

# The Renal Pharmacist

Volume 7, Issue 2

#### Summer 2005

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#### ADDRESS/INFO CHANGES

Please forward any address/phone number changes to the Secretary/ Treasurer. Her e-mail is julie.scott@ grhosp.on.ca. We are constantly updating our membership mailing list. Thank you.

# View from the Chair

Summer is finally here and the RPN executive have been busy over the winter season preparing the 2005 CE events. In February we had Dr. Karen Shalansky come to the CSHP PPC conference to give us an excellent presentation on the MDRD (Modification of Diet and Renal Disease) and how it compares to the Cockcroft-Gault GFR estimation. On May 5th, Dr. Sophie Jamal provided us with an enlightening presentation on fractures in dialysis patients. We are looking forward to continuing the educational series with Dr. Wendy Lim speaking to us on low-molecular weight heparins in CKD in the Fall and CANNT 2005 in Halifax.

Recently we were made aware of the U.S. Centers for Medicare & Medicaid Services (CMS) publishing revisions to the Conditions of Coverage for End Stage Renal Disease Facilities. This document details the requirements that must be met by dialysis facilities in the U.S. in order to receive reimbursement from Medicare. I wanted to highlight the section within this document which discusses the role of a consultant pharmacist in the dialysis unit (http://www.cms.hhs.gov/providerupdate/regs/cms3818p.pdf - page 42). The CMS acknowledged the complex medication regimens of a dialysis patient, and includes in their document that medication review be part of the regular patient assessment. Despite recognizing literature demonstrating cost-effectiveness of having a pharmacist within the dialysis unit, there were no specific recommendations made on the requirement of pharmaceutical services. The CMS did, however, invite comments regarding the role of the pharmacist. The Nephrology Pharmacists Associates (NPA) were seeking a national response in support of requiring a consultant pharmacist in dialysis facilities. The RPN responded with a letter from a Canadian perspective to the CMS. We shared our positive experience in Canada of having clinical pharmacists affiliated with most dialysis units. Our letter emphasized the strong impact of a nephrology pharmacist on the guality of care delivered to ESRD patients. The importance of having a pharmacist as part of the multi-disciplinary team to ensure accuracy and safety of medications for our patients was also stressed. Hopefully there will be a strong enough response to the call for comments that the CMS will include a consultant pharmacist as a member of the multi-disciplinary team in U.S. dialysis units in the near future. We wish the NPA much success in their endeavor!

#### Jenny Ng

Chair, Renal Pharmacist Network

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# The Cost of Living for Hemodialysis Patients in the Durham Region

Submitted by Hilary Jennings, Renal Pharmacist, Lakeridge Health Corp., Whitby ON

As a relative newcomer to the field of renal pharmacy, I am amazed at the number of patients concerned about out-ofpocket costs associated with hemodialysis. Our program will supply medications to patients temporarily on a compassionate basis. In most cases, the prices of medications do not seem high, however when compared to the patient's monthly disposable income the cost may be prohibitive. The following chart outlines some of the major costs associated with hemodialysis. The individuals are fictional but represent typical patients seen in our centre. Note that the resultant disposable income must cover all incidentals which have not been taken into account in the chart.

#### Sources of income:

A low income senior is an individual with a yearly income less than \$16018 or a couple with a yearly income less than \$24175. The ODSP full entitlement is \$930/month/ individual and \$1417/month/ couple. A single person can earn up to \$160/month at a job and keep their full ODSP cheque.

#### Medication costs:

Trillium deductibles were obtained from the Trillium Drug Program Guide. Co-pay costs are based on an average of ten prescriptions filled 4 times per year. The co-pay is \$2 for low income seniors and individuals on ODSP and \$6.11 for high income seniors. Calcium costs are based on a dose of 1000 mg TIDCC and an OTC cost of \$10.99 for 200 tablets. Replavite cost is based on a dose of 1 tablet daily and an OTC cost of \$9.99 for 100 tablets. The cost of quinine sulfate is based on a dose of 300mg daily and the Shoppers Drug Mart prescription cost of \$51.48 for 90 capsules (quinine is not covered by ODB).

