**TABLE 41.** History of hip fracture and age (all dialysis patients)

														-
					Age (years)	rs)					No information			
History of hip fracture	77	20-29	20-29 30-39	40-49	50-59	69-09	62-02	68-08	≥90	Subtotal	available	Total	Mean	SD
Male														!
Without a history	87	743	4082	9 849	26 312	35 719	31 639	10 892	790	120 113	0	120113	94.06	12.49
With a history	1	7	13	51	226	435	621	328	40	1 717	0	1717	70.51	11.11
Subtotal	88	745	4095	0066	26 538	36 154	32 260	11 220	830	121 830	0	121 830	64.15	12.49
Fracture prevalence <sup>†</sup>	114.9	26.9	31.8	51.8	85.9	121.8	196.3	301.1	506.3	142.9	1	142.9		
Unspecified	0	7	40	11	214	345	354	109	7	1 153	0	1 153	65.22	12.29
No information available	47	252	1299	3 206	8 474	11 581	10 410	3 660	307	39 236	4	39 240	64.17	12.60
Total	135	1004	5434	13 183	35 226	48 080	43 024	14 989	1144	162 219	4	162 223	64.16	12.52
Female													1	;
Without a history	62	412	2052	5 165	14 909	20 877	19 726	9 801	966	74 000		74 001	65.75	12.83
With a history	_	4	16	53	181	441	941	677	117	2 509	0	2 509	74.60	10.65
Subtotal	63	416	2068	5 194	15 090	21 318	20 667	10 580	1113	76 509		76 510	66.04	12.86
Fracture prevalence <sup>†</sup>	161.3	97.1	78.0	56.1	121.4	211.2	477.0	794.8	1174.7	339.1	0.0	339.0		
Unspecified	-	4	17	48	137	204	219	128	<b>«</b>	99/	0	99/	67.04	13.02
No information available	33	147	716	1 777	4 968	6 847	6 584	3 392	371	24 835	1	24 836	65.78	13.10
Total	26	267	2801	7 019	20 195	28 369	27 470	14 100	1492	102 110	2	102 112	65.98	12.92

<sup>†</sup>Fracture prevalence: the rate of patients with a history of hip fracture per 10 000 dialysis patients.

 TABLE 42.
 History of hip fracture and duration of dialysis (all dialysis patients)

		MANAGE TO THE TOTAL THE TOTAL TO THE TOTAL TOTAL TO THE T	Duratic	Durations of dialysis (years)	ears)					
History of hip fracture	4	2-4	5-9	10-14	15-19	20-24	>25	Total	Mean	SD
Without a history	45 747	50 271	48 547	23 732	12 101	7082	6655	194 135	08.9	6.95
With a history	895	1 099	1 044	459	242	159	328	4 226	7.83	8.34
Subtotal	46 642	51 370	49 591	24 191	12 343	7241	6983	198 361	6.82	6.99
Fracture prevalence <sup>†</sup>	195.6	218.6	215.0	193.4	200.0	224.5	492.9	217.7		
Unspecified	562	430	439	230	125	62	71	1 919	6.61	7.26
No information available	14 934	16 770	16 046	7849	4 004	2300	2173	64 076	6.79	6.95
Total	62 138	68 570	920 99	32 270	16 472	9603	7229	264 356	6.81	6.98

Tracture prevalence: the rate of patients with a history of hip fracture per 10 000 dialysis patients.

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TABLE 43. History of hip fracture and presence or absence of diabetes mellitus (all dialysis patients)

History of hip fracture	Diabetic	Non-diabetic	Subtotal	No information available	Total
Male					
Without a history	43 751	76 330	120 081	. 32	120 113
With a history	704	1 013	1 717	0	1 717
Subtotal	44 455	77 343	121 798	32	121 830
Fracture prevalence <sup>†</sup>	160.9	132.7	143.0	_	142.9
Unspecified	499	654	1 153	0	1 153
No information available	14 116	25 085	39 201	39	39 240
Total	59 070	103 082	162 152	71	162 223
Female				•	
Without a history	21 223	52 769	73 992	9	74 001
With a history	859	1 649	2 508	1	2 509
Subtotal	22 082	54 418	76 500	10	76 510
Fracture prevalence <sup>†</sup>	404.7	312.5	339.0	1111.1	339.0
Unspecified	231	535	766	0	766
No information available	6 863	17 949	24 812	24	24 836
Total	29 176	72 902	102 078	34	102 112

<sup>&</sup>lt;sup>†</sup>Fracture prevalence: the rate of patients with a history of hip fracture per 10 000 dialysis patients.

first to ask patients about the history of hip fracture as a fracture-related question. The rate of patients with a history of hip fracture per 10 000 dialysis patients is described as the "fracture prevalence" (equal to 100-fold of the percentage of patients with a history of fracture with respect to the total number of dialysis patients). It is known that bone metabolism markedly differs between male and female patients and between diabetic and non-diabetic patients; therefore, fracture prevalences were summarized according to gender, and then according to the presence or absence of diabetes mellitus.

### 1. Tabulation according to gender

- a. Gender. Table 41 shows the relationship between the history of hip fracture and age in male and female patients. The fracture prevalence in all the male patients was 142.9, whereas that in all the female patients was 339.0, which was more than twice that in all the male patients.
- b. Age. The relationship between the fracture prevalence and age was examined using the data shown in Table 41. In both male and female patients the fracture prevalence increased with age. The fracture prevalence in female patients was higher than that in male patients in all age groups. In particular, the gender difference was marked in patients aged 70 years or older.
- c. Duration of dialysis. The fracture prevalences are summarized according to the duration of dialysis in Table 42. The total fracture prevalences in all the

patients are shown by each duration because the durations of dialysis are not tabulated according to gender. The fracture prevalence sharply and discontinuously increased with dialysis durations exceeding 25 years.

- d. Presence or absence of diabetes mellitus. Table 43 shows the relationship between the history of hip fracture and the presence or absence of diabetes mellitus. In both males and females, the fracture prevalence in diabetic patients was higher than that in non-diabetic patients.
- e. Body mass index (BMI). Table 44 shows the relationship between a history of hip fracture and BMI. In both male and female patients, the lower the BMI, the higher the fracture prevalence. This suggests that malnourished patients are more prone to fracture.
- f. Pre-dialysis serum creatinine concentration. Table 45 shows the relationship between the history of hip fracture and pre-dialysis serum creatinine concentration. In both male and female patients, the fracture prevalence increased with decreasing serum creatinine concentration. This also suggests that, similar to BMI, malnourished patients are more prone to fracture.
- g. Pre-dialysis serum albumin concentration prior to starting dialysis. Table 46 shows the relationship between the history of hip fracture and pre-dialysis serum albumin concentration prior to starting

 TABLE 44. History of hip fracture and body mass index (BMI) (all dialysis patients)

							BMI (	BMI (kg/m²)							١		No nformation		
History of hip fracture <12 12-13 14-15 16-17	<12 <12	12-13	14-15	16-17	18-19	20-21	22-23	24-25	26-27	28-29	30-31 32-33 34-35 36-37	2-33 3	1-35 30	5-37 ≥	≥38 Sı	Subtotal	available	Total	Mean SD
Male																			
Without a history	88	253	2104		21 282	26 157	19 737	10513	4585	1929						6777		120 113	
With a history	7	15	100		371	324	185	29	23	11						1 362		1717	
Subtotal 91	91	268	2204	9 753	21 653	26 481	19 922	10 580	4608	1940	821	386 1	190	95 14	149 9	99 141	22 689	121 830	21.48 3.73
Fracture prevalence	224.7	592.9	475.3		5 174.3	123.9	93.7	63.7	50.2	57.0						139.3		142.9	
Unspecified	0	_	20		172	221	140	83	41	18						791		1153	21.55 3.42
No information	4	29	280		2 536	3 188	2 401	1 241	514	250						1 751		39 240	
available																			
Total	95	298	2504	10 960	24 361	29 890	22 463	11 903	5163	2208	7 286	422 2	212	103 16	168 11	111 683	50 540	162 223	21.48 3.76
Female																			
Without a history	8	465	3266	10108	14 785	12 970	8 448		2509	1272						9 859	14 142	74 001	-
With a history	7	48	183	468	503	369	220		34	16						1 950	559	2 509	
Subtotal	87	513	3449	10 576	15 288	13 339	8 668		2543	1288						1 809	14 701	76 510	20.65 4.03
Fracture prevalence <sup>†</sup>	875.0	1032.3	560.3	463.0	340.2	284.5	260.4		135.5	125.8					_	325.8	395.3	339.0	
Unspecified	0	11	35	95	129	116	99	36	20	16	9	4	4	1	1	540	226	99/	20.56 4.09
No information 9 65 387 130	6	65	387	1 302	1846	1 589	1 039		323	133						7 440	17 396	24 836	20.70 4.80
available																			
Total	96		589 3871 11 973	11 973	17 263	15 044	9 773	5 509	2886	1437	673	337 1	171	5 9/	91 6	69 789	32 323	102 112	20.65 4.12

Tracture prevalence: the rate of patients with a history of hip fracture per 10 000 dialysis patients.

TABLE 45. History of hip fracture and pre-dialysis serum creatinine concentration (all dialysis patients)

		•	Pre-dialysis	serum creati	e-dialysis serum creatinine concentration (mg/dL)	ration (mg/d	L)			No information			
History of hip fracture	<4.0	4.0-5.9	6.0-7.9	8.0-9.9	10.0–11.9	12.0-13.9	14.0-15.9	≥16.0	Subtotal	available	Total	Mean	SD
Male													
Without a history	1551	5012	12 714	23 031	29 940	26 066	14 459	6050	118 823	1 290	120 113	11.03	3.13
With a history	37	158	343	476	437	180	20	12	1693	24	1 717	9.21	2.67
Subtotal	1588	5170	13 057	23 507	30 377	26 246	14 509	6062	120 516	1 314	121 830	11.01	3.13
Fracture prevalence <sup>†</sup>	238.6	315.2	269.8	206.7	146.0	69.1	34.6	19.8	142.5	186.0	142.9		
Unspecified	22	61	134	264	292	201	8	35	1 103	20	1 153	10.41	3.05
No information available	274	845	2 046	4 013	5 243	4 454	2 477	1117	20 469	18 771	39 240	11.09	3.14
Total	1884	9209	15 237	27 784	35 912	30 901	17 080	7214	142 088	20 135	162 223	11.02	3.13
Female													
Without a history	1717	5341	13 593	22 780	19 939	8 100	1 450	271	73 191	810	74 001	9.29	2.56
With a history	117	407	870	738	267	59	7	7	2 467	42	2 509	7.62	2.25
Subtotal	1834	5748	14 463	23 518	20 206	8 159	1 457	273	75 658	852	76 510	9.24	2.57
Fracture prevalence <sup>†</sup>	681.4	762.0	640.0	324.0	133.9	72.8	48.3	73.8	337.1	518.5	339.0		
Unspecified	30	75	175	228	184	51	7	0	750	16	99/	8.63	2.43
No information available	583	941	2372	3 994	3 656	1 483	235	49	13 019	11 817	24 836	9.34	2.57
Total	2153	6764	17 010	27 740	24 046	9 693	1 699	322	89 427	12 685	102 112	9.24	2.57
										***************************************			

<sup>1</sup>Fracture prevalence: the rate of patients with a history of hip fracture per 10 000 dialysis patients.

