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Bulletin de la Dialyse à Domicile

Simplified Calculation of Month-on-Month Annualized Peritoneal Dialysis Associated Peritonitis Rate – Validation in ANZDATA, NZ PD and RDPLF registries

(Calcul simplifié du taux de péritonite mensuel annualisé : validation dans les registres ANZDATA, NZ PD et RDPLF)

Mark R Marshall[1,2], Gerald P Waters[3,4], Christian Verger[5]

1.Faculty of Medical and Health Sciences, University of Auckland, Auckland, New Zealand, 2.Department of Renal Medicine, Counties Manukau Health, Auckland, New Zealand ,
3. Regional Renal Service, Waikato District health Board, Hamilton, New Zealand, 4. New Zealand Peritoneal Dialysis Registry, Hamilton, New Zealand
5. Le Registre de Dialyse Péritonéale de Langue Française et hémodialyse à domicile (RDPLF), Pontoise, France

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Summary

Peritonitis is the most important therapy-related complication of peritoneal dialysis (PD). Monthly or quarterly PD peritonitis rate statistics are used to identify special cause variation within or between individual PD centres, to highlight any need for quality improvement. Unfortunately, many PD centres do not accurately "patient flow" (i.e., when patients start and finish on PD), and therefore cannot measure PD peritonitis rate. In this study, we validate an estimating formula for month-on-month annualised PD peritonitis rate, that calculates time-at-risk from "patient stock" (i.e., the number of prevalent patients on PD at the beginning and end of the month). We compared centers' estimated peritonitis rates with gold-standard measurements in the Australia and New Zealand Dialysis and Transplant Registry / New Zealand PD Registry, and Le Registre de Dialyse Péritonéale de Langue Française et hémodialyse à domicile. A total of 268 centers from 9 countries with 1,020,260 patient-months of follow-up and 19,669 episodes of peritonitis were modeled. Overall agreement was excellent between estimates and gold-standard measurements with a concordance correlation coefficient (CCC) of 0.998 (95% confidence interval [CI] 0.998-0.998) in both registries. There was statistically significant lower agreement for smaller centers, although the CCC was still greater than 0.995. There were no instances of clinically significant misclassification of centers as being compliant or non-compliant with PD peritonitis standards with the use of the estimating formula. The simplified method of calculating the PD peritonitis rate is accurate and will allow more centers around the world to measure, report, and work on reducing PD peritonitis rates.

Key words: PD peritonitis, Peritoneal dialysis, ANZDATA, NZ PD Registry, RDPLF

Résumé

La péritonite est la plus importante complication liée au traitement de la dialyse péritonéale (DP). Les statistiques mensuelles ou trimestrielles sur le taux de péritonite en DP sont utilisées pour identifier les causes des variations au sein d'un centre de DP ou entre ces centres, pour améliorer la qualité de prise en charge. Malheureusement, de nombreux centres de DP ne mesurent pas avec précision le «flux de patients», et ne peuvent donc pas mesurer le taux de péritonite en DP. Dans cette étude, nous validons une formule d'estimation du taux de péritonite en DP annualisé mois par mois, qui calcule le temps à risque à partir du nombre de patients prévalents en DP au début et à la fin du mois. Nous avons comparé ces taux de péritonite estimés et ceux obtenjs avec la méthode de référence dans les centres du registre Australia and New Zealand Dialysis and Transplant Registry / New Zealand PD Registry, et du Registre de Dialyse Péritonéale de Langue Française et hémodialyse à domicile. Un total de 268 centres de 9 pays avec 1 020 260 mois-patients de suivi et 19 669 épisodes de péritonite ont été modélisés. La concordance globale était excellente entre les estimations et celles avec la mesure de référence, avec un coefficient de corrélation de concordance (CCC) de 0,998 (intervalle de confiance à 95 % [IC] 0,998-0,998) dans les deux registres. La concordance était statistiquement plus faible dans les petits centres, bien que le CCC soit toujours supérieur à 0,995. Il n'y a pas eu de cas d'erreur de classification cliniquement significative des centres comme étant conformes ou non conformes aux normes de péritonite en DP avec l'utilisation de la formule d'estimation. La méthode simplifiée de calcul du taux de péritonite en DP est précise et pourrait permettre à un plus grand nombre de centres dans le monde de mesurer, de déclarer et de travailler à la réduction leurs taux de péritonite en DP.

