







SAFE MEDICATION USE IN PATIENTS WITH IMPAIRED RENAL FUNCTION

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Faculty/Presenter Disclosure

- Faculty: Dr. Allan Grill
- I have the following relevant financial relationships to disclose:
- Consultant for: CCO Ontario Renal Network
- Relationships with commercial interests:
 - Not Applicable





Disclosure of Commercial Support

- This program has received NO Commercial support
- This program has received NO in-kind support
- Potential for conflict(s) of interest:
 - Not Applicable



Remembrance Day







Ontario Renal Network

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@allan_k_grillMD#myFMF





Learning Objectives

- To recognize common causes of adverse drug reactions (ADRs)
- To appreciate common medication prescribing challenges in patients with chronic kidney disease (CKD), including LTC settings
- To propose innovative solutions in primary care that promote improved medication prescribing practices for patients with CKD/impaired renal function





About the Ontario Renal Network

- Responsible for overseeing and funding the delivery of chronic kidney disease (CKD) services across Ontario
- A 'network' of all the kidney care programs in Ontario
- Early detection and prevention of progression of CKD in the primary care setting is a main priority
- Ontario Renal Plan II is a roadmap that outlines how the Ontario Renal Network (ORN) will try to improve the lives of those living with CKD





Accessing KidneyWise Toolkit

kidneywise.ca







Ontario Renal Network

Prevalence of CKD

- Abnormality in kidney structure or function, present for > 3 months
 - eGFR < 60; urine ACR > 3 (2 out of 3 samples)
- 10% of North Americans have CKD
 - 26 million people
- 25% of North Americans > age 65 have CKD
- Only 3% of CKD patients progress to ESRD











GFR Categories in CKD

1.2.3: Assign GFR categories as follows (Not Graded):

GFR categories in CKD				
GFR category	GRF (ml/min/1.73m ²)	Terms		
G1	≥ 90	Normal or high		
G2	60 - 89	Mildly decreased*		
G3a	45 -59	Mildly to moderately decreased		
G3b	30 - 44	Moderately to severely decreased		
G4	15 - 29	Severely decreased		
<u>G5</u>	<15	Kidney failure		

*Relative to young adult level.

In the absence of evidence of kidney damage, neither GFR category G1 nor G2 fulfill the criteria for CKD.

KDIGO CKD Guidelines, 2012



Adverse Drug Reaction (ADR)





Ontario Renal Network



Case 1

- 85 year old male with DM and stable CKD (stage 4; eGFR 28); lives in a nursing home
- Presents to their primary care provider (PCP) with shingles, started on Valacyclovir (Valtrex) 1g tid
- 2 days later presents with delirium, agitation requiring neuroleptics to control
- Recommended dose (eGFR < 30) 1g daily





- 76 year old female with CKD (eGFR 35).
- Ongoing issues with lower back pain started on baclofen by PCP after trial of Tylenol ineffective
- The following day, presents with confusion followed by stupor – sent to the ER. Subsequently develops NSTEMI in hospital and dies

BMJ. 2009 Dec 31;339:b4559. doi: 10.1136/bmj.b4559.

Reduced level of consciousness from baclofen in people with low kidney function.

Su W¹, Yeqappan C, Carlisle EJ, Clase CM.





Case 3

- 83 year old male with CHF, HTN and CKD (creatinine 180; eGFR 35) on ramipril 5 mg daily
- Admitted to hospital for a CHF exacerbation and started on spironolactone - stabilized
- 2 weeks after discharge, PCP checks eGFR/electrolytes, and stops spironolactone due to elevated potassium level. Furosemide started prn while awaiting cardiology follow-up
- 1 month later, patient is admitted to ortho after a fall for R hip # surgery, and gets discharged 5 days later on spironolactone in addition to his other medications
- Presented to ER 5 days later with leg weakness. Creatinine 350, eGFR 16, K 7.8



Institute of Medicine - 1999

- 44,000-98,000 deaths in US due to medical errors; 1 million injuries
- 7,000 deaths annually in the U.S. due to medication errors alone