TABLE 46. History of hip fracture and pre-dialysis serum albumin (all dialysis patients)

			ysis serum entration (			300	No information	,		
History of hip fracture	<3.0	3.0-3.4	3.5-3.9	4.0-4.4	≥4.5	Subtotal	available	Total	Mean	SD
Male										
Without a history	5182	18 332	54 480	32 273	3226	113 493	6 620	120 113	3.74	0.44
With a history	199	410	731	258	21	1 619	98	1 717	3.52	0.49
Subtotal	5381	18 742	55 211	32 531	3247	115 112	6 718	121 830	3.74	0.44
Fracture prevalence <sup>†</sup>	384.0	223.7	134.2	79.9	65.1	142.7	148.0	142.9		
Unspecified	59	201	593	222	9	1 084	69	1 153	3.66	0.42
No information available	894	3 089	9 229	5 481	597	19 290	19 950	39 240	3.74	0.44
Total	6334	22 032	65 033	38 234	3853	135 486	26 737	162 223	3.74	0.44
Female										
Without a history	3419	12 636	35 564	17 286	1189	70 094	3 907	74 001	3.70	0.42
With a history	284	741	1 020	270	17	2 332	177	2 509	3.47	0.47
Subtotal	3703	13 377	36 584	17 556	1206	72 426	4 084	76 510	3.69	0.43
Fracture prevalence <sup>†</sup>	830.7	586.4	286.8	156.2	143.0	332.7	453.0	339.0	-,	
Unspecified	64	` 166	385	116	4	735	31	766	3.57	0.46
No information available	595	2 248	6 233	2 933	239	12 248	12 588	24 836	3.70	0.43
Total	4362	15 791	43 202	20 605	1449	85 409	16 703	102 112	3.69	0.43

<sup>&</sup>lt;sup>†</sup>Fracture prevalence: the rate of patients with a history of hip fracture per 10 000 dialysis patients.

dialysis. In both male and female patients the fracture prevalence increased with decreasing serum albumin concentration. This also suggests that, similar to BMI and serum creatinine concentration, malnourished patients are more prone to fracture.

h. Percutaneous ethanol injection therapy (PEIT). Table 47 shows the relationship between the history of hip fracture and the use of PEIT for secondary hyperparathyroidism. In both males and females, the fracture prevalence in patients who had been treated with PEIT was clearly higher than that in patients who had not been treated.

- i. Parathyroidectomy (PTx). Table 48 shows the relationship between the history of hip fracture and treatment of secondary hyperparathyroidism with PTx. Similarly to the results for PEIT, the fracture prevalence was higher in patients who had been treated with PTx than in those who had not been treated.
- j. Serum intact parathyroid hormone (iPTH) concentration. Table 49 shows the relationship between the history of hip fracture and serum iPTH concentration. The fracture prevalences in male patients with serum iPTH concentrations of 140-800 pg/mL were

**TABLE 47.** History of hip fracture and treatment with percutaneous ethanol injection therapy (PEIT) (all dialysis patients)

	PEIT tre	atment			No information	
History of hip fracture	No	Yes	Subtotal	Unspecified	available	Total
Male		•				
Without a history	116 336	956	117 292	1441	1 380	120 113
With a history	1 534	74	1 608	39	70	1 <b>717</b>
Subtotal	117 870	1030	118 900	1480	1 450	121 830
Fracture prevalence <sup>†</sup>	131.9	774.1	137.1	270.6	507.2	142.9
Unspecified	159	8	167	980	6	1 153
No information available	955	62	1 017	2	38 221	39 240
Total	118 984	1100	120 084	2462	39 677	162 223
Female						
Without a history	71 424	781	72 205	924	872	74 001
With a history	2 270	74	2 344	59	106	2 509
Subtotal	73 694	855	74 549	983	978	76 510
Fracture prevalence <sup>†</sup>	317.8	947.5	324.6	638.5	1 215.6	339.0
Unspecified	143	1	144	619	3	766
No information available	598	50	648	0	24 188	24 836
Total	74 435	906	75 341	1602	25 169	102 112

<sup>&</sup>lt;sup>†</sup>Fracture prevalence: the rate of patients with a history of hip fracture per 10 000 dialysis patients.

**TABLE 48.** History of hip fracture and treatment with parathyroidectomy (PTx) (all dialysis patients)

	PTx perf	ormed			No information	
History of hip fracture	No	Yes	Subtotal	Unspecified	available	Total
Male						
Without a history	112 956	5115	118 071	951	1 091	120 113
With a history	1 474	154	1 628	28	61	1 717
Subtotal	114 430	5269	119 699	979	1 152	121 830
Fracture prevalence <sup>†</sup>	130.5	301.1	137.9	294.4	559.1	142.9
Unspecified	263	10	273	874	6	1 153
No information available	1 425	288	1 713	3	37 524	39 240
Total	116 118	5567	121 685	1856	38 682	162 223
Female						
Without a history	68 115	4626	72 741	591	669	74 001
With a history	2 188	177	2 365	44	100	2 509
Subtotal	70 303	4803	75 106	635	769	76 510
Fracture prevalence <sup>†</sup>	321.2	382.6	325.1	744.5	1 494.8	339.0
Unspecified	166	12	178	585	3	766
No information available	835	284	1 119	0	23 717	24 836
Total	71 304	5099	76 403	1220	24 489	102 112

<sup>†</sup>Fracture prevalence: the rate of patients with a history of hip fracture per 10 000 dialysis patients.

relatively lower than those in the other male patients, and the fracture prevalences in female patients with serum iPTH concentrations of 60–600 pg/mL were relatively lower than those in the other female patients. Outside these serum iPTH concentration ranges the fracture prevalence tended to be high in both male and female patients.

## (1) Tabulation considering BMI

As described above, the history of fracture is strongly related to BMI; therefore, the relationship between the history of hip fracture and serum iPTH concentration was examined by taking the classification according to BMI into consideration, which is shown in the three-dimensional graphs in Figure 3. Here, the graphs were prepared on the basis of the data collected as of June 2008 (2). In patients with a low BMI, a U-shaped relationship was observed between the serum iPTH concentration and the fracture prevalence, with both excessively high and low serum iPTH concentrations related to a high fracture prevalence. This tendency weakened with increasing BMI, showing little relationship between serum iPTH concentration and the fracture prevalence in patients with a high BMI.

# (2) Tabulation considering serum albumin concentration

Similarly, the relationship between the history of hip fracture and serum iPTH concentration was examined by taking the classification according to serum albumin concentration into consideration, which is shown in three-dimensional graphs in Figure 4. These graphs were also prepared on the basis of the

data collected as of June 2008 (2). Similarly to the case of BMI, a U-shaped relationship was observed between serum iPTH concentration and the fracture prevalence in patients with low serum albumin concentrations. A weak relationship was observed between serum iPTH concentration and the fracture prevalence in patients with high serum albumin concentrations.

k. Pre-dialysis serum calcium concentration. Table 50 shows the relationship between the history of hip fracture and pre-dialysis serum calcium concentration. The serum calcium concentrations shown in this table were corrected using serum albumin concentrations using the equation shown below (when the serum albumin concentration is <4.0 g/dL):

Corrected serum Ca concentration (mg/dL) = Serum Ca concentration (mg/dL) + (4.0 – Serum albumin concentration (g/dL))

In male patients, it is clear that the fracture prevalence decreased with decreasing serum calcium concentration, and increased with increasing serum calcium concentration. A similar tendency was observed in female patients; however, the fracture prevalence was also high in female patients with serum calcium concentrations <7.0 mg/dL, which is different from the male patients.

### 2. Pre-dialysis serum phosphorus

Table 51 shows the relationship between the history of hip fracture and pre-dialysis serum phosphorus concentration. In both males and females, the fracture prevalence increased with decreasing

History of hip fracture and serum intact parathyroid hormone (iPTH) concentration (all dialysis patients) LABLE 49.

							Serum iP	Serum iPTH concentration (pg/mL)	atration (1	og/mL)							No information			
History of hip fracture	8	20-39	40-59	20-39 40-59 60-79	80-99	100-119	120-139	140-159	160-179	180-199	80-99 100-119 120-139 140-159 160-179 180-199 200-359 360-599 600-799 800-999 ≥1000	360-599	662-009	800-999	≥1000	Subtotal	available	Total	Mean	SD
Male																				
Without a history	5629	7992	-	7334	7162		6782	6154	5457		22 079	8413	2043	829	887	100 109	20 004	120 113	192.49 2	201.44
With a history	100	111		107	106		107	81	8		274	111	24	13	19	1 414		1717	٠.	79.09
Subtotal	5729	8103	7510	7441	7268		6889	6235	5523	5122	22 353	8524	2067	872	96	101 523		121 830		02.73
Fracture prevalence	177.7	138.9		145.9	148.0		157.8	131.6	120.9		124.1	131.9	117.5	151.3	214.2	141.2		142.9		
Unspecified	62	119		8	9/		\$	51	22		172	21	14	4	-	919		1 153	154.81	157.84
No information	838	1181		1070	1076	1012	903	8	827		3 269	1390	330	159	158	15 320		39 240	٠.	11.90
available																				
Total	6629	9403	8640	8577	8420	8043	7846	7250	6405	5973	26 094	9971	2411	1035	1065	117 762	44 461	162 223	193.46 2	203.69
Female																				
ory	3636	5315	4787	4518	4	4055	3746	3663	3117		13 231	5631	1419	715	\$	61 852	12 149	74 001	• •	20.11
	130	224	185	138		141	121	<b>5</b>	104		398	140	\$	18	42	2 041	468	2 509	٠,	82.04
	3766	5539	4972	4656	4	4136	3873	3767	3221		13 629	5771	1473	733	746	63 893	12 617	76 510	200.04	222.35
prevalence	357.5	421.4	386.5	305.4		347.7	339.0	283.9	333.7		300.8	248.6	380.5	251.7	596.6	330.0	385.2	339.0		
Unspecified	42	78	25	4		4	4	42	ß		117	36	11	9	7	605	161	766	٠.	173.71
No information	555	838	747	989	650	633	585	518	512	<del>1</del> 63	2 137	88	243	135	155	9840	14 996	24 836	213.24 2	45.10
available																				
Total	4363	6455	5771	5388	5238	4873	4204	4327	3756	3486	15 883	0629	1727	874	903	74 338	27 774	102 112	201.51 2	225.21
Practure prevalence: the rate of patients with a history	: the rat	e of patie	ents witl	α histo		fracture	per 10 00	of hip fracture per 10 000 dialysis patients	atients											

serum phosphorus concentrations, and decreased with increasing serum phosphorus concentrations.