Mot clefs : Péritonite en DP, dialyse péritonéale, ANZDATA, NZ PD Registry, RDPLF

Corresponding author : Mark R Marshall, PO Box 29, Helensville 0840, New Zealand.
markrogermarshall@icloud.com phone: ++64 9 2760000, fax: ++64 9 2760034, cell: ++64 9 21393037

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INTRODUCTION

The identification of excess peritonitis or high peritonitis rates is essential for quality control within peritoneal dialysis (PD) services. Traditionally, this is ascertained as special cause variation in PD peritonitis rates at a unit level, calculating rates of PD peritonitis from the number of episodes, as a function of PD patient time-at-risk [1]. The recommended computation uses "patient flow" data over a period of observation - that is, calculating PD time-at-risk function as the number of PD patient-days at risk, as the cumulative total of each patient's number of days on PD from their starting and finishing dates.

$$\frac{Number\ of\ PD\ peritontis\ episodes\ during\ Year\ for\ N\ patients}{\sum_{Patient\ N}^{Patient\ 1}\left(\frac{Days\ on\ PD\ during\ Year}{365.25}\right)} \quad Eq\ 1$$

Recently, we validated a simplified method of calculating PD peritonitis rate using patient time-at-risk from "patient stock" data - that is, calculating PD patient-days from the number of prevalent PD patients at the center at the start of the period of observation and the corresponding number at the end. This enables calculations of PD peritonitis rates in the absence of accurate "patient flow" data (that is, the dates when patients start and finish PD), so long as there is reliable "patient stock" data (that is, the numbers of prevalent patients on PD at given points in time) [2].

$$\frac{Number\ of\ PD\ peritontis\ episodes\ during\ Year\ for\ a\ given\ center}{\left(\frac{N_{Year\ Start} + N_{Year\ Finish}}{2}\right)} \quad Eq\ 2$$

While this estimating formula has been validated for annual PD peritonitis rates, it would be convenient to extend this concept to the calculation of month-on-month annualized PD peritonitis rates (here-after referred to as "monthly peritonitis rates"), a commonly used PD quality indicator. This simplification also replaces the traditional time-at-risk denominator with one calculated from "patient stock" - that is, the number of prevalent PD patients in a center at the beginning and end of each month, a more easily accessible statistic for most PD centers. The algebraic equivalence between the estimates and gold-standard measurements relies on two key assumptions: namely, that patients start and finish PD at a uniform rate throughout the months (that is, at random), and that the number of patients who start on PD after the beginning of the month and also finish before the end of the month is small.

$$\left[\frac{Number\ of\ PD\ peritontis\ during\ Month\ for\ a\ given\ center}{\left(\frac{N_{Month\ Start} + N_{Month\ Finish}}{2}\right)}\right] \times 12 \quad Eq\ 3$$

In this paper, we explore the accuracy of the estimating formula in two databases. The first is Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) / New Zealand (NZ) PD Registry. The second is Le Registre de Dialyse Péritonéale de Langue Française et hémodialyse à domicile (the RDPLF).

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METHODS

Study Design

We performed an observational cohort study to measure agreement between gold-standard annual PD peritonitis rates and those estimated using the simplified formula. The National (NZ) Health and Disability Ethics Committee (IORG0000895) approved the study protocol, and waived the need for patient consent under the provisions for observational research.

Patient Participants and Data Source

The ANZDATA Registry collects data on all kidney failure (KF) patients in Australia and New Zealand. For the purposes of this study, PD patients are defined as those with a diagnosis of KF for whom PD is an indefinite treatment. Data on PD peritonitis has been collected since 2004 (in NZ, directly by ANZDATA until June 2021, but through data linkage with the NZ PD Registry thereafter). Details of the structure and methods of all registries are reported elsewhere (www.anzdata.org.au, www.pdregsitry.org.nz, [3-5]).

The RDPLF collects corresponding data on all KF patient on PD in Mainland France, as well as data from larger PD centres in Algeria, Francophone Belgium, the Kingdom of Morocco and Southern Provinces, Luxembourg, Francophone Switzerland, and Tunisia. PD peritonitis has been collected since the registry's inception in 1986. Details of the structure and methods of the RDPLF is reported elsewhere (https://rdplf.org/ [6]).

We created a study cohort from the two registries. In ANZDATA, this comprised children and adults with KF on PD from 1-Jan-2004 to 31-December-2019. In the RDPLF, the study cohort comprised corresponding adult patients between the dates of 1-Jan-2000 and 31-December-2020.

Primary Exposure and Outcome Variables

The primary exposure in this study is PD peritonitis, as recorded in the respective registries based upon the opinion of the treating physician / PD team. Gold-standard month-on-month annualized PD peritonitis rate measurements were performed using Equation 1 above (modified for a monthly calculation), and estimates from Equation 3.