#### Housing

Market rent varies widely throughout the region (estimate given in chart). Individuals who are employed or who receive a pension may qualify for subsidized housing which usually calculated based on ~30% of their income. Subsidized housing is available to individuals receiving ODSP and is calculated based on a sliding scale (estimate given in chart). There is a shortage of subsidized housing in the Durham region which is undoubtedly the case in most regions.

#### Nutrition

The cost of Ensure Plus or Resource Fruit Beverage is calculated based on a need for 2 units/day with an estimated cost of \$100/month (prices may vary). Individuals on ODSP may qualify for additional subsidies to help pay for the cost of supplements (\$25-60/month). The cost of food listed in the chart is based on figures from the Durham Region Health Department, Nutritious Food Basket Project. Note that food costs for individuals with kidney disease are often higher due to the need for high protein foods.

			The Co:	st of Livin	g on Hem	nodialysis ii	n the Durha	am Regior				
			Individual # 1 - Plan/C	· Trillium Drug ouple	Individual # 2 Plan/	- Trillium Drug Single	Individual # 3 Income Senia	- ODB/ High or/ Couple	Individual # . income se	4 - ODB/ Low snior/Single	Individual # 5 ODSP/No 8 income/	- Maximum dditional Single
			Yearly	Monthly	Yearly	Monthly	Yearly	Monthly	Yearly	Monthly	Yearly	Monthly
	Net Income		47200	3933.33	27100	2258.33	50000	4166.67	1 5000	1250	11160	930
		Deductible	1626	135.50	826	68.83	100	8.33	0	0	0	0
		Co-pay	80	6.67	80	6.67	244.4	20.37	80	6.67	80	6.67
	Drug Costs	Calcium	118.8	9.9	118.8	6.6	118.8	9.9	118.8	6.6	118.8	6.6
	,	Replavite	35.88	2.99	35.88	2.99	35.88	2.99	35.88	2.99	35.88	2.99
		Quinine	205.92	17.16			205.92	17.16	205.92	17.16		
		Car (lease + gas)	4800	400	4800	400						
_		Parking	420	35	420	35	420	35				
	Transportation	Community care					1296	108				
Costs		Handitrans (local)							1 008	84	1008	84
		Market rent	1 2000	1000			12000	1 000			1 2000	1000
	Housing	Subsidised Housing			8490	707.5			4860	405		
		Resource fruit										
	Minterlation	beverage or			1200	1 00			1200	100		
		beverage										
		Food	2743.68	228.64	1529.28	127.44	2743.68	228.64	1529.28	127.44	1529.28	127.44
	Total Costs		\$ 22,030.28	\$ 1,835.86	\$ 17,499.96	\$ 1,458.33	\$ 17,164.68	\$ 1,430.39	\$ 9,037.88	\$ 753.16	\$ 14,771.96	\$ 1,231.00
Disposible	e Income for individual o income - Total cost:	or couple = (Net :s)	\$ 25,169.72	\$ 2,097.48	\$ 9,600.04	\$ 800.00	\$ 32,835.32	\$ 2,736.28	\$ 5,962.12	\$ 496.84	\$ (3,611.96)	\$ (301.00)

	Individual	Couple
Low income senior	< 16018/year	< 24175
	930/ month	1417/month
ODSP - max	A single person can earn up to \$160 per month at a job and keep	A family can earn up to \$235 per month at a job and keep their full
	their full ODSP cheque.	ODSP cheque.
Calc	ium cost is based on a dose of 50	0 mg TIDCC
Quinine	ost based on 300 mg three times/	week pre-dialysis
Co-pav cost ba	sed on Average of ten prescription	s filled 4 times per vear
(2.00\$ for low income	seniors, Ontario Works Act, Ontar	io Disability Assistance Act &
	.11\$ /prescription for high income	seniors)

# MDRD to Assess Renal Function: How Does it Compare?

Submitted by Karen Shalansky, Pharm.D., Vancouver General Hospital, Vancouver, BC., April, 2005

#### Background

In British Columbia, every time a serum creatinine is ordered, all laboratories automatically calculate an estimated glomerular filtration rate (eGFR) using the abbreviated MDRD equation. The goal is to identify patients with chronic kidney disease (CKD) which is defined as either kidney damage or eGFR < 60mL/minute for > 3 months.<sup>1</sup> Primary care physicians are encouraged to regularly screen high risk populations (i.e. diabetics, elderly, those with a history of hypertension or cardiovascular disease, family history of CKD, and First Nations), determine their underlying cause of CKD and follow clinical practice guidelines created to delay the progression of CKD (www.healthservices.gov.bc.cula/msp/protoguides).

