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SUPPLEMENTAL MATERIAL

Title: Opioid Analgesics and Adverse Outcomes among Hemodialysis Patients

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Supplemental Table 1. Equianalgesic Dosing Calculations

Supplemental Table 2. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis and Current Procedural Terminology (CPT) Codes for Altered Mental Status, Fall, and Fracture Ascertainment

Supplemental Table 3. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis and Procedure Codes for Comorbidity Ascertainment

Supplemental Table 4. Risk of Altered Mental Status, Fall, and Fracture Among Adults Receiving Hemodialysis with Medicare Part D Coverage in 2011 by Opioid Dose and Agent (Low-Income Subsidy Sensitivity Analysis)

Supplemental Table 5. Risk of Altered Mental Status, Fall, and Fracture Among Adults Receiving Hemodialysis with Medicare Part D Coverage in 2011 by Opioid Dose and Agent (New User Analysis)

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Supplemental Table 6. Risk of Altered Mental Status, Fall, and Fracture Among Adults Receiving Hemodialysis with Medicare Part D Coverage in 2011 by Number of Concomitant Opioid Agents Accounting for Dose

Supplemental Table 7. Risk of Altered Mental Status, Fall, and Fracture Among Adults Receiving Hemodialysis with Medicare Part D Coverage in 2011 by Opioid Dose and Agent (Subgroup Analyses)

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Supplemental Table 1: Equianalgesic Dosing Calculations

Generic Name	Route	Oral Morphine Equivalents
BUPRENORPHINE	PATCH, TRANSDERMAL WEEKLY	Multiply dose in mcg/hr by 2.2
BUPRENORPHINE HCL	AMPUL (ML)	75
BUPRENORPHINE HCL	TABLET, SUBLINGUAL	38.8
BUTORPHANOL TARTRATE	AEROSOL, SPRAY (ML)	15
BUTORPHANOL TARTRATE	VIAL (SDV,MDV OR ADDITIVE) (ML)	15
CODEINE SULF	TABLET	0.1
FENTANYL	PATCH, TRANSDERMAL 72 HOURS	Multiply dose in mcg/hr by 2.7
FENTANYL CITRATE	LOZENGE ON A HANDLE	Multiply dose in mcg by 0.1
FENTANYL CITRATE	TABLET, EFFERVESCENT	Multiply dose in mcg by 0.1
FENTANYL CITRATE	TABLET, SUBLINGUAL	Multiply dose in mcg by 0.1
FENTANYL CITRATE/PF	AMPUL (ML)	Multiply dose in mcg by 0.2
FENTANYL CITRATE/PF	VIAL (SDV,MDV OR ADDITIVE) (ML)	Multiply dose in mcg by 0.2
HYDROMORPHONE HCL	LIQUID (ML)	5
HYDROMORPHONE HCL	SUPPOSITORY, RECTAL	5
HYDROMORPHONE HCL	TABLET	5
HYDROMORPHONE HCL	TABLET, EXTENDED RELEASE 24 HR	5
HYDROMORPHONE HCL	VIAL (SDV,MDV OR ADDITIVE) (ML)	17.5
HYDROMORPHONE HCL/PF	AMPUL (ML)	17.5
HYDROMORPHONE HCL/PF	DISPOSABLE SYRINGE (ML)	17.5
HYDROMORPHONE HCL/PF	VIAL (SDV,MDV OR ADDITIVE) (ML)	17.5
MEPERIDINE HCL	SOLUTION, ORAL	0.1
MEPERIDINE HCL	TABLET	0.1
MEPERIDINE HCL	VIAL (SDV,MDV OR ADDITIVE) (ML)	0.4
MEPERIDINE HCL/PF	AMPUL (ML)	0.4