3. Tabulation according to the presence or absence of diabetes mellitus

The following results are based on the data collected as of June 2008 (2).

a. Serum iPTH concentration and BMI. Figure 5 shows three-dimensional graphs obtained by summarizing the relationship between the fracture prevalence, serum iPTH concentration, and BMI separately in diabetic and non-diabetic patients. Note that the scale of the fracture prevalence in the graph for diabetic patients is much greater than that for non-diabetic patients because the rate in the former is higher than that in the latter generally.

In the diabetic patients with a low BMI, there was a clear relationship between serum iPTH concentration and fracture prevalence; specifically, the fracture prevalence in patients with high serum iPTH concentration was very high. Moreover, the fracture prevalence tended to be rather high in patients with low serum iPTH concentrations; however, the relationship between serum iPTH concentration and the fracture prevalence weakened as BMI increased.

For the non-diabetic patients with a low BMI there was some relationship between the serum iPTH concentration and the fracture prevalence. Unlike in diabetic patients, however, the fracture prevalence in the non-diabetic patients with low serum iPTH concentrations tended to be rather high, and the increase in the fracture prevalence in patients with high serum iPTH concentrations was not so marked; however, the relationship between the serum iPTH concentration and the fracture prevalence weakened as BMI increased, similarly to the case of diabetic patients.

b. Serum iPTH and serum albumin concentrations. Figure 6 shows three-dimensional graphs obtained by summarizing the relationship between the fracture prevalence, serum iPTH concentration, and serum albumin concentration separately in diabetic and non-diabetic patients. Note that the scale of fracture prevalence in the graph for diabetic patients is much greater than that for non-diabetic patients.

The tendency in serum albumin concentration was similar to that in BMI. That is, for diabetic patients with a low serum albumin concentration, a U-shaped relationship was found between serum iPTH concentration and the fracture prevalence, where the fracture prevalence was high for both the high and low

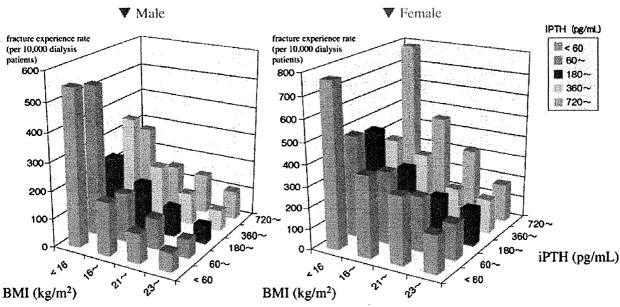


FIG. 3. Relationship between the history of hip fracture, serum intact parathyroid hormone concentration (iPTH), and body mass index (BMI) (all dialysis patients).

serum iPTH concentrations. The increase in the fracture prevalence in the high serum iPTH concentration region was significant.

For non-diabetic patients with low serum albumin concentrations there was also a clear relationship between serum iPTH concentration and the fracture prevalence; however, a marked increase in the fracture prevalence was observed in non-diabetic patients with low serum iPTH concentrations, unlike in diabetic patients. For both diabetic and non-diabetic patients, the relationship between serum iPTH concentration and the fracture prevalence was weak in the region of high serum albumin concentration.

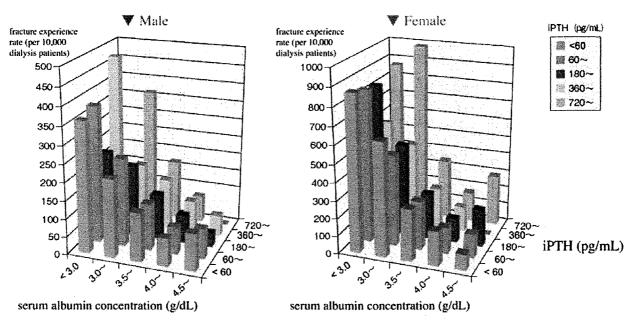


FIG. 4. Relationship between the history of hip fracture, serum intact parathyroid hormone concentration (iPTH), and serum albumin concentration (all dialysis patients).

History of hip fracture and corrected pre-dialysis serum calcium concentration<sup>†</sup> (all dialysis patients) TABLE 50.

					Correc	ted pre-di	ialysis seru	ım calciun	1 concenti	Corrected pre-dialysis serum calcium concentration $^{\dagger}$ (mg/dL)	(JP)				•	No information			
History of hip fracture	<6.0	6.0-6.4	<6.0 6.0-6.4 6.5-6.9 7.0-7.	4	7.5-7.9	8.0-8.4	8.5-8.9	9.0-9.4	9.5-9.9	10.0-10.4	10.5–10.9	9.5-9.9 10.0-10.4 10.5-10.9 11.0-11.4 11.5-11.9 =12.0	11.5–11.9	≥120	Subtotal	available	Total	Mean	SD
Male															-				
Without a history	114	147	308			12 307			20 295	12 279	5747	2081	774	999	113 190	6 923	120 113	9.25	0.89
With a history		7	ĸ			14			307	160	83	36	16	15	1 610	107	1717	9.31	0.94
	115	149	311			12 451			20 602	12 439	5840	2117	967	581	114 800	7 030	121 830	9.25	0.89
· prevalence <sup>‡</sup>	87.7	136.1	4.76	8		117.0			151.3	130.3	161.8	173.0	206.7	265.0	142.2	154.6	142.9		
	0	1	7	7		118		255	201	128	61	10	s	<b>∞</b>	1 080	73	1 153	9.29	0.87
ion available	23	33	89			2 106			3 253	2 052	1008	370	125	164	18 633	20 607	39 240	9.28	1.03
	142	183	372		4110	14 675	30 815		24 056	14 619	6069	2497	920	753	134 513	27 710	162 223	9.25	0.91
Female																			
out a history	62	74	137		1381				15 152	9 492	4724	1762	999	469	69 901	4 100	74 001	9. <del>4</del>	0.91
	es	7	•		36	-			<del>2</del>	272	183	8	33	જ	2 3 2 3	186	2 509	9.46	0.98
	8	76	143	435	1417				15 618	9 764	4907	1831	669	498	72 224	4 286	76 510	9.44	0.91
Fracture prevalence*	483.9	270.3	438.0	~	260.7				307.6	286.6	387.4	391.6	495.5	618.3	332.3	453.7	339.0		
	0	-	Н		σ				163	109	4	<b>3</b> 6	9	7	735	31	766	9.49	0.91
No information available	10	16	30		221				2 461	1 612	877	297	117	115	11 884	12 952	24 836	9.46	1.02
Total	75	88	174		1647	5 956	15 590	21 657	18 242	11 485	5828	2154	822	620	84 843	17 269	102 112	9.44	0.93

<sup>†</sup>When the serum albumin concentration is <4.0 g/dL: Corrected serum calcium concentration (mg/dL) = Serum calcium concentration (mg/dL) + (4.0 - Serum albumin concentration (g/dL)). <sup>‡</sup>Fracture prevalence: the rate of patients with a history of hip fracture per 10 000 dialysis patients.

TABLE 51. History of hip fracture and pre-dialysis serum phosphorus concentration (all dialysis patients)

-			Pre-dialysis se	orum phospho	re-dialysis serum phosphorus concentration (mg/dL)	on (mg/dL)				No information			
History of hip fracture	<b>⊗</b> .0	3.0-3.9	4.0-4.9	5.0-5.9	6.0-6.9	7.0-7.9	8.0-8.9	≥9.0	Subtotal	available	Total	Mean	SD
Male													
Without a history	5198	15 487	30 054	32 411	20 541	8 988	3695	2187	118 561	1 552	120 113	5.30	1.51
With a history	140	299	466	416	233	82	32	18	1 689	88	1717	4.90	1.50
Subtotal	5338	15 786	30 520	32 827	20 774	9 073	3727	2205	120 250	1 580	121 830	5.29	1.51
Fracture prevalence	269.3	193.1	155.1	128.4	113.4	94.6	999	82.3	142.5	180.4	142.9		
Unspecified	4	147	293	310	179	99	32	14	1 087	98	1153	5.20	1.43
No information available	923	2 535	4 971	5 430	3 510	1 537	574	358	19 838	19 402	39 240	5.29	1.51
Total	6307	18 468	35 784	38 567	24 463	10 676	4333	2577	141 175	21 048	162 223	5.29	1.51
Female													
Without a history	3398	9 463	19 515	20 557	12336	4 981	1798	1019	73 067	934	74 001	5.22	1.46
With a history	215	449	713	603	583	115	49	19	2 452	22	2 509	4.80	1.46
Subtotal	3613	9 912	20 228	21 160	12 625	5 096	1847	1038	75 519	166	76 510	5.20	1.46
Fracture prevalence	632.7	474.5	365.4	293.3	234.3	230.9	272.5	186.5	335.6	610.3	339.0		
Unspecified	41	123	219	184	110	42	18	•••	745	21	992	5.03	1.47
No information available	663	1 661	3 176	3 523	2 288	<b>9</b>	282	172	12 628	12 208	24 836	5.21	1.46
Total	4317	11 696	23 623	24 867	15 023	2 998	2150	1218	88 892	13 220	102 112	5.20	1.46

Practure prevalence: the rate of patients with a history of hip fracture per 10 000 dialysis patients.