#### **GFR Estimation**

To estimate GFR, a substance must be 1) freely filtered by the glomerulus; 2) not be secreted or reabsorbed; and 3) have a constant concentration during the period of measurement.<sup>2</sup> Inulin, administered intravenously, is considered the gold standard marker of GFR. However, the measurement of GFR with inulin is expensive and time-consuming. Isotope markers such as 125I-iothalamate are also fairly accurate, but expensive measures of GFR. A 24-hour creatinine clearance (CrCl) can be used to estimate GFR, but this method requires accurate urine collections, is time-consuming and delays results by 24 hours. Serum creatinine (SCr), while accessible and inexpensive, is not a sufficiently accurate measure upon which to base clinical decisions. SCr is derived from the breakdown of creatine and phosphocreatine in muscle. It is primarily excreted by glomerular filtration but is also 10-15% actively secreted. As renal function declines, more is secreted, leading to a falsely elevated eGFR. SCr may not rise until later stages of kidney disease when greater than 50% loss of kidney function has occurred. There is also an age-related decline in muscle mass and thus, less SCr produced in the elderly.

In order to improve the accuracy of SCr alone in assessing renal function, several formulas have been developed which incorporate various parameters in their formula such as age, weight and SCr. The most common formula used today is the Cockcroft-Gault developed in 1976 (Equation 1).<sup>3</sup> The equation was derived from 249 males with stable kidney function ranging from 11 mL/minute to normal. A correction factor of 0.85 was arbitrarily added for females due to the assumption of a 10-20% difference in relative amounts of fat and muscle in women compared to men.<sup>3</sup> The Cockcroft-Gault equation was validated against 24-hour Cr Cl and was found to have a correlation co-efficient (r) of 0.84 or r2 of 0.71 (see Table 1 for explanation of r2).

#### MDRD

In 1999, Levey et al developed the MDRD equation to further improve upon the prediction of GFR from SCr.<sup>4</sup> The equation was derived from 1628 patients enrolled in an earlier study entitled "Modification of Diet in Renal Disease"<sup>5</sup>, thus the abbreviation MDRD. The original study was a multi-centre controlled trial to evaluate the effect of protein restriction and strict BP control on the progression of renal disease. Eligibility for patient inclusion were GFR < 70 mL/minute (mean GFR 39.8 mL/minute) and age < 70 years. The MDRD equation (Equation 2) does not include weight, but does include serum albumin, BUN and an African American factor.<sup>4</sup>

#### **Comparison of MDRD to Cockcroft-Gault**

In the Levey study<sup>4</sup>, the MDRD equation showed better correlation to measured GFR (as determined by 125Iiothalamate) compared to Cockcroft-Gault (r2 = 0.903 vs 0.842 for Cockcroft-Gault). An abbreviated MDRD equation was developed to allow for an easier assessment of GFR.<sup>6</sup> In the abbreviated MDRD, both BUN and serum albumin are removed from the equation (Equation 3). The accuracy of this formula is still intact with an r2 of 0.892. Note that in British Columbia, the African American factor is not included in the abbreviated MDRD calculation. Table 3 shows renal function estimates of the MDRD equation compared to Cockcroft-Gault. In general, eGFR using the MDRD formula is slightly lower than Cockcroft-Gault at more normal SCr and in younger patients, and approaches similar values to Cockcroft-Gault as the SCr and age increase.