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MEPERIDINE HCL/PF	DISPOSABLE SYRINGE (ML)	0.4
MEPERIDINE HCL/PF	VIAL (SDV,MDV OR ADDITIVE) (ML)	0.4
METHADONE HCL	CONCENTRATE, ORAL	4.7
METHADONE HCL	SOLUTION, ORAL	4.7
METHADONE HCL	TABLET	4.7
MORPHINE SULFATE	AMPUL (ML)	3
MORPHINE SULFATE	CAPSULE, EXTENDED RELEASE PELLETS	1
MORPHINE SULFATE	CAPSULE,EXTENDED RELEASE MULTIPHASE 24HR	1
MORPHINE SULFATE	DISPOSABLE SYRINGE (ML)	3
MORPHINE SULFATE	SOLUTION, ORAL	1
MORPHINE SULFATE	SUPPOSITORY, RECTAL	1
MORPHINE SULFATE	TABLET	1
MORPHINE SULFATE	TABLET, EXTENDED RELEASE	1
MORPHINE SULFATE	VIAL (SDV,MDV OR ADDITIVE) (ML)	3
NALBUPHINE HCL	AMPUL (ML)	3
OXYCODONE HCL	CAPSULE (HARD, SOFT, ETC.)	1.5
OXYCODONE HCL	CONCENTRATE, ORAL	1.5
OXYCODONE HCL	SOLUTION, ORAL	1.5
OXYCODONE HCL	TABLET	1.5
OXYCODONE HCL	TABLET, EXTENDED RELEASE 12 HR	1.5
OXYMORPHONE HCL	TABLET	3
OXYMORPHONE HCL	TABLET, EXTENDED RELEASE 12 HR	3
TAPENTADOL HCL	TABLET	0.4
TRAMADOL HCL	TABLET	0.2
TRAMADOL HCL	TABLET, EXTENDED RELEASE 24 HR	0.2
TRAMADOL HCL	TABLET, RAPID DISSOLVE	0.2
TRAMADOL HCL	TABLET,EXTENDED RELEASE MULTIPHASE 24 HR	0.2

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ACETAMINOPHEN WITH CODEINE	ELIXIR	0.1
ACETAMINOPHEN WITH CODEINE	TABLET	0.1
HYDROCODONE BIT/ACETAMINOPHEN	CAPSULE (HARD, SOFT, ETC.)	1.2
HYDROCODONE BIT/ACETAMINOPHEN	SOLUTION, ORAL	1.2
HYDROCODONE BIT/ACETAMINOPHEN	TABLET	1.2
OXYCODONE HCL/ACETAMINOPHEN	CAPSULE (HARD, SOFT, ETC.)	1.5
OXYCODONE HCL/ACETAMINOPHEN	SOLUTION, ORAL	1.5
OXYCODONE HCL/ACETAMINOPHEN	TABLET	1.5
PENTAZOCINE HCL/ACETAMINOPHEN	TABLET	0.6
PROPOXYPHENE/ACET AMINOPHEN	TABLET	0.15
TRAMADOL HCL/ACETAMINOPHEN	TABLET	0.2

Supplemental Table 2: International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis and Current Procedural Terminology (CPT) Codes for Altered Mental Status, Fall, and Fracture Ascertainment

Outcome	ICD-9-CM	CPT
<i>Altered mental status</i>	292.11, 292.12, 292.2, 292.81, 292.84, 292.89, 292.9, 293.0, 293.1, 298.9, 348.30, 348.39, 349.82, 760.72, 760.77, 780.02, 780.09, 780.1, 780.97	
<i>Fall</i>	E880.0, E880.1, E880.9, E884.9, E884.2, E884.3, E884.4, E884.5, E884.6, E885.0, E885.9, E888.0, E888.1, E888.8, E888.9	
<i>Fracture</i>		
Hip/femur	733.14, 733.15, 820.xx, 821.xx	27125, 27220, 27222, 27226, 27227, 27228, 27230, 27232, 27235, 27236, 27238, 27240, 27244, 27245, 27246, 27248, 27254, 27500, 27501, 27502, 27503, 27506, 27507, 27508, 27509, 27510, 27511, 27513, 27514
Pelvis	808.xx	27190, 27193, 27194, 27215, 27216, 27217, 27218, 27200, 27202
Leg/foot	733.16 (path tibia), 822.xx (patella), 823.xx (tibia & fibula), 824.xx (ankle), 825.xx (tarsal, metatarsal), 826.xx (phalanges)	27350, 27520, 27524, 27530, 27532, 27535, 27536, 27538, 27540, 27750, 27752, 27756, 27758, 27759, 27760, 27762, 27766, 27767, 27768, 27769, 27780, 27781, 27784, 27786, 27788, 27792, 27808, 27810, 27814, 27816, 27818, 27822, 27823, 27824, 27825, 27826, 27827, 27828, 28315, 28400, 28405, 28406, 28415, 28420, 28430, 28435, 28436, 28445, 28450, 28455, 28456, 28465, 28470, 28475, 28476, 28485, 28490, 28495, 28496, 28505, 28510, 28515, 28525, 29851, 29855, 29856
Arm/hand	733.11 (path humerus), 733.12 (path radius), 812.xx (humerus), 813.xx (radius & ulna), 814.xx (carpal bone, wrist), 815.xx (metacarpal), 816.xx (phalanges), 817.xx (multiple)	23600, 23605, 23610, 23615, 23616, 23620, 23625, 23630, 23665, 23670, 23675, 23680, 24500, 24505, 24506, 24510, 24515, 24516, 24530, 24531, 24535, 24536, 24538, 24540, 24542, 24545, 24546, 24560, 24565, 24566, 24570, 24575, 24576, 24577, 24579, 24581, 24582, 24583, 24585, 24586, 24587, 24588, 24620, 24625, 24635,

