Rapport Activités du Collège – 2018 – Part 2

Résultats d'une étude avec les centres de traitement de l'insuffisance rénale chronique et les Registres néphrologiques belges (GNFB et NBVN) concernant le placement de patients en dialyse sur la liste d'attente pour une greffe de rein – 2018.1; et concernant la faisabilité d'une visite d'inspection du centre de dialyse – 2018.2

1. Study project 2018.1: what are the obstacles to put dialysis patients, aged between 18 and 64 years of age, on the transplant waiting list ?

1.1 Introduction

A kidney transplant is considered the best form of non-curative renal replacement therapy in terms of both efficiency and quality of life, and at a less expensive cost than a continued treatment with dialysis.

The importance of "kidney transplantation" is recognized in the recently ratified agreement about "dialysis financing"; the number of transplants of the last 3 years is included in the formula for calculating the percentage of "low care / low cost" renal therapies.

The NBVN as well as the GNFB registry have repeatedly shown that on average "only one third" of the dialysis patients aged 18 to 65 years, are **actively** waiting on the Eurotransplant [ET] kidney transplant waiting list [Table 1], whereas, intuitively, a much higher percentage would be expected. There might even be a decreasing trend.

Table 1: Prevalence of the active ET kidney (Ki) transplant waiting list and dialysis patients covered in the NBVN and GNFB registries – all ages and age category 18-64 years.

Belgium	*All ages* **active** total Ki WL Belgium	*All ages* ***active*** *Ki-only WL* Belgium	*All ages* ***active*** *Ki+Pa WL* Belgium	18-64 yrs ***active*** Ki-only WL Belgium	18-64 yrs dialysis patients Belgium	18-64 yrs dialysis patients NBVN	18-64 yrs dialysis patients GNFB	18-64 years % dialysis patients **active** on the WL
01/01/2012	883	***837***	*19*	**740**	**2204**	1277	927	**33.5% (Belgium)**
01/01/2013	791	***748***	*26*	**648**		1199	NA	
01/01/2014	770	***721***	*31*	**632**		1210	NA	
01/01/2015	878	***821***	*40*	**691**		**1197**	NA	**36% (NBVN)**
01/01/2016	871	***813***	*37*	**687**		**1182**	NA	**32% (NBVN)**
01/01/2017	797	***742***	*30*	**640**		1155	NA	
01/01/2018	849	***793***	*25*	**677**	**2688**	**1134**	**1554**	**25.0% (Belgium)**

1.2 Aim

1. Survey of the reasons, prohibiting dialysis patients from being listed on the kidney transplant waiting list – age category – 18-64 years of age – reference date – January 1, 2018 [NBVN].

2. Survey of the time flow, starting from the proposal "transplant option" to the final active waiting status on the ET waiting list, considering all 'intermediate stations' (start investigations, registration transplant center, additional interventions, registration at Eurotransplant, …) [GNFB].

1.3 Results

1.3.1 – Causes of non-listing on the ET waiting list - NBVN

A. Background:

On January 1, 2018, 1138 patients – aged 18-64 years – were treated with dialysis, either hemodialysis or peritoneal dialysis, in the NBVN organization. This population corresponds to only 24% of the total dialysis population [N=4701]. One large center didn't submit the requested data (77 patients – aged 18—64 years). The analysis was done on the total of 1061 patients.

NBVN Age: 18-64 years	ET-Waiting list Transplantable **"callable"**	ET-Waiting list Not-transplantable **"not callable"**	Not on the ET Waiting list	Total	Centers
1/1/2015	378 – 36%	201 – 19%	466 – 45%	1045	25 / 26
1/1/2016	323 – 32%	147 – 15%	531 – 53%	1001	23 / 26
1/1/2018	331 – 31%	90 – 8%	640 – 60%	1061	25 / 26

The number of actively waiting dialysis patients decreased slightly over the recent years. The large difference between the categories "Not-transplantable" and "Not on the ET Waiting list" might be due to a misconception of the word "not transplantable", mixing its clinical and administrative meaning.