#### Limitations of MDRD

The MDRD equation was developed from a very select population of patients less than 70 years old with varying degrees of CKD. It has not been validated in several populations including those with normal renal function (> 70 mL/minute), IDDM, children (< 18 years), renal transplant patients, pregnancy and low serum albumin. The MDRD was recently assessed in 580 patients with normal renal function (mean GFR 101 mL/minute) and showed poor correlation (r2 = 0.19) compared to measured GFR with non-radiolabeled iothalamate.7 The authors created their own guadratic equation with a correction factor for healthy patients. Caution must be exercised when using the MDRD in extremes of age and weight, diseases of skeletal muscle (e.g. paraplegia) and high protein diets. As with all prediction equations based on SCr, a steady state SCr is necessary for accurate assessment of renal function. Certain drugs may interfere with SCr secretion including cimetidine and trimethoprim-sulfamethoxazole. As well, certain conditions (e.g. diabetic ketoacidosis) and drugs (e.g. cefoxitin) may interfere with the SCr assay.

#### Is the MDRD Superior to Cockcroft-Gault?

The abbreviated MDRD equation was chosen as the laboratory method to determine GFR in British Columbia due to its nonreliance upon weight, which is often an unknown factor in laboratories, and its more accurate assessment of GFR over the Cockcroft-Gault equation in the study from which it was derived. There are several limitations to the MDRD formula, primarily the limited populations it has been tested in, especially in healthy patients with normal renal function, and the complexity to calculate the formula with just paper and pencil. A few trials have compared the MDRD to Cockcroft-Gault in the elderly<sup>8</sup>, African Americans<sup>9</sup> and transplant patients<sup>10</sup> (Table 1). In the elderly, the MDRD showed very good correlation to measured GFR but did not improve the estimate compared to the Cockcroft-Gault equation. The MDRD more accurately predicted GFR than the Cockcroft-Gault for African Americans, but was not as good for predicting renal function in transplant patients. Wuyts et al found the Cockcroft-Gault to be more precise than the abbreviated MDRD in 80 adult patients with CKD.11

#### Conclusion

Determination of eGFR using the abbreviated MDRD equation by B.C. laboratories was initiated to raise the awareness of

health care professionals to renal dysfunction. The original intent was to allow primary care physicians to stage CKD and act prospectively to slow its progression to end-stage renal disease and dialysis. In general, eGFR calculations are typically slightly lower with the MDRD compared to Cockcroft-Gault except with extremes of age and/or elevated SCr where the two formulas become more similar. The MDRD has not been evaluated in many populations and may not be applicable in patients with normal renal function or in children. The Cockcroft-Gault equation has stood the test of time with at least 24 studies from 1976-1998 assessing it in various populations against various standards with an r2 ranging from 0.62-0.88.13,14 Of note, most drug company dosage adjustment guidelines for renal dysfunction are based on GFR determinations using the Cockcroft-Gault equation. The National Kidney Foundation endorses both the MDRD and Cockcroft-Gault equations with the caveat that while the MDRD is more precise than the Cockcroft-Gault for persons with GFR less than ~ 90mL/minute, it has not been validated in diabetic kidney disease, patients with serious co-morbidities, normal persons or persons older than 70 years of age.<sup>1</sup> It is important to recognize that any equation based on SCr to assess renal function has inherent limitations and is best used as a quide, rather than an absolute, to the level of renal dysfunction.

### EQUATIONS

#### **Equation 1. Cockcroft-Gault**

Male: CrCl (mL/min) = <u>(140-Age) x Wt (kg)</u> SCr (umol/l x 0.0113) x 72

Female x 0.85

#### **Equation 2. MDRD (American Units)**

Male: eGFR (mL/min/1.73m<sup>2</sup>) = 170 x SCr (mg/dl)<sup>0.999</sup> x Age<sup>0.176</sup> x BUN (mg/dl)<sup>0.17</sup> x Serum Albumin (g/dl) x 1.18 (African American)

Female: x 0.762

#### **Equation 3. Abbreviated MDRD (American Units)**

Male: eGFR (mL/min/1.73m<sup>2</sup>) = 186 x SCr(mg/dl)<sup>-1.154</sup> x Age-0.203 x 1.212 (African American) Female x 0.742