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		24650, 24655, 24660, 24665, 24666, 24670, 24675, 24680, 24685, 25500, 25505, 25510, 25514, 25515, 25520, 25525, 25526, 25530, 25535, 25540, 25541, 25545, 25560, 25565, 25570, 25574, 25575, 25600, 25604, 25605, 25606, 25607, 25608, 25609, 25622, 25624, 25628, 25630, 25635, 25645, 25650, 25651, 25652, 25680, 25685, 26600, 26605, 26607, 26608, 26615, 26645, 26650, 26665, 26720, 26725, 26727, 26735, 26740, 26742, 26746, 26750, 26755, 26756, 26765, 29847
Axial	807.0x-807.1x, 807.2-807.3 (ribs/sternum); 810.xx, 811.xx (clavicle, scapula)	21800, 21820, 23500, 23505, 23515, 23570, 23575, 23585

Fracture for a given type required the presence of both an ICD-9-CM diagnosis code and CPT code.¹⁻
⁵ In order to maximize the ability to ascertain incident fractures, we excluded vertebral fractures and required that no fracture of a given type occurred within the previous 30 days.⁶

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Supplemental Table 3: International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis and Procedure Codes for Comorbidity Ascertainment

Comorbidity	ICD-9 Codes
Alcohol dependence	291.x, 303.x, 305.x
Coronary artery disease	00.66, 36.0x, 410.x, 411.x, 413.x
Cancer	140.x-165.x, 170.x-172.x, 174.x, 175.x, 180.x-209.x, 238.6, 273.3
Other cardiac disease	v42.2, v43.3, 394.x-397.1, 424.x, 746.3-746.6
Dysrhythmia	37.7x, 37.8x, 37.9x, v45.00, v45.01, v45.02, v45.09, v53.31, v53.32, 426.x, 427.0, 427.1, 427.20, 427.3x, 427.4x, 427.81, 427.9, 996.01, 996.04
Congestive heart failure	398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.13, 404.91, 428.x
Cerebrovascular disease	433.x, 434.x, 435.x, 436.00, 437.x, 438.x
Diabetes	249.x, 250.x, 357.2, 362.0x
Drug dependence	292.x, 304.x, 305.x
Opioid dependence	304.x, 305.5
Hypertension	401.0, 401.1, 401.9, 402.x, 403.x, 404.x, 405.x
Chronic obstructive pulmonary disease	490, 491.x-496
Peripheral vascular disease	38.03, 38.04, 38.05, 38.08, 38.33-38.48, 39.22-39.29, v43.4, 440.2x, 440.3x, 440.4x, 441.x, 443.x, 445.x, 447.10, 557.10, 557.90
Tobacco dependence	305.1x
Liver disease	v42.7, 070.x, 456.1, 456.21, 570-573.x
Dementia	290.x, 294.1x, 331.x
Depression	296.2x, 296.3x, 296.5x, 296.82, 300.40, 301.12, 309.0, 309.10, 311
Seizures/epilepsy	345.x
Osteoporosis	731.0, 733.0, 733.00, 733.01, 733.02, 733.03, 733.09, 733.7
Osteopenia	733.90

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Supplemental Table 4: Risk of Altered Mental Status, Fall, and Fracture Among Adults Receiving Hemodialysis with Medicare Part D Coverage in 2011 by Opioid Dose and Agent (Low-Income Subsidy Sensitivity Analysis)