Data Measurement and Quantitative Variables

We also used patient and center characteristics in our models, to identify any effect modification on concordance statistics arising from variation in patient case mix between centers. In ANZDATA / NZ PD Registry models, potential effect modifiers were: country, age at PD inception, PD sub-modality (automated PD continuous ambulatory PD), gender, ethnicity (Caucasian / other, Aboriginal or Torres Strait Islander, Asian, NZ Maori, Pacific peoples), primary kidney disease (diabetic nephropathy, ischemic / hypertensive nephropathy, glomerulonephritis, other), late referral for nephrology pre-dialysis care (<3 months before dialysis inception), and rurality (living in a major city, living in a regional town or remotely). Corresponding characteristics in RDPLF models were: country, age at PD inception, PD sub-modality (APD, CAPD), gender, diabetes mellitus (none, type 1 or type 2), and medical co-morbidity (Charlson co-morbidity index [CCI] [7]).

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Statistical Methods

We assessed agreement between gold-standard and estimated monthly PD peritonitis rates using concordance statistics. As described in our previous article [2], the relationship-scale framework underpins Lin's implementation of the concordance correlation coefficient (CCC), which combines measures of both precision (Pearson correlation coefficient) and accuracy (the bias-correction factor). The combination of these statistics described how far the observed data deviate from the line of perfect concordance (that is, the line at 45 degrees on a square scatterplot). Lin's CCC increases in value as a function of the tightness of the data about its reduced major axis (the precision of the estimation) and the nearness of the data's reduced major axis to the line of perfect concordance (the accuracy of the estimation) [8-11]. The data-scale framework underpins Bland and Altman's limits-of-agreement (LoA) procedure, which is complementary to the relationship-scale approach [12].

Effect modification was ascertained by comparing concordance statistics between sub-groups of centers, sorted by their patient case mix and center characteristics. For example, in Australia and New Zealand centers during June 2004, 2 subgroups of centers were created according proportion of their patients who live either regionally or remotely (>median for all centers in June 2004 versus < median). We then checked for significant differences in Lin's CCC between each subgroup. In ANZDATA, we assessed for effect modification by the following factors: country (Australia versus New Zealand), pediatric [< 18 years] versus adult [>= 18 years]), size of PD population, proportion of patients on APD, proportion of males, proportion with indigenous or Pacific ethnicity, proportion with high-risk primary kidney disease (ischemic or diabetic nephropathy), late referral for nephrology pre-dialysis care, and rurality. In RDPLF, the corresponding assessments involved: country (France, Algeria, Francophone Belgium, the Kingdom of Morocco and Southern Provinces, Luxembourg, Francophone Switzerland, and Tunisia), size of PD population, mean age of patients at PD inception, proportion of patients on APD, proportion of males, proportion of patients with diabetes mellitus, and presence and extent of medical co-morbidity (> median CCS versus < median CCS).

Comparisons of CCC between subgroups were made using a z-test with a null hypothesis that the difference between CCC was of zero. For subgroups of more than two, comparisons were made by ANOVA [13].

In all analyses, and error trap was utilized to exclude those centers with an annualized PD peritonitis rate > 10 episodes per patient-year when measured month-on-month.

RESULTS

Descriptive Data

We modelled 268 centers from 9 countries with 1,020,260 patient-months of follow-up (647,581 RDPLF, 372,679 ANZ). There were 19,669 episodes of peritonitis over this period. Summary statistics of center characteristics (or more accurately, summary statistics of each center-month characteristics) are shown in *Tables I and II*. Fifteen center-months from ANZDATA were excluded through the error trap of >10 episodes per patient-year (annualised), and 108 center-months from the RDPLF.

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Table I: Summary characteristics of centers in Australia and New Zealand 2004 - 2019

		N	Median	P25	P75
PD centers	Total	80			
	New Zealand	12			
	Australia	68			
Total center-months		12,851			
Patient	Stock (N @ end of month)		27	11	62
	Flow (total N during month)		29	11	64
Age (years)	@ PD start		58.37	55	61.33
Gender*	Male		0.58	0.5	0.66
	Female		0.42	0.34	0.50
Residential status*	Major city		0.66	0	0.89
	Regional		0.29	0.08	0.75
	Remote		0	0	0.04
Referral for RRT*	Late		0.17	0.11	0.25
	Timely		0.82	0.74	0.88
Ethnicity*	Caucasian / other		0.79	0.60	0.9
	Aboriginal / Torres Strait Islander		0	0	0.06
	Asian		0.07	0	0..8
	NZ Maori		0	0	0.03
	Pacific People		0	0	0.04
Primary kidney disease*	Diabetic		0.28	0.17	0.37
	Hypertensive / ischaemic		0.13	0.06	0.19
	Glomerulonephritis		0.25	0.18	0.32
	Other		0.29	0.21	0.40
Modality*	APD		0.6	0.33	0.8
	CAPD		0.4	0.2	0.67