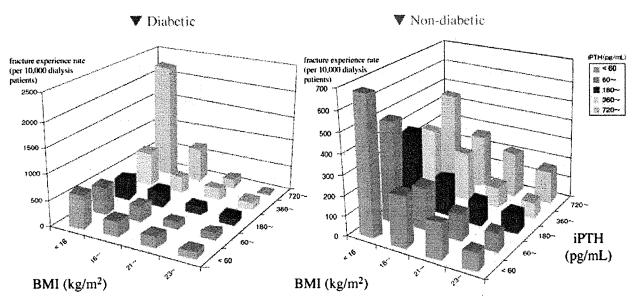


FIG. 5. Relationship between the history of hip fracture, serum intact parathyroid hormone concentration (iPTH), and body mass index (BMI) (all dialysis patients categorized into diabetic and non-diabetic groups). Note: the scale of fracture prevalence in the graph for diabetic patients is greater than that for non-diabetic patients.

c. Serum calcium and phosphorus concentrations. Figure 7 shows three-dimensional graphs obtained by summarizing the relationship between the serum calcium and phosphorus concentrations, and the fracture prevalence separately for diabetic and non-diabetic patients. No matter whether the patients are diabetic or non-diabetic, the fracture prevalence increased with decreasing serum phosphorus concen-

tration and with increasing corrected serum calcium concentration prior to the dialysis session.

# E. Clinical condition of patients at the start of dialysis

In the survey conducted at the end of 2007, the clinical condition of the patients when dialysis was

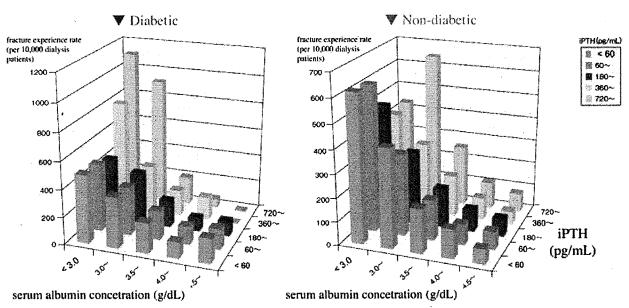


FIG. 6. Relationship between the history of hip fracture, serum intact parathyroid hormone concentration (iPTH), and serum albumin concentration (all dialysis patients categorized into diabetic and non-diabetic groups). Note: the scale of fracture prevalence in the graph for diabetic patients is greater than that for non-diabetic patients.

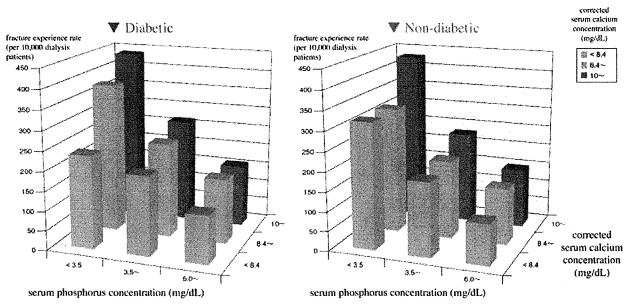


FIG. 7. Relationship between the history of hip fracture, corrected serum calcium concentration, and serum phosphorus concentration prior to the introduction to dialysis (all dialysis patients). Note 1: fracture prevalence for diabetic patients is greater than that for non-diabetic patients. Note 2: when the serum albumin concentration is <4.0 g/dL, the following equation is used: Corrected serum calcium concentration (mg/dL) = Serum calcium concentration (mg/dL).

fist carried out was examined following the previous survey. The subjects of the survey on the clinical condition should be the patients who were newly begun on dialysis in 2007 and responded to the questionnaire using floppy disks concerning their clinical condition. The number of patients who satisfied these criteria was 30 510 (male, 19 748; female, 10 762). The survey results regarding renal function were analyzed for the 17 765 patients whose data were available at the start of dialysis.

The following are the summaries of the treatment methods for end-stage renal failure, the renal function of the patients when beginning dialysis, as well as major symptoms experienced at the start of dialysis.

# 1. Treatment methods at the end of the first year of dialysis

Table 52 shows a summary of treatment methods for renal failure examined at the end of 2007 for all subject patients. The following are the treatment methods examined at the end of 2007 for the patients who began dialysis in 2007, of whom 92.0% underwent hemodialysis. The percentages of patients who underwent hemodiafiltration (2.5%) and peritoneal dialysis (5.4%) were slightly higher than those in the previous year (the results of the 2006 survey were: facility hemodialysis, 92.4%; hemodiafiltration, 2.2%; hemofiltration, 0.2%; hemoabsorption, 0.0%; home

hemodialysis, 0.0%; continuous ambulatory peritoneal dialysis (CAPD), 5.0%; and intermittent peritoneal dialysis (IPD), 0.2% (1)).

# 2. Clinical symptoms and signs of patients at the introduction of dialysis

Table 53 shows a summary of the various clinical symptoms and signs and disorders experienced by the patients with respect to the items related to the clinical symptoms included in the criteria for the introduction of dialysis in patients with chronic renal failure (CRF) (12), which was provided by a renal failure research group of the Ministry of Health, Labor and Welfare, and those related to the calculation of Carlsson's scores (13). Regarding the symptoms related to the criteria for the introduction of dialysis in CRF patients, digestive symptoms, retention of body fluid, and fluid abnormalities were observed in approximately one-half of the patients. Following these symptoms, blood abnormalities and cardiovascular symptoms were observed in approximately 40% of the patients; moreover, impaired eyesight was observed in 22.9%, and nervous disorder symptoms in 13.8% of the patients. The percentages of these symptoms were almost the same as those in the 2006 survey. Regarding the items related to Carlsson's score, diabetes mellitus, congestive cardiac failure, and brain infarction were observed as major contributing factors.

IABLE 52. Pre-dialysis serum creatinine concentrations of the first dialysis and treatment methods used at the end of 2007 (only patients begun on dialysis in 2007 who responded to the questionnaire using floppy disks)

								Commendation of the description of the control of t	3		440			10	LL.	(										
						Pre-	Pre-dialysis serum	creat		inine concentration	n of the f	first dialysis	sis (mg/dL)	( <u>1</u>								noite				
Method of dialysis	0.2>	6.5-0.5	6.€–0.€	6°t-0°t	6.2-0.2	6'9-0'9	6.7 <u>–</u> 0.7	6.8-0.8	6'6-0'6	6.01-0.01	6,11-0,11	6.21-0.21	6.E1-0.E1	6'+1-0'+1	12:0-12:9	6.81-0.81	6.71-0.71 9.81-0.81	6.61-0.61	0.02≤	Subtotal	<sub>4</sub> %	oviolini ovi Sidaliava	Total	↓%	пвэМ	ВD
Facility hemodialysis	91	308	623	1116	1	1971	2310	2510	1837		227	'	Ι''			1	l	ı		16 261	91.5	11 798 2	28 059	92.0	8.32	3.55
(%) Hemodiafiltration	(0.6)	(1.9)	(3.8)	(6.9) 46	(10.0)	(12.1)	(14.2)	(15.4) 96	(11.3)	(7.7)	(5.1)	(3.4) (3.4)	6 (23)	9.4	£.	(0.7) (0.5) 3 4	.5 6.4)	(0.3)	(j.0) 6 6 7	(100.0) 573	3.2	193	766	2.5	8.16	3.85
(%)	(1.2)	(2.3)	(3.3)	(8.0)		(12.6)	(14.3)	(16.8)	(9.2)		(4.2)		_							(100.0)	ċ	;	ş			,
Hemofiltration	0	0	0	7		7		<b>-</b>			0									10	0.1	7	77	7.7	. 66.0	70.7
(%) Hemoadsorption	0.0	(0.0 0.0	0.0	(50.0)		(20.0)	(10.0) 0	(10.0)	(10.0)		0.0)		_							(100.0) 0	0.0	ю	т	0.0	ı	1
(%) Home hemodialusis	<	c	c	c		c	c	c	c		-										0.0		m		12.35	1.63
(%)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(50.0)	(0.0)	(20.0)	(0.0)	(0.0)	(0.0) (0.0)	.0) (0.0)	0) (0.0)	(0.0)	(100.0)	53	738	1 657			33.
(%)	(0.7)	(1.1)	(2.4)	(4.5)	(6.6)	(13.2)	(12.8)	(20.1)	(10.8)		(6.5)				_											
Total	10 10	331	45	1205	1752	2166	2511	2792	1990		912		٠,								100.0	12 745	30 510	100.0	8.34	3.55
(%)	(0.6)	(1.9)	(3.7)	(6.8)	(6.9)	(12.2)	(14.1)	(15.7)	(11.2)		(5.1)				_											
										The second second	-						_									

Percentage of the left cell value relative to the total number of its column. Values in parentheses below each figure represent the percentage relative to the total of each row

3. Pre-dialysis serum creatinine concentration of the first dialysis

The pre-dialysis serum creatinine concentration of the first dialysis (hereafter, serum creatinine concentrations at the introduction of dialysis) are summarized below.

- a. Treatment method at the end of the first year of dialysis. The relationship between the treatment method at the end of the first year of dialysis and the serum creatinine concentration at that time is already shown in Table 52. No clear difference in the trend of serum creatinine concentration at the start of dialysis was observed between the treatment methods.
- b. Gender. Table 54 shows the relationship between the serum creatinine concentration at the introduction to dialysis and gender. The mean serum creatinine concentrations in male and female patients at the introduction to dialysis were 8.69 and 7.69 mg/dL, respectively; the level was higher in male patients than in female patients. Both levels were nearly the same as those in the 2006 survey.
- c. Age. Table 55 shows the relationship between the serum creatinine concentration at the introduction to dialysis and age. The serum creatinine concentration at the introduction to dialysis in patients aged less than 15 years was low, and that in patients aged 15 years or older tended to decrease with age.
- d. Primary disease. Table 56 shows the relationship between the serum creatinine concentration at the introduction to dialysis and primary disease. The serum creatinine concentration at the introduction to dialysis in patients with diabetic nephropathy as the primary disease was lower than that in patients with chronic glomerulonephritis.
- 4. Estimated glomerular filtration rate of patients at the introduction to dialysis. The estimated glomerular filtration rate (eGFR) (mL/min/1.73 m²) of patients was calculated and tabulated in terms of gender, age, and serum creatinine concentration of the patients at the introduction to dialysis. The eGFR was obtained by multiplying the value obtained using the modification of diet in renal disease (MDRD) equation by the Japanese factor (14).