Nobody's Perfect



Medication Mistakes

Every year 2.6 billion prescriptions are filled by pharmacies and 3.75 billion drugs are administered at hospitals. Every year approximately 1.5 million people suffer injuries because of prescription errors.

on

2.5 billion outpatient Rxs;3.75 billion inpatient drug orders

You may be Entitled to Compensation for: - Medical Expenses - Lost Income - Pain and Suffering - Wrongful Death (If Applicable) - Other Losses

Call d'Oliveira & Associates at 1-800-992-6878 for a Free (No Obligation) Case Evaluation

Adverse Drug Reaction (ADR)

- An undesirable effect of a drug beyond its anticipated therapeutic effects occurring during clinical use (WHO definition)
- 3-6% of all hospital admissions relate to medication adverse events (100,000/year); 700,000 ER visits
- 1 in 200 seniors hospitalized for a drug adverse reaction (Canada, 2010-2011)
 - 5x the rate of younger adults
 - Increases LOS by 3.15 days
 - Cost implications \$3,400/hospital admission
- 5% prescribing error in primary care (UK data)



- Frailty
 - Physiological changes (liver; body mass)
 - Affects drug metabolism; distribution of lipophilic/lipophobic drugs; elimination
 - Progressive decline involving multiple body systems
 - Chronological age may not accurately reflect function





- RCTs may not be generalizable to all (e.g. elderly patients; advanced CKD)
 - 'Treat to target' may cause more harm than benefit





- Polypharmacy → prescribing cascade
 → drug-drug interactions
- Estimated 2/3 of ambulatory patients over age 60 are taking ≥ 4 meds/day



"Each capsule contains your medication, plus a treatment for each of its side effects."



- Quality of Life
- Time to benefit (T2B) > estimated life expectancy
- Goals of Care (e.g. dementia)
 - Shared decision making
- Individual patient preference
- Is QOL improving?





Allergies





- CKD/impaired renal function
- Medication dosing requires special attention – many are metabolized/cleared by the kidneys – increases risk
- Polypharmacy is typical given increased age and complex comorbidities – increased risk of drug interactions





- 25-30% of patients when admitted to hospital have CKD (eGFR<60)
 - ↑ exposure to medications
- Check dose; contraindication?
 - Calculate CrCl
 - Check eGFR
 - Drug index (e.g. CPS)





 Estimated that 19%-69% of meds prescribed to patients with renal impairment contain dosing errors

 Farag et al. AJKD 2014

 Up to 20% of hospital admissions due to AKI have been attributed to Drug Induced Nephrotoxicity
 Elasy et al. Semin Dial 1996





CKD – Inpatient Medication Errors

Total medication orders	773113 (100%)
Medication that were nephrotoxic or requiring dose alteration because of kidney disease	108537 (14%)
Subset of orders included in analysis	97 131 (100%)
Number with recommended dose modification	14440 (14.9%)
Dose alteration	3490
Frequency alteration	4787
Dose and frequency alteration	6163
Warnings	253
Substitutes	27

Weir et al. CONH 2014

- 7904 patients admitted to hospital in U.S. over 8 months
- 14% of medication orders were nephrotoxic or required dose alteration based on patient's renal function



CKD – Outpatient Medication Errors

- Outpatient setting: antibiotics are the most common cause of ADRs among seniors
- Study frequency of excess dosing in CKD patients (eGFR < 30) not on dialysis; 2 years; southwestern ON
- 66% of Rxs were dosed in excess of recommendations
- Nitrofurantoin was prescribed incorrectly 100% of the time

Table 3. Total Prescriptions and Dosing Errors for Study Antibiotics

Medication	Total Prescriptions	Dosing Errors	
Ciprofloxacin	271	147 (54)	
Cefixime	11	9 (82)	
Cefprozil	114	70 (61)	
Cephalexin	425	258 (61)	
Clarithromycin	251	130 (52)	
Nitrofurantoin	169	169 (100)	
Sulfamethoxazole- trimethoprim	214	185 (86)	
	9	£ (==,	
Fotal	1,464	970 (66)	