	Altered Mental Status		Fall		Fracture	
	<i>HR (95% CI)</i>	<i>p-value</i>	<i>HR (95% CI)</i>	<i>p-value</i>	<i>HR (95% CI)</i>	<i>p-value</i>
Opioid Dose						
<i>Categorical:</i>						
None	1.00 (ref)		1.00 (ref)		1.00 (ref)	
Lower Dose ^a	1.23 (1.18-1.29)	<.001	1.24 (1.16-1.32)	<.001	1.43 (1.31-1.55)	<.001
Higher Dose ^b	1.63 (1.53-1.75)	<.001	1.41 (1.27-1.57)	<.001	1.66 (1.44-1.92)	<.001
<i>Continuous:</i>						
Total Opioid Dose (per 60 mg)	1.27 (1.24-1.31)	<.001	1.04 (1.03-1.05)	<.001	1.04 (1.04-1.05)	<.001
Opioid Agent (per 60 mg)						
<i>Recommended:</i>						
None	1.00 (ref)		1.00 (ref)		1.00 (ref)	
Hydromorphone	1.39 (1.23-1.57)	<.001	1.02 (0.99-1.04)	0.16	1.03 (1.02-1.04)	<0.001
Fentanyl	1.15 (1.07-1.23)	<.001	1.02 (0.92-1.14)	0.63	1.02 (0.88-1.19)	0.74
Methadone	1.14 (1.01-1.29)	0.04	1.12 (0.96-1.31)	0.15	1.06 (0.84-1.34)	0.63
<i>Use with Caution:</i>						
Hydrocodone	1.34 (1.25-1.43)	<.001	1.32 (1.26-1.40)	<.001	1.39 (1.30-1.47)	<.001
Oxycodone	1.29 (1.23-1.36)	<.001	1.13 (1.05-1.22)	0.001	1.27 (1.20-1.32)	<.001
Tramadol	1.43 (1.25-1.62)	<.001	1.34 (1.11-1.63)	0.003	1.60 (1.35-1.91)	<.001
<i>Avoid:</i>						
Codeine	3.80 (2.17-6.64)	<.001	1.22 (0.46-3.17)	0.69	3.05 (0.96-9.57)	0.06
Morphine	1.39 (1.25-1.53)	<.001	1.17 (1.01-1.36)	0.04	1.07 (0.84-1.37)	0.58

Abbreviations: HR = hazard ratio, CI = confidence interval

^aPeriods of lower dose (0 < average daily total dose ≤60 mg oral morphine equivalents) opioid exposure

^bPeriods of higher dose (average daily total dose >60 mg oral morphine equivalents) opioid exposure

Based on 108,901 (77%) of the cohort that received the low-income subsidy for the entire study duration.

Results are adjusted for age, sex, race, duration on dialysis, network, body mass index, alcohol dependence, coronary artery disease, cancer, other cardiac disease, dysrhythmia, congestive heart failure, cerebrovascular disease, diabetes, drug dependence, opioid dependence, hypertension, inability to ambulate, inability to transfer, chronic obstructive pulmonary disease, peripheral vascular disease, tobacco dependence, liver disease, dementia, depression, seizures/epilepsy, osteoporosis, osteopenia, skilled nursing facility resident, medication burden, number of hypertensive medications, and concomitant medications.

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Supplemental Table 5: Risk of Altered Mental Status, Fall, and Fracture Among Adults Receiving Hemodialysis with Medicare Part D Coverage in 2011 by Opioid Dose and Agent (New User Analysis)

	Altered Mental Status		Fall		Fracture	
	<i>HR (95% CI)</i>	<i>p-value</i>	<i>HR (95% CI)</i>	<i>p-value</i>	<i>HR (95% CI)</i>	<i>p-value</i>
Opioid Dose						
<i>Categorical:</i>						
None	1.00 (ref)		1.00 (ref)		1.00 (ref)	
Lower Dose ^a	2.10 (1.91-2.31)	<.001	1.66 (1.44-1.91)	<.001	2.31 (1.95-2.75)	<.001
Higher Dose ^b	2.95 (2.39-3.65)	<.001	1.78 (1.22-2.61)	0.003	1.76 (1.04-3.00)	0.04
<i>Continuous:</i>						
Total Opioid Dose (per 60 mg)	2.08 (1.94-2.23)	<.001	1.53 (1.41-1.64)	<.001	1.63 (1.53-1.74)	<.001

Abbreviations: HR = hazard ratio, CI = confidence interval

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^bPeriods of higher dose (average daily total dose >60 mg oral morphine equivalents) opioid exposure

Results are adjusted for age, sex, race, duration on dialysis, network, body mass index, alcohol dependence, coronary artery disease, cancer, other cardiac disease, dysrhythmia, congestive heart failure, cerebrovascular disease, diabetes, drug dependence, opioid dependence, hypertension, inability to ambulate, inability to transfer, chronic obstructive pulmonary disease, peripheral vascular disease, tobacco dependence, liver disease, dementia, depression, seizures/epilepsy, osteoporosis, osteopenia, skilled nursing facility resident, medication burden, number of hypertensive medications, and concomitant medications.