When the serum creatinine concentration was measured by the Jaffe method, the following equation was used:

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**TABLE 53.** Items related to clinical symptoms at the introduction of dialysis (only patients begun on dialysis in 2007 who responded to the questionnaire using floppy disks)

Clinical symptoms and signs or disorder at the introduction of dialysis	Symptom free	Experiencing symptoms	Subtotal	Unspecified	No information available	Total
Retention of body fluid: generalized edema, severe hypoproteinemia, pneumonedema	7 421	7541	14 962	502	15 046	30 510
(%) Fluid abnormality: uncontrollable electrolyte and acid-base imbalance	(49.6) 7 572	(50.4) 7210	(100.0) 14 782	611	15 117	30 510
(%) Digestive system: nausea, vomiting, loss of appetite, diarrhea	(51.2) 7 169	(48.8) 7549	(100.0) 14 718	658	15 134	30 510
(%) Cardiovascular system: serious hypertension, cardiac	(48.7) 9 101	(51.3) 5611	(100.0) 14 712	539	15 259	30 510
failure, pericarditis (%) Nervous system: central and peripheral nervous	(61.9) 12 696	(38.1) 2035	(100.0) 14 731	647	15 132	30 510
disorder, mental disorder (%) Blood abnormalities: severe anemia, bleeding tendency	(86.2) 8 594	(13.8) 6245	(100.0) 14 839	498	15 173	30 510
(%) Impaired eyesight: uremic retinopathy, diabetic retinopathy	(57.9) 11 243	(42.1) 3343	(100.0) 14 586	825	15 099	30 510
(%) History of cardiac infarction before the start of dialysis (%)	(77.1) 14 620 (90.4)	(22.9) 1558 (9.6)	(100.0) 16 178 (100.0)	371	13 961	30 510
Congestive cardiac failure (%)	11 625 (72.2)	(9.6) 4465 (27.8)	16 090 (100.0)	364	14 056	30 510
History of quadruple amputation, complication of arteriosclerosis obliterans, or aortic aneurysm ≥6 cm (%)	15 295 (93.5)	1055 (6.5)	16 350 (100.0)	261	13 899	30 510
History of brain infarction or transient ischaemic attack (%) Dementia	13 711 (84.8)	2458 (15.2)	16 169 (100.0)	398	13 943	30 510
(%) Chronic lung disease	14 871 (91.3) 15 557	1412 (8.7) 592	16 283 (100.0) 16 149	225 253	14 002 14 108	30.510 30.510
(%) Collagen diseases (%)	(96.3) 15 786 (97.5)	(3.7) 410 (2.5)	(100.0) 16 196 (100.0)	227	14 087	30 510
Peptic ulcer (%)	14 539 (94.3)	876 (5.7)	15 415 (100.0)	739	14 356	30 510
Chronic hepatic disease (without portal hypertension) or chronic hepatitis (%)	15 145 (94.0)	970 (6.0)	16 115 (100.0)	233	14 162	30 510
Diabetes mellitus (without end-stage organ damage, patients treated by dietary therapy alone are not included)	11 605	4302	15 907	257	14 346	30 510
(%) Hemiplegia	(73.0) 15 231	(27.0) 952	(100.0) 16 183	182	14 145	30 510
(%) Diabetes mellitus: severe retinopathy, nervous disorder, renal disorder, labile diabetes	(94.1) 10 452	(5.9) 5530	(100.0) 15 982	249	14 279	30 510
(%) Malignant tumors (those without metastasis and who have survived five years since diagnosis are not included)	(65.4) 15 188	(34.6) 994	(100.0) 16 182	234	14 094	30 510
(%) Leukemia (acute and chronic) (%)	(93.9) 16 146 (99.3)	(6.1) 109 (0.7)	(100.0) 16 255 (100.0)	175	14 080	30 510
Lymphoma (%)	16 065 (99.3)	113 (0.7)	16 178 (100.0)	233	14 099	30 510
Moderate and end-stage hepatic disease (%) Metastacizing melionant tumors	15 782 (97.3)	430 (2.7)	16 212 (100.0)	188	14 110	30 510
Metastasizing malignant tumors (%) Acquired immunodeficiency syndrome (%)	15 897 (98.4) 13 544 (99.4)	257 (1.6) 75 (0.6)	16 154 (100.0) 13 619 (100.0)	232 2724	14 124 14 167	30 510 30 510

Pre-dialysis serum creatinine concentration at the introduction to dialysis and gender (only patients begun on dialysis in 2007 who responded to the questionnaire using floppy disks) TABLE 54.

					Pre-	dialysis s	serum cre	eatinine c	oncentra	tration at the introduction to dialysis (mg/dL	he intro	duction	to dialy	sis (mg/c	<u> </u>						noit		
•	0.2>	6.2-0.2	6.E-0.E	6.4-0.4	6.2-0.8	6.6–0.8	6.T-0.T	6.8-0.8	6.6–0.6	6.01-0.01	6.11-0.11	12.0-12.9	6.51-0.51	6.41-0.41	6.21–0.21	6.81-0.81	6.71-0.71 6.81-0.81	6.61-0.61	0.02≤	Subtotal	oM olintorma aldaliava	lstoT	пвэМ
		Ι,,	ł	633	1017	1290	1643	1850	1366	961	673	446	786	1						11 445	8 303	19 748	8.69 3.61
	(0.4)	(1.3)	(2.9)	(5.5)	(8.9)	(11.3)	(14.4)	(16.2)	(11.9)	(8.4)	(5.9)	(3.9)	(5.6)	(1.6)	(1.3)	(0.8)	(0.6) (0.5)	(03) (03)	(1.3)	(100.0)		,	6
		٠,		572	735	876	898	942	624	408	239	92	102							6 320	4 447	70/01	CC.C 60.1
				(6.1)	(11.6)	(13.9)	(13.7)	(14.9)	(6.6)	(6.5)	(3.8)	(2.5)	(1.6)	_		_				(100.0)	- !		,
	٠.	_	_	1205	1752	2166	2511	2792	1990	1369	912	909	398						, ,	17 765	12.745	30 510	8.34 3.55
				(8.9)	(6.6)	(12.2)	(14.1)	(15.7)	(11.2)	(7.7)	(5.1)	(3.4)	(2.2)	_		_				(100.0)	_ '		
1formation				0	0	0	0	0	0	0	0	0	0							0	0	0	
6)																						0	į
_		~			1752	2166	2511	2792	1990	1369	912					125 85	89 73	47	193	1/ /65	17 /45	30.510	8.34 5.33
	(0.0)	(1.9)	(3.7)	(8.9)	(6.6)	(12.2)	(14.1)	(15.7)	(11.2)	(7.7)	(5.1)	(3.4)	(2.2)	(1.4)	(1:1)						_		

Values in parentheses below each figure represent the percentage relative to the total of each row.

Pre-dialysis serum creatinine concentration at the introduction to dialysis and age (only patients begun on dialysis in 2007 who responded to the questionnaire using floppy disks) TABLE 55.

	SD	1.93	5.55	4.91	3.88	3.13	3.01	2.48	3.55	1.77	3.55		1
	Mean	5.83	12.81								8.34		
	Total	28	251	1 606 1					30 492	18	30 510	67.33	13.22
	No information available	17	711	706	2 421	5 193	4 087	188	12 729	16	12 745	67.29	13.41
	i Subtotal	11	(100.0) 134	(100.0) 900	(100.0) 3 536	(100.0) 7 274	(100.0) 5 675	(100.0)	(100.0) 17 763	(100.0)	17 765	(100.0) 67.37	13.08
	0.05≤	0	(0.0) 17	6. 9.0	(4.9) 78	(27)	(0.6)	(0.3)	(0.0) 193	0	193	(1.1)	15.40
	6.61-0.61	0	(0.0)	(2.2)	(2.0)	(0.4)	(0.2)	(0.0)	(0.0)	(0.3)	47	(0.3) 49.02	13.93
	9.81-0.81	0	(0.0) 8	(6.0) 18	(2.0)	(0.5)	(0.3)	(0.1)	(0.0)	0.4	73	(0.4)	17.20
	6.71-0.71	0	(0.0)	(4.5) 20	(27)	(0.8)	(0.4)	(0.1)	(0.0) 89	(0.5) 0		(0.5)	- 1
(Jp/gi	6.61–0.61	٥	3 3	(2.2)	(2.1)	(1.5)	(0.5)	(0.2)	(0.0)	(0.7)	125	(0.7)	13.78
sis (m	6.21 <u>–0.21</u>	0	(0.0) 8	(6.0) 29	(3.2)	(1.8)	(0.9)	0.4)	(0.0)	0	189	(1.1) 56.31	14.55
o dialy	6.41-0.41	0	(0.0)	(3.7)	(2.9)	(2.2)	(1.5) (2.5)	(0.6)	(0.0)	0 (1.4)	249	(1.4) 60.19	13.34
tion to	6.EI-0.EI	Į.							(0.4)		398	(27) 60.22	13.61
troduc	12.0-12.9	0	(0.0)	(8.2)	(6.3)	(5.3)	(3.3)	(1.9)	(1.7)	0.4)	909	(3.4) 61.85	13.27
the in	6.11 <u>-</u> 0.11	1				_	_	_	(1.7)	_	912	(5.1)	13.30
ions at	6.01–0.01	0	(0.0)	(12.7)	(9.7)	(10.5)	(8.1)	(5.2)	(4.3)	0	369	(7.7) 63.99	12.88
entrat	6.6-0.6	ĺ	_	_	_	_	_	_	(7.3)	_′	066	(11.2) 65.60	12.47
eatinine concentrations at the introduction to dialysis (mg/dL	6.8-0.8	ŀ							(12.0)		_	(15.7) 67.18	
	6. <i>T</i> –0. <i>T</i>						•		(10.3)		(4	(14.1) 69.29	
erum c	6'9-0'9		_	_	_	_	_	_	(15.5)	_		(12.2) 70.34	- 1
Pre-dialysis serum	6.2–0.8	1		_	_	_	_	_	(16.7)	_	٠.	(9.9) 71.58	- 1
Pre-d	6' <del>1-</del> 0'1								(12.9)			(6.8) 72.31	
	6.E–0.E								(8.6)		,	(3.7)	- 1
	6.2-0.2	l						_	(6.4) (6.4) (6.4)	_	•	(1.9) 72.85	- 1
	0.2>	1						•	(2.1) (104 33		,	(0.6) 73.23	- 1
	Age (years)									(%) No information		(%) Mean	

Values in parentheses below each figure represent the percentage relative to the total of each row.