B. Characteristics of the dialysis population aged 18-64 years

The age group 55-64 years is the largest group of the dialysis population 18-64 years [N=544; 57%] and has the highest percentage dialysis patients not listed on the transplant waiting list [N=369; 68%] – Figure 1.

Age group	**Transplantable** "callable"	**Not-transplantable** "not callable"	**Not on the waiting list**	**Total dialysis patients**	
18-24	10 – 48%	3	8 – 38%	21	*2%*
25-34	35 – 49%	7	30 – 42%	72	*7%*
35-44	62 – 45%	15	61 – 44%	138	*13%*
45-54	92 – 32%	22	172 – 60%	286	*27%*
55-64	132 – 24%	43	369 – 68%	544	*57%*
Total	**331 – 31%**	**90**	**640 – 60%**	**1061**	*100%*

There is no difference regarding gender.

The distribution of the underlying kidney disease varies considerably per age category, but the age group explains the percentage "Not on the waiting list" to a better extent. Patients with cystic kidneys (ADPKD), immunological kidney diseases and diabetic nephropathy in the context of type 1 diabetes mellitus are often younger and have the lowest percentage "Not on the waiting list". Patients with diabetic nephropathy in the context of type 2 diabetes mellitus are older and have, as such, a clearly higher percentage "Not on the waiting list".

Renal disease	Transplantable "callable"	Not-transplantable "not callable"	Not on the waiting list	Total dialysis patients	
Immunological glomerulonephritis	94	17	119 – 52%	230	*22%*
Tubulo-interstitial nephritis	39	7	93 – 67%	139	*13%*
Type 2 diabetes	23	13	102 – **74%**	138	*13%*
Vascular disease	31	12	75 – 64%	118	*11%*
Unknown	31	11	72 – 63%	114	*11%*
Cystic kidneys	46	13	33 – **36%**	92	*9%*
Other renal disease	23	5	48 – 63%	76	*7%*
Type 1 diabetes	24	5	41 – 59%	70	*7%*
Hereditary renal disease	17	3	31 – 60%	51	*5%*
Irreversible acute kidney failure	2	3	18 – 78%	23	*2%*
Cardiorenal syndrome	1	1	8 – 80%	10	*1%*
Total	**331**	**90**	**640 – 60%**	**1061**	*100%*

No analysis was done with regard to the time the patients were already on dialysis [dialysis vintage].

It should be noted that potential candidates for a kidney transplant are hardly put on the ET transplant waiting list before starting dialysis.

Because the allocation factor "waiting time" is calculated from the start of the (last) dialysis period in the ET kidney allocation program [change made in 1999] and the allocation factor "waiting time" substantially impacts the position on the final allocation list in the event of a suitable kidney donor, pre-emptive placement on the waiting list or accelerated placement after the start of dialysis is less mandatory to speed up a selection because the waiting time is either absent or very low.

C. Reasons – Not on the waiting list

The College survey (completed by 23 of the 26 dialysis centers) showed some corrections about transplantability status with regard to the earlier NBVN survey. Lesser patients were on the renal transplant waiting than initially reported.

The total patients not being on the waiting list amounted to 632 patients – no information was given on 17 patients. The analysis population consisted of 615 patients – Figure 2.

One quarter of the dialysis patients is either currently involved in an assessment of the candidacy for a renal transplantation (20% - N=136) or awaiting the final registration at the Eurotransplant waiting list (5% - N=31). Not surprisingly this is particularly the case among the

patients aged less than 45 years and/or having either a renal cystic disease or immunological renal disease.