Farag et al. AJKD 2014



CKD – Outpatient Medication Errors

- Further analysis
- N = 564 physicians
- Canadian medical graduates and family physicians may be at increased risk of dosing errors

Characteristic	No Errors (n = 117)	Any Error (1+) (n = 447)	Ρ
Age			
Mean ± SD	52 ± 11	51 ± 11	0.6
Median [IQR]	50 [44-60]	50 [43-59]	0.7
Years since graduation			
Mean ± SD	26 ± 11	25 ± 11	0.5
Median [IQR]	24 [18-34]	24 [17-32]	0.4
Location of medical education			0.01
Canada	62 (53)	292 (65)	0.01
International	22 (19)	72 (16)	0.5
Unknown	33 (28)	83 (19)	0.02
Specialty			<0.001
IM or IM subspecialty	11 (9)	9 (2)	< 0.001
Family and ED	57 (49)	325 (73)	< 0.001
Other	16 (14)	30 (7)	0.01
Missing	33 (28)	83 (19)	0.02

Farag et al. AJKD 2014



Table 5. Physician Characteristics for Entire Study Period

Drug Dosing Errors

 So why are we making so many drug dosing errors in patients with CKD/impaired renal function?



Assessment of Kidney Function

- Calculated GFR approximations
 - CrCl by Cockcroft-Gault formula
 - eGFR by MDRD formula (Modification of Diet in Renal Disease)
 - eGFR by CKD EPI formula (Chronic Kidney Disease Epidemiology Collaboration)



Cockroft-Gault Formula \rightarrow CrCl

CrCl (ml/min) = $(140 - age) \times wt \times 1.23 \times (0.85 \text{ if female})$

72 x Scr (mg/dL)

- 1976 CG formula developed to estimate creatinine clearance (CrCl) in men; adjustment added for women
- Serum creatinine measurement not standardized across labs at the time
- Imprecise measure of glomerular filtration rate (GFR)
 - Lower estimation than actual GFR
 - Less accurate at older ages; variation in muscle mass, body size – not adjusted for body surface area



The MDRD & CKD-EPI Formulas \rightarrow eGFR

- eGFR (ml/min/1.73m²) different units than CG
- MDRD = 32788 x Cr^{-1.154} x age ^{-.203} x constant
- constant = 1 (white males); 0.742 for females; 1.21 for African Americans
- CKD-EPI = 141 × min(S_{cr}/κ, 1)^α × max(S_{cr}/κ, 1)^{-1.209} × 0.993^{Age} × 1.018 [if female] × 1.159 [if black]
- CKD-EPI formula replaced MDRD still limited re: extremes in size given chosen 'constants'
- <a>www.nkdep.nih.gov (online calculator)





SCr	Gender	Age	IW	CG (ml/min)	MDRD (ml/min 1.73m²)	CKD EPI (ml/min/ 1.73m²)
130	М	40	70	66.1	56	59
130	М	80	60	34	49	44
130	F	80	50	24.1	37	33





Which formula should be used to make drug dosing decisions?



Measuring Kidney Function

- Despite the limitations of all 3 formulas...
- 1998 FDA recommends pharma industry use CG formula to estimate GFR when designing pharmacokinetic studies & drug dosing guidelines
- 2017 labs in Canada have standardized serum creatinine assays and are using the CKD-EPI formula for estimating GFR; international consensus that CKD-EPI is more accurate than CG (including the National Kidney Foundation)
- Yet many product labels, and physicians, still use CG formula for drug dose adjustments


Measuring Kidney Function

- So why is this even important?
- Accurate estimates of kidney function are essential for optimal dosing of drugs cleared by the kidney
- If kidney function overestimated → inappropriate large doses → toxicity
- If kidney function underestimated → subtherapeutic dosing → treatment failure → prolonged illness



Stevens et al. Am J Kidney Dis 2009

- 5,500 patient database
- Studies measured GFR (mGFR) using gold standard urinary clearance method
- Kidney function estimated using CG & MDRD adjusted for BSA (ml/min)
- Measured concordance between mGFR vs. MDRD/CG
 - 78% vs. 73%
- Drug simulation study (15 drugs)
 - Commonly used
 - Renally cleared
 - Associated w/ dosing errors/ ADRs