TABLE 56. Pre-dialysis serum creatinine concentration at the introduction to dialysis and primary diseases (only patients begun on dialysis in 2007 who responded

Chronic glomerulonephritis (0.5. (%) (0.5. (%) (%) (%) (%) (%) (%) (%) (%) (%) (%)				14	re-dialysi	s serum c	creatinine	concentra	tions at t	the introduction	fuction to	o dialysis	to dialysis (mg/dL)							tion		
, n	6.2-0.2	6.ε–0.ε	6.4-0.4	6.2-0.2	6.6-0.8	6.7–0.7	6,8-0,8	6'6-0'6	6.01-0.01	6.11-0.11	12.0-12.9	6.£1–0.£1	14.0-14.9	6.21-0.21	6'91-0'91	6.81-0.81	6,61-0,61	0.02≤	Subtotal	No information and silable	IstoT	Mean
	8.	8.5			426	535	1	i i		l .	1 .	1	1		Ι.	1	Ι.	5,	4042	2 958	7 000	9.03
	-1	4			(10) (2) (3)	16 (132)					_				_	_	_	<u>.</u>	133	8	214	9.12
		(3.0) 9			9.8.	¥ (120)					_				_		_	3 (8)	295	216	511	8.50 3.52
		(3.1)			(13.2)	(11.5)					_				_		(0.3)	(1.0)	(100.0)	Ħ	8	9.04 5.36
pregnancy toxemia (%) Other nephritides that cannot 0		(0.0)			(10.7) 8	(21.4)		(10.7)	(10.7)	(3.6)	(3.6)	(0.0)	(3.6) (	3 (0.0)	(0.0) (0.0) 0 1	.0) (0.0)	_	(3.6)	(100.0) 81	જ	131	9.31 3.65
be classified (%) (%) (9.0)		(6.2)			(6.9)	(6.9)					_				_		_	(1.2)	(100.0)	755	9	
		73 (0.5)			27,7	(16.9) 302					_				_		_	252	(100.0) 2072	1 308	3380	8.16 3.06
tension		(3.5)			13.4 4. 4.	11.6					_						_	(0.0 (0.0 (0.0 (0.0 (0.0 (0.0 (0.0 (0.0	(100.0) 103 103 103	88	188	9.91 4.17
(%) Diabetic nephropathy (9)	• • •	3.00 1.00 1.00 1.00 1.00 1.00 1.00 1.00			(13.6) 1047 23.23	(10.7) 1187 7.50												<b>3</b> 8 8	7933	5 438 1	13 371	7.94 3.20
(%) Systemic lupus erythematosus 1		±,5			13(137)	22.0					_				_		_	1 (0.0)	138	8	225	7.24 3.43
		(8.0)			9.4	(152) 12					_				_		_	(0.7)	(100.0)	70	157	6.97 2.60
		4.6			(10.3)	(13.8)									_		_	0.0	(100.0) 63	Ħ	8	
(%) Renal failure due to congenital 0		(6.3) 1			(11.1)	(11.1)					_				_		_	(0.0 0.0	(100.0) 25	.01	35	
		(4.0)			(12.0)	(16.0)					_				_		_	(0.0)	(100.0)	4	72	7.14 2.61
		4 8			, 6	, 15					_				_		_	, 6	. 6	•	2	
Kidney and urinary tract stone 0		0 6			5.5	3.5												7 2	37	17		10.27 5.14
L		6.0			8 6	2 2 2													76.0	88	4	7.95 3.82
Obstructive urinary tract difficulty 0		0 0			3 (2.5)	(6.54)					_							] - E	55.0	42		9.93 4.31
		0.4 6			() e {	15												9 6	(156.0) (15.0)	2	139	9.52 3.56
c kidney					() e ()	£ 70 (					_								8 8	19		10.07 5.80
					18 (	192					_							28.7	1.568	1 457		8.50 3.83
duction after transplantation		4.1. (1.1.)			(H.7)	222					_							0 (1.8)	(100.0) 51 51 50 50	4		8.53 3.08
		) (2) (3) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4			£ 5	45					_				_			5,79	418	<del>8</del>	992	7.26 3.40
•		<b>3</b> 65			2166 33.33	2508 2508 3443												193	(100.0)	12 650	30 409	
No information available 0 Total 104		ું.≎ <b>શે</b>			2166	2511									_		_	193	(100.0) 6 17 765	95 12 745	101 30 510	7.97 2.19 8.34 3.55

Values in parentheses below each figure represent the percentage relative to the total of each row.

Estimated glomerular filtration rates (eGFR) at the introduction to dialysis and the treatment methods used at the end of year of introduction (only patients begun on dialysis in 2007 who responded to the questionnaire using floppy disks) TABLE 57.

noite	21	Mo inform available Total Mean	28 059 Total Mean S.44 Mean S.44 Mean S.44 Mean	28 059 S.44 Mean 766 S.70	28 059 Total 766 5.70	28 059 S.44 Mean 766 S.70 S.86	28 059 7 Total 766 5.70 7.88 7.99 7.99 7.99 7.99 7.99 7.99 7.99	28 059 Total 766 S.70	28 059 S.44 766 S.70 22 5.86 3.25 3.25	Total T66 5.70 3 3.25 4 5.10 3 3.25 5.44 5.10 3 3.25 5.44 5.10 3 3.25 5.44 5.10 5.	28 059 5.44 766 5.70 22 5.86 3.25 3.25 1657 5.19	Total 28 059 5.44 766 5.70 3 3.25 1 657 5.19	Total Mean 766 5.70 22 5.86 3.25 3 3.25 1 657 5.19 30 510 5.43
† Hoite	Subtotal	14 133	(0.2) (100.0) 0 428 3:	(100.0)	OT	_			(0.0) (100.0)	600	(100.0)	066 CT	
	6.92-0.82	S	(0.0)	(0.2)	) )	(0.0)	c	) )	(0:0)	1 9	(0. 1.	`	(0.0)
	6.72-0.62	l	1) (0.1) 1						(0.0) (0.0)				
	22.0-23.9	l				(0.0) (0.0) 0 0			(0.0) (0.0)				
_	6.12-0.0 <u>c</u>	l				(0.0)			(0.0)				
v1.73 m²)	6.61-0.81					0.0)			(0.0)				
(mL/mir	6· <i>L</i> I-0·9I	ı				(0:0)			(0.0)				
o dialysis	6.21-0.41					(0.0)			(0.0)				
duction t	12.0–13.9					(0.0)			(0:0)				
at the intro	6.11-0.01					(0.0)			(0.0)				
eGFR at	6.6–0.8					(10.0)			(0.0)				
	6.T.0.8	10				(30.0)			(0.0)			•	
	6.8-0.4	5390	(38.1)	(41.1)	S	(50.0)	(	0	(0.0)	315	(41.3)	5886	(38.4)
	2.0-2.9	4513	(31.9)	(28.7)		(10.0) 0	,	7	(100.0)	2/3	(35.8)	4912	(32.0)
	6.1-0.1	326	(2.3)	(2.1)	0	(0.0)	(	0	(0.0)	77	(1.6)	347	(23)
	0.1>	22	(0.2)	(0.2)	0	(0.0)	,	0	(0.0)	>	(0.0)	23	(0.1)
	Method of dialysis	Facility hemodialysis	(%) Hemodiafiltration	(%)	Hemofiltration	(%) Hemoadsorption	(%)	Home hemodialysis	(%)	Peritoneal dialysis	(%)	Total	(%)

Values in parentheses below each figure represent the percentage relative to the total of each row.

Estimated glomerular filtration rates (eGFR) at the introduction to dialysis and gender (only patients begun on dialysis in 2007 who responded to the questionnaire using floppy disks) TABLE 58.

	ap	3.49	,	2.73	:	3.43		t	3.43	
	Меап	5.68	5	¥.		5.43		ı	5.43	
	Total	19 748	275.01	70/01		30 510	•	0	30 510	
noiti	No informa available	668 6	31.00	C/7 C		15 174		0	15 174	
	Subtotal	9 849	(100.0)	749/	(100.0)	15 336	(100.0)	0	15 336	(100.0)
	0.0€≤	21	(0.2)	Ī	(0.5)	32	(0.2)	0	32	(0.2)
	6.62-0.82	3	(0.0)	4	(0.1)	7	(0:0)	0	7	(0:0)
	6.72-0.82	8	(0.1)	_	(0.1)	15	(0.1)	0	15	(0.1)
	24.0-25.9	14	(0.1)	7	(0:0)	16	(0.1)	0	16	(0.1)
	22.0-23.9	∞	(0.1)	٥	(0.1)	14	(0.1)	0	14	(0.1)
	6.12-0.0 <u>2</u>	16	(0.2)	2	(0.2)	3	(0.2)	0	53	(0.2)
1.73 m <sup>2</sup> )	6.61-0.81	35	(0.4)	2	(0.3)	20	(0.3)	0	50	(0.3)
L/min/Jr	6.71-0.81	65	(0.7)	23	(0.5)	8	(0.0)	0	8	(0.6)
ialysis (n	6.21-0.41	89	(0.7)	43	(0.8)	111	(0.7)	0	111	(0.7)
on into d	12.0-13.9	153	(1.6)	3	(1.1)	216	(1.4)	0	216	(1.4)
introducti	6.11-0.01	280	(2.8)	113	(2.1)	393	(5.6)	0	393	(5.6)
eGFR at introduction into dialysis $(mL/min/1.73~m^2)$	6.6–0.8	661	(6.7)	244	(4.4)	505	(5.9)	0	905	(5.9)
	6·L-0·9	1649	(16.7)	637	(11.6)	2286	(14.9)	0	2286	(14.9)
	6.8.0.4	4169	(42.3)	1717	(31.3)	5886	(38.4)	0	5886	(38.4)
	6.2-0.5	2515	(25.5)	2397	(43.7)	4912	(32.0)	0	4912	(32.0)
	6.1–0.1	174	(1.8)	173	(3.2)	347	(2.3)	0	347	(2.3)
	0.1>	10	(0.1)	13	(0.2)	23	(0.1)	0	23	(0.1)
	Gender	Male	(%)	Female	(%)	Subtotal	(%)	No information	Total	(%)

Values in parentheses below each figure represent the percentage relative to the total of each row.