#### To convert Abbreviated MDRD to SI units

 $\begin{array}{l} \mbox{Male eGFR (mL/min/1.73m^2) = exp(5.228 - 1.154 \ x \ ln(SCr \ x \ 0.0113) - 0.203 \ x \ ln(age)) \ x \ 1.212 \ (African \ American) \ Female eGFR (mL/min/1.73m^2) = exp(5.228 - 1.154 \ x \ ln(SCr \ x \ 0.0113) - 0.203 \ x \ ln(age) \ -0.299) \ x \ 1.212 \ (African \ American) \ American) \ Female eGFR (mL/min/1.73m^2) = exp(5.228 - 1.154 \ x \ ln(SCr \ x \ 0.0113) - 0.203 \ x \ ln(age) \ -0.299) \ x \ 1.212 \ (African \ American) \ American) \ Female eGFR (mL/min/1.73m^2) = exp(5.228 - 1.154 \ x \ ln(SCr \ x \ 0.0113) \ - 0.203 \ x \ ln(age) \ -0.299) \ x \ 1.212 \ (African \ American) \ American) \ American) \ American) \ Female eGFR (mL/min/1.73m^2) = exp(5.228 - 1.154 \ x \ ln(SCr \ x \ 0.0113) \ - 0.203 \ x \ ln(age) \ -0.299) \ x \ 1.212 \ (African \ American) \ Americ$ 

# MDRD to Assess Renal Function - continued

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## Table 1. Comparison of Formulas

Author N Standard		Standard Measure	rd Measure Corrrelation (r <sup>2</sup> ) <sup>a</sup>	
		of GFR	MDRD	Cockcroft-Gault
Cockcroft-Gault 1976 <sup>3</sup>	236 males	24-hr CrCl	_	0.71
Levey et al 19994 (MDRD)	1629 patients with renal	<sup>125</sup> I-lothalamate	0.90	0.84
	dysfunction (age < 70 yrs)			
Lamb et al 2003 <sup>8</sup>	52 elderly (69-92 yrs)	<sup>51</sup> Cr-EDTA	0.84	0.84
Lewis et al 2001 <sup>9</sup>	1703 African Americans	<sup>125</sup> I-lothalamate	0.81	0.72
Bedros et al 1998 <sup>10</sup>	?No. transplant patients	448lohexol	0.59	0.62
Wuyts B et al 2003 <sup>11</sup>	80 patients (51-81 yrs) (median CrCl 43mL/min)	<sup>51</sup> Cr-EDTA	0.66-0.74 <sup>b</sup> (abbrev)	0.76-0.81 <sup>b</sup>

ar = correlation co-efficient. If formula shows perfect prediction, then r = 1; r<sup>2</sup> is a measure of the amount of variance the two values share. An r<sup>2</sup> > 0.81 shows very good correlation, r<sup>2</sup>  $\ge$  0.49 shows good correlation<sup>12</sup>

bSCr measured by 4 different methods, thus, correlation varied according to method used

### **Table 2. Renal Function Estimates**

S-Cr, Umol/L	Age	Sex	eGFR	
			Cockcroft-Gault mL/minute	MDRD mL/min/1.73m <sup>2</sup> (abbreviated)
124	45	Male	71	58 (58.4)
124	70	Male	52	54 (52.5)
354	45	Male	25	17 (17.4)
354	70	Male	18	15 (15.9)

Assumptions: Race: White; Weight 75kg; Albumin 4g/L for S-Cr 124 and 3.5g/L for S-Cr 354; BUN 7.1mmol/L for S-Cr 124 and 17.8 for S-Cr 354

## MEMBER PROFILE Reshma Rathod



Reshma Rathod graduated from the University of Toronto pharmacy program in 1999. She has worked in hospital pharmacy ever since. Prior to working in nephrology, she worked in rehab, surgery and medicine. She works at Lakeridge Health Corporation and has experience working with all modalites of nephrology patients. She currently focuses on inpatient nephrology and predialysis patients. She enjoys working along the continuum of care with renal patients and rises to the challenge of keeping abreast of the many different therapeutic areas. Her biggest challenge is overseeing a large number of patients, and attempting to address all their medication related issues.

