle-school campus may be consumed and when the student doesn't get high, they increase number of pills consumed rapidly, go home, or to bed, and never wake up

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Integrating Methadone into the Hospice Medication Formulary

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What do you need to start utilizing Methadone in a hospice and/or palliative care program?

- The Who
- The Where
- The When

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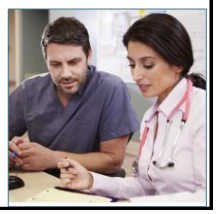
What do you need to start utilizing Methadone in a hospice and/or palliative care program?

- The Who:
  - A Prescriber with clinical experience and expertise in Methadone administration
    - "If you have to ask a question, you shouldn't be prescribing Methadone."
    - Dr. Jules Sherman, DO, FAAHPM , FAACO, OHI Methadone Guru



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The Who:

Nurses who are great communicators and can explain Methadone to patients

- Cultural stigma - patients have limited knowledge and have negative impressions of Methadone
- Used to treat addicts
- Families associate Methadone with a risk of addiction, or suspects the prescriber thinks their loved one is an addict
- Requires excellent communication and talking points by the Case Manager presenting Methadone as an analgesic choice

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The Who:

Nurses and social workers who can do a great home, family, and patient assessment

- Requires careful assessment of patient and home setting
- Zero tolerance for misuse or diversion
- Requires personal caregiver to monitor patient, especially starting Methadone

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The Who:

Good Candidates for Methadone

- History of opioid-induced hallucinations or opioid-induced neurotoxicity
- Pain-resistant to other opioids, on high doses of other opioids requiring frequent dose titration, tolerance, or poor response to other long-acting opioids
- Patients who have not been on other long-acting opioids but are clearly going to need opioid maintenance therapy until death
- Elderly patients with chronic musculoskeletal pain and few comorbidities

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The Who:

Good Candidates for Methadone

- Patients that need a long-acting opioid in a liquid formulation: Patient's with G tubes, unable to swallow tablets
- True morphine allergy - no plant-based allergens as in opium-based opioids
- Cancer pain
- Patients with CKD
- Neuropathic pain & not responding to neuropathic adjuvants alone, or also require opioid therapy

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The Who:

Poor Candidates for Methadone

- On many drugs that interact with Methadone
- Lives alone, cognitive deficit, unreliable or has unreliable caregivers, patient or caregivers have trouble comprehending instructions
- Any potential for abuse or diversion
- ES Liver Disease

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The Who:

Poor Candidates for Methadone

- Imminent death
- History of unpredictable adherence to their medication regimen
- Known to use pain medications for purposes other than pain relief: "chemical copers"
- Cardiac patients at high risk for arrhythmias and/or hypokalemia

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Cardiac History:

Palliative medicine patients on Methadone EKG monitoring

- Prior to start of therapy
- 2-4 weeks after starting Methadone
- With each significant dose, increase if:
  - Risk factors
  - Prior QTc >450 ms
  - History of syncope
- TDD Methadone reaches 30-40 mg and again at 100 mg/day
- New risk factors for QTc prolongation or signs/symptoms arrhythmia

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Cardiac Monitoring: Hospice

- Hospices generally do not monitor EKGs, weigh "burdens and benefits"
- Risk, in reality, is relatively low: most concerning if patients are on high doses of Methadone administered IV - daily dose > 100mg may need monitoring or narrow patient selection
- Remain alert for risk factors and correct those you can - electrolytes, other meds that cause QT prolongation

(HPC expert group recommendations)

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Choosing Appropriate Patients:

- Home and Caregiver Assessment by nurse and social worker
- Medication list reviewed by the team physician or pharmacist
- Patient Assessment
- Discussion with the IDT
- Review *Methadone Information Sheet* with patient & family

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What do you need to start utilizing Methadone in a hospice and/or palliative care program?

The Where:

- Conversion or initiation of Methadone at low doses is generally safe in the home
- Conversion from high doses may require IPU for comfort and safety
- Continuous care generally not a good option

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What do you need to start utilizing Methadone in a hospice and/or palliative care program?

The When:

- **M**ethadone **M**onday - start first dose of Methadone on Sunday night so that the team is available to monitor the patient all week
- Daily check-in using the Methadone surveillance sheet - highest risk of toxicity days 2-5
- Highly recommend the prescribing physician be the only physician monitoring the patient during the initiation of Methadone

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Starting Methadone Pearls:

- Verify prior prescriptions
- Calculate dose based on current LA and IR opioid use
- Utilize a conversion table that has been accepted for use across the organization
- Review medication interactions
- Consider individualization of dose based on age, frailty, and organ dysfunction
- Discussion with pharmacist

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Starting Methadone Pearls:

- Discontinue all other scheduled opioids before first dose of Methadone
- Destroy/secure other LA opioids (check med containers/pill planner)
- Identify prn short acting (IR) opioid for breakthrough pain – ensure comfort during initiation of Methadone
- **Be sure family / patient do not take the PRN pain breakthrough medication RTC!**
- Do not start or increase other sedating/hypnotic medications or gabapentin
- Do not increase the initial scheduled Methadone dose within the first 5 - 7 days of starting therapy