Reasons of non-listing on the transplant waiting list (N, %)		
No ongoing transplant evaluation	448	73%
Ongoing transplant evaluation	**88**	**14%**
Transplant evaluation finished – awaiting evaluation by the transplant center	**7**	**1%**
Following visit transplant center, extra examinations ongoing / additional surgery planned	**41**	**6%**
Awaiting registration on the Eurotransplant waiting list	31	5%
Total	615	100%

A medical contra-indication is the main reason why patients are not involved in an evaluation for a transplantation [73%].

Besides truly somatic or mental issues, several centers stressed upon the "unchangeable" non-compliant behavior with regard to smoking, drinking of alcohol or use of illicit drugs.

Some patients have been evaluated by the dialysis centers but were declined as a suitable transplant candidacy following evaluation by a transplant center. The current analysis does not provide information on the acceptance and refusal rate by the transplant centers, upon referral of a patient for evaluation.

Fifteen percent of the patients declared not to be interested to be transplanted, regardless of their age.

No ongoing transplant evaluation due to (N, %) :		
Medical contra-indication : somatic and/or mental illness, persistent non-compliant behavior (smoking, use of alcohol, use of illicit drugs, …)	**307**	**69%**
Decline by the transplant center after visit	**19**	**4%**
No interest of the patient, though potential candidate	69	15%
Immigrant – no legal residence permit	**37**	**8%**
Other - potential recovery of renal function - just transferred from another dialysis center - on waiting list outside Belgium	16	4%
Total	448	100%

Several dialysis patients could not be evaluated due to their immigrant status, and their corresponding lack of an official health insurance. As long as these patients don't have a residence permit, the Belgian transplant centers are obliged to refrain them from any transplant evaluation. As such, many (young) patients are condemned to a long (and more expensive) dialysis period, due to the lengthy procedure of the Immigration Office.
On the other hand, as long as the return to their land of origin is pending, it might not be wise to transplant the patients in the meantime, since anti-rejection medication might not be available in their land of origin, provided they have to go back; the fate of their renal transplant might be comprised upon return.

For some patients, an evaluation of transplant candidacy is not appropriate since there is a reasonable chance of recovery of their renal function with potential freedom from dialytic treatment.

Figure 1 : Distribution of the dialysis patients on the waiting list for kidney transplantation