Reshma has been involved with RPN for 3 years in the position of co-communications co-ordinator.

In her spare time, she enjoys cooking, working out, shopping and relaxing with family.

Thank you Reshma for your commitment to nephrology patients.

#### WHAT'S THAT SMELL?

Do your Renagel® tablets smell like they have been dipped in a cleaning solvent, like ammonia bleach? A patient made me smell his open bottle. It nearly knocked me over. Yes, it definitely smelled like bleach. He called the company, Genzyme, and this is the response he received.

"Investigations have been conducted resulting in complaints reporting a strange odour coming from the tablet bottle. An "ammonia-like" odour is expected and is not an indication of any quality problems related to the product. All product on the manufacturer's stability program sampled after three months was noted to have a faint smell of ammonia. The odour is the result of oxidation of some of the free amine groups on the polymer, and is not an indication of degradation or any quality problems related to the product."

There you have it. Chemistry at its best!! Why couldn't I think of that??

- Lisa Sever, Renal Pharmacist, York Central Hospital, Richmond Hill, ON

# WEBSITE UPDATE

#### www.renalpharmacists.net

In case you've had the pleasure of browsing the Website lately, you would notice that several enhancements have been added to the site. A team of 3 renal pharmacists including Jiten Janie, Hillary Jennings and myself have been working very hard over the last few months to update the information in the website and enhance some of the features.

When you first sign-on you will be asked to update your account information including a clause that allows you to opt out of the mass e-mail system. The mass emails are only sent by the Web Administrator (currently me) or as a reminder of Quarterly Educational meetings. If you do not want to be part of these emails, you need to click "no" on the "e-mail list" option.

In the discussion forums, there is also a spot to allow an email to be sent to you when there is a new posting. At the top right hand corner, it says notify me of all new posts. Click on the activate box if you would like this feature. This can be turned off if later you change your mind. The number of emails generated this way varies per Discussion Forum use; I've received only 4 last week and was able to offer opinion on some efficiently.

The Articles of Interest are again current, and the Web Resources links are all working again. Keep an eye on the Website in the coming weeks as the team continues to add new features such as "Clinical Practice Guidelines", allowing searches through old Newsletter articles, and many more items.

If you have any ideas or comments on what is working or not working on the site, please email me at **bbruinooge@yorkcentral.on.ca** 

- Brenda Bruinooge, Renal Pharmacist, Web site coordinator.

#### NEW WEBSITES

www.thekidney.org



# ARTICLES OF INTEREST

Please refer to the website www.renalpharmacists.net for a more complete list and links to the abstracts.

Schaeffner ES, Kurth T, de Jong PE, Glynn RJ, Buring JE, Gaziano JM. Alcohol consumption and the risk of renal dysfunction in apparently healthy men. Arch Intern Med. 2005 May 9;165(9):1048-53.

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#### UPCOMING CONFERENCES

#### **CSHP** Annual General Meeting

August 13 - 16, 2005 Ottawa, Ontario http://www.cshp.ca/events/cshpEvents\_e.asp

#### **RPN Educational Evening**

September 20, 2005 – 6pm Speaker: Dr. Wendy Lim Topic: Anticoagulation Holiday Inn Yorkdale, Toronto, ON

Prevention of Renal Disease 4<sup>th</sup> Annual Conference September 23-24, 2005 Toronto, ON http://www.nephroprevention.com/ CANNT's 37th National Symposium October 13, 2005

Halifax, Nova Scotia http://www.cannt.ca/

American Society of Nephrology November 8-14, 2005

Philadelphia, PA http://www.asn-online.org



To all of those who contributed (especially the new contributors!) and to ORTHO BIOTECH for printing and distributing the newsletter.

#### RPN EXECUTIVE ELECTIONS • SEPT.05

The RPN needs volunteers. If you can devote a few hours per month to your renal profession, contact Jenny Ng using the information on the front of this newsletter.

If you are interested in assisting the RPN in any other way, please feel free to contact any member of the Executive. As many of the communications are done by teleconference and email, these positions are open to any renal pharmacist in Canada.

Check out the RPN Website at www.renalpharmacists.net on a regular basis for 2005 CE activities.