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During Initiation/Conversion:

- Follow the organization's protocol for instructions on frequency of visits and phone calls to the patient during the conversion process
- Daily updates to the physician during the first 5-7 days
- Any report of drowsiness, new neurologic symptoms, pain score of "0", or "0" doses of breakthrough pain medication in a 12 H period prompts nurse visit to the home, patient assessment, and report to hospice physician

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Pearls for Dosing:

- 30-40 mg/day maximum starting dose when converting from another opioid regardless of how many mg of other opioid the patient was on
- Maximum initial dose for opioid naïve patients: 2.5-5 mg/day
- Elderly (over 85 years) or frail - start with ½ the dose for healthy adult–initial dosing 1.25-2.5 mg/day
- Reduce calculated dose by 25% if on enzyme-inhibiting medication

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Patient Education for Initiation Period:

- Patient will gradually take less breakthrough medication every day: patient taking less PRNs means Methadone is effective
- Take breakthrough medication ONLY on an as-needed basis, not on a routine/schedule
- Signs Methadone dose is too high (refer to *Methadone Patient Information Sheet*)
- Medication Log - Methadone and breakthrough doses, RN to review each visit

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After Initiation – Titrating Methadone:

- Generally safe to increase Methadone by 30- 50% of the established dose at 5–7-day intervals when patients are using 3 or more doses of breakthrough medication daily and report substantial levels of baseline pain
- The case manager will monitor patients on Methadone as they would any other patient
- Nurse will reinforce Methadone safety rules regularly with the patient and family
- During visits nurse will check that the Methadone is stored safely
- Nurse should inform prescribers that a patient is on Methadone when obtaining any new medication orders

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Keys to using Methadone successfully:

- Team Effort!!
- Knowledgeable providers
- Organizational Tool Kit

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Take-Home Point:

In the hands of a knowledgeable prescriber, Methadone may safely and effectively improve pain and quality of life for patients in palliative and hospice care settings, reduce costs, and improve out comes for patients with life limiting illnesses.

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Review of the Tool Kit:

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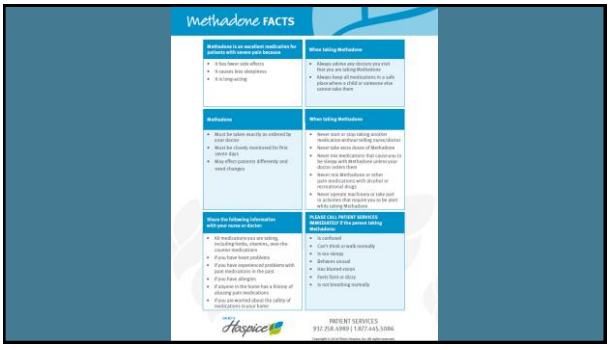
Methadone FACTS
Methadone is an excellent medication for patients with severe pain because
When taking Methadone
Methadone
When taking Methadone
Where the following information with your nurse or doctor.
PLEASE CALL PATIENT SERVICES IMMEDIATELY if the person taking Methadone:
PATIENT SERVICES
937.258.6989 | 1.877.445.5086

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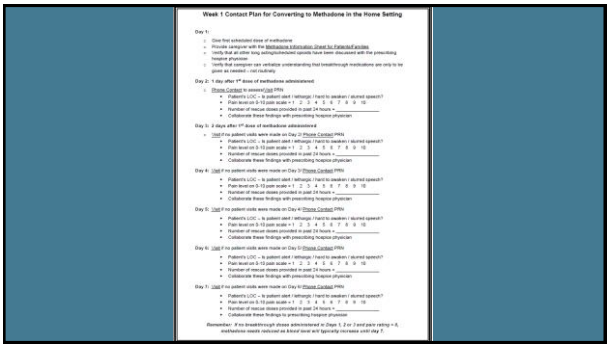
Week 1 Contact Plan for Converting to Methadone in the Home Setting
Day 1:
Day 2: 1 day after 1st dose of methadone administered
Day 3: 2 days after 1st dose of methadone administered
Day 4:
Day 5:
Day 6:
Day 7:

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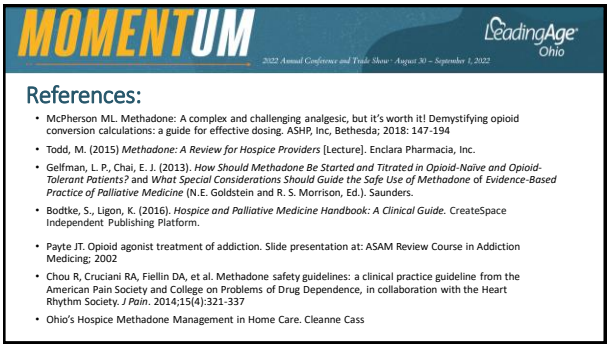
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