### Peritoneal Dialysis in Italy: the 8th GPDP-SIN census 2022

Census

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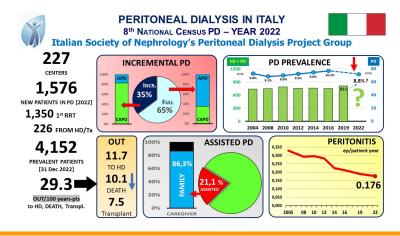
### **ABSTRACT**

**Objectives.** The results are reported here of the 8<sup>th</sup> National Census (Cs-22) of Peritoneal Dialysis in Italy, carried out in 2022-23 by the Italian Society of Nephrology's Peritoneal Dialysis Project Group and relating to 2022.

Methods. The Census was conducted in the 227 non pediatric centers which performed Peritoneal Dialysis (PD) in 2022. The results have been compared with the previous Censuses carried out since 2005. Results. Incidence: in 2022, 1350 patients (CAPD=52.1%) started on PD (1st treatment for ESRD). PD was started incrementally by 35.3% in 136 Centers. The catheter was placed exclusively by a Nephrologist in 17.0% of known cases. Prevalence: there were 4152 (CAPD=43.4%) patients on PD on 31/12/2022, with 21.1% of prevalent patients on assisted PD (family member caregiver: 86.3%). Out: in 2022 the PD dropout rate (ep/100 pt-yrs) was: 11.7 to HD; 10.1 death, down; 7.5 Tx. The main cause of transfer to HD remains peritonitis (23.5%), although its reduction over the years is confirmed (Cs-05: 37.9%). Peritonitis/EPS: the incidence of peritonitis in 2022 was 0.176 ep/pt-yr (696 episodes). The incidence of new cases of EPS fell in 2021-22 (7 cases). Other results: the number of Centers using 3.86% for the peritoneal equilibration test (PET) (57.7%) increased. PD for heart failure continues to be used in 44 Centers (66 pts).

Conclusions. Cs-22 confirms PD's good results in Italy.

**KEYWORDS**: Peritoneal Dialysis, technique failure, incremental Peritoneal Dialysis, peritonitis, peritoneal equilibration test (PET)



### **Background**

The Peritoneal Dialysis Project Group (GPDP) of the Italian Society of Nephrology (SIN) investigates the state of Peritoneal Dialysis (PD) in Italy periodically by means of a Census carried out in the Centers which use it [1–6]. In the last edition, relating to 2019 [6], the situation was shown to be substantially stable, although the survey was conducted at the height of the CoViD pandemic and for the first time was incomplete.

All the Centers using PD took part again in the current edition, which was the Eighth and relates to 2022. It should be remembered, however, that these Centers represent around two-thirds of public Centers (PD is not available as a service in the remainder). When it is considered also that PD is not used in private Centers, the method is actually provided in a minority of Italian Dialysis Centers, and used by less than 10% of patients on Dialysis. The reasons for such a disheartening picture were investigated in the very first Census carried out by SIN in 2004 [7] and are likely to still be the same, all the more so if the constant improvement in the results achieved by PD over the years is considered.

The current edition features various grounds for interest and new aspects. First of all, it is the first "post-CoViD" edition. The number of Centers taking part using the new data collection system [6] increased significantly, allowing for greater precision in the data collected. For the first time the Census thoroughly investigated not only the incidence, but also the etiology of peritonitis, and certain structural aspects of PD Centers, such as the dedicated personnel and the training which will be examined in future.

This report presents the results of the 8<sup>th</sup> edition, conducted in 2022-2023 and relating to 2022, compared with those of the previous years.

Completing the report is the examination by leading experts on the subjects of certain aspects of PD, including the incremental prescription, peritoneal sclerosis and an assessment of peritoneal permeability.

### Materials and methods

The GPDP Census collects aggregate data relating to PD, and is targeted at all the non-pediatric Centers which have used PD in the year in question.

<u>Data collection</u>. As for 2019 [6], in the current edition the aggregate data were collected in two different ways. The first was analytical, using specially designed software: a sort of medical record in which individual patients are entered systematically and the data are exported for the Census in aggregate form. For the protection of privacy, the program was developed without a cloud component, so all the data collected are stored locally and the possibility of backup to server is delegated to the operator.

The number of Centers using this system increased from 110 in 2019 to 175 in 2022. The method used by the remaining 52 Centers was the traditional collection of data by filling in the online questionnaire used for previous editions.

In total, the Census reports data from 227 Centers, which is 100% of Italian PD Centers. Of the 8 editions so far, only the Census relating to 2019 was incomplete (198 Centers).

<u>Participating Centers.</u> The initial list of public Centers using PD established in the first SIN Census conducted for 2004 [7] has been updated over the years through attendances at Congresses, Conferences and subsequent SIN Censuses.

The number of Centers taking part for 2022 was 229, 2 of which were excluded as they did not treat any patients during 2022 (having ceased PD activity). While all the Centers responded to the questions on the incidence and prevalence of PD, 50 Centers provided no data on the incidence and prevalence of HD (Figure 1).

<u>Information.</u> The structure of the Census provides for a series of repeated pieces of information – unchanged since the first edition in 2005 [1] – relating to incidence, prevalence, method change or interruption, assisted PD, peritonitis, and non-renal PD.

Encapsulating peritoneal sclerosis (EPS) has been added since 2008, and home visits and the peritoneal equilibration test (PET) since 2010 [2]. The questions on catheters resumed in the 2016 edition [5].

Furthermore, with the analytical data collection method information has become available for the first time on the causes of Renal Insufficiency, causes of death, certain organizational aspects such as training methods and available resources, and the etiology of peritonitis.

<u>Data verification and comparison.</u> The data collected initially were subjected to an initial congruence analysis. Any inconsistent data were corrected wherever possible by follow-up phone call, or were considered missing or incomplete, as appropriate. Any corrections and the number of Centers involved are reported in detail in the presentation of the single results.

<u>Definitions and calculations.</u> All the patients who started as first treatment on PD and HD from 01/01/2022 to 31/12/2022 were considered incident. Of these, the patients on  $\leq 2$  exchanges/day or  $\leq 4$  sessions/week with CAPD (Incr-CAPD) and APD (Incr-APD) respectively were considered as on incremental PD (Incr-PD). Prevalence referred to patients on dialysis at December  $31^{st}$ . For these, a need for assistance referred to the involvement of a caregiver in the performance of the dialysis procedures. Patients on PD due to non-renal causes (GFR  $\geq 15$  ml/min/1.73m²) were considered separately: the Census data always refer to patients who started PD due to ESRD.