 TABLE 59.
 Estimated glomerular filtration rates (eGFR) at the introduction to dialysis and age (only patients begun on dialysis in 2007 who responded to the questionnaire using floppy disks)

	2D	3.14	3.60	2.72	3.27	3.54	3.37	16	3.43		3.43	
	Меап	~		4.54 2		5.37 3		_			5.43 3	
	IstoT	28	251	1 606			29162		30 492	18	30 510	67.33 13.22
noiti	Mo informa aldaliava	18	137	832	2 928	6 144	4 882	215	15 156	18	15 174	67.28 13.37
	Subtotal	10	114	(100.0) 774	3 029	(100.0) 6 323	(100.0) 4 880	(100.0) 206	(100.0) 15 336	(100:0)	15 336	67.39 13.07
	0.0€≤	0 8	1.0	(6:0) (6:0)	(0.0)	(0.2)	0.2 9	(0.2)	(1.0)	0.00	32	68.91 14.59
	6.62-0.82	0 8	000	(0.0)	(0.1)	(0.1) 3	10.0)	0.0	(0.0)	0.0	7	62.57
	6.72-0.32	0 8	0.0	0.0	3.0	(0.1) 5.1)	7	(0.1)	(0.0)	0(0.1)	15	69.80 12.43
	24:0-25:9	0 8	0.0	0.0	(0.0)	(0.1) <b>8</b>	(0.1) 6	(0.1) 0	(0.0)	(0.I) 0	16	71.81 71.81 11.07
	6.62-0.22	0 8	0.0	0.0	(0.0)	(0.0) 5	7	(0.1) 1	(0.5)	0.1)	14	75.64
(	6.12-0.02	0 8	0.0	(0.0 4	3 (0.5)	(0.1) 13	(0.2) <b>8</b>	(0.2)	(50 8)	0.5	88	(6.2) 65.59 16.50
/1.73 m²	6.6 <u>1</u> –0.8 <u>1</u>	0 8	000	0:0	0.05	(03) 18	(03) 21	(0.4) 1	50.5)	(E) 0	50	71.50 11.70
(mL/min	6°LT-0'9T	0 9	) () ()	(0.0	(0.5)	(0.5) 32	(0.5 42	(0.9)	0.7	(0.0 (0.0	<b>2</b> 6	70.91 70.91 12.51
dialysis (	14:0-15:9	1,000	(10.0)	33(1.8)	0.45 4.45	(0.5) 38 (0.5)	(0.6 (0.6)	(1.0)	(1.9)	0.5)	111	70.27
introduction to	12.0-13.9	200	(20:0) 1 1	(0.9)	(0.5)	<b>8</b> (1.0)	(13)	(1.8) 8	(3.9)	0	216	70.68 12.79
the introd	6.11-0.01	1,	(10.0) 3	(2.6) 13	(1.7)	(1.8) 146	(2.3)	(3.4)	393	0 (5.6)	393	70.59 12.95
GFR at th	6.6-0.8	3	(30.0) 5.0)	(1.8)	(4.1)	(4.1) 315	6 8 6 6	(83)	(10.7)	(6.6) (6.6)	905	70.82
ě	6°L-0°9	1,	10.0	(8.8) 88 89	366.8)	(12.1) 943	(14.9) 855	(17.5) 43	(20.9) 2286	(14.9) 0	2286	(54.5) 69.80 12.30
	6.8-0.4	230	(8) (8)	(25.4) 257	(33.2)	(36.5) 2508	(39.7) 1917	(39.3) 68	(33.0)	(38.4) 0	5886	(30:4) 67.96 12.41
	6.2-0.2	0 0	(0:0) <b>2</b> 2	(45.6) 329	(42.5) 1170	(38.6) 2069	(32.7) 1246	(25.5) 46	(22.3) 4912	(32.0)	4912	(32.0) 65.06 13.26
	1.0-1.9	0	0,4 0,0	(12.3) 56	(7.2)	(3.9) 115	1.8 8.	(0.9) 1	(0.5)	0 (53)	347	57.26 15.35
	0.1>	Į.							(0.0)			(63.17 63.17 14.73
	Age (years)	<b>d5</b>	(%) 15–29	% % 7 4	(%) 45–59	(%) 60-74	(%) 75-89	(%) %) %)	(%) Subtotal	(%) No information	available Total	(%) Mean SD

Values in parentheses below each figure represent % relative to the total of each row.

TABLE 60. Estim	ated glı	отегш	Estimated glomerular filtra	tion ra	tes (eGi res	FR) at pondec	the intr 1 to the	oductic questic	on to d onnaire	ialysis e using	and p ; flopp	rimar 1y disk	s)	seases (o	(only patients	tents	oo ungaq	dialysis	/007 u	who	
	A.W.					eGFR a	at introduc	tion into c	dialysis (m	L/min/1.7	73 m²)						I	noiti			
Primary disease	0.1>	6°I-0°I	6.2–0.2	6°S-0°P	6.7-0.8	6.9-0.8	6.11-0.01	6.61-0.51	6'51-0'+1	6.71-0.81	6.61-0.81	6.15-0.02	6.62-0.22	54.0-25.9	6.72-0.62	6.62-0.82	≥30.0 Subtotal	Mo informs sylable	Total	Mean	SD
Chronic glomerulonephritis	8	128	1338	1273	416	147	09	29	17	19	ۇ و	2 5	e (	3	`			3 539	7 000	4.94	3.30
(%) Chronic pyelonephritis	(0.2)	6.7	(38.7)	37.	(12.0)	6.2)	(7.0	0.8)	1 (0.5)	(0.5)	(0.2)	(0.1)	(0.1)	(0.1) 0 0 0 0	0.1)	(0.0)		.0)	214	4.63	2.31
(%) Rapidly progressive	(0.9) 0	(3.7)	(42.2) 94	(33.9) 83	(11.9)	(5.5)	(0.0)	(0.0)	(0.9)	(0.9)	(0.0)	(0.0)	(0.0)	(0.0)	_	_		.0) 258	511	5.08	2.99
giomerwonephrus (%) Nephropathy of pregnancy /	(0.0)	(4.3)	(37.2)	(32.8)	(14.6)	(5.9)	(2.4)	0.4	(0.8)	(0.8)	(0.4)	(0.0)	(0.0)	(0.4)	(0.0)	0.0) (0.0)		.0) 16	39	3.96	1.70
pregnancy toxemia (%) Other nephritides that cannot be	(4.3)	(0.0)	(52.2)	(30.4)	(13.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)		-	0.0) (0.0)		.0)	131	4. 48.	2.65
classified (%) Polycystic kidney disease	(0.0)	(4.2)	(42.3) 163	(33.8)	(9.9) 43	(4.2)	( <del>4</del> ,2)	(0.0)	(0.0)	0 (1.4)	(0.0)	(0.0)	(0.0)	(0.0)	_	0.0)		.0) 306	694	4.41	1.79
(%) Nephrosclerosis	(0.5)	(3.9)	(42.0) 610	(39.9)	(11.1)	(1.5)	(0.5)	(0.0)	(0.3)	(0.0)	(0.3)	(0.0)	(0.0)		_	•			3 380	5.31	2.90
(%) Malignant hypertension	0.0	5 5	88.85 4.65	9, 9, 9, 9, 9, 9, 9, 9, 9, 9, 9, 9, 9, 9	(1.5) (1.5)	(6.0)	2.1.	(1.6)	(0.5) 0 0 0 0 0	0.4)	(0.2) 0 (0.2)	0.1)	(0.1)					.0)	188	4.36	1.74
(%) Diabetic nephropathy	10 (0.0)	(S. 8)	1852	(41.9) 2785 (40.5)	1170	468	198	(0.0) 120 5	(0.0) (0.0) (0.0)	(0.0) 41 6	(0.0) 28 (0.0)	(0.0)	(0.0) <b>8</b> (0.0)			- ,		·	13 371	5.73	3.44
(%) Systemic lupus erythematosus	1 (0.1)	(7T) 0	36	( <del>4</del> 0.0)	(1/.1) 19	14.8)	3	1	7 (0.7)	1 (0.0)	1.4)	1 (07)	(o.t)		_			104	225	6.15	3.98
(%) Amyloidal kidney	(0.8)	(0.0)	(29.8)	(33.9)	(15.7)	(11.6)	(2.5)	(0.8)	(1.7)	(0.8)	(0.8)	(0.8)	(0.0)	(0.0)		_		.0)	157	6.48	4.50
(%) Gouty kidney	(0.0)	(0.0)	(31.0)	(26.8) 24	(21.1)	(11.3)	(5.8)	(1.4)	(0.0)	(1.4)	(1.4)	(1.4)	(0.0)		_	-		.0) 31	85	5.40	3.07
(%) Renal failure due to congenital	(0.0)	(0.0)	(29.6)	4. 4. o	(14.8)	(1.9) 0	(3.7)	(3.7)	0.0	(1.9) 0	(0.0)	(0.0)	(0.0)			_		(0.	35	4.30	1.37
abnormal metabolism (%) Kidney and urinary tract	(0.0)	(6.3)	(25.0)	(56.3)	(12.5)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	0.0) ((0.0)		.0.	16	5.97	3.70
tuberculosis (%) Kidney and urinary tract stone	(0.0)	(0.0)	(25.0) 11	(50.0)	(8.3)	(0.0)	(8.3)	(0.0)	(8.3)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	_			(O. 7.	*	4.63	2.99
(%) Kidney and urinary tract tunor	(0.0)	(13.3)	(36.7)	(33.3)	(10.0)	(0.0)	(3.3)	(0.0)	(0.0)	(3.3)	0.0	(0.0)	0.0	(0.0)	_			(ö.	141	7.35	8.65
(%) Obstructive urinary tract difficulty	0000	3 3	3. 12 3. 13 3. 13	(30.8) 19	(15.4) 5	0.0	(70 g	(3.1) 0 0	(T) 0 0 0 0 0 0	0 0 0	0 0	600	000	(0.0)				(). 6 <del>)</del>	26	4.07	1.39
(%) Myeloma	0.0)	(6.9) 4 ?	(45.8) 24 (5.8)	(9,6) (8,6) (9,6)	3 (10.4)	(0.0)	(0.0) - 1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	_			67	139	4.25	1.78
(%) Hypoplastic kidney	0.0	(6. (9. 4. £	10 10	(43.3) 6	1 (5.0)	2 2 (3)	1-(-)	0.0)	000	0000	1 (0.0)	900	0.0	0.0				(i.	47	5.24	4.00
(%) Unspecified	0.0	51	(58.5) (58.5)	3 <b>2</b> 9	(3.8)	() 88 8	6. 9 6. 6	5, 12, 5 (5, 6)	16.09	(0:0) (0:0) (0:0)	(s, s)	(0.0)	1 (0.0)	1 (0.0)				1 680	3 025	5.45	3.60
(%) Reintroduction after transplantation	0.0	(§ 0 (§	19 (3.7)	() () () () () () () () () () () () () (	(13.6)	6.0.5	₹ 7 7	0 0	0 0	(s) 0 (s)	0 0 6 4 0 6		(1.0)	(0.1) 0 0				47	16	5.45	2.23
(%) Others	0.0	6.0)	103	111	(13.6)	29 (8.0)	£ 51	(a.b)	11.0	6.4	6.0	(0.0)	000	(0.0)				403	992	6.85	5.45
(%) Subtotal	23.0	34.5	4910	5884	2286	8, 8 9, 8, 8	383	216	111	25 S		(0.0) (0.0) (0.0)	(0.0) 14 (0.0)	16				15 078	30 409	5.43	3.43
No information available Total (%)	(0.1)	£6	4912 (32.0)	2 2 5886 (38.4)	2286 (14.9)	905 (5.9)	393 (2.6)	216 (1.4)	0.5 (6.7)	0.40 0.00	(0.3)	(0.2) (0.2) (0.2)	(0.1) (0.1)	(0.1) (0.1)	15 O (10)	(0.0)	0 5 32 15 336 (0.2) (100)	.0) 96 15174 .0)	101 30 510	5.31	3.43
	-											***************************************								ļ	

Values in parentheses below each figure represent the percentage relative to the total of each row.