Table II: Summary characteristics of centers in RDPLF 2000-202

	N		Median	P25	P75
PD centers	Total	188			
	Algeria	1			
	Belgium	17			
	France	155			
	Luxembourg	1			
	Morocco and Southern Provinces	5			
	Switzerland	3			
	Tunisia	6			
Total center-months		38,093			
Patient	Stock (N @ end of month)		16	8	26
	Flow (total N during month)		17	9	27
Age (years)	@ PD start		66.32	60.98	70.82
Gender*	Male		0.58	0.5	0.68
	Female		0.42	0.32	0.5
Diabetes* mellitus			0.3	0.19	0.41
Charlson Comorbidity Index			5.75	4.83	6.51
Modality*	APD		0.37	0.20	0.57
	CAPD		0.63	0.43	0.80

Main Results

Overall, the average agreement between estimates and gold-standard measurements of PD peritonitis rates were extremely high, as assessed using concordance statistics and Bland and Altman analysis. For ANZDATA / NZ PD, the CCC was 0.998 (95% confidence interval [CI] 0.998-0.998) and average bias (95% LoA) 0.001 (-0.086-0.088). For the RDPLF, the corresponding statistics were 0.998 (0.998-0.998) and 0.001 (-0.089-0.091), respectively.

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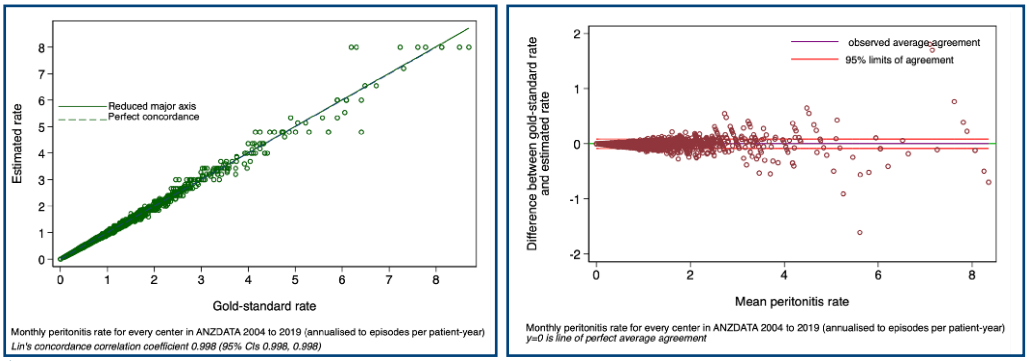
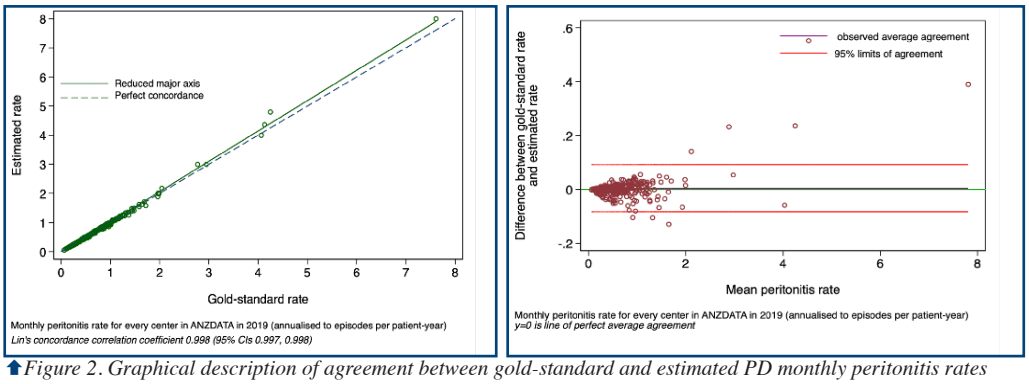
Graphical descriptions of relationship-scale and data-scale agreement for ANZDATA are shown in *Figure 1* for the entire period of observation and in *Figure 2* for the last year of available data (2019). *Table III* shows the results of testing within subgroups of centers defined by their patient case mix. Statistically, there was significantly better agreement in centers that were larger, in NZ versus Australia, less rural, with a higher proportion of patients on APD, and with a higher proportion of patients with high-risk primary renal disease. All of the agreement statistics were extremely high, however, and the differences in CCC between groups being generally less that 0.0001.