The calculation of the follow-up to which events are related represents the critical aspect of the Census. With it being impossible to calculate the actual data (the sum of the periods all patients spent on PD in 2022) the follow-up has always been estimated by taking the mean of prevalent patients at the beginning and the end of the year, a method which has also recently been validated [8].

The prevalent patients at the beginning of the year were calculated by taking the prevalent patients at the end of the year, adding drop-outs for all causes, and subtracting new patients to PD (information available). This year it was possible to calculate the follow-up precisely for the 175 Centers which used the "2.2" program.

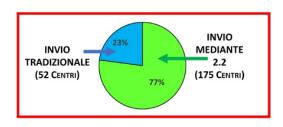
In these Centers the comparison between the two methods showed that "traditional" follow-up underestimates the "actual" follow-up by 5.4%, so it overestimates by an equivalent amount the incidence of the events considered. As the data collection system was still mixed for 2022, the traditional method was used to calculate follow-up for all 227 Centers in order to be able to compare current results with previous years.

The drop-outs from PD recorded in the year were related to 100 patient-years of follow-up, while for peritonitis the incidence was calculated as episodes/patient-years (ep/pt-year).

Episodes of EPS refer to the entire 2021-22 two-year period in the case of traditional collection, and the 2020-22 three-year period for the analytical method.

Statistical analysis was limited to looking for any differences with the Chi-square test.

# CENSIMENTO GPDP 2022 CENTRI PARTECIPANTI



CENTRI CON ALMENO 1 PAZIENTE TRATTATO IN DP NEL 2022	227	
CENTRI CON DATI COMPLETI PER DP	227	100%
CENTRI CON DATI COMPLETI (INC/PREV) PER HD	177	78%

Figure 1: centers which used PD in 2022 for at least 1 patient. They all sent the data relating to PD; 50 of these did not send the incidence and prevalence data relating to HD. The system used for sending the data is shown in the graphic: 52 by means of the traditional system, which provides for the entry of aggregate data; 175 using the dedicated program in which each patient is entered separately, and the program calculates and sends the aggregate data.

### Results

### Incidence and initial method

In 2022 PD was started on as first treatment by 1350 patients, 703 of whom using CAPD and 647 APD. The Centers with no incidence in PD in 2022 numbered 11. As regards HD, 177 Centers provided incidence and prevalence data. In these 177 Centers, 1066 patients started on PD as first treatment, and 4329 on HD, giving a percentage incidence of PD of 19.8% (Table I) (Figure 2). So in relation to the 177 Centers which also sent data on HD, a fall in both the number of patients treated overall with PD in Italy (-15.4% compared to 2016) and the percentage incidence of PD was recorded for 2022. The most widely-used initial PD method remains CAPD (52.1%).

	ALL CENTERS					CENTERS WITH HD DATA			
YEAR	CENTERS	CAPD	APD	CAPD	Тот. РД	CENTERS	PD	HD	PD
	(n)	(n)	(n)	(%)	(n)	(n)	(n)	(n)	(%)
2005	222	794	649	55.0	1443	222	1443	4502	24.3
2008	223	759	620	55.0	1379	223	1379	4646	22.9
2010	224	763	666	53.4	1429	224	1429	4695	23.3
2012	224	778	655	54.3	1433	224	1433	4700	23.4
2014	225	945	707	57.2	1652	225	1652	4442	27.1
2016	237	895	700	56.1	1595	230	1549	4907	24.0
2019	198	741	622	54.4	1363	186	1272	4582	21.7
2022	227	703	647	52.1	1350	177	1066	4329	19.8

Table I: incident patients and initial PD method in the non-pediatric Centers which used PD in 2022 compared with previous years. The number of Centers not sending HD incidence data has constantly increased since 2016.

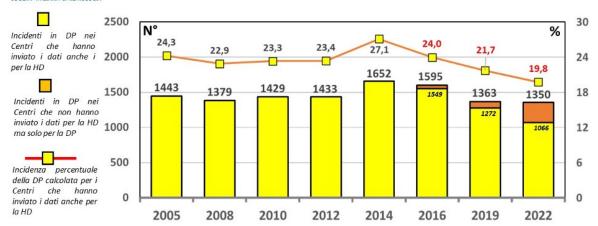
pazienti incidenti)

# **CENSIMENTO GPDP 2022**

## **INCIDENZA**

LE PERCENTUALI SONO CALCOLATE SUI CENTRI CON DATI COMPLETI PER DP ED HD

GRUPPO di PROGETTO di DIALISI PERITO: SOCIETA' ITALIANA di NEFROLOGIA



NOTE – Nel 2019 il Cersimento non è stato completo (198 Centri) – il numero complessivo di pazienti INCIDENTI in DP nei diversi anni è indicato in cima ad ogni colonna. Nel 2016, 2019 e 2022 è aumentato il numero dei Centri che non hanno fornito i dati della HD (vedi testo). In corsivo è stato riportato il numero di pazienti in per i quali è stata calcolata l'incidenza percentuale.

Figure 2: number of new patients on 1st treatment (incident) in the years surveyed. The percentage incidence is calculated on the total number of incident patients (PD + HD). Since 2016 a number of Centers have not sent HD incidence data, so the PD percentage is only calculated for the Centers which have sent the data (light yellow, value in italics). The total number of incident patients is given at the top of each column. It is to be remembered that the 2019 data are incomplete.

For the first time, basic nephropathy data are available, though only for the Centers which sent data using the 2.2 system. The conditions in which PD is most used are Nephroangiosclerosis (24.4%) and chronic Glomerulonephritis (22.3%). Diabetic nephropathy is the cause of ESRD in 15.4% of cases, while in 15.3% it is not known (Figure 3).



Figure 3: type of nephropathy in incident patients on PD. This was not requested by the traditional system for sending the data, so the breakdown shown in the Figure refers to 1004 patients in 174 Centers (1 Center was excluded for data incongruence).

### Placement of the peritoneal catheter

All insertions were considered for the placement of the catheter. Excluding 96 patients due to incongruent data (which will be verified in a subsequent analysis), in the 1480 patients who started on PD in 2022, there was a further increase in placements by a surgeon alone, the number of placements by a surgeon and a nephrologist together was stable, and placements by a nephrologist alone diminished (Figure 4).

