

ANNUAL REPORT 2019

The Norwegian Renal Registry (Norsk Nyreregister)

This report will also be available on:
<http://www.nephro.no/registry.html>

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History and Organization of Norwegian Renal Registry (NRR)

The Norwegian Renal Registry is an epidemiology quality registry for patients with severe renal disease. Inclusion in the registry is based on written informed consent and patients are followed for their entire life course. Patients in whom a diagnostic kidney biopsy is obtained or who have developed chronic kidney disease stadium 5 (CKD5) are included in the registry. Acute kidney failure patients are not included in the registry unless they develop chronic kidney failure (dialysis > 3 months).

The current version of NRR is a merge in 2016 of the Norwegian Nephrology Registry and the Norwegian Renal Biopsy Registry and consists of two sections; Section for dialysis and transplantation (at Oslo University Hospital) and Section of kidney biopsy (at Haukeland University Hospital). In the merge all historic data from the Norwegian Nephrology Registry was continued, while historic data from the Norwegian Renal Biopsy Registry was not eligible for transfer into the new registry. The historic biopsy data is however still available for analyses.

The Norwegian Nephrology Registry was formally constituted in 1994 as a collaboration between The Norwegian Renal Association (Norsk Nyremedisinsk Forening) and Oslo University Hospital-Rikshospitalet, with the latter as the formal owner. National data on renal replacement therapy (RRT) had been collected within The Renal Association since 1980 in a less formalized manner, and the transplant center had stored data on transplanted patients since the late sixties. Further, Norwegian renal units had reported to the ERA-EDTA-registry since the late sixties. Since the mid -90ies, a process of transition from a pure epidemiological registry into a quality-oriented registry has progressed.

Norwegian Renal Biopsy Registry was established in 1988. It has been run by the Renal unit at Haukeland University Hospital. Both, nephrologists and pathologists contributed with data related to non-neoplastic kidney biopsies. The aim of the registry was, first of all, to provide a platform for development of expertise and improvement of quality, second to have a material available for research. In 2012, the registry was acknowledged as one of the national quality registries. From 2012, the registry has been building a digital slide archive of kidney biopsies. In 2015, the registry had collected clinical and pathological data of about 13,000 non-neoplastic kidney biopsies.

National organization and policy

Norway had 5.346 mill. inhabitants (July 2019) and 18 counties with populations ranging from 75,711 to 685,811 inhabitants. Each county has a central renal unit and some have two, further some have satellite units run in close contact with the central unit. There is only one transplant center (two during 1963-82). Pre-transplant work-up, as well as post-transplant follow-up beyond 2 months, is handled by the county-centers. County boarders does not always coincide with the area that the different renal units cover and this report present data based on county boarders as well as divided in RHF and HF levels, whenever appropriate.

During 2017 Finnmark was separated from Tromsø, so now there are 26 centers responsible for reporting data to NRR, and they all do. Each center is responsible to report all patients from whom a diagnostic kidney biopsy is taken and all patients established in CKD5 on a continuous basis (eGFR < 15 ml/min/1.73 m² for more than 2 months). Progression to need of renal replacement therapy (dialysis, transplantation), changes between dialysis modality (PD, "center HD", "home HD"), transfer between centers or immigration/emigration, graft loss and deaths is reported on a continuously basis. During 2019, data from the last visit before December 31st 2019 was to be reported for all CKD5 patients, either if they were not

treated with renal replacement therapy or if they received dialysis or had a functioning renal graft. The overall report rate by the finalization of this report was 98.1%.

Transplantation has always been considered the renal replacement treatment of choice, if possible, with a living related donor. Since 1984, also unrelated donors have been used. Acceptance criteria for transplantation have been wide, strict age limits have not been applied. Over time, an increasing number of non-transplantable patients have also been offered life-long dialysis.

Individual coverage of the registry for the entire cohort is estimated to be at least 92%. Transplanted patients are crosschecked continuously against the transplantation lists at OUS-Rikshospitalet and annual crosschecks against each of the 26 centers lists of dialysis patients are performed per December 31st each year. For patients in renal replacement therapy the individual coverage is close to 100% (currently 38 patients (0.49%) alive without consent). CKD5 patients not treated with renal replacement therapy have only been included in the registry since 2016 and the coverage is improving for each year. Based on prevalence data from the literature it is expected that there is between 550-600 prevalent CKD5 patients not on RRT in Norway. For 2019 this result in an estimated coverage of about 85%. However, considering that some Norwegian centers have reported many patients and some none, this coverage estimate is probably too high. Scaling the prevalence for the top five reporting centers give an anticipated national coverage of about 63%. A coverage analysis of non-neoplastic kidney biopsies has been performed in 2014 and 2015. The coverage was dropping from 89% in 2014 to 71% in 2015 because of a change in the reporting procedure. At regular intervals, reporting of deaths to the registry is checked against the Norwegian National Registry (NO: *Folkeregisteret*).

NNR is one of 51 national medicine quality registries (<https://www.kvalitetsregistre.no/registeroversikt>). NNR has identified 22 quality indicators in order to cover all relevant subgroups of patients in the registry. The quality indicators are reported annually (<https://www.kvalitetsregistre.no/registers/norsk-nyreregister>) These data are in addition included in the present report. A list of all quality indicators can be found here: <https://www.nephro.no/nnr.html>.

Incidence data 2019

During 2019 a diagnostic kidney biopsy with clinical data was available from 573 patients, 329 were reported as new patients established in CKD5 (without RRT) and 602 patients started renal replacement therapy (i.e. 112.6 per mill. inhabitants). The incidence of new patients in renal replacement therapy show an average increase by the year.

Biopsy

Table 1. Number of kidney biopsies per regional health authority

	2015	2016	2017	2018	2019
Helse Sør-Øst	320	297	305	353	346
Helse Vest	172	126	134	137	113
Helse Midt	64	62	54	78	60
Helse Nord	40	47	52	54	54

Helse Sør-Øst: South-Eastern Norway Regional Health Authority

Helse Vest: Western Norway Regional Health Authority

Helse Midt: Central Norway Regional Health Authority

Helse Nord: Northern Norway Regional Health Authority

This does not include neoplastic or transplant biopsies.