⬆*Figure 1. Graphical description of agreement between gold-standard and estimated PD monthly peritonitis rates (annualised to episodes per patient-year) for every center in ANZDATA 2004-2019*



⬆*Figure 2. Graphical description of agreement between gold-standard and estimated PD monthly peritonitis rates (annualised to episodes per patient-year) for every center in ANZDATA during the latest year available (2019)*

⬇*Table III: Effect modification of concordance statistics in ANZDATA / NZ PD Registry centers according to their case mix*

Characteristics		Lin's CCC (95% CIs)	P-value of two-way interaction
Center size	> median number of patients	0.999 (0.999-0.999)	<0.0001
	< median number of patients	0.998 (0.998-0.998)	
Age	Adult	0.998 (0.998-0.998)	0.11
	Pediatric	0.998 (0.998-0.998)	
Country	Australia	0.998 (0.998-0.998)	<0.0001
	New Zealand	0.999 (0.999-0.999)	
Indigenous / Pacific peoples	> median proportion	0.998 (0.998-0.998)	0.15
	< median proportion	0.997 (0.997-0.998)	
Major city residents	>=50% of patients	0.998 (0.998-0.998)	0.008
	<50% of patients	0.998 (0.997-0.998)	
High-risk primary kidney disease (diabetic / ischemic)	> median proportion	0.998 (0.998-0.998)	0.0001
	< median proportion	0.998 (0.998-0.998)	
APD versus CAPD	> median proportion on APD	0.998 (0.998-0.998)	<0.0001
	< median proportion on APD	0.997 (0.997-0.997)	

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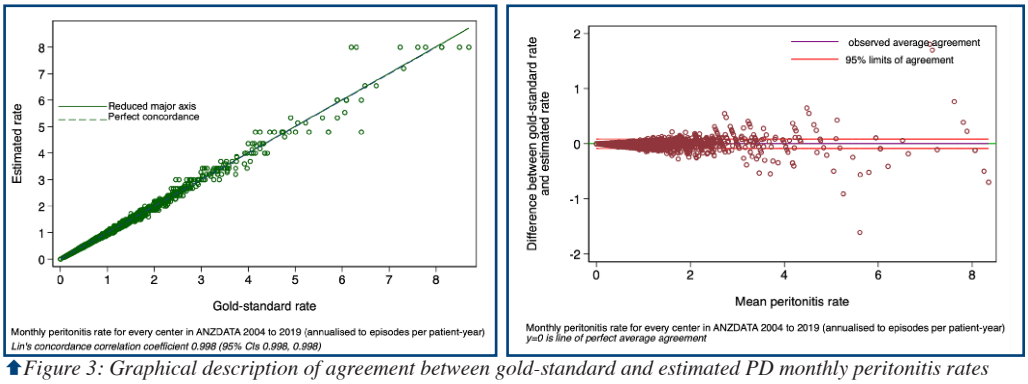
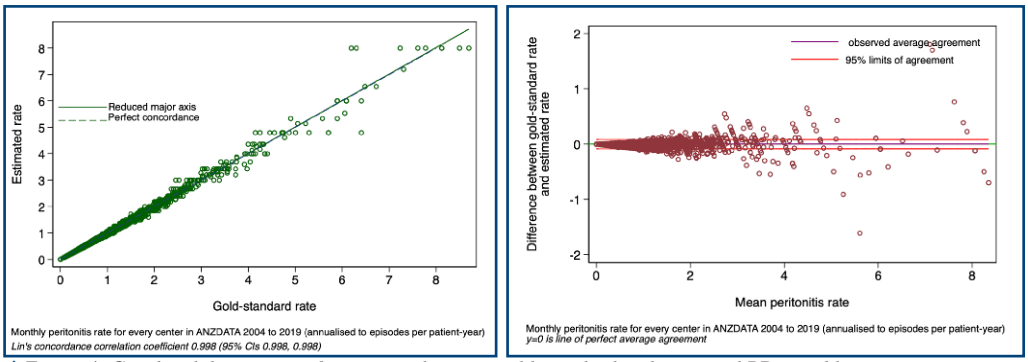
Graphical descriptions of relationship-scale and data-scale agreement for the RDPLF are shown in *Figure 3* for the entire period of observation and in *Figure 4* for the last year of available data (2020). *Table IV* shows the results of testing within subgroups of centers defined by their patient case mix. Like ANZDATA, agreement statistics were extremely high across all groups, with the size of any differences being small with generally less than 0.001.



⬆*Figure 3: Graphical description of agreement between gold-standard and estimated PD monthly peritonitis rates (annualized to episodes per patient-year) for every center in the RDPLF 2000-2020*



⬆*Figure 4: Graphical description of agreement between gold-standard and estimated PD monthly peritonitis rates (annualized to episodes per patient-year) for every center in the RDPLF during the latest year available (2020)*

⬇*Table IV: Effect modification of concordance statistics in the RDPLF centers according to their case mix*