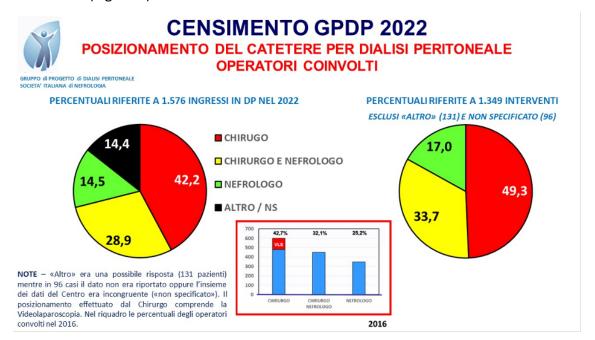


Figure 4: operators involved in the placement of the peritoneal catheter. The percentage has also been calculated excluding the catheters for which the response was "other" or not specified. The 2016 data are given in the box (excluding "other" and not specified).

### Initial dialysis dose – incremental peritoneal dialysis

PD was started with the incremental method (Incr-PD) by 477 patients in 2022, equaling 35.3% of total incident patients (Figure 5); it was used for at least 1 patient by 136 Centers, equaling 59.9% of the 227 Centers (63.0% when excluding the 11 Centers with no incidence).

For the patients who started PD with an incremental dose, the most widely-used method, as in previous years, was CAPD (82.8%), as opposed to the patients who started with a full-dose prescription, for whom APD is significantly more widely-used (64.7% - p<0.0001) (Figure 5). CAPD is a PD method that is increasingly associated with the incremental prescription and the Centers that perform it.

Over the years the number and percentage of incident patients on Incr-PD have been constantly rising, from the 11.9% of 2005 to the current 35.3% (Figure 6). The number of Centers prescribing it, which increased until 2016, remained the same in 2022 in terms of percentage (62.9% in 2016; 63.0% in 2022 of the Centers which started new patients on PD) (Figure 7). The increase recorded in 2022 can therefore be attributed to an increased use in the Centers which already used it, where it was prescribed for 47.8% of patients.

The Centers using Incr-PD are "larger" than the Centers which do not prescribe it, in terms of both incident (7.3 pt/year vs 4.4 pt/year) and prevalent patients (21.3 patients vs 15.0 patients) (Figure 8). Excluding the Centers with zero incidence and those which did not send HD data, the use of incremental PD is associated, as in previous years, with greater use of PD in general (22.4% in 114 Centers vs 14.4% in 56 Centers – p<0.005) (Figure 9).

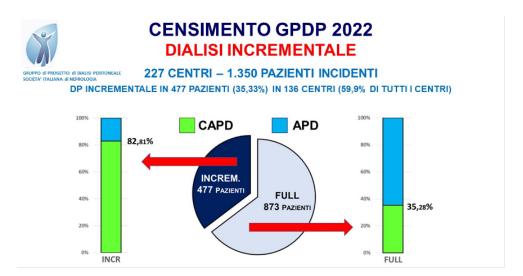


Figure 5: incremental dialysis in 2022. The method of PD used (CAPD and APD) is given in the lateral columns for "incremental" (on the left) and "full dose" patients (right).

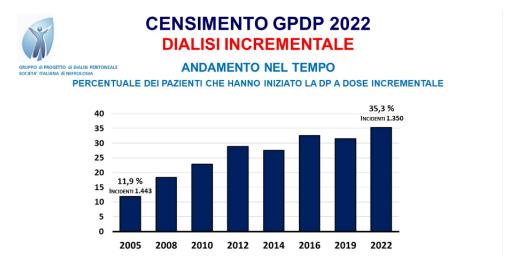
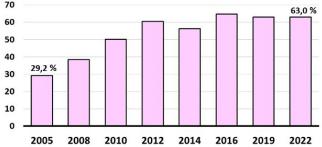


Figure 6: percentage of total incident patients who started PD with an incremental prescription (2 or fewer exchanges on CAPD and 4 or fewer sessions on APD).





NOTE – La percentuale riportata è riferita ai Centri che hanno registrato almeno 1 paziente incidente nell'anno considerato. Come noto un ridotto numero di Centri (variabile da anno ad anno) non registrano nuovi pazienti incidenti (si ricorda che il Censimento riguarda tutti i Centri che hanno TRATTATO almeno 1 paziente nell'anno censito, sia che si tratti di un paziente già in trattamento, di un ingresso da altro trattamento o di un paziente trasferito da altro Centro)

Figure 7: percentage of Centers which used the incremental prescription for at least one patient. The percentage was calculated excluding the Centers which did not start any incident patients. If it is related to the total number of Centers the value is slightly lower, but the trend over time does not change.

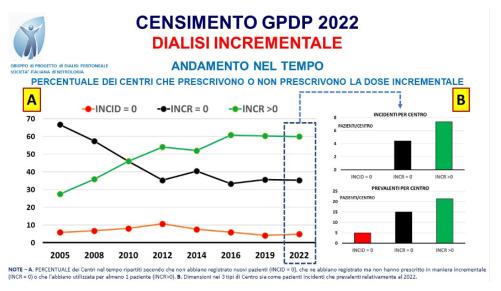


Figure 8: A) percentage of Centers over time divided into those which recorded no new patients (INCID = 0), those which recorded new patients but did not prescribe the incremental mode (INCR = 0), and those which used it for at least 1 patient (INCR>0). B) Size of the 3 types of Centers, in terms of both incident (above) and prevalent patients (below) in relation to 2022.

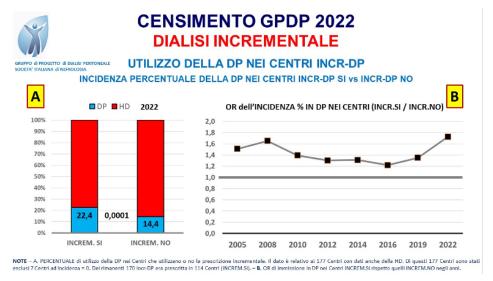


Figure 9: A) the percentage use of PD for incident patients in the Centers which do or do not use the incremental prescription. The data relates to the 177 Centers which also provided HD data. Of these, 7 were excluded for Incidence = 0. Of the remaining 170, Incr-PD was prescribed in 114 Centers (INCREM.SI). B) The PD admission Odds Ratio in INCREM.SI with respect to INCREM.NO Centers over the years.

### Patients from other treatments

In 2022, 178 patients transferred from HD to PD (Figure 10) (Table II).

	1st TREAT.	FROM HD	FROM TX	NEW TO PD	FROM HD (%)	FROM Tx (%)
2005	1443	89	25	1557	5,7	1,6
2008	1379	82	32	1493	5,5	2,1
2010	1429	126	36	1591	7,9	2,3
2012	1433	113	50	1596	7,1	3,1
2014	1652	161	46	1859	8,7	2,5
2016	1595	119	50	1764	6,7	2,8
2019	1363	125	44	1532	8,2	2,9
2022	1350	178	48	1576	11,3	3,0

Table II: patients (absolute value and percentage of all new patients to PD) from HD and return post-Transplant.