Table 3. Concordance Between Kidney Function Categories Assigned Using mGFR Versus Estimated Kidney Function

			Discordant (%)	
Equation	Concordant	(%)*	< mGFR	> mGFR
MDRD Study	78		14	8
CG	73		12	16
CGIBW	66		29	5



Comparing Estimates in Drug Dosing

Concordance in dosing recommendations

Estimation Method	Concordant (9	%) Discordant (%) < mGFR	Discordant (%) > mGFR
MDRD Study	88	6	6
CG	85	5	10
CG-IBW	82	13	4

American Journal of Kidney Diseases 2009;54:33-42



Comparing Estimates in Drug Dosing

Concordance in dosing recommendations

Estimation Method	Concordant (%)	Discordant (%) < mGFR) Discordant (%) > mGFR
MDRD Study	88	6	6
CG	85	5	10
CG-IBW	82	13	4

American Journal of Kidney Diseases 2009;54:33-42



Comparing Estimates in Drug Dosing

- In most drug dosing situations in outpatient primary care for patients with CKD/impaired renal function, using serum eGFR as a reference is safe and acceptable
- In situations when patients are very sick, have extremes in body mass (obese vs. thin/frail), or medication chosen has high toxicity – order a 24 hr. urine for the most accurate estimation of GFR



Potential Interventions - prescriber

- One might hypothesize that eGFR reporting would reduce prescribing errors in CKD
 - More awareness of CKD
- Initiation of eGFR reporting not associated with a decline in rate of antibiotic dosing errors
- Knowledge gap
 - ? Not looking for CKD



Farag et al. AJKD 2014



 Prescribing physician may not have known patient had low kidney function → KidneyWise



Scope of the problem

 Number of medications available in Canada to lower glucose levels in patients with diabetes







Contraindicated Caution/reduced dose Not recommended Safe



Quiz!

- Which of these drugs is **least** dependent on renal elimination?
 - a) Digoxin
 - b) Gabapentin
 - c) Ranitidine
 - d) Enalapril





- Which of these drugs is **least** dependent on renal elimination?
 - a) Digoxin
 - b) Gabapentin
 - c) Ranitidine
 - d) Enalapril



Drug	% excreted extrarenally
Digoxin	30
Ranitidine	20
Lisinopril	20
Dabigatran	20
Famciclovir	14
Atenolol	12
Enalapril	10
Acyclovir	10
Allopurinol	10
Lithium	2
Gabapentin	2

Medications that require dose adjustment in CKD



- Prescribing physician may not have known patient had low kidney function → KidneyWise
- Prescribing physician may not have known that the drug required a dose adjustment



ORN - CKD Safe Medication List

- It is difficult for PCPs to easily access a list of commonly prescribed, potentially harmful medications in those patients with CKD or ESRD.
- The development of such a list would contribute to an effective strategy to reduce and prevent harm to patients with CKD.





Approach – CKD Safe Medication List

Overview of Approach



Note: this study received ethics approval from the Hamilton Integrated Research Ethics Board



Literature Review and Medication Review



Modified Delphi Study Panel

Number of Experts =17	Ν	%
Geographic distribution		
Ontario	12	71
British Columbia	3	18
Alberta	1	6
Saskatchewan	1	6
Specialties		
Pharmacists	5	29
Nephrologists	5	29
Internists/Pharmacologists	3	18
Emergency Department Physicians	1	6
Nurse Practitioners	1	6
Medication Safety Specialists	1	6
Primary Care Physicians	1	6
Gender		
Male	10	59
Female	7	41



Acetaminophen should be adjusted at the following eGFR values

			Neither			
	Strongly disagree	Somewhat disagree	agree or disagree	Somewhat agree	Strongly agree	N/A
45-59	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc
30-44	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc
15-29	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc
<15	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc

Acetaminophen should be avoided at the following eGFR values

			Neither			
	Strongly disagree	Somewhat disagree	agree or disagree	Somewhat agree	Strongly agree	N/A
45-59	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	0
30-44	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc
15-29	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	0
<15	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc

Please provide any additional comments here



Modified Delphi Process Chart





Results: Recommended draft list of medications to be **AVOIDED**

eGFR <45	eGFR <30	eGFR <15
Dapagliflozin	Canagliflozin	Apixaban
	Dabigatran	Baclofen
	Empagliflozin	Bisphosphonates
	Glyburide	Duloxetine
	Metformin	Edoxaban
	Nitrofurantoin	Fibrates
	Ribavirin	Rivaroxaban
		Saxagliptin



Results: Recommended draft list of medications to be **DOSE-ADJUSTED**

Medication	eGFR 45-59	eGFR 30-44	eGFR 15-39	eGFR <15
Amantadine		Х	Х	Х
Digoxin		Х	Х	Х
Famciclovir		Х	Х	Х
Gabapentin		Х	Х	Х
Metoclopramide		Х	Х	Х
Lithium		Х	Х	Х
Oseltamivir		Х	Х	Х
Pregabalin	Х	Х	Х	Х
Sitagliptin		Х	Х	Х
Sotalol		Х	Х	Х
Topiramate		Х	Х	Х
Valacyclovir		Х	Х	Х
Venlafaxine		Х	Х	Х



ORN - CKD Safe Medication List

- Reduce the risk of ADRs/ADEs in patients with CKD and/or impaired kidney function by:
 - Adjusting the dose of particular drugs used routinely in primary care practice
 - Avoiding the use of particular drugs common to primary care practice





- Could EMR systems help prevent medication errors?
- Vanderbuilt University Hospital 598 inpatients
- Chose 122 nephrotoxic/renally cleared meds
- Passive: non-interactive message on EMR Rx order interface
- Warnings sent to MD if sCr level ↑ by 0.5mg/dL w/in 48 hrs.
- Active: interuptive alert that required the ordering MD to:
 - Modify or discontinue the order
 - Mark the order as correct remain unchanged
 - Defer the alert will reappear at next log-in

McCoy et al. AJKD 2010











- Prescribing physician may not have known patient had low kidney function → KidneyWise
- Prescribing physician may not have known that the drug required a dose adjustment
- Physician may have over-ridden alert for adjustment/contraindication for low eGFR



Potential interventionspharmacist

- Provide the pharmacist with the necessary info re: patient's kidney function via EMR
- Access to OLIS (Ontario Laboratories Information System)



- Prescribing physician may not have known patient had low kidney function \rightarrow *KidneyWise*
- Prescribing physician may not have known that the drug required a dose adjustment
- Physician may have over-ridden alert for adjustment/contraindication for low eGFR
- Pharmacist who filled prescription may not have known patient had a low eGFR





Potential interventions - patient

 Provide/create educational resources for patients so they can advocate on their own behalf

Ontario Renal Network Réseau Rénal de L'Ontario

Medications and Chronic Kidney Disease (CKD): Staying Safe

Some general tips:

- If you are seeing a doctor or pharmacist who may not know your full health history, let them know that you have CKD. Sharing with them your most recent creatinine or eGFR (if you know them) will be very helpful for them when prescribing a new medication.
- When planning on taking a medicine that is not a prescription (including herbal or alternative) medicines), check with the pharmacist before you do so to be sure that it is safe.

Many medications are removed from the body by the kidney. If you have CKD, the dose of these medications may need to be decreased or may not be safe to use. Below is a list of some commonly prescribed medicines that may need to be adjusted if you have CKD.

Antibiotics

- Cephalexin (Keflex)
- Ciprofloxacin (Cipro)
- Amoxicillin (Amoxil)
- TMP/SMX (Septra)
- Nitrofurantoin (Furadantin)
- Clarithromycin (Biaxin)
- Acyclovir (Zovirax)
 - Famciclovir (Famvir)

Medications known as non-

steroidal anti-inflammatories

function worse. Examples of

- naproxen (Naprosyn, Aleve)

- ibuprofen (Advil, Motrin)

- Diclofenac (Voltaren)

meloxicam (Mobicox)

- indomethacin (Indocid)

You should ask you doctor and/or

these medications if you have CKE

pharmacist before taking any of

- celecoxib (Celebrex)

NSAIDs include::

(NSAIDs) can make your kidney

Digoxin (Lanoxin)

 Acebutolol (Rhotral/Sectral) Bisoprolol (Monocor) ...