Characteristics		Lin's CCC (95% CIs)	P-value of two-way interaction
Center size	> median number of patients	0.999 (0.999-0.999)	<0.0001
	< median number of patients	0.998 (0.998-0.998)	
Age	> median	0.998 (0.998-0.998)	0.0002
	< median	0.998 (0.998-0.998)	
Country	Algeria	n/a	<0.0001
	Belgium	0.998 (0.998-0.998)	
	France	0.998 (0.998-0.998)	
	Luxembourg	0.998 (0.997-0.999)	
	Morocco and Southern Provinces	0.994 (0.993-0.994)	
	Switzerland	0.999 (0.999-0.999)	
	Tunisia	0.999 (0.999-0.999)	
Charlson Comorbidity Index	> median score	0.998 (0.998-0.998)	<0.0001
	< median score	0.998 (0.998-0.998)	
APD versus CAPD	> median proportion on APD	0.999 (0.999-0.999)	0.0001
	< median proportion on APD	0.997 (0.997-0.998)	

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To ascertain practical limits for the use of the estimating formula, we examined the effects of estimation on misclassification – that is, whether center-months were classified as having estimated rates above or below the International Society of Peritoneal Dialysis (ISPD) standard of 0.4 episodes per patient-year [1], when the actual rate showed the opposite. In ANZDATA there were 105 centre-months in ANZDATA out of 12,651 that were misclassified by the estimating formula. The delta between the estimated and actual rates for misclassified months are shown in *Figure 5*. It can be seen that these instances occurred when the actual rates were close to 0.4 episodes per patient-month, with estimates that were close but nonetheless directionally on the opposite side of the 0.4 threshold. In RDPLF, there were 130 centre-months out of 38,093 that were correspondingly misclassified. *Figure 6* shows the corresponding delta, with the same insight that misclassifications occurred when the actual rates were close to 0.4 episodes per patient-month.

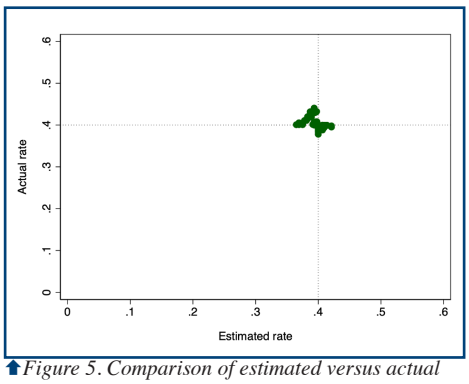

Figure 5. Comparison of estimated versus actual PD peritonitis rates in ANZDATA, for centre-months that were misclassified by the estimating formula as being incorrectly above or below the ISPD threshold of 0.4 episodes per patient-month.

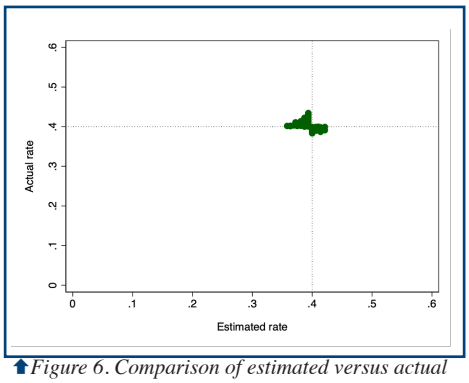

Figure 6. Comparison of estimated versus actual PD peritonitis rates in RDPLF, for centre-months that were misclassified by the estimating formula as being incorrectly above or below the ISPD threshold of 0.4 episodes per patient-month.

In ANZDATA, 13 centres had more than 5% of centre-months where agreement between estimated and actual peritonitis rates fell outside Bland and Altman's limits of agreement. Of note, these were all small centers, with an average of just over 6 prevalent patients on PD in any given month. *Figure 7* shows a time series of each center's estimated and actual peritonitis rates over the entire period of observation. Importantly, there were no instances where these centres were misclassified in terms of compliance through use of the estimating formula. In RDPLF, 12 centres had more than 5% of centre-months outside Bland and Altman's limits of agreement. As is the case with ANZDATA, these were mostly small centers, with an average of just over 6.5 patients in any given month. *Figure 8* shows a time series of their estimated and actual rates over the entire period of observation. Once again, there were no instances where such centres in RDPLF were misclassified through use of the estimating formula.

DISCUSSION

In this paper, we show that month-on-month annualized PD peritonitis rate can be accurately estimated using the number of episodes of PD peritonitis for a given center over the month along with their "patient stock" (i.e., prevalent patients on PD at the start and the end of the month). This avoids the need for cumbersome measurements based on "patient flow" (i.e., number of PD patients-days during the month). We show that this estimation is almost perfect for almost every type of PD center, although it is technically most accurate in larger ones. Notwithstanding, concordance was still very good in centers of ever kind in both ANZDATA and RDPLF (Lin's CCC > 0.99). The use of the estimating formula PD peritonitis rate in this study did not lead to