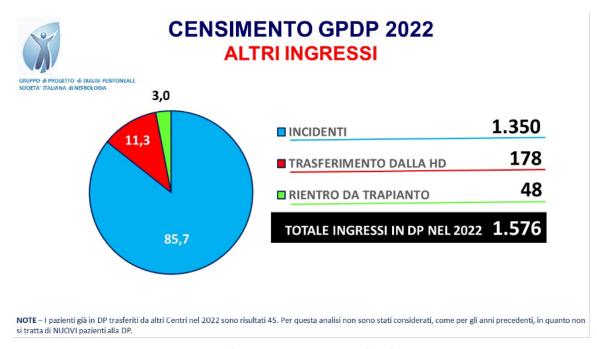
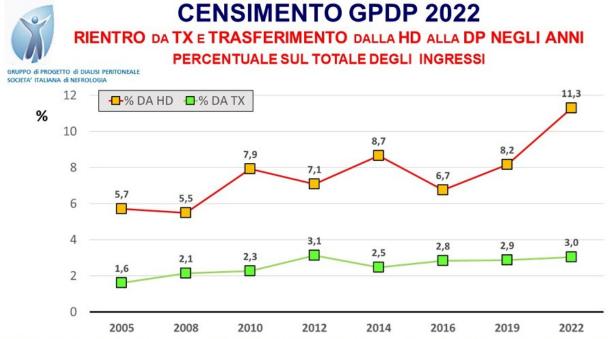


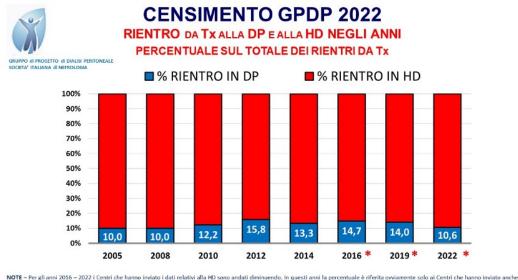
Figure 10: new patients to PD, sum of incident patients, transfers from HD and returns post-Tx.

As expected, this data is decidedly lower than the number of patients switching from PD to HD (464 drop-outs in 2022), but higher in both absolute and percentage terms: indeed, in 2022 it represents 11.3% of all new patients to PD compared to 5.7% in 2005 (Figure 11). If for every 100 patients who transferred from PD to HD in 2005 17 took the reverse path, in 2022 the latter figure was 37. As regards a return to PD post-Transplant, the numbers and percentages have remained substantially unchanged over time (Figure 12).



NOTE – Il totale degli ingressi è dato dalla somma dei pazienti incidenti in DP, dei pazienti rientrati dal trapianto e di quelli trasferiti dalla HD. Non sono stati considerati i pazienti trasferiti ad altri Centri (45 nel 2022) per evitare di considerarii 2 volte.

Figure 11: trend over time in the percentage of patients who started on PD from HD and Tx out of the total number of new patients on PD.



NOTE - Per git anni 2016 - 2027 i Centri che hanno inviato i dati relativi alla FID sono andati diminuendo. In questi anni la percentuale e inferita ovviamente solo ai Centri che hanno inviato anche i dati della HD (230, 186 e 177 rispettivamente)

Figure 12: percentages of patients returning post-Transplant on HD (red) and on PD. Only Centers with complete data for HD as well are considered.

### Change of PD method

Information on the change of method were available for 224 Centers. In these Centers, 165 patients transferred from CAPD to APD in 2022, while 43 transferred from APD to CAPD (Figure 13). As in previous years, the reason for the change in around half of cases was patient and/or caregiver choice. Other grounds were insufficient clearance / UF for the switch from CAPD to APD, and catheter malfunction for the switch from APD to CAPD.

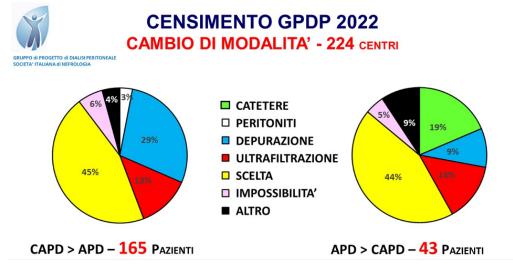


Figure 13: change of PD method in 2022. Three Centers did not provide the data.

### Prevalence and PD method

At December 31<sup>st</sup> 2022 there were 4152 patients on PD, with 1803 on CAPD and 2349 on APD. Therefore, compared with 2016, a reduction of 9.9% was recorded in the prevalent population (Figure 14) (Table III). In the 177 Centers with complete incidence and prevalence data for HD as well, there were 3191 patients on PD and 18,259 on HD, with a 14.9% PD prevalence.

The most widely-used PD method among prevalent patients is APD (56.6%) (Figure 15), with a further increase compared to previous years (Table III).

The turnover calculated as the ratio of prevalent patients to the total of new patients on PD in 2022 was 31.6 months, substantially unchanged compared to previous years (it was 32.9 months in 2008). The trend in turnover over the years is given in detail in Figure 16.

	ALL CENTERS					CENTERS WITH HD DATA			
YEAR	CENTERS	CAPD	APD	CAPD	тот. РД	CENTERS	PD	HD	PD
	(n)	(n)	(n)	(%)	(n)	(n)	(n)	(n)	(%)
2004 *	222				4234	222	4234	20921	16.8
2008	223	1926	2168	47.0	4094	223	4094	20478	16.7
2010	224	1929	2293	45.7	4222	224	4222	21175	16.6
2012	224	1981	2318	46.1	4299	224	4299	20844	17.1
2014	225	2099	2381	46.9	4480	225	4480	21716	17.1
2016	237	2147	2460	46.6	4607	230	4484	21286	17.4
2019	198	1857	2065	47.3	3922	186	3613	18671	16.2
2022	227	1803	2349	43.4	4152	177	3191	18259	14.9

Table III: prevalent patients at 31/12/2022 and PD method in the non-pediatric Centers which used PD in 2022 compared with previous years. The number of Centers not sending HD incidence data has increased constantly since 2016. \* the values of the First SIN Census carried out in 2004 are given since data relating to HD were not requested in the first GPDP Census in 2005.



Figure 14: number of patients treated with PD at December 31st of each year (prevalent) in the years surveyed. The percentage prevalence was calculated on total prevalent patients (PD + HD). Since 2016 a number of Centers have not sent HD prevalence data, so the PD percentage is only calculated for the Centers which have sent the data (light blue, value in italics). The total number of prevalent patients is given at the top of each column. It is to be remembered that the 2019 data are incomplete. In 2005 the HD prevalence data were not requested, so those of the 2004 SIN Census are considered.

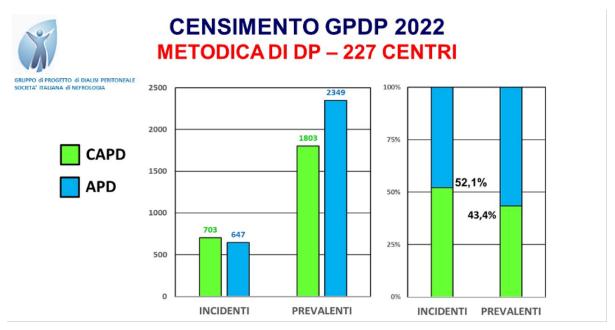
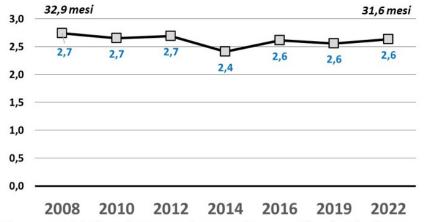


Figure 15: breakdown of incident and prevalent patients between CAPD and APD.



# CENSIMENTO GPDP 2022 DURATA MEDIA DELLA DP

SISTEMA TRADIZIONALE = PREVALENZA / INGRESSI



NOTE – La durata della DP può essere ricavata moltiplicando per 12 il rapporto INGRESSI / PREVALENZA. Ciò è ovviamente valido in condizioni di steady state mentre per il 2022 potrebbe non essere questa la condizione anche se la minore incidenza è stata in parte compensata dall'aumento dei pazienti provenienti dalla HD.

Figure 16: duration of PD calculated by multiplying the NEW/PREVALENCE ratio by 12. This is obviously valid in steady state conditions, while for 2022 this may not be the case, although the lower incidence was partly offset by the rise in patients from HD.

### Assisted PD

In Cs-22 the number of prevalent patients requiring a caregiver (assisted PD) was 878 (21.15% of all prevalent patients on PD) (Figure 17). Compared to 2019 (976 patients on Assisted PD in an incomplete Census), this is a significant reduction (p<0.005).

The caregiver is a family member in 86.3% of cases, a live-in carer in 7.4%, a home nurse in 1.7%; finally, 4.6% (40 patients) perform PD in facilities for the elderly. A reduction was recorded for 2022 in the number of live-in carers, with an increased involvement of family members. The number of patients treated with PD in residential care homes was unchanged (Figure 18).

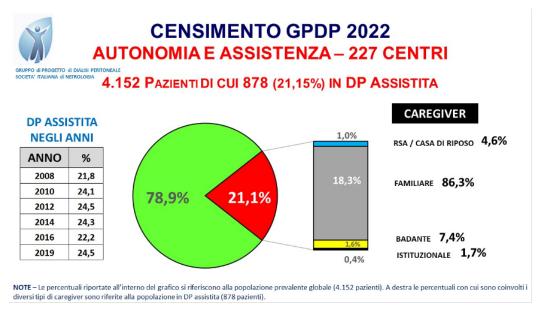


Figure 17: assisted PD in the prevalent patients on 31/12/2022 and type of caregiver involved. Given inside the graphic for the latter are the percentages referred to the total of prevalent patients, and near every single component the percentages in relation to the total number of patients on assisted PD.

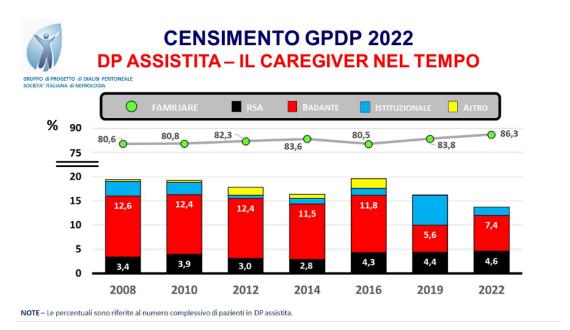


Figure 18: trend over time in caregivers involved in assisted PD.

# Change of method and drop-out

Figure 19 shows overall drop-out and drop-out due to transfer to HD, death, and transplant, expressed as both number of patients and events/100 pt-years.

The number of deaths recorded in 2022 was 400 (10.1 ep/100 pt-years), 464 patients transferred to HD (11.7 ep/100 pt-years) and 296 to transplants (7.5 ep/100 pt-years). A reduction in mortality was confirmed for 2022 compared to 2016.

Other causes of drop-out from PD in 2022 were voluntary refusal to continue dialysis (burn out) for 21 patients, Recovery of Residual Renal Function (RFRR) in 14 patients and on "other" grounds for 6 patients. Burn out was proposed for the first time in 2022, and may have been attributed in the past to death or "other" grounds.

With regard to drop-out to HD (Figure 20), the single main cause remains peritonitis (23.5%), but its reduction over the course of the years was confirmed (2005: 37.9%; 2008: 36.7%; 2010: 30.4%; 2012: 28.2%; 2014: 24.8%; 2016: 23.8%). The second cause — significantly on the increase — is the impossibility to continue on PD (22.4%). Traditionally this refers to events that render the patient no longer suitable for the performance of the dialysis procedures due to the onset of barriers to independence (physical, psychological, cognitive) in the event of absence or loss — if already on Assisted PD — of the caregiver. Other clinical events may also be attributed to this cause however. Finally, catheter is increasing as cause of drop-out (14.0%). The main cause of death is heart disease (42.3%), while peritonitis represents 1.9% of deaths (Figure 21).

### CENSIMENTO GPDP 2022 FINE DELLA DP EPISODI /100 ANNI PZ **EVENTI** SOCIETA' ITALIANA di NEFROLOGI MORTE MORTE HD Tx TOT HD Tx TOT 2005 512 565 263 1340 11,8 13,0 6,1 30,9 1313 2008 498 516 299 12,4 12.8 7.4 32.7 2010 504 481 290 1275 12,4 11,8 7.1 31,3 2012 511 485 288 1284 12,3 11,7 30,9 6.9 1359 2014 528 502 329 12.4 11,8 7,7 32,0 2016 554 521 311 1386 12,5 11.8 7,0 31,3 2019 426 325 220 11,6 8.9 6,0 26,5

NOTE - Nel 2019 la raccolta dati è risultata incompleta (198 Centri).

2022

464

400

Figure 19: causes of drop-out from PD over the years. In 2019 the Census was incomplete.

296

1160

11,7

10,1

7,5

29,3

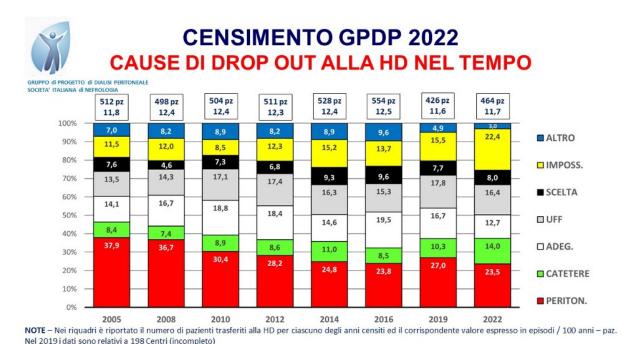
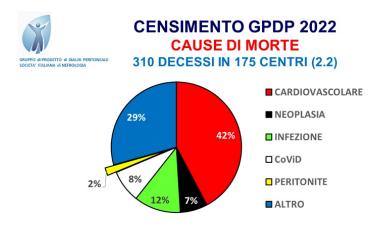


Figure 20: causes of transfer to HD over the years. In 2019 the Census was incomplete.



NOTE – La causa di morte è stata indagato solo con il sistema 2.2 mediante il quale hanno inviato i dati 175 Centri.

Figure 21: causes of death in the Centers that used the dedicated 2.2. program to send the data.

### Peritonitis

The number of episodes of peritonitis recorded in 2022 was 696 in 226 Centers, which for a total follow-up of 3943.5 years (47.322 months) is equivalent to 0.176 episodes per patient-year, or in other terms 1 episode every 68.0 patient-months, a lower incidence than recorded in previous years. As far as the percentage of negative cultures is concerned (134 episodes, equaling 19.3% of the total), the data is not significantly different to previous years (Table IV). The peritonitis trend is given in both Table IV and Figure 22. The etiology was analyzed for 627 cases of peritonitis reported in 211 Centers. One Center did not report the data, and 15 reported a higher number defined by the etiological agents than the cases of peritonitis reported overall (+18). However, as 8 Centers reported a lower number of etiological agents for peritonitis than the total declared (-17), the net difference was only 1 episode, confirming the validity of the overall data. Half (50.1%) were caused by Gram positives, 27.9% by Gram negatives and 2.7% by unspecified germs (Figure 23). Cases of culture-negative peritonitis in these Centers were lower (17.9%) than those declared overall by all the Centers (134 episodes, 19.3%). Figure 24 details the different isolated microorganisms. Of the episodes of peritonitis recorded in 2022, 323 (46.4%) occurred during CAPD and 373 (53.6%) APD, reflecting the breakdown of the 2 methods in prevalent patients.

		INCID		
	PERITONITIS	ep/pt-year	pt-month/ep	NEGAT (%)
2005	1026	0.329	36.5	17.1
2008	1171	0.292	41.1	17.1
2010	1209	0.296	40.5	18.5
2012	1179	0.282	42.5	15.9
2014	953	0.224	53.5	19.9
2016	939	0.212	56.6	17.3
2019	667	0.189	63.5	18.7
2022	696	0.176	68.0	19.3

Table IV: the episodes of peritonitis recorded by 73% of surveyed Centers are given for 2005, while not all recorded them in 2019 (and 4 did not report the data). For 2022 the data refer to all the Centers, except 1 which was unable to retrieve the data. The calculation is taken from the overall number. Any discrepancy with the number of etiological agents has not been taken into account for standardization with the previous years (in which the etiology was not investigated).

### **CENSIMENTO GPDP 2022 PERITONITI INCIDENZA** NEGAT (%) PERITONIT ep/anno-pz mesi-pz/ep **\*** 2005 1026 0,329 36.5 17.1 2008 1171 0,292 41.1 17.1 2010 1209 0,296 40,5 18,5 2012 1179 42.5 15.9 0,282 2014 953 0,224 53,5 19,9 2016 939 0,212 56.6 17.3 **\*** 2019 667 0,189 63,5 18,7

0,176

2022

696

# 3943,5 ANNI-PAZ CALCOLO DEL FOLLOW UP CON IL MEOTODO TRADIZIONALE IL METODO TRADIZIONALE SEMBRA SOTTOSTIMARE DEL 5,4% IL TEMPO DEL FOLLOW UP RISPETTO IL «GOLD STANDARD» 2.2 (differenza ingresso e uscita nel 2022 per ogni paziente) ATTENZIONE Sottostima del tempo = sovrastima

dell'incidenza

NOTE – Il 2005 riporta le peritoniti registrate dal 73% dei Centri censiti mentre il 2019 non ha censito tutti i Centri (e 4 non riportavano il dato). Per il 2022 i dati sono riferiti a tutti i Centri tranne 1 per impossibile recupero del dato. Il calcolo è ricavato dal numero complessivo. Di eventuali discrepanze con il numero di agenti etiologici non si è tenuto conto per omogeneità con gli anni precedenti (nei quali l'etiologia non era indagata).

68.0

Figure 22: incidence of peritonitis in 2022. The peritonitis reported for 2005 was recorded by 73% of the Centers surveyed, while not all were surveyed in 2019 (and 4 did not report the data). For 2022 the data refer to all the Centers, except 1 due to impossibility to retrieve the data. The count is taken from the total number. Any discrepancy with the number of etiological agents was not taken into account for standardization with the previous years (in which the etiology was not investigated).

19.3



Figure 23: etiology of peritonitis – breakdown based on the main categories.



NOTE – I Centri che hanno riportato un numero di agenti etiologici inferiore a quello globale sono risultati 8 per un numero di peritoniti inferiore di 17: sono stati considerati come casi NON specificati. I Centri che invece hanno riportato un numero superiore sono risultati 15 per un numero di casi in eccesso di 18 e NON sono stati considerati per l'analisi dell'etiologia. Un Centro non ha riportato il dato. Da notare che la differenza tra difetto ed eccesso è di 1, un valore che non incide assolutamente sull'incidenza globale.

Figure 24: etiology of peritonitis in detail.

### Encapsulating peritoneal sclerosis (EPS)

Of the 7 new episodes of EPS reported during the period 2020-22, 5 were diagnosed in the course of PD and 2 following transfer to HD. No cases were reported following a transplant (Figure 25).

A separate paper in this number is dedicated to discussing this finding, which is similar to 2019, but in constant decline.



Figure 25: sclerosing peritonitis over time. For 2022 only the number of extracted cases is reported.

### PET

Peritoneal permeability is assessed by most of the Centers (88.1%). although the number of Centers which do not consider it has grown further (2.2% in 2010 vs 11.9% in 2022).

For some time now the most widely-used method is 3.86%-PET rather than Twardowski's 2.27%-PET (Figure 26). The number of Centers measuring peritoneal permeability using more sophisticated techniques or in another way increased.