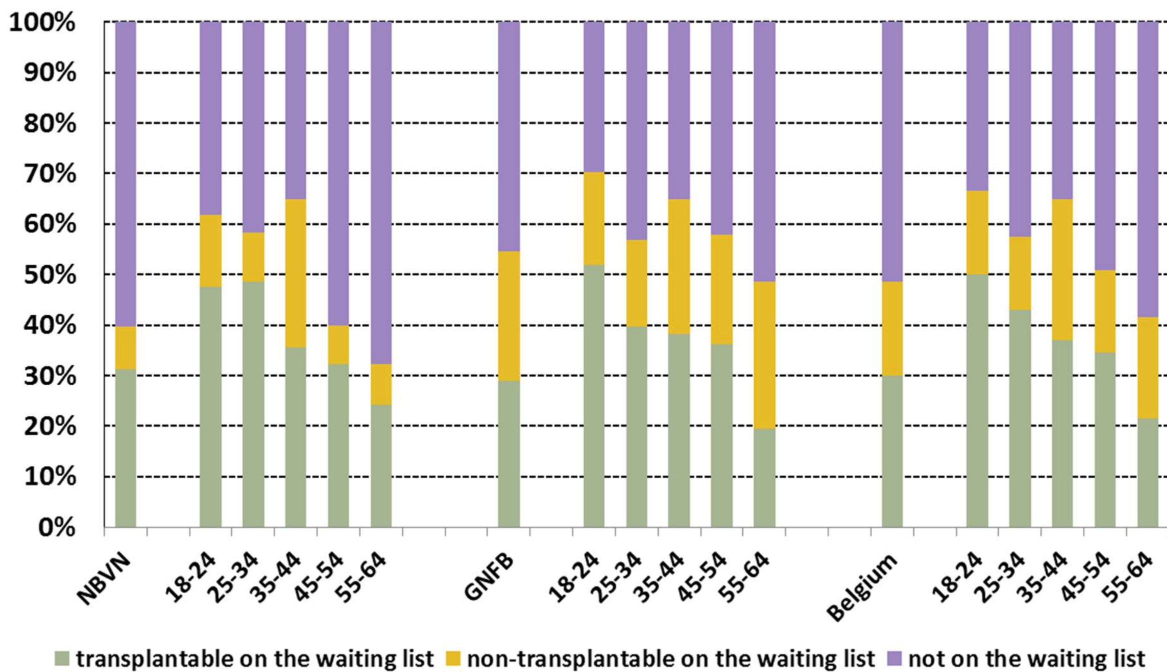
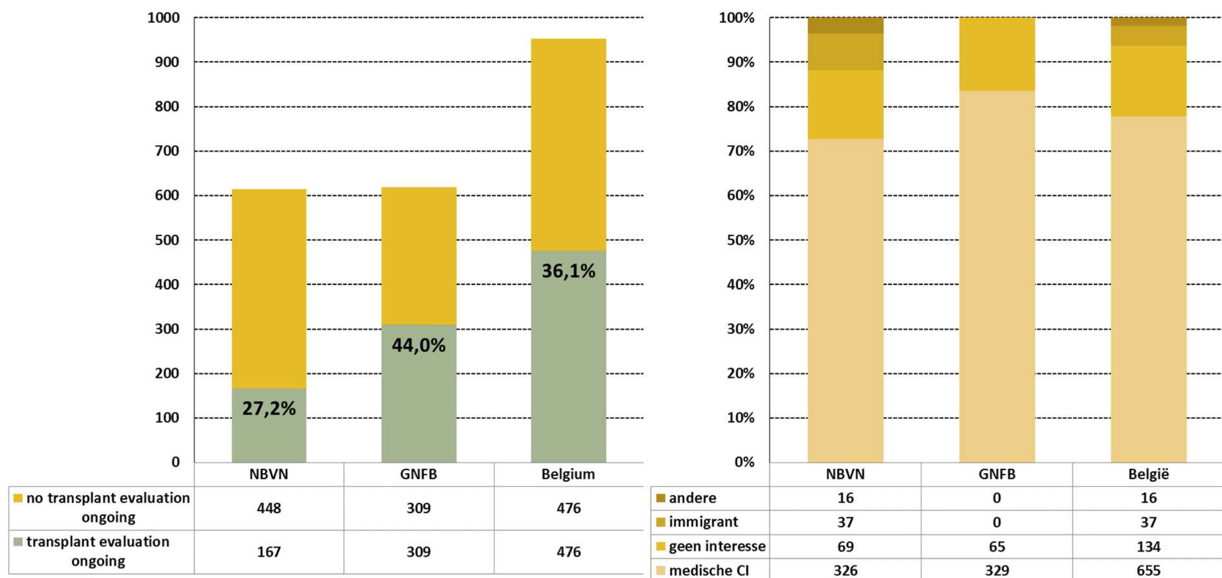


Figure 2 : Distribution of the reasons why the dialysis patients are not on the renal transplant waiting list



1.3.2 – Causes of non-listing on the ET waiting list - GNFB

A. Background:

On January 1, 2019, 1549 patients – aged 18-64 years – were treated with dialysis, either hemodialysis or peritoneal dialysis, in the GNFB organization. This population corresponds to 34% of the total dialysis population [N=4429].

NBVN Age: 18-64 years	ET-Waiting list Transplantable **"callable"**	ET-Waiting list Not-transplantable **"not callable"**	Not on the ET Waiting list	Total	Centers
1/1/2019	449 – 29%	397 – 26%	703 – 45%	1549	35/35

In comparison with NBVN, the percentage of patients being on the transplant waiting list but with a non-transplantable status is much higher, ie. 26% versus 9%. Notwithstanding, the percentage actively waiting patients is similar – 29% GNFB versus 31% NBVN.

B. Characteristics of the dialysis population aged 18-64 years

The age group 55-64 years is also the largest group of the GNFB dialysis population 18-64 years [N=741; 48%] and has also the highest percentage dialysis patients not listed on the transplant waiting list [N=369; 68%].
The percentages 'transplantable' per age group are comparable to those of the NBVN – Figure 1.

Age group	Transplantable "callable"	Not-transplantable "not callable"	Not on the waiting list	Total dialysis patients	
18-24	14 – 52%	5	8 – 30%	27	*2%*
25-34	46 – 40%	20	50 – 43%	116	*7%*
35-44	87 – 38%	61	80 – 35%	228	*15%*
45-54	158 – 36%	95	184 – 42%	437	*28%*
55-64	144 - 19%	216	381 – 51%	741	*48%*
Total	**449 – 29%**	**397**	**703 – 45%**	**1549**	*100%*

C. Reasons – Not on the waiting list

The total number of GNFB patients not being on the waiting list amounts to 703 patients – Figure 2.

Forty percent of the dialysis patients is either currently involved in an assessment of the candidacy for a renal transplantation or awaiting the final registration at the Eurotransplant waiting list (44% - N=309).

Reasons of non-listing on the transplant waiting list (N, %)		
No ongoing transplant evaluation	394	56%
Ongoing transplant evaluation	**309**	**44%**
Total	703	100%

A medical contra-indication is the main reason why patients are not involved in an evaluation for a transplantation [83%].
In a subset of the patients, it was found that the majority of the patients had more than one medical problem, excluding them from transplantation (cardiovascular, behavioral, treatment pathogenicity, non-cardiovascular).

Seventeen percent of the patients declared not to be interested to be transplanted, regardless of their age.

No ongoing transplant evaluation due to (N, %) :		
Medical contra-indication : somatic and/or mental illness, persistent non-compliant behavior (smoking, use of alcohol, use of illicit drugs, …)	**329**	**83%**
No interest of the patient, though potential candidate	65	17%
Total	394	100%

No information was collected about the dialysis patients with an immigrant status.

1.3.3 – Trajectory from patient selection till listing on the active waiting list - GNFB

In addition, the GNFB evaluated the workflow from the transplant proposal to the patient till the registration on the ET kidney transplant waiting list, in a patient cohort 2011-2018.

Two scenarios were evaluated:
- pre-emptive listing prior to the start of dialysis [112 patients]
- listing after the start of dialysis [349 patients].

In this analysis there was no age restriction.

1.3.3a. Successful listing on the kidney transplant waiting list – prior to the start of dialysis.
On average the patients were listed 10 months (IQR 3 – 15 months; median 7 months) before the start of dialysis. Forty-nine patients got their transplant in the period 2011-2018 - after an average of 31 months on dialysis (IQR 3 – 44 months; median – 23 months).

1.3.3b. Successful listing on the kidney transplant waiting list – after the start of dialysis.
On average the time between the start of dialysis and the registration on the transplant waiting list was 19 months (IQR 6 – 24 months, median 13 months). No information was retrieved on the time point upon which one started the pre-transplant work-up after the start of dialysis.
The total dialysis time till transplant (154 patients) was on average 38 months (IQR 2 – 50 months; median 35 months).

In conclusion, one should aim at starting the transplant work-up and listing the patient on the transplant list prior to the start of dialysis, since this approach will in general shorten the time on dialysis (median 23 months (listing prior to dialysis) versus median 35 months (listing after start dialysis). As such, there is a psychological and economical benefit.

1.4. Conclusion

The option "survival benefit through kidney transplantation" can only be offered selectively to the dialysis population, theoretically suited to the age criterion of 18-64 years.