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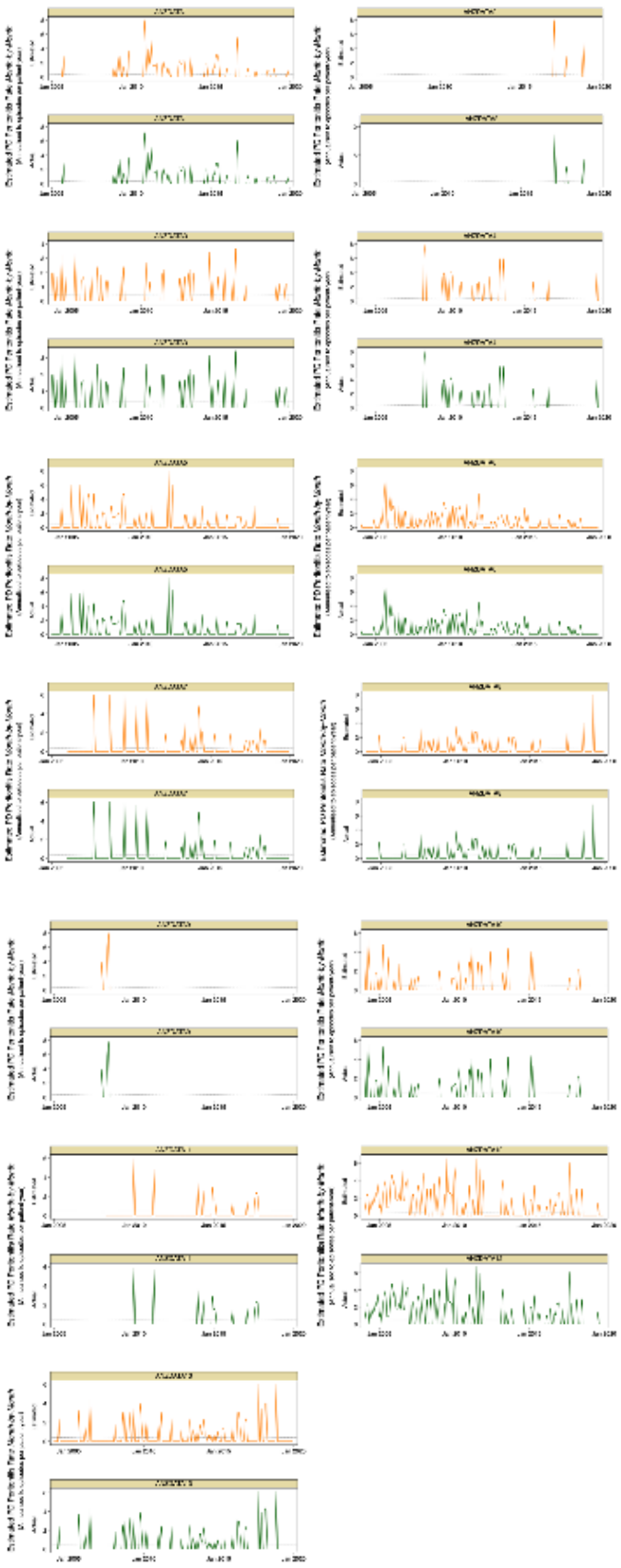

Figure 7. Time series of estimated and actual PD peritonitis rates of the 13 centres in ANZDATA with more than 5% of their monthly estimated and actual PD peritonitis rates outside Bland and Altman's limits of agreement.

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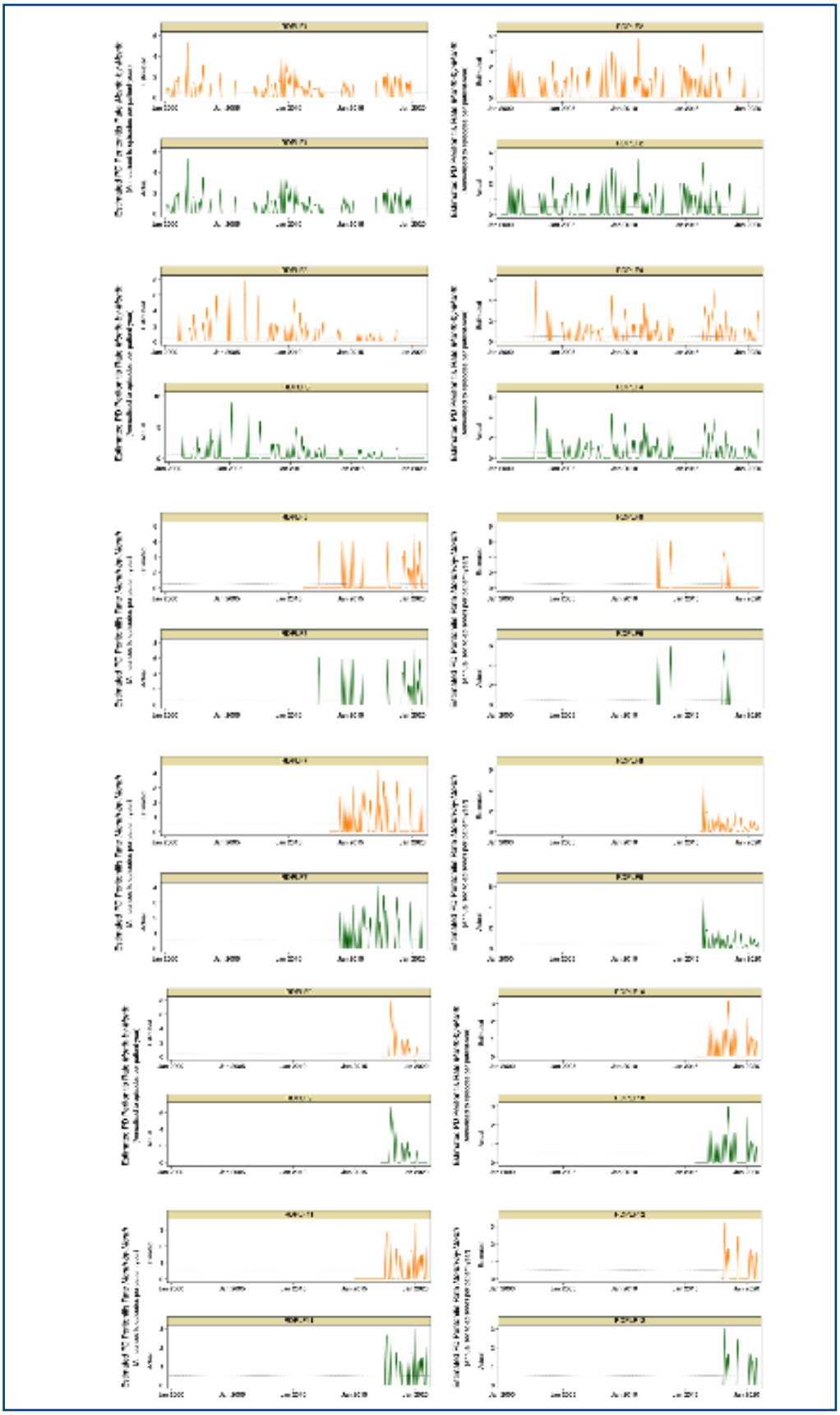

⬆*Figure 8. Time series of estimated and actual PD peritonitis rates of the 12 centres in RDPLF with more than 5% of their monthly estimated and actual PD peritonitis rates outside Bland and Altman's limits of agreement.*

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any clinically significant misclassification of centres in terms of compliance with current ISPD standards for PD peritonitis rate.

It is recommended by the ISPD that centres monitor their PD peritonitis rate at short intervals during the year, to address emerging issues with the quality of their PD care [1]. In a recent systematic review, it was determined that only a minority of health jurisdictions capture PD peritonitis rates in a systematic way [14]. The reason for this is that the majority of PD centers in the world do not routinely measure or report PD peritonitis rate, and it is only those with appropriate information systems and staffing resources that are able to do so. The options of a simplified yet accurate calculation allows PD centres without optimal infrastructure and resources to measure PD peritonitis rates, and deploy what assets are available quickly and efficiently to improve clinical PD delivery in the field.

We recommend the gold-standard method (rather than this new simplified one) under certain circumstances. First, it should be used if there is a strong and unbalanced pattern to starting and discontinuation of PD at a center (e.g. when a center is losing patients or gaining them over the month in a dramatically non-linear manner). Second, any PD peritonitis rate that is close to the threshold of 0.4 PD peritonitis episodes per patient-year with the estimating formula ought to be checked with the gold-standard one – the simplified method should be used with a view to increasing the access of patients to appropriate care, not to limit it.

CONCLUSIONS

In our recent validation of an estimating formula for calculating annual PD peritonitis rates, the results from estimating and gold-standard methods were not perfectly concordant. This small deficiency in accuracy has caused concern amongst authors of ISPD guidelines, and prompted a note of caution from them around the use of the estimating formula [1]. In this study, the use of the estimating formula for month-on-month annualized PD peritonitis rate was extremely accurate, such that there is little or no chance of compromised clinical decision making from any misclassification error. A corresponding centre-by-centre analysis is underway for our original estimating formula for calculating annual PD peritonitis rates, and will be presented shortly.

Finally, there is some further work to be done to test the new estimating formula in different health jurisdictions to ensure external validity in other settings. In the meantime, we hope that this formula allows for wider monitoring and clinical quality assurance to prevent and address high rates of this complication.

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The ANZDATA, RDPLF, and NZ PD Registries exists because of the tireless work of the nephrology community throughout Australasia and the Francophone world in collecting the information.

CONFLICT OF INTEREST

The authors declare no conflict of interest for this article.

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