The Centers using 3.86%-PET are larger, with a lower drop-out due to UFF/insufficient clearance (Figure 27).



Figure 26: assessment of peritoneal permeability with the various methods.



Figure 27: characteristics of the Centers divided on the basis of assessment of peritoneal permeability adopted and incidence of drop-out due to UFF or poor clearance.

### PD for heart failure

The Census considers separately new patients to PD on NON renal grounds (GFR > 15 ml/min/1.73m<sup>2</sup>). The main non-renal reason remains treatment for heart failure (PUF), which regarded 66 patients in 44 Centers in 2022. The data is unchanged with respect to 2010 (Figure 28). In these Centers, with a larger PD program and greater use of Assisted PD, PUF represents 15% of new patients to PD (Figure 29).



Figure 28: use of PUF (PD in refractory heart failure (HF) at GFR > 15 ml/min/1.73m<sup>2</sup>) compared with 2010.

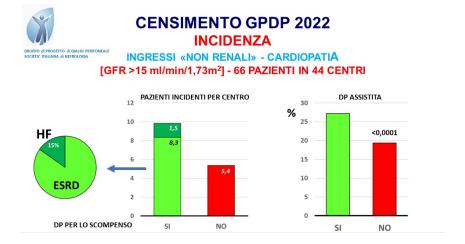
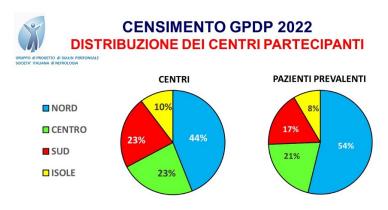


Figure 29: characteristics of the Centers which use PD for refractory heart failure (HF).

### Analysis of the Centers

Mean incidence was 5.9 patients per Center and mean prevalence 18.3 patients per Center, with considerable variability between one Center and another (Figure 30). Most of the Centers involved and of the prevalent patients are concentrated in the North (102 Centers, 45%). Figure 31 shows the geographical distribution.

The 2022 Census considered various aspects which characterize PD Centers. The data is being analyzed and will be published soon.



ATTENZIONE – Abruzzo e Molise, contrariamente al passato, sono inseriti nella macroarea SUD, secondo le categorie ISTAT (in passato era stato seguito il criterio di rispettare le sezioni SIN per la quale la sezione A.La.M.M.U. comprende appunto Abruzzo e Molise).

Figure 30: distribution of centers and patients by Macro area.





Figure 31: breakdown by incidence and prevalence of the PD Centers which took part in the 2022 Census.

### Discussion

### Limitations and new features

The PD Census – at its 8<sup>th</sup> edition counting 2022 – represents the result of a constant organizational effort by GPDP-SIN and all the PD points of contact in the Centers in Italy using PD. Following the difficulties of the last edition caused by the pandemic, PD Center participation in 2022 was once again 100%.

As has been reiterated several times, its main limitation lies in the fact that it is a photograph of the Centers which perform PD alone, though this is also its raison d'être. A second limitation results from the growing difficulty the PD points of contact have in sending even the most basic information relating to patients on HD in their Centers. Found for the first time in 2016, the number of Centers not sending HD data reached 22% in 2022.

A third limitation is the calculation of follow-up. With the data available, prevalence at the end of the year, new patients to PD and drop-outs the follow-up has always been calculated by subtracting from and adding to end-of-year prevalence half of the new patients to PD and half of the drop-outs recorded in the year respectively. This system has been preferred to considering the mean between current prevalence and prevalence recorded at the time of the previous Census (a system only used in calculating the incidence of EPS) due both to the interval in between, at times 3 or more years, and – at least initially – the lack of historical data. As usual, however, we report the absolute patient and event values so that anyone who wishes to perform recalculations can do so. It should be remembered only that the system adopted is the most "anti-economic" in that it leads to an underestimation of the follow-up, and therefore an overestimation of the incidence of events. Despite this, it has been shown that the results of PD in Italy are more than valid.

The most important new feature is represented by the new system for collecting the data by means of a dedicated program that can be used to send it in aggregate form. This system has greatly reduced data incongruence and has increased the information available, enabling increasingly detailed processing. As it is not yet used by all the Centers, however, traditional calculation and processing methods have been applied in this edition to all the Centers.

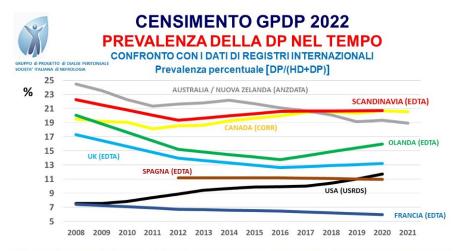
### Use of PD

The number of incident and prevalent patients on PD is decreasing: compared to 2016, in 2022 there was a fall in the total number of incident patients of 15.4%, and in the number of prevalent patients of 9.9%. Percentage incidence and prevalence – calculated only for the Centers which sent HD data – are also dropping: compared to 2016, incidence fell from 24.0% to 19.8% and prevalence from 17.4% to 14.9%. It should be remembered furthermore that these percentage values refer only to the Centers using PD. If the number of prevalent patients on PD in 2022 is related to dialysis (HD + PD) prevalence data in Italy (estimated by the Italian Dialysis and Transplant Register to be 811 patients per million inhabitants (pmp) for 2019 [9]), then PD prevalence in Italy is 8.7% (Figure 32), which is disheartening in comparison with other Western countries (Figure 33) (Figure 36 – A) [10–13], where the percentage prevalence is higher, not diminishing, and at times continuously increasing, as in the USA.

The reduction in prevalence has involved different regions and macro-areas to a variable degree (Figure 34) (Figure 35).



Figure 32: PD pmp prevalence in relation to the total (HD + PD) reported by the Italian Dialysis and Transplant Register. The percentages show the relationship between the two prevalences. It is to be remembered that, unlike RIDT, the Census does NOT include pediatric patients.



NOTE – Il Canada è senza il Quebec (reinserito negli ultimi 2 anni, qui non considerato) – Spagna comprende diverse regioni aumentate nel corso degli anni – Scandinavia = Danimarca, Svezia, Norvegia, Finlandia, Islanda – La Francia nel 2008 riportava i dati di 16 di 26 regioni e nel 2012 riportava i dati di 20 regioni

Figure 33: trend in percentage PD prevalence reported by the main international registers.

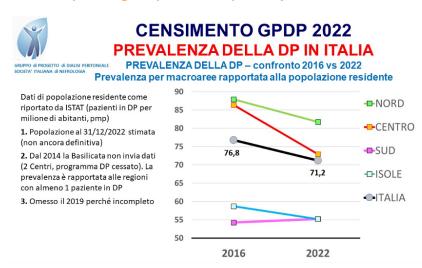


Figure 34: comparison between 2022 and 2016 of prevalence referred to the resident populations in the various Italian Macro areas.