Medical contraindications and non-compliance behavior are the main reasons for not preparing patients for a kidney transplant.

Fortunately, about one third of the Belgian dialysis patients not on the waiting list is indeed in an active evaluation process or just finished it. This constant flow in the assessment of dialysis patients as potential transplant candidates demonstrates a positive attitude towards renal transplantation among the dialysis centers. One recommendation can be formulated : this evaluation for a renal transplant should be planned prior to the start of dialysis, since it might in general reduce the time till listing and also the time on dialysis. This will result also in an economical benefit on behalf of the government (ie. lesser time in dialysis) and in a better psychological state on behalf of the patient,

All Belgian kidney transplant centers have a guideline for examining a (pre-)dialysis patient for the purpose of a successful kidney transplant. In addition, clear information how to select

suitable dialysis patients aiming at such a successful kidney transplantation is available in the European Renal Best Practice, under the auspices of the ERA-EDTA organization[1].

A more structured questionnaire why the "kidney transplant" option was excluded might serve as an additional quality indicator of the care performance of a dialysis center. However, the College doubts the added value of such an interrogation.

Any dialysis patient being listed on the kidney transplant waiting list requires constant evaluation of his/her persistent suitability by the local nephrologists and by the transplant center to ensure a successful renal transplantation on behalf of the recipient. Various kidney transplant centers have opted for a "return day" in order to "check" this recipient suitability, but also to refresh what to do upon the call that a donor kidney is available, the transplant procedure and the follow-up after transplant.

There is a significant difference concerning the percentage patients registered as 'non-actively' waiting on the renal transplant waiting list. Strictly spoken, the "passive" state is reserved for the 100% suitable transplant candidates who are temporarily not available for a transplant due to an intervening situation (e.g. medical illness / surgery, holiday, …). On the other hand, it is not unlikely that transplant centers register immediately all the potential transplant candidates on the transplant waiting list using the code 'non-transplantable'; once the candidates are considered to be 100% suitable for a transplant, they are activated and put as 'actively waiting – "callable" ' on the waiting list. In the latter case much more patients are listed – but not actively waited. Within the Eurotransplant organization the number of non-actively waiting transplant candidates is no longer published.

Finally, according to this study, the Belgian nephrologists are well aware to the option of transplantation, and there is no major indication that suitable dialysis patients are unnecessarily refrained from this option.

1.5. Recommendations

1. **Patients with nearly end-stage kidney failure and who are probably good candidates for a renal transplant, should be evaluated prior to the start of dialysis.**

2. **Patients should be registered on the kidney transplant waiting list, only as of the moment they are truly considered to be a suitable candidate and can be actively waiting for a renal transplant.**

[1] Abramowicz D, Cochat P, Claas FH, Heemann U, Pascual J, Dudley C, Harden P, Hourmant M, Maggiore U, Salvadori M, Spasovski G, Squifflet JP, Steiger J, Torres A, Viklicky O, Zeier M, Vanholder R, Van Biesen W, Nagler E. European Renal Best Practice Guideline on kidney donor and recipient evaluation and perioperative care. Nephrol Dial Transplant. 2015 Nov;30(11):1790-7.

2. Study project 2018.2 : Analysis of the feasibility of an inspection visit of the dialysis centers - NBVN

The aim is to investigate to what extent the visitation of a dialysis center might contribute to the improvement of the quality of dialysis care, in addition to the existing initiatives of the Flemish, Brussels and Walloon governments, and to the Federal instructions. Implications in terms of organization, financing and reporting must be investigated in advance prior to its implementation.

2.1 Evaluation by the GNFB: this communication will follow in December 2019

2.2 Evaluation by the NBVN:

A. Initiative created by the NBVN

In 2018, a center review report was elaborated at the level of the individual dialysis center, in which 5 quality indicators were evaluated. The selection of these quality indicators was based on the experience of the Nefrovisie organization that groups the Dutch dialysis centers : epidemiology of the dialysis patients, survival of the dialysis patients, dialysis access of the hemodialysis patients, listing on the transplant waiting list and renal function upon start of chronic dialysis [or indication for chronic dialysis]. There is a major variation of these quality indicators among the NBVN dialysis centers.