- Hydrochlorothiazide (HCTZ)
- Spironolactone (Aldactone)
- Levofloxacin (Levaguin)
- - - Simvastatin (Zocor)

Other medications Allopurinol (Zvloprim)

- Ranitidine (Zantac)
- Metoclopramide (Reglan)
- Gabapentin (Neurontin)
- 3-methyl morphine (Codeine)
- Risedronate (Actonel)
- Alendronate (Fosamax)
- Etidronate (Didronel/Didrocal)
- Aluminum/magnesium-containing

B

- meds (Maalox/Mylanta/Gaviscon)
- Dabigatran (Pradaxa)
- Rivaroxaban (Xarelto)
- Anixaban (Eliquis)

If you are ill...

If you become ill and dehydrated (i.e. yomiting or diarrhea). some medications could cause your kidney function to get worse or lead to side effects. If you are unable to drink enough fluid to keep hydrated, you should STOP the following medications until you are hydrated again:

- Blood pressure pills
- Water pills (diuretics)
- Metformin
- Diabetes pills Pain medications
- NSAIDc

If you are unsure whether or not to stop a medication, check with your doctor or pharmacist.



- Ramipril (Altace) Lisinopril (Zestril/Prinivil)
- Enalapril (Vasotec) Pravastatin (Pravachol)

Heart and blood pressure meds

Atenolol (Tenormin)

- Gemfibrozil (Lopid)

- Prescribing physician may not have known patient had low kidney function \rightarrow *KidneyWise*
- Prescribing physician may not have known that the drug required a dose adjustment
- Physician may have over-ridden alert for adjustment/contraindication for low eGFR
- Pharmacist who filled prescription may not have known patient had a low eGFR
- Patient did not have information on hand to advocate on their own behalf





Potential interventions



Potential interventions

- Make resources more readily available for PCPs advising them re: prescribing in CKD
- Integrate sensible alerts into EMR prescribing systems based on level of kidney function
- Develop ways to ensure a patient's pharmacy has the necessary info regarding a patient's level of kidney function
- Provide patients with information on important medications that may require dosing changes or discontinuation





Med Reviews - Essential

- Periodic health exam
- New patients/ admissions
- Support meetings with pharmacy
- Cross reference diagnosis list and medication list
 - Deprescribe
- Consider annual eGFR
- SADMANS Diabetes Canada




Choosing Wisely Canada





A toolkit for deprescribing proton pump inhibitors in EMR-enabled primary care settings

LESS SEDATIVES FOR YOUR OLDER RELATIVES.

A toolkit for reducing inappropriate use of benzodiazepines and sedative-hypnotics among older adults in hospitals

version 1.1



Drug Safety Information

MedEffect Canada

Together we can improve health product safety

Adverse Reactions to Drugs and Other Health Products

Get Informed! Keep Informed! Report Adverse Reactions.



www.healthcanada.gc.ca/medeffect





Resources

- Rx files
- The STOPP/START criteria
 - Screening Tool of Older Persons' potentially inappropriate Prescriptions
 - Screening Tool to Alert doctors to Right Treatment
- www.deprescribing.org
- www.medstopper.com





Conclusions

- Medication prescribing errors are common in patients with CKD and are potentially harmful
- Many medications commonly prescribed in primary care require dose adjustment in CKD
- eGFR is a sensible measure to assess level of kidney function in the context of medication dosing in the majority of cases
 - Severity of illness, extremes of body mass, drug toxicity
- Integrated electronic patient-level information on level of kidney function between prescribers and pharmacists reduces errors
- Medication reviews should be performed at regular intervals with particular attention to dose adjustments in patients with renal impairment to prevent Adverse Drug Reactions



Acknowledgments

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Questions ?

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