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Supplemental Table 6: Risk of Altered Mental Status, Fall, and Fracture Among Adults Receiving Hemodialysis with Medicare Part D Coverage in 2011 by Number of Concomitant Opioid Agents Accounting for Dose

	Altered Mental Status		Fall		Fracture	
	<i>HR (95% CI)</i>	<i>p-value</i>	<i>HR (95% CI)</i>	<i>p-value</i>	<i>HR (95% CI)</i>	<i>p-value</i>
Total Opioid Dose (per 60 mg)						
Concomitant Number of Opioid Medications						
1	1.31 (1.27-1.36)	<.001	1.04 (1.03-1.04)	<.001	1.04 (1.04-1.05)	<.001
2	1.27 (1.21-1.32)	<.001	1.13 (1.11-1.16)	<.001	1.13 (1.10-1.17)	<.001
≥3	1.39 (1.22-1.59)	<.001	1.04 (0.82-1.32)	0.75	1.02 (0.74-1.43)	0.89

Abbreviations: HR = hazard ratio, CI = confidence interval

^aPeriods of lower dose (0 < average daily total dose ≤60 mg oral morphine equivalents) opioid exposure

^bPeriods of higher dose (average daily total dose >60 mg oral morphine equivalents) opioid exposure

Results are adjusted for age, sex, race, duration on dialysis, network, body mass index, alcohol dependence, coronary artery disease, cancer, other cardiac disease, dysrhythmia, congestive heart failure, cerebrovascular disease, diabetes, drug dependence, opioid dependence, hypertension, inability to ambulate, inability to transfer, chronic obstructive pulmonary disease, peripheral vascular disease, tobacco dependence, liver disease, dementia, depression, seizures/epilepsy, osteoporosis, osteopenia, skilled nursing facility resident, medication burden, number of hypertensive medications, and concomitant medications.

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Supplemental Table 7: Risk of Altered Mental Status, Fall, and Fracture Among Adults Receiving Hemodialysis with Medicare Part D Coverage in 2011 by Opioid Dose and Agent (Subgroup Analyses)

	Altered Mental Status			Fall			Fracture		
	Lower Dose ^a vs. None HR (95% CI)	Higher Dose ^b vs. None HR (95% CI)	<i>p</i> -value <i>inter-</i> <i>action</i>	Lower Dose ^a vs. None HR (95% CI)	Higher Dose ^b vs. None HR (95% CI)	<i>p</i> -value <i>inter-</i> <i>action</i>	Lower Dose ^a vs. None HR (95% CI)	Higher Dose ^b vs. None HR (95% CI)	<i>p</i> -value <i>inter-</i> <i>action</i>
Age (years)									
≥65	1.28 (1.20-1.35)	1.57 (1.42-1.75)	0.46	1.22 (1.12-1.33)	1.33 (1.13-1.57)	0.24	1.35 (1.21-1.50)	1.66 (1.37-2.02)	0.32
<65	1.28 (1.21-1.36)	1.71 (1.58-1.86)		1.33 (1.22-1.44)	1.49 (1.32-1.69)		1.49 (1.33-1.68)	1.53 (1.28-1.84)	
Sex									
Male	1.28 (1.20-1.36)	1.60 (1.45-1.76)	0.52	1.32 (1.21-1.45)	1.64 (1.42-1.90)	0.07	1.55 (1.37-1.76)	1.72 (1.40-2.12)	0.30
Female	1.29 (1.22-1.36)	1.72 (1.58-1.88)		1.26 (1.17-1.36)	1.32 (1.15-1.51)		1.37 (1.24-1.52)	1.60 (1.35-1.91)	
Race									
White	1.33 (1.26-1.41)	1.85 (1.70-2.01)	<.001	1.29 (1.20-1.40)	1.45 (1.28-1.65)	0.09	1.41 (1.28-1.56)	1.64 (1.40-1.92)	0.21
Black	1.20 (1.13-1.27)	1.42 (1.28-1.58)		1.22 (1.11-1.34)	1.41 (1.19-1.66)		1.42 (1.23-1.64)	1.54 (1.17-2.01)	
Other	1.62 (1.29-2.60)	1.83 (1.29-2.60)		1.76 (1.37-2.26)	1.96 (1.19-3.24)		1.94 (1.40-2.68)	2.75 (1.50-5.07)	
Dialysis Duration (years)									
≥4	1.30 (1.23-1.38)	1.64 (1.50-1.79)	0.59	1.32 (1.22-1.43)	1.31 (1.14-1.51)	0.04	1.42 (1.27-1.59)	1.39 (1.14-1.70)	0.06
<4	1.26 (1.19-1.34)	1.70 (1.55-1.86)		1.24 (1.14-1.35)	1.61 (1.41-1.84)		1.46 (1.31-1.63)	1.91 (1.60-2.28)	

Abbreviations: HR = hazard ratio, CI = confidence interval

^aPeriods of lower dose (0 < average daily total dose ≤60 mg oral morphine equivalents) opioid exposure

^bPeriods of higher dose (average daily total dose >60 mg oral morphine equivalents) opioid exposure

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