This center review report will be offered to the NBVN dialysis centers in May 2019.
However, a procedure how to deal with and to evaluate so-called positive and negative out-layers has not yet been designed by the NBVN Board of Directors.

B. Initiatives of the Flemish government – department Welfare, Public Health & Family – Healthcare inspection.

The Healthcare Inspectorate of the Flemish government is already carrying out various visitations. The philosophy of these inspections focusses on 2 processes:

- ✓ system supervision - focused on structure, process and quality systems - this is currently been handed over to accreditation organizations - see below.
- ✓ compliance monitoring - focused on the concrete assessment of care processes (surgical, internal - cardiology, mother & child, etc.). Such visits are not announced on beforehand.

It should be noted that a specialized care monitoring process looking at the dialysis patient is currently under development. Hopefully the NBVN organization will be consulted when drawing up the requirement framework.

C. Overview of the hospital accreditation of the NBVN dialysis centers

All 26 NBVN dialysis centers (high-care dialysis) reside in a hospital, having an active accreditation, issued either by JCI or by NIAZ-Qmentum.

JCI – Joint Commission International	NIAZ – Qmentum
Aalst, OLV ziekenhuis	Bonheiden, Imeldaziekenhuis
Antwerpen, AZ Monica	Brugge, AZ Sint-Lucas
Antwerpen, GZA Sint-Augustinus	Gent, AZ Sint-Lucas
Antwerpen, UZ Antwerpen	Gent, UZ Gent
Antwerpen, ZNA *(has also a separate ISO-9001 certificate for the dialysis department and outpatient clinic)*	Hasselt, Jessaziekenhuis
Brugge, AZ Sint-Jan	Lier, H.-Hartziekenhuis
Brussel, UZ Brussel	Malle, AZ Sint-Jozef
Dendermonde, AZ Sint-Blasius	Sint-Niklaas, AZ Nikolaas
Genk, Ziekenhuis Oost-Limburg	Turnhout, AZ Turnhout
Gent, AZ Maria Middelares	
Ieper, Jan Yperman Ziekenhuis	
Kortrijk, AZ Groeninge	
Leuven, UZ Gasthuisberg	
Roeselare, AZ Delta	
Ronse, AZ Glorieux	
Sint-Truiden, Sint-Trudo Ziekenhuis	
N= 2909 dialysis patients – 64%	**N= 1612 dialysis patients – 36%**

There is no information available about the Kliniek Sint-Jan / Clinique Saint-Jean, in the Brussels-Capital Region.

D. Advice

The Netherlands has a lot of experience with the procedure of visitation of a dialysis center made by an ad hoc peer-review committee, consisting of nephrologists and dialysis nurses, and checking the basic prerequisites of renal care – drafted by the dialysis community (www.nefrovisie.nl/visitatie-certificering), in addition to a concomitant certification by an external certification body - such as NIAZ-Qmentum or HKZ.

Because of the emergence of a more hospital-wide accreditation in The Netherlands, one questions about the content and necessity of this dialysis-specific accreditation, due to the large overlap between the two accreditation programs.

In Belgium, the direction of inspection would be reversed. Is there a need for a more specific visitation of a dialysis center, apart from the broader hospital inspection ? The Flemish initiative to implement such a specific inspection is currently prepared at the department of Welfare, Public Health & Family.

We recommend that the dialysis centers, with its nephrologists and renal nurses, are consulted in time. The NBVN organization is currently not involved in this project.

So, the implementation of inspection visits – designed and governed by the College of Nephrologists – might be superfluous till further notice.

Namens het college,
Au nom du collège

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