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eGFR of male patients =  $186 \times (\text{serum creatinine} \text{ concentration prior to first dialysis}^{(-1.154)} \times (\text{age at introduction into dialysis}^{(-0.203)}) \times 0.881$ 

When the serum creatinine concentration was determined by the enzyme method, the following equation was used:

eGFR of male patients =  $175 \times (\text{serum creatinine} \\ \text{concentration prior to first dialysis}^{(-1.154)}) \times (\text{age at introduction to dialysis}^{(-0.203)}) \times 0.741$ 

The eGFR of female patients was calculated by multiplying the value obtained using the above equations, that is, the eGFR of male patients, by 0.742.

- a. Treatment method at the end of year of introduction into dialysis. Table 57 shows the relationship between eGFR at the introduction to dialysis and the treatment method at the end of the year of introduction (2007). The mean eGFR at the introduction to dialysis of patients who underwent home hemodialysis was as low as 3.25 (±0.25) mL/min, which was difficult to evaluate accurately because the number of patients evaluated was only two. No significant difference in eGFR was found among the patients who were treated by other methods.
- b. Gender. Table 58 shows the relationship between eGFR at the introduction to dialysis and gender. Similarly to the result of the 2006 survey, the eGFR of female patients was lower than that of male patients, despite the fact that the serum creatinine concentration at the introduction to dialysis of the female patients was lower than that of the male patients.
- c. Age. Table 59 shows the relationship between eGFR at the introduction to dialysis and age. The eGFR of the patients tended to increase with age, which was similar to that in the 2006 survey.
- d. Primary disease. Table 60 shows the relationship between eGFR at the introduction to dialysis and primary disease. The eGFR tended to be high for patients with renal or urinary tract tumors, amyloid nephropathy, SLE nephritis, and diabetic nephropathy as the primary diseases.

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# Revised Equations for Estimated GFR From Serum Creatinine in Japan

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**Background:** Estimation of glomerular filtration rate (GFR) is limited by differences in creatinine generation among ethnicities. Our previously reported GFR-estimating equations for Japanese had limitations because all participants had a GFR less than 90 mL/min/1.73 m<sup>2</sup> and serum creatinine was assayed in different laboratories.

**Study Design:** Diagnostic test study using a prospective cross-sectional design. New equations were developed in 413 participants and validated in 350 participants. All samples were assayed in a central laboratory.

**Setting & Participants:** Hospitalized Japanese patients in 80 medical centers. Patients had not participated in the previous study.

Reference Test: Measured GFR (mGFR) computed from inulin clearance.

Index Test: Estimated GFR (eGFR) by using the modified isotope dilution mass spectrometry (IDMS)-traceable 4-variable Modification of Diet in Renal Disease (MDRD) Study equation using the previous Japanese Society of Nephrology Chronic Kidney Disease Initiative (JSN-CKDI) coefficient of 0.741 (equation 1), the previous JSN-CKDI equation (equation 2), and new equations derived in the development data set: modified MDRD Study using a new Japanese coefficient (equation 3), and a 3-variable Japanese equation (equation 4).

**Measurements:** Performance of equations was assessed by means of bias (eGFR – mGFR), accuracy (percentage of estimates within 15% or 30% of mGFR), root mean squared error, and correlation coefficient.

**Results:** In the development data set, the new Japanese coefficient was 0.808 (95% confidence interval, 0.728 to 0.829) for the IDMS–MDRD Study equation (equation 3), and the 3-variable Japanese equation (equation 4) was eGFR (mL/min/1.73 m²) = 194 × Serum creatinine<sup>-1.094</sup> × Age<sup>-0.287</sup> × 0.739 (if female). In the validation data set, bias was  $-1.3 \pm 19.4$  versus  $-5.9 \pm 19.0$  mL/min/1.73 m² (P = 0.002), and accuracy within 30% of mGFR was 73% versus 72% (P = 0.6) for equation 3 versus equation 1 and  $-2.1 \pm 19.0$  versus  $-7.9 \pm 18.7$  mL/min/1.73 m² (P < 0.001) and 75% versus 73% (P = 0.06) for equation 4 versus equation 2 (P = 0.06), respectively.

**Limitation:** Most study participants had chronic kidney disease, and some may have had changing GFRs. **Conclusion:** The new Japanese coefficient for the modified IDMS–MDRD Study equation and the new Japanese equation are more accurate for the Japanese population than the previously reported equations. *Am J Kidney Dis* 53:982-992. © *2009 by the National Kidney Foundation, Inc.* 

INDEX WORDS: Glomerular filtration rate; Japanese; inulin clearance; serum creatinine.

## Editorial, p. 932

G lomerular filtration rate (GFR) is the most accurate index for assessing overall kidney function and an important tool for making diagnostic decisions in clinical practice. GFR may be measured by using the clearance of an exogenous marker; inulin is the gold standard, but the method is not applicable to daily practice because it is time consuming, labor intensive,

and expensive. Kidney function usually is assessed from serum creatinine (SCr) concentration alone, but SCr is affected by creatinine generation, including muscle mass and dietary intake, in addition to GFR.<sup>2</sup> GFR can be estimated from SCr level by using equations that include age, sex, race, and serum urea nitrogen (SUN) and albumin levels, as surrogates for creatinine generation, and are more accurate than estimates based on SCr level alone.<sup>1,3,4</sup>

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A list of the investigators who helped develop the Japanese equation for estimated GFR appears at the end of the article.

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The Modification of Diet in Renal Disease (MDRD) Study equation<sup>5</sup> and Cockcroft-Gault (CG) equation<sup>6</sup> are most commonly used for GFR estimation worldwide. Recently, the 4-variable MDRD Study equation was reexpressed by Levey et al<sup>7</sup> for use with isotope dilution mass spectrometry (IDMS)-standardized SCr values (the IDMS-MDRD Study equation). Several studies have validated the MDRD Study equation in whites and blacks. 8-14 In studies of more than 5,500 participants, Stevens et al<sup>15,16</sup> reported that GFR estimates using the IDMS-MDRD Study equation were unbiased and accurate for interpretations of GFR less than 60 mL/min/1.73 m<sup>2</sup>, but warned that estimates just less than 60 mL/min/1.73 m<sup>2</sup> must be interpreted with caution to prevent misclassification of chronic kidney disease. The equation is less accurate for Asians, with greater bias at estimated GFR (eGFR) less than 60 mL/min/1.73 m<sup>2</sup>. 17-19 Accordingly, both Ma et al 17 and our investigators 18,19 modified the MDRD Study equation by using separate "correction coefficients" for Chinese and Japanese. In both studies, the new equations were more accurate than the MDRD Study equation, but the correction coefficients were considerably different, with a Chinese coefficient of 1.233<sup>17</sup> and Japanese coefficient of 0.741.<sup>19</sup>

The difference in correction coefficients between Japanese and Chinese has not been explained. In our previous study, there may have been nonuniformity of creatinine assays because study samples for SCr were assayed in multiple laboratories and during different periods. Furthermore, data from participants with GFR greater than 90 mL/min/1.73 m<sup>2</sup> were not used for deriving the equation in the study. To verify results of our previous study, a new project was launched by the Japanese Society of Nephrology (JSN) with cooperation of nephrologists nationwide. The new study was conducted in 763 individuals to measure GFR and SCr by using inulin clearance (Cin) and standardized assays. A new Japanese correction coefficient was derived, as were new 3- and 5-variable Japanese equations.

## **METHODS**

## Inclusion and Exclusion Criteria

Inclusion criteria were: (1) age 18 years and older; (2) relatively stable kidney function, assessed by using SCr

level; and (3) patient's agreement to have urinary Cin measured using a continuous infusion.

Exclusion criteria were: (1) acute kidney injury, (2) apparent malignancy, (3) problems in micturition, (4) pregnancy, (5) inulin allergy, (6) amputation, and (7) individuals for whom the investigator judged that measuring Cin was inappropriate. Although some study participants were hospitalized for diagnosis of rapidly progressive or acute glomerulonephritis, renal biopsies and Cin measurements were performed after their conditions became relatively stable. We did not record data for day-to-day SCr level changes.

### Study Population of the Data Set

The study recruited participants from 80 medical centers throughout Japan between December 2006 and July 2007. Participants included mostly nephrology inpatients. Hospitalization of 5 to 14 days for kidney biopsy or education about lifestyle change was commonly practiced in Japan. Data for Cin and SCr were collected from 878 participants, mostly those with chronic kidney disease and a small number of healthy kidney donors. A total of 115 participants were excluded for the following reasons: 36 lacked data for urine volume, 11 were 17 years and younger, 2 had high serum inulin concentrations, 4 had lack of data for inulin blank, 51 had high values for inulin blank, 9 had a low volume of voided urine (<10 mL), and 2 had extraordinarily high GFRs. The final study population included 763 participants. Data collected from December 1, 2006, to April 20, 2007 (n = 413), were used as the development data set, and those obtained from April 21, 2007, to July 31, 2007 (n = 350), were used as the validation data set. The institutional review board at all the study institutions approved anonymous use of data for the present study. All patients signed written informed

## Cin and Creatinine Renal Clearance

Cin and creatinine clearance (Ccr) were measured simultaneously in 757 participants. In 6 participants, only Cin was measured. The method for measuring renal Cin was described elsewhere. 18 Briefly, Cin and Ccr were calculated from serum and urine concentrations and urine flow rate. Inulin (1%) was administered by means of a continuous intravenous infusion for 2 hours under overnight fasting, but hydrated, conditions. During the inulin infusion, serum samples were collected 4 times at 0 (blank), 45, 75, and 105 minutes for creatinine and inulin, and urine samples were collected between 30 and 60, 60 and 90, and 90 and 120 minutes for inulin and creatinine after completely emptying the bladder at 30 minutes from the start of the inulin infusion. Inulin samples were assayed by means of an enzymatic method using a kit (Diacolor Inulin; Toyobo Co, Osaka, Japan). The mean value of 3 measurements was used for the Cin and Ccr study.

### **SCr Measurement**

Serum samples were assayed for creatinine in a central laboratory (Central Laboratory; SRL Co, Hachioji, Japan) by means of the enzymatic creatinine assay method using an