Figure 35: comparison between 2022 and 2016 of absolute value prevalence and referred to the resident populations in the various Italian Regions.



Figure 36: international comparisons. In A absolute value and percentage prevalence reported by several registers. Canada includes Québec since 2020. Scandinavia includes Denmark, Iceland, Sweden, Norway, Finland. In B the outcome data reported by the Registers in France and ANZ.

### <u>Incremental Dialysis</u>

Incremental Dialysis has been investigated ever since the first edition, documenting its characteristics and evolution over time in a manner which is detailed, and still unique – in terms of national Registers – in literature [14]. In 2022 this method grew further due to its greater use in the Centers that already prescribed it, and it seems to increasingly affect the choice of PD method: CAPD for the incremental prescription and APD for full-dose PD. Its use associated with a higher percentage use of PD is confirmed, while an important – but not yet resolved – aspect remains its role in the constant decrease observed in the incidence of peritonitis. Dr. Valerio Vizzardi of the Brescia Center, who has extensive experience in the use of this prescription, examines its importance and limitations in a dedicated annex to this report.

### Assisted PD

This aspect will also be considered separately, though a significant reduction in recourse to Assisted PD is seen for 2022.

As is the case with other aspects, assisted PD is used more in larger Centers. The most common caregiver by far is a family member. In this, the situation in Italy is consistent with that in other countries, except – as is well-known and has already been extensively discussed previously – for France.

### Drop-out from PD

The improvement seen in mortality is confirmed in 2022, while transfer to HD and transplant remain substantially unchanged. Excluding 2019, the year in which the Census was conducted at the height of the pandemic and was as a result incomplete in terms of both number of Centers taking part and information received, it is the first time drop-outs from PD have fallen below 30 episodes per 100 patient years.

Very little register data is available. Compared with ANZ and France, the Italian rate of turnover is the lowest, and mortality is comparable if not better, although burn-out (voluntary withdrawal from dialysis) is significantly lower than in other countries (Figure 36 - B).

Highlighted in terms of causes of drop-out to HD is an increase in catheter malfunction and the impossibility to continue PD. The fact that the data for the latter differ from France and ANZ is likely to be due to their more limited definition of the category.

A possible association with the lesser role of the Nephrologist in placement and the less frequent recourse to Assisted PD recorded in 2022, however appealing, remains to be established.

The reduction over the years in drop-out due to peritonitis is confirmed, consistent with the decrease observed in the incidence of peritonitis.

Finally, if drop-outs due to insufficient clearance and UFF are considered together, they are superimposable with the situation in other countries (Figure 36 - B).

### **Peritonitis**

The incidence of peritonitis fell in 2022 to 0.176 episodes/patient year. Essentially, it has dropped from 5 episodes per patient-year in the 80s to less than 1 episode every 5 years. In particular, the incidence of peritonitis has almost halved from the first Census in 2005 (1 episode every 36 months) to today (1 episode every 68 months). This value is among the lowest recorded in the West, and is markedly lower than the maximum target recommended by the 2022 ISPD guidelines [15] and consistent with world trends for this complication (Figure 37) [16].

As regards the etiology too, which was investigated in a complete manner for the first time, the Census data are consistent with what has been observed in other Registers and multi-center studies [17–19].

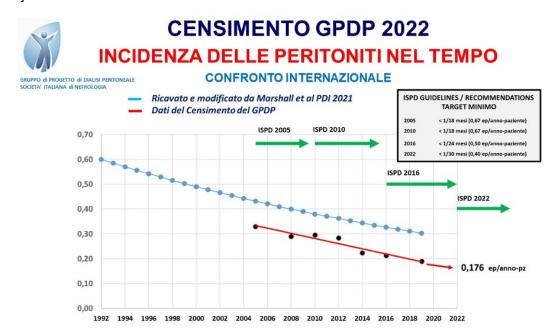


Figure 37: trend in peritonitis over time. Register data sourced from Marshall et al [16]. The maximum ISPD – 2022 guideline targets are reported, along with the comparison with the GPDP Census data.

### **EPS**

The 2022 data seem to confirm the major reduction in this PD complication, limited as it was to just a few cases in PD and in HD. This data is controversial – and in certain respects dangerous – because it could lead to less attention being given to the complication in PD to be feared most, so it was worthy of the in-depth analysis carried out by Prof. Guido Garosi and Dr. Nicoletta Mancianti attached to the Report.

### Assessment of peritoneal permeability

The monitoring of peritoneal permeability, and the way in which it is done, is an important PD program quality indicator. The Census data show a constant increase over the years in the use of 3.86%-PET, from 15.6% of the Centers in 2010 to 57.7% in 2022. Contributing to this success has certainly been the research carried out by Dr. Vincenzo La Milia, who has examined the reasons in an annex to the Report.

### PD due to refractory heart failure

When terminal-stage heart failure is reached, treatment of congestion by means of PD represents a possible solution which was already proposed many years ago. The experience reported in literature [20–21] shows clear positive effects on symptomatology, quality of life and admissions to hospital. Indications on when to start the therapy still remain uncertain, and a real comparison with HD is practically impossible, although the data do not show significant differences. The Census highlights an important aspect associated with this therapy. Over a period of more than 10 years, its use in Italy remains relegated to the same number of Centers and for the same number of patients. The Centers that use it are larger and make greater use of assisted PD.

### Center Effect

The number of Centers which use PD has remained substantially the same over the years. In various aspects of PD examined (Incr-PD, drop-out to HD, assisted PD, non-renal PD, PET), it seems that the so-called "Center effect" – in short, size of PD program (prevalent patients) – is important: the larger the program, the better the use and results of PD seem to be. The 2022 Census investigated in greater detail the characteristics of Centers, such as the presence of dedicated doctors and nurses, the availability of dedicated premises and of a home visit program, training methods. A detailed analysis of this important aspect is underway for forthcoming publication.

### **Conclusions**

The PD Census relating to 2022 confirms the quality of PD in Italy in terms of prescription elasticity, reduction in mortality, reduction in peritonitis and EPS, the still extensive recourse to Assisted PD, although this is on the decrease, and monitoring of the peritoneal membrane. However, the use of PD seems to be diminishing. Limited as it is to PD Centers, the Census does not make it possible to identify the reasons for this fall. It just highlights its contrast with the results obtained. Thanks to the active participation of the PD contacts in the individual Centers, the Census confirms itself as a valid, constantly-developing tool for knowing the actual situation.

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