Figure 1. Number of native kidney biopsies per hospital in 2019

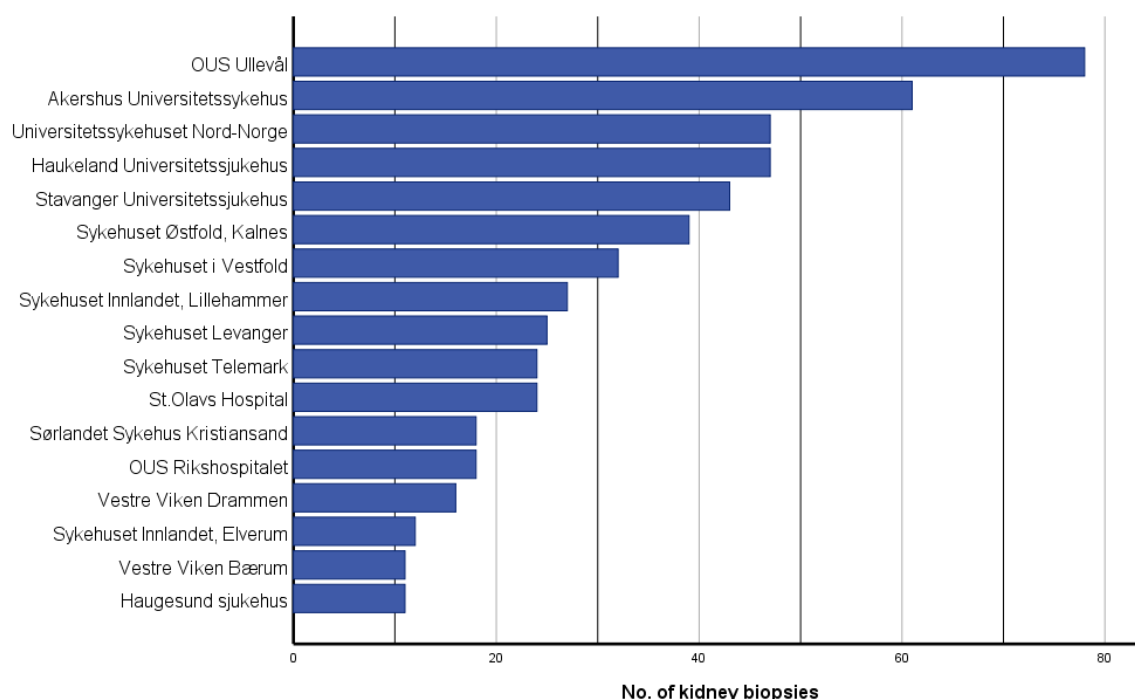


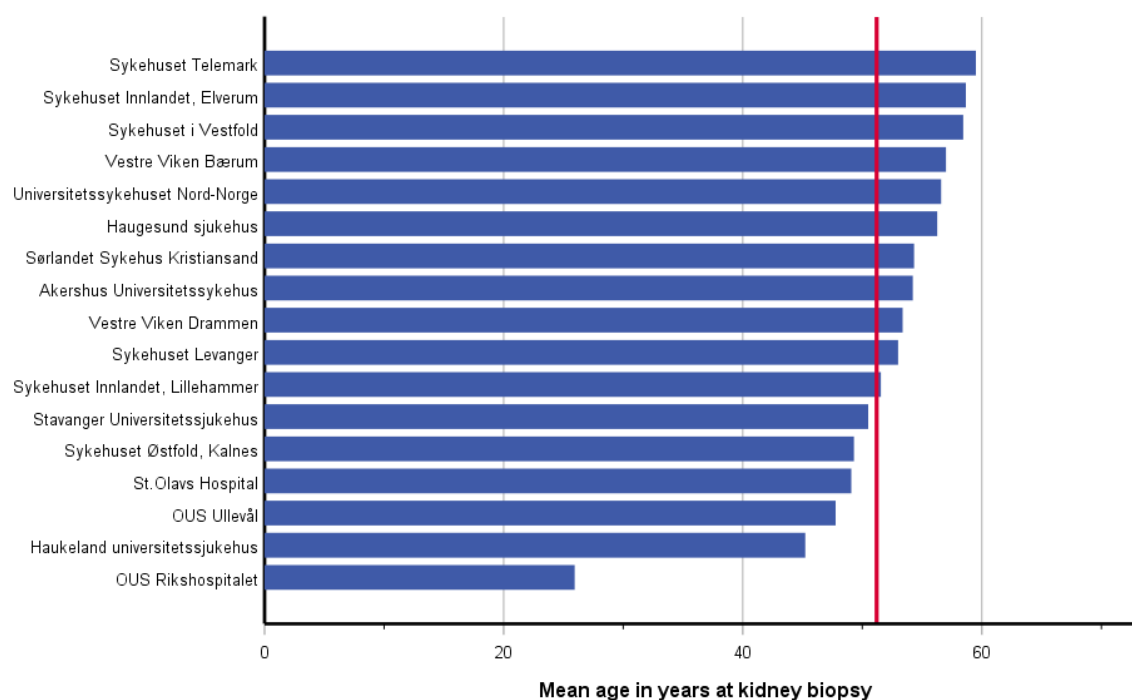
Figure 1 shows the number of kidney biopsies performed per hospital in 2019. Nine hospitals were excluded from the analysis, as they reported less than ten native kidney biopsies in 2019.

Table 2. Mean age at kidney biopsy, per Regional Health Authority

	Helse Sør-Øst N=346	Helse Vest N=113	Helse Midt N=60	Helse Nord N=54	Total N=573
Mean age in years (\pm SD)	51.3 \pm 20.1	49.5 \pm 19.6	51.9 \pm 19.2	56.6 \pm 20.9	51.2 \pm 20.0

Mean age at kidney biopsy in 2019 was 51.2 (\pm 20.0) years (Figure 2), which is comparable to mean age at kidney biopsy in 2018. As in the three previous years, the highest mean age at kidney biopsy was reported in Northern Norway (Helse Nord), while the lowest mean age at biopsy was reported in Western Norway (Helse Vest).

The percentage of kidney biopsies performed in the pediatric age range remained similar to the two previous years; 5.1 % of all kidney biopsies reported were performed in patients under the age of 18 years old. The majority of these biopsies were performed at OUS Rikshospitalet (37.7 %) in Helse Sør-Øst, and 65.5 % of all native kidney biopsies in the pediatric age range were performed in Helse Sør-Øst. 3.7 % of all reported kidney biopsies were performed in patients above 80 years of age, which is similar to 2018. As in 2017 and 2018, most of the octogenarians (66.7%) were biopsied in the South-Eastern Regional Health Authority (Helse Sør-Øst).

Figure 2. Average age at kidney biopsy per hospital in 2019

The red line is set at the national mean age at kidney biopsy.

Table 3. Reported clinical indications for kidney biopsy, number (%) of kidney biopsies in the Regional Health Authorities

	Helse Sør-Øst N(%)	Helse Vest N(%)	Helse Midt N(%)	Helse Nord N(%)	Totalt N(%)
Nephrotic syndrome	50 (14.5 %)	20 (17.7 %)	12 (20.0 %)	12 (22.2 %)	94 (16.4 %)
Nephritic syndrom	54 (15.6 %)	29 (25.7 %)	10 (16.7 %)	13 (24.1 %)	106 (18.5 %)
Acute kidney failure	75 (21.7 %)	24 (21.2 %)	9 (15.0 %)	9 (16.7 %)	117 (20.4 %)
Chronic kidney failure	90 (26.0 %)	18 (15.9 %)	14 (23.3 %)	14 (25.9 %)	136 (23.7 %)
Proteinuria	183(52.9 %)	58 (51.3 %)	24 (40.0 %)	31 (57.7 %)	296 (51.7 %)
Hematuria	125 (36.1 %)	52 (46.0 %)	28 (46.7 %)	16 (29.6 %)	221 (38.6 %)
Other	10 (2.9 %)	2 (1.8 %)	0 (0 %)	0 (0 %)	12 (2.1 %)

It is possible to report more than one clinical indication for biopsy. As a result, the total number of clinical indications exceeds the total number of reported kidney biopsies for 2019. Some regional differences are apparent. Nephritic syndrome was more frequently reported in Western and Northern Norway. An increase in chronic kidney failure as an indication for kidney biopsy was reported in South-Eastern Norway as compared to 2018.

Figure 3. Proteinuria and albuminuria (mg/mmol creatinine) at the time of kidney biopsy in the different Regional Health Authorities

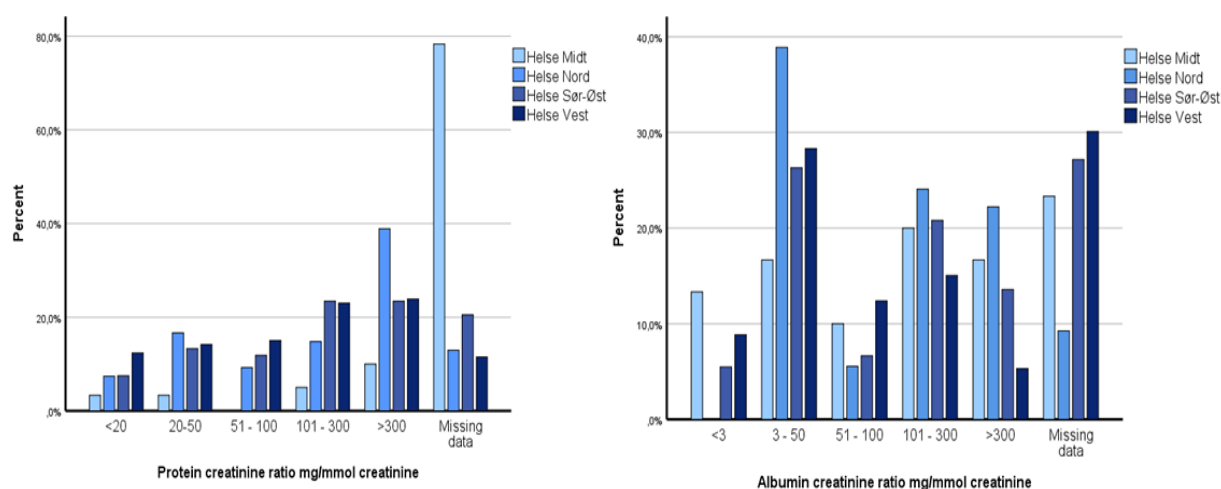


Figure 4. Serum creatinine ($\mu\text{mol/liter}$) at the time of kidney biopsy, per Regional Health Authority

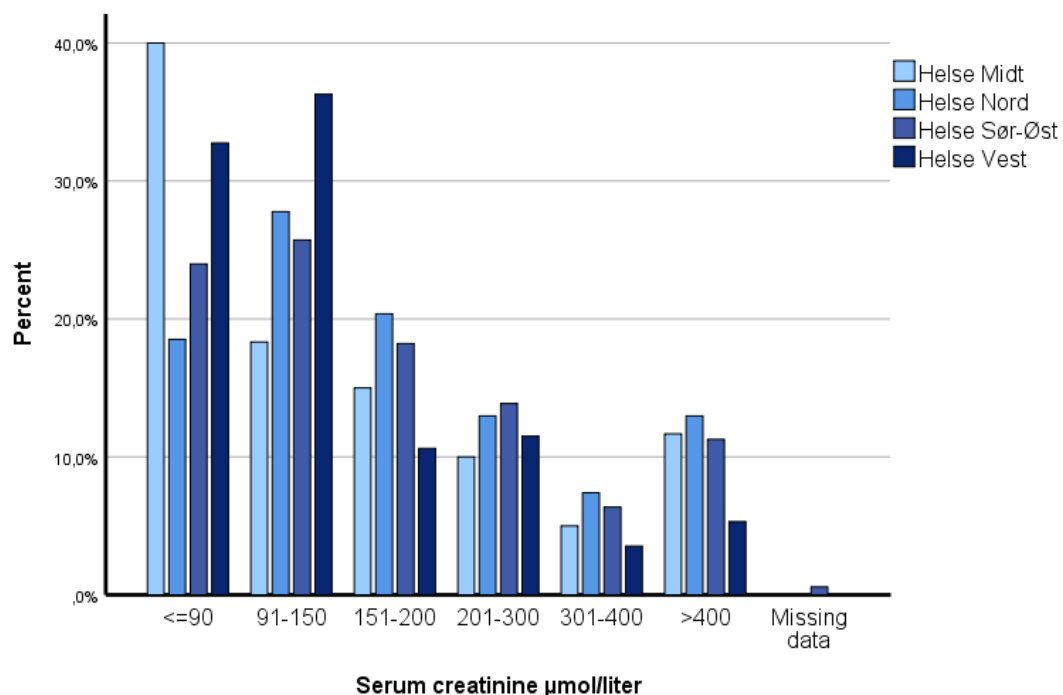
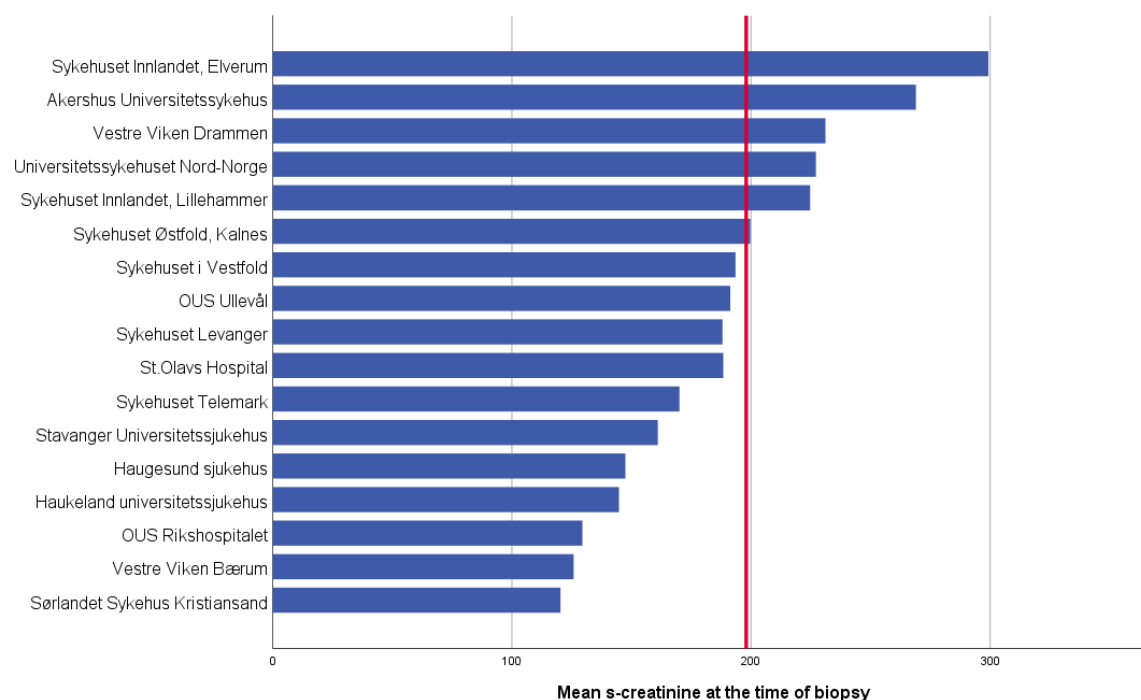


Figure 5. Mean s-creatinine at the time of kidney biopsy, per hospital



Only hospitals which reported 10 or more native kidney biopsies are included in the analysis.
The red line is set at the national average

Table 4. Quality indicators for division of kidney biopsy

Quality indicator	Target	What does it indicate?
Percentage of serious complications	<2 %	Procedure related safety
Percentage of kidney biopsies with 10 or more glomeruli	90 %	Procedure related quality
Number (%) of kidney biopsies with a final diagnosis within 1 month	80 %	Indicates quality related to structure in the investigative process
Number of primary kidney biopsies with moderate to severe chronic changes	< 30%	Indicates if patients are investigated in a timely fashion

Percentage of serious complications

Table 5. Procedure related complications

	2015	2016	2017	2018	2019
Serious complications		0.6 %	2.0 %	0.6 %	2.1 %
No complications	74 %	82.9 %	78.3 %	81.0 %	79.6%
Not reported	16.9 %	9.1 %	13.0 %	9.8 %	11.8%

Most kidney biopsies are reported without procedure related complications. In 2019 twelve serious complications, i.e. blood transfusions and/or interventions, were reported in ten biopsies. However, 11.8 % of all biopsies are reported with missing data on this very important quality indicator. It is important to strive for more complete reporting of serious procedure related complications, as changes in the number of serious complications may impact on local and/or national guidelines for kidney biopsies and patient care.

Complications can be reported to the registry after the initial clinical data report has been submitted, if necessary.

Table 6. Reported complications in 2019 per Regional Health Authority

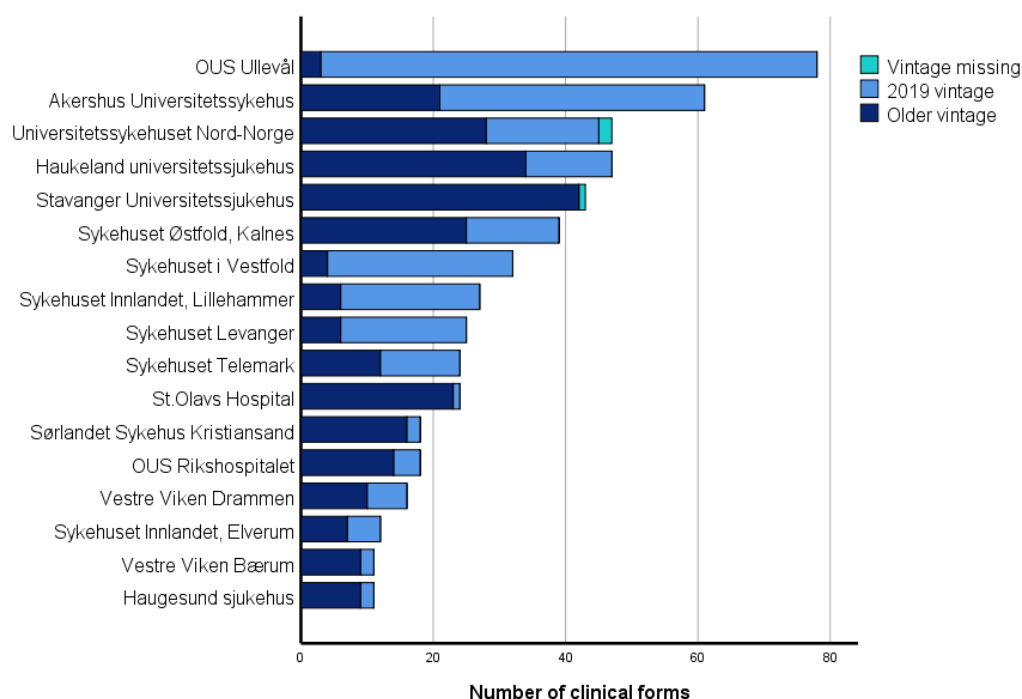
	Helse Sør-Øst N(%)	Helse Vest N(%)	Helse Midt N(%)	Helse Nord N(%)	Total N(%)
None	277 (80.1 %)	91 (80.5 %)	48 (80.0 %)	40 (74.1%)	456 (79.6 %)
Transfusion	4 (1.2%)	2 (1.8 %)	1 (1.7 %)	1 (1.9%)	8 (1.4%)
Intervention	3 (0.9%)	1 (0.9 %)	0 (0%)	0 (0%)	4 (0.7 %)
Other	27 (7.8 %)	5 (4.4 %)	5 (8.3 %)	2 (3.7 %)	39 (6.8 %)
Hematuria	5 (1.4 %)	1 (0.9 %)	1 (1.7 %)	4 (7.4 %)	11 (1.9 %)
Missing data	37 (10.7 %)	16 (14.2 %)	6 (10.0 %)	9 (16.7 %)	68 (11.8%)

It is possible to report more than one complication per procedure. Clinical data were reported for 573 kidney biopsies in 2019, 79.6 % of which were reported to be without complications. Information on complications was missing in 11.8 % of cases.

Twelve (2.1 %) serious complications were reported to the registry in 2019, eight blood transfusions and four intervention. Thirty-nine “other” complications were reported, most of which were related to pain and/or subcapsular hematomas not requiring further action.

Table 7. Procedure-related parameters

	Helse Sør-Øst N (%)	Helse Vest N (%)	Helse Midt N (%)	Helse Nord N (%)	Total N (%)
Biopsy performed by					
Nephrologist	6 (1.7 %)	79 (69.9 %)	0 (0 %)	3 (5.6 %)	88 (15.4 %)
Radiologist	326 (94.2 %)	25 (22.1 %)	59 (98.3 %)	48 (88.9 %)	458 (79.9 %)
Not reported	14 (4.0 %)	9 (8.0 %)	1 (1.7 %)	3 (5.6 %)	27 (4.7 %)
Biopsyneedle					
14G	5 (1.4 %)	2 (1.8 %)	0 (0 %)	0 (0 %)	7 (1.2 %)
16G	9 (2.6 %)	97 (85.8 %)	51 (85.0 %)	42 (77.8 %)	199 (34.7 %)
18G	294 (85.0 %)	12 (10.6 %)	2 (3.3 %)	2 (3.7 %)	310 (54.1 %)
Ukjent	38 (11.0 %)	2 (1.8 %)	7 (11.7 %)	10 (18.5 %)	57 (9.9 %)
No. of passes					
1	46 (13.3 %)	37 (32.7 %)	2 (3.3 %)	1 (1.9 %)	86 (15.0 %)
2	156 (45.1 %)	53 (46.9 %)	29 (48.3 %)	21 (38.9 %)	259 (45.2 %)
3	78 (22.5 %)	12 (10.6 %)	19 (31.7 %)	18 (33.3 %)	127 (22.2 %)
4 or more	35 (10.1 %)	3 (2.7 %)	5 (8.3 %)	6 (11.1 %)	49 (8.6 %)
Not reported	31 (9.0 %)	8 (7.1 %)	5 (8.3 %)	8 (14.8 %)	52 (9.1 %)
Level of care					
Out-patient	17 (4.9 %)	13 (11.5 %)	5 (8.3 %)	1 (1.9 %)	36 (6.3 %)
In-patient	228 (65.9 %)	55 (48.7 %)	42 (70.0 %)	40 (74.1 %)	365 (63.7 %)
Not reported	101 (29.2 %)	45 (39.8 %)	13 (21.7 %)	13 (24.1 %)	172 (30.0 %)

Figure 6. Number of clinical forms and vintage, per hospital

The variables included on the clinical form used by the clinician to report kidney biopsies to the registry change over time. Of the 573 clinical forms reporting kidney biopsies for 2019 received by September 2020, 35.6 % were 2016 vintage. Updated clinical forms can be downloaded or printed from www.nephro.no. Only hospitals with 10 or more reported kidney biopsies are included in the graph.

Percentage of kidney biopsies with 10 or more glomeruli

The kidneys consist of three compartments, which may be attacked by disease: the glomeruli, the tubuli/interstitial tissue and the vasculature.

A kidney biopsy is often necessary in order to investigate which compartment or compartments of the kidney are affected by disease and which kidney disease is responsible for the clinical picture observed. The normal kidney contains about 1 million glomeruli, which continuously filter the blood, producing pre-urine. Several different disease processes can affect the glomeruli, and sufficient material in the kidney biopsy is necessary in order to be able to make an accurate diagnosis. A disease process may not affect all glomeruli, and different stages of disease process may be observed in different glomeruli. The number of affected glomeruli and the degree of affliction may impact the clinician's decisionmaking process. The number of glomeruli in a kidney biopsy may be obtained by different methods. The most common approach is to count the number of glomeruli in the material prepared for light microscopy. For a reliable diagnosis, at least 10 glomeruli should be present in the biopsy material prepared for light microscopy. The national average number of glomeruli in 2018 is 16.5 per kidney biopsy. Three hospitals reported 10 or more glomeruli in 90% of kidney biopsies.

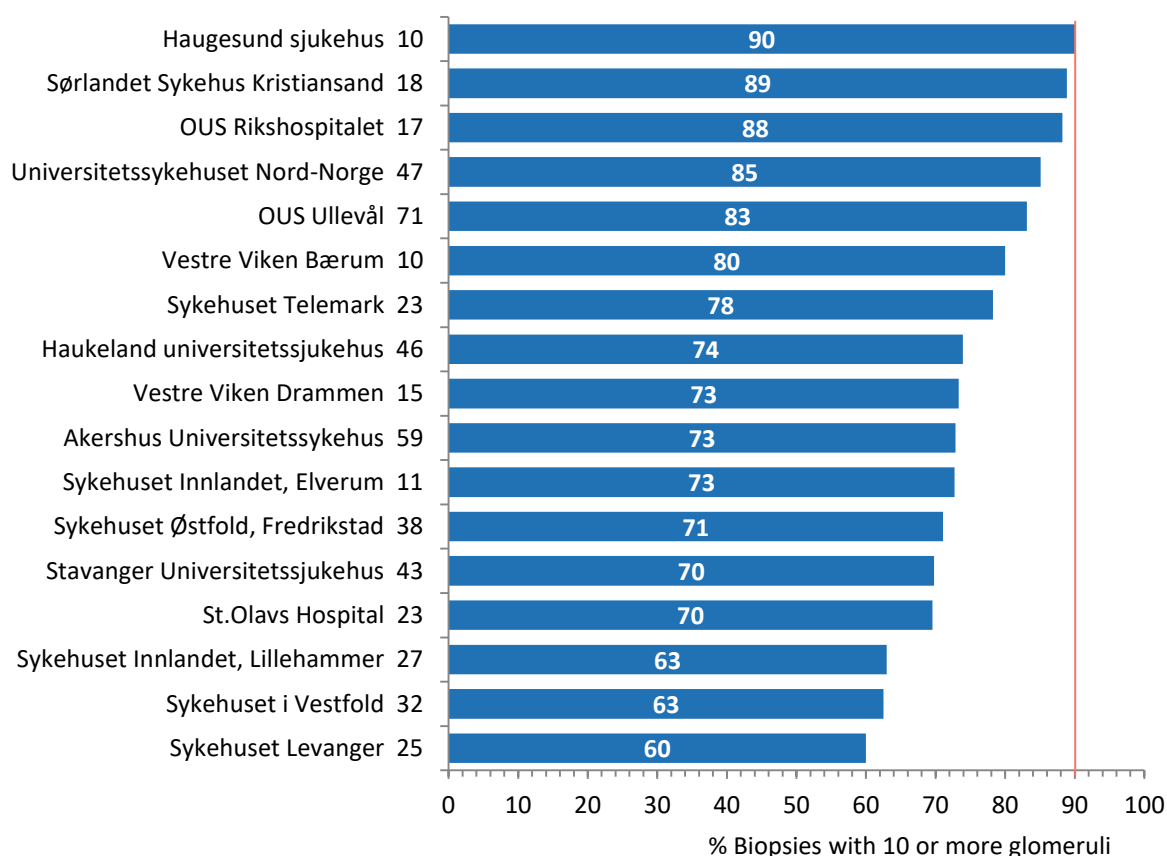


Figure 7: Percent biopsies with 10 or more glomeruli by hospital in 2019. The number behind the hospital name is the number of non-neoplastic kidney biopsies per year. The calculation is based on the number of glomeruli in the paraffin embedded biopsy tissue. Only hospitals with 10 or more non-neoplastic kidney biopsies are shown. Red line indicates quality indicator goal.

Figure 8 shows the number of glomeruli in paraffin embedded material prepared for light microscopy. Only hospitals which performed 10 or more kidney biopsies are included in the analysis. An alternative assessment of the number of glomeruli is the inclusion of all material from a kidney biopsy, taking in also material prepared for electron microscopy and immunofluorescence. If applying this assessment method, 3 hospitals achieved 10 or more glomeruli per biopsy in 90% of cases (see Figure 8).

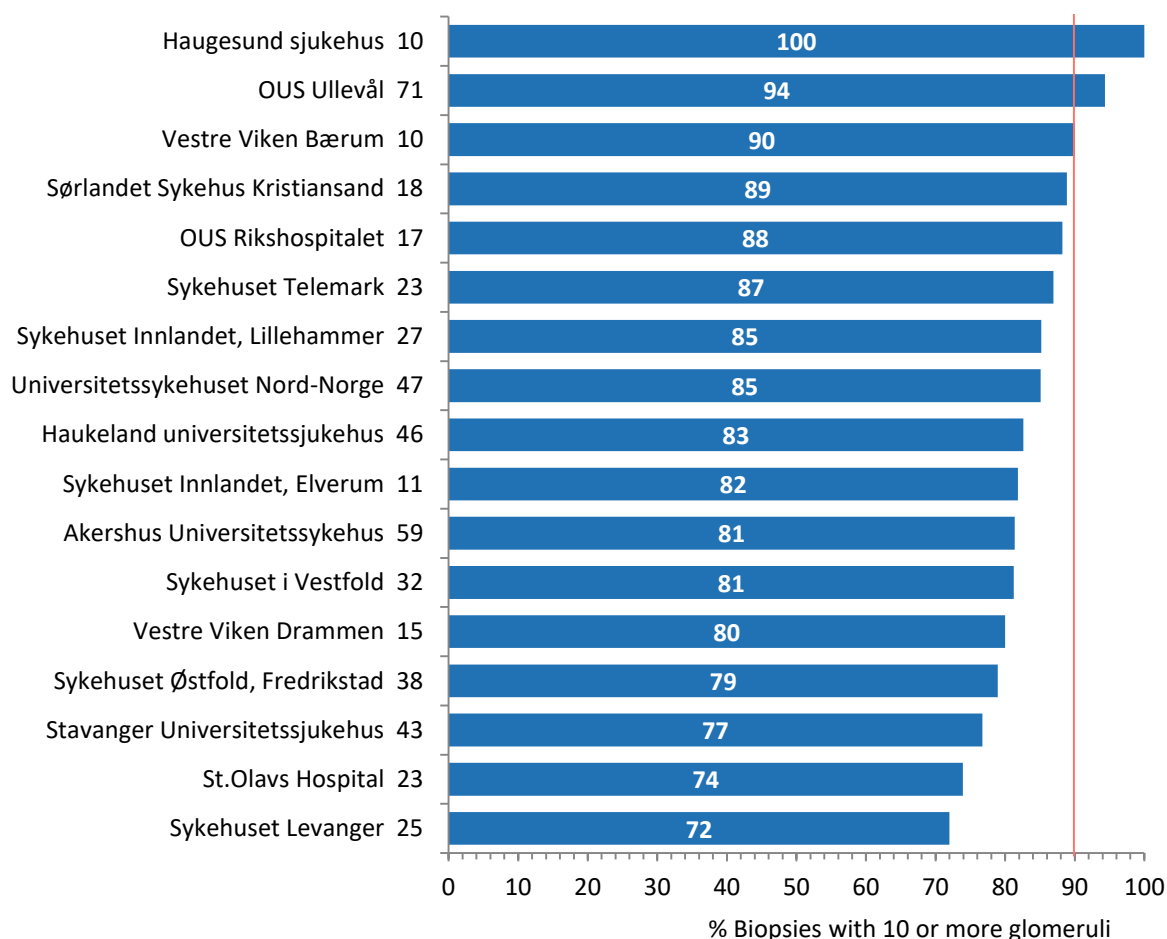


Figure 8: Percent biopsies with 10 or more glomeruli by hospital. The number behind the hospital name is the number of non-neoplastic kidney biopsies per year. The calculation is based on the number of glomeruli both in the paraffin embedded biopsy tissue, the frozen tissue for immunohistochemistry (only few departments) and the tissue processed to electron microscopy. Only hospitals with 10 or more non-neoplastic kidney biopsies are shown. Red line indicates quality indicator goal.

Figure 9 shows the trend of mean number of glomeruli over time from 2016 – 2019. There has been a trend for a slight increase in number of glomeruli.

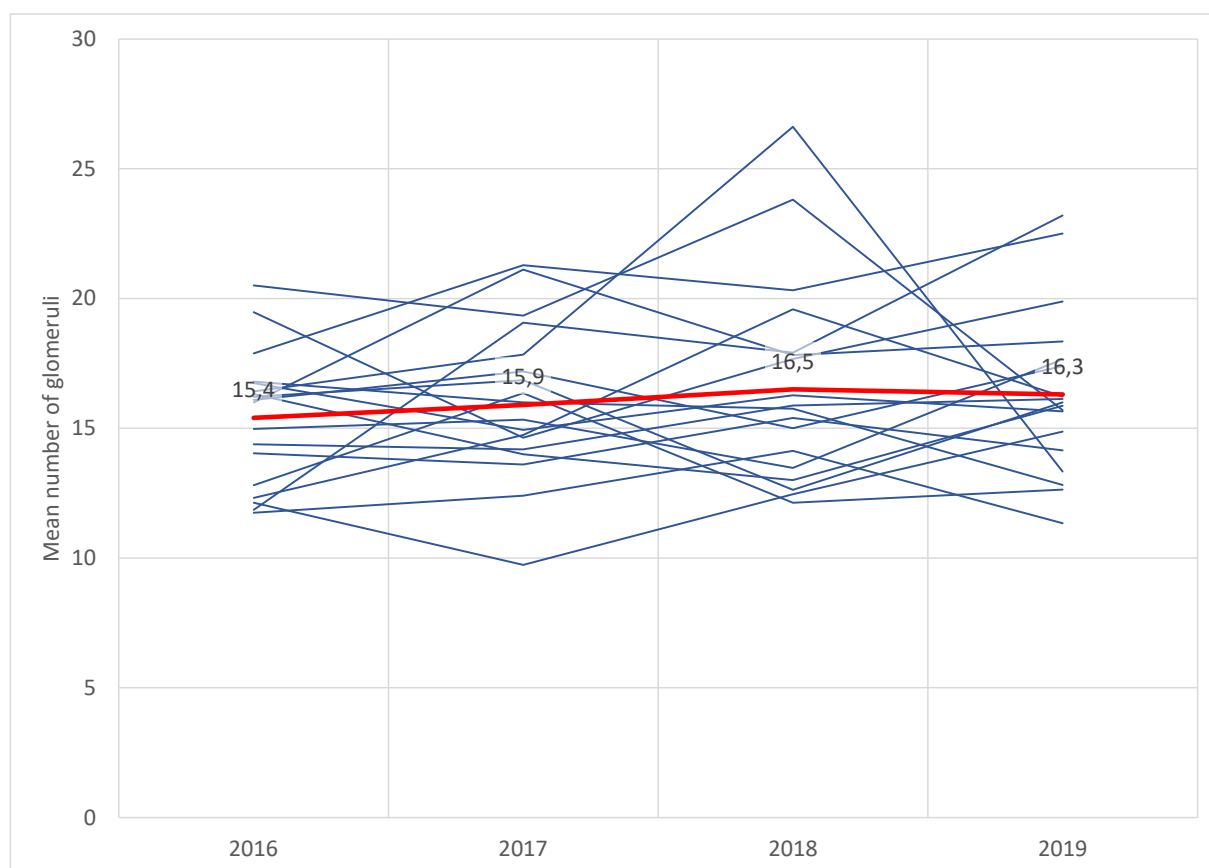


Figure 9: Mean number of glomeruli from 2016 – 2019. Blue lines represent the hospitals and the red line represent the mean number of glomeruli of all biopsies taken.

Number of primary kidney biopsies with moderate to severe chronic changes

Chronic changes in the renal tissue are persistent and irreversible. A high proportion of chronic changes in the biopsy may indicate a future risk of loss of kidney function, and low potential for stabilization or recovery of kidney function with medical intervention. It is important to diagnose kidney disease early on in the disease process, before the disease manifestations result in chronic, irreversible changes. If the kidney biopsy shows moderate to pronounced chronic changes, this is a sign that the biopsy was taken late in the course of the disease and the investigation process was not optimal. The proportion is calculated by dividing the number of biopsies showing moderate to pronounced chronic changes by the total number of biopsies at the center. Some patients have multiple kidney biopsies. For the calculation, only the first biopsy taken from a patient is used.

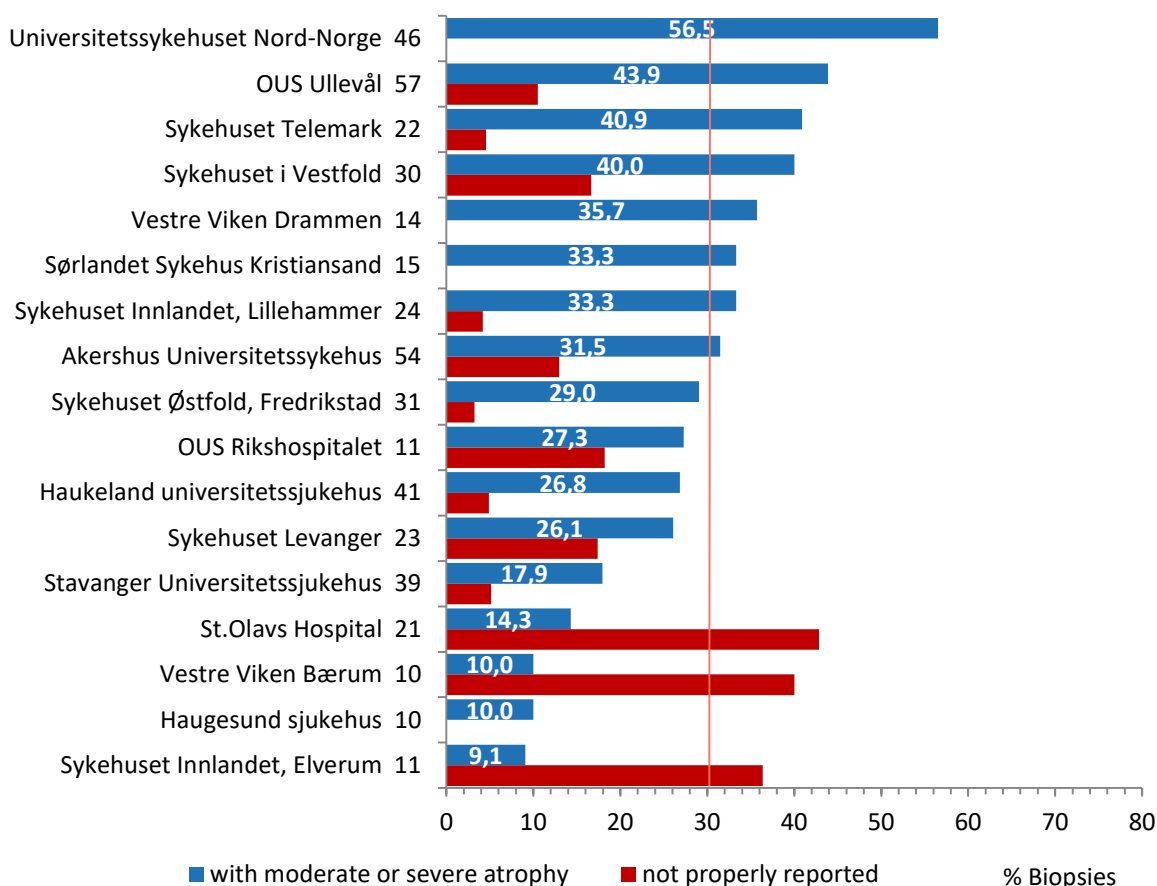


Figure 10: Percent biopsies with moderate or severe tubular atrophy (blue bars) by hospital. Red bars represent percent biopsies without proper registration of tubular atrophy by hospital. The number behind the hospital name is the number of primary non-neoplastic kidney biopsies per year. Only hospitals with 10 or more non-neoplastic kidney biopsies are shown. Red line indicates quality indicator goal.

Figure 10 shows two important aspects related to chronic changes in kidney biopsies. First, about half of the hospitals do show a significant number of biopsies with moderate or severe tubular atrophy. Second, some of the pathology reports do not show a proper registration of tubular atrophy. Tubular atrophy is either mentioned in the report, but not semi-quantitatively assessed, or tubular atrophy is not mentioned at all. In the latter case it is uncertain if tubular atrophy is absent, or if the data has been missed. In the light of these findings, low percentage of biopsies with moderate or severe tubular atrophy in hospitals with a high percentage of not properly registered tubular atrophy should be considered with caution.

Number (%) of kidney biopsies with a final diagnosis within one month

The turn-around-time is the time interval from the registration of a kidney biopsy in the pathology department until the nephropathologist has signed the final report including the electron microscopic investigation. This time interval is a quality indicator, as the clinician will base treatment choices on the final pathology diagnosis. Delays in reporting may cause delay in treatment, and consequently impact patient outcomes negatively. The electron microscopy examination in particular is time-consuming, and a kidney biopsy is therefore often reported in stages. Kidney biopsies from severely ill patients are usually communicated orally by the pathologist to the clinician by telephone as soon as the biopsy is prepared for light microscopy. This oral report is followed by a preliminary written report, which may or may not include immunohistochemistry. The final pathology report is signed after electron microscopy.

Only 1 pathology department met the quality standard of a final diagnostic report in 80% of cases within 1 month (figure 11).

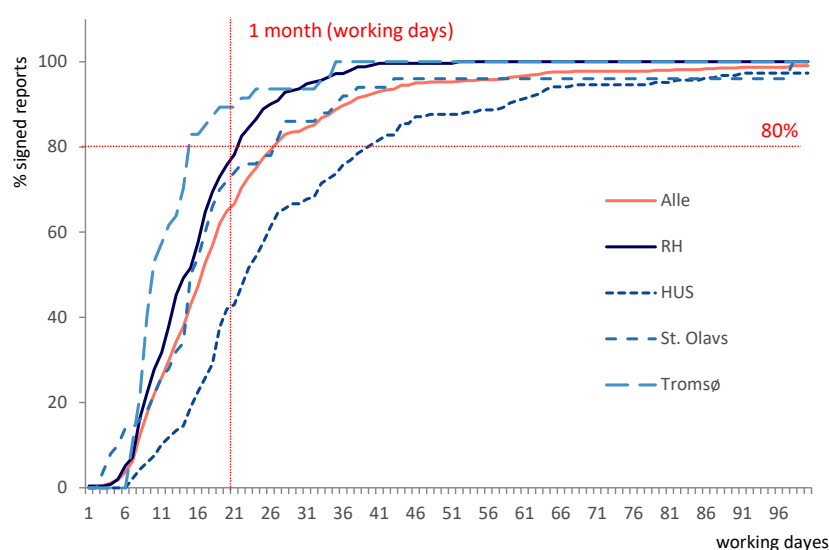


Figure 11: Percent kidney biopsies finally reported within one month (21 working days) by pathology department.

Over the years there has been a slightly negative overall trend towards longer reporting time (figure 12).

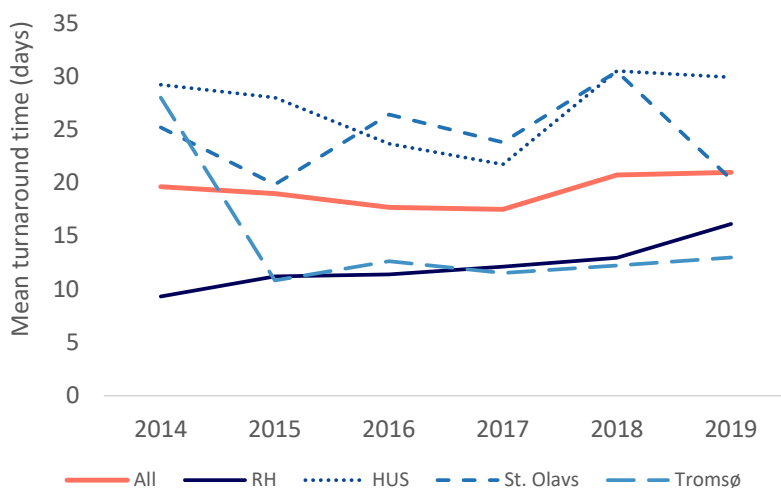


Figure 12: Mean turnaround time by pathology department from 2014 - 2019.

Table 8. Overview pathology diagnoses in Norway in 2019

	All	RH	HUS	St. Olavs	Tromsø	Førde	Ålesund
Minimal change nephropathy	23	8	8	2	4	0	1
FSGS[1] primary	15	6	7	1	0	0	1
FSGS secondary	15	7	7	1	0	0	0
Membranous GN[2]	28	11	9	4	3	0	1
IgA nephropathy	96	35	44	6	9	2	0
Mesangioprol. GN without IgA	6	3	2	1	0	0	0
Endokapillary prol. GN	4	2	1	1	0	0	0
Membranoproliferativd GN	11	5	3	2	1	0	0
ANCA associated GN	31	14	10	4	2	0	1
Anti-GBM nephritis	3	1	0	1	1	0	0
GN with crescents not ANCA	5	2	3	0	0	0	0
HSP[3]	4	1	3	0	0	0	0
Lupus nephritis - I	0	0	0	0	0	0	0
Lupus nephritis - II	1	0	0	0	1	0	0
Lupus nephritis - III	11	5	4	1	0	0	1
Lupus nephritis - IV	2	2	0	0	0	0	0
Lupus nephritis - V	4	3	1	0	0	0	0
Lupus nephritis - VI	1	0	1	0	0	0	0
Lupus nephritis - not classified	2	2	0	0	0	0	0
Diffuse proliferative GN	0	0	0	0	0	0	0
Dense deposit disease	0	0	0	0	0	0	0
Fibrillary glomerulopathy	4	1	2	1	0	0	0
Immunotactoid GP[4]	0	0	0	0	0	0	0
Cryoglobulinemia	1	1	0	0	0	0	0
Pre-eclampsia-ass. GN	0	0	0	0	0	0	0
Sclerosing GN	1	1	0	0	0	0	0
GN unclassified	6	4	1	1	0	0	0
Alport syndrome	3	1	0	0	2	0	0
Thin basement membrane GP	16	8	2	4	2	0	0
Fabry's disease	4	0	4	0	0	0	0
Other hereditary diseases	0	0	0	0	0	0	0
Diabetic nephropathy	35	18	9	3	5	0	0
Benign nephrosclerosis	34	11	12	4	6	1	0
Malign nephrosclerosis	3	1	2	0	0	0	0
Cholesterol emboli	2	0	1	0	1	0	0
Vasculitis other	2	2	0	0	0	0	0
TMA[5]	3	1	2	0	0	0	0
TMA - atypical HUS[6]	0	0	0	0	0	0	0
Scleroderma	0	0	0	0	0	0	0
Amyloidosis not classified	1	0	1	0	0	0	0
Amyloidosis - AA	5	4	1	0	0	0	0
Amyloidosis - AL	11	5	5	0	1	0	0
Amyloidosis other	0	0	0	0	0	0	0
Myeloma kidney	9	3	3	0	2	1	0
Ig[7] deposition disease	3	2	1	0	0	0	0
ATN[8]	12	9	2	1	0	0	0
Acute interstitial nephritis	1	1	0	0	0	0	0
Tubulointerstitial nephritis	46	26	12	3	3	1	1
Granulomatous TIN[9] / Sarc.	1	0	1	0	0	0	0
TIN - drug associated	3	2	1	0	0	0	0
Lithium nephropathy	1	0	1	0	0	0	0
Phosphate nephropathy	0	0	0	0	0	0	0
Oxalate nephropathy	0	0	0	0	0	0	0
TIN with uveitis	1	0	0	1	0	0	0
TIN aminoglycosides ass.	0	0	0	0	0	0	0
TIN autoimmune disease ass.	1	1	0	0	0	0	0
TIN cisplatin ass.	0	0	0	0	0	0	0
TIN hantavirus infection	0	0	0	0	0	0	0
Calcineurin inhibitor toxicity	1	1	0	0	0	0	0
Normal	11	3	1	6	1	0	0
Uncharacteristic atrophy	26	19	5	1	1	0	0
End stage kidney	1	0	1	0	0	0	0
No code - free text	15	7	4	1	1	2	0
Not representative	25	13	11	0	1	0	0
All	550	252	188	50	47	7	6

Abbreviations in the table:

1	Focal and segmental glomerulosclerosis	RH	Rikshospitalet
2	Glomerulonephritis	HUS	Haukeland University Hospital
3	Henoch Schönlein's purpura		
4	Glomerulopathy		
5	Thrombotic microangiopathy		
6	Hemolytic uremic syndrome		
7	Immunoglobulin		
8	Acute tubular necrosis		
9	Tubulointerstitial nephritis		

The table gives an overview about registered non-neoplastic kidney biopsies and the related pathology diagnoses in 2019. Numbers are shown for all biopsies and the different departments.

CKD5 not in RRT

The age and sex distribution of CKD5 patients not treated with RRT is as expected in relation to the RRT population that has been followed in Norway for many years. A majority of patients are male (63.1%) and median age at time of entering CKD5 stage was 70.6 years (mean 67.0 years), ranging from 0.5 to 91.9 years. Patients had been known at the nephrology unit in 91% of the cases and a total of 82% were considered as RRT candidates and 9% were definitely not candidates for RRT treatment (9% unsure/missing status). The main reason for not being RRT candidate was comorbidity. A selection of clinical chemistry values and drugs used by patients entering the CKD5 stage in 2019 are shown in **Table 9**.

Table 9. Status at start of CKD5 (without RRT) in 2019

	Total (n:329)
eGFR (CKD-EPI, mean) [mL/min/1.73m ²]	12
eGFR (CKD-EPI) - % <15 mL/min/1.73m ²	97%
Creatinine (mean) [μmol/L]	419
Albumin (mean) [g/L]	38
Haemoglobin (mean) [g/dL]	11.0
Haemoglobin - % with <10 g/dL	22 %
Proteinuria (ACR>3 and/or PCR>15)	88 %
ESA use	33 %
Active D vitamin use	52 %
Statin use	56 %
Not on antihypertensive drugs	6 %
Using ACEi/ARB	46 %
Using ≥3 antihypertensive drugs	55 %

Hypertension was the main cause of renal failure with 43% of the patients having this as their main diagnosis. Diabetes was the primary diagnosis in 14% of the patients. Including diabetes as comorbidity, a total of 36% patients was diabetic (92% Type II diabetes mellitus) and they had had the diagnosis for a median of 18 years at time of entering the CKD5 stage.

For patients starting RRT during 2019 the median (range) time in the CKD5 stage was 11.5 (0 to 124) months. During 2019, 69 patients in this stage died, 48% of these were considered candidates for RRT when entering the CKD5 stage.

CKD5 in RRT (Dialysis or Transplantation)

A majority of the patients are male (67.8 %) and median age at start of RRT was 68.0 years (mean 63.8 years), ranging from 0.7 to 94.4 years. At time of start of dialysis 37 % were assessed by the treating physician to be a Tx-candidate. Of the patients starting haemodialysis and that had been known at the treating center for at least 4 months 35 % started dialysis using an AV-fistula as blood access, a reduction from previous years where the figure has been around 40%. A selection of clinical chemistry values and drugs used for patients starting RRT in 2019 are shown in **Table 10**.

Table 10. Status at start of RRT

	Total (n:602)	HD (n:384)	PD (n:155)	Preempt. Tx (n:63)
Creatinine (mean) [$\mu\text{mol/L}$]	635	656	638	492
Albumin (mean) [g/L]	41	39	46	43
Haemoglobin (mean) [g/dL]	10,2	9,9	10,5	11.3
Haemoglobin - % <10 g/dL	45 %	54 %	33 %	16 %
ESA use	54 %	57 %	58 %	25 %
Active D vitamin use	61 %	57 %	72 %	63 %
Statin use	56 %	56 %	61 %	41 %
Not on antihypertensive drugs	8 %	9 %	3 %	16 %
Using ACEi/ARB	30 %	27 %	34 %	33 %
Using ≥ 3 antihypert. drugs	51 %	51 %	61 %	24 %

As might be anticipated, pre-emptively transplanted patients had a somewhat lower serum creatinine, thus higher renal function, and a higher haemoglobin than those starting dialysis. Among patients known less than four months, 63 % had haemoglobin <10 g/dL.

In Figure 13 to 16 below the annual incidence of new patients in RRT by first treatment modality, age and if they are considered as Tx-candidates by the local treating physician is presented.

Figure 13:

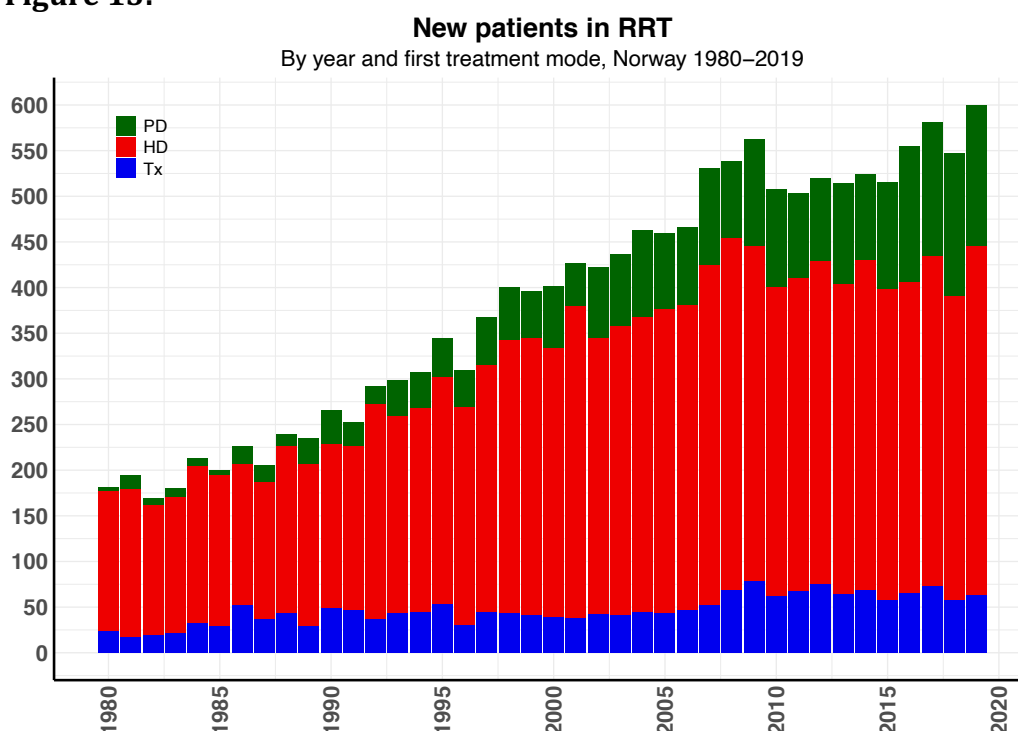


Figure 14:

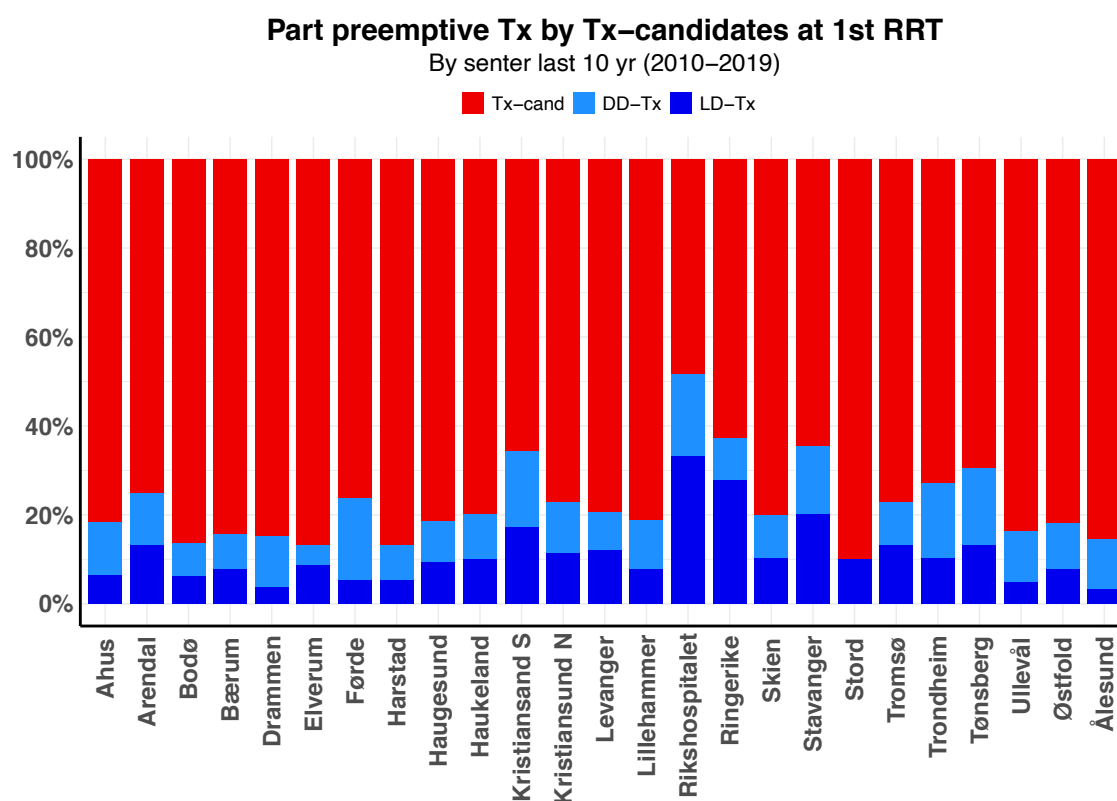


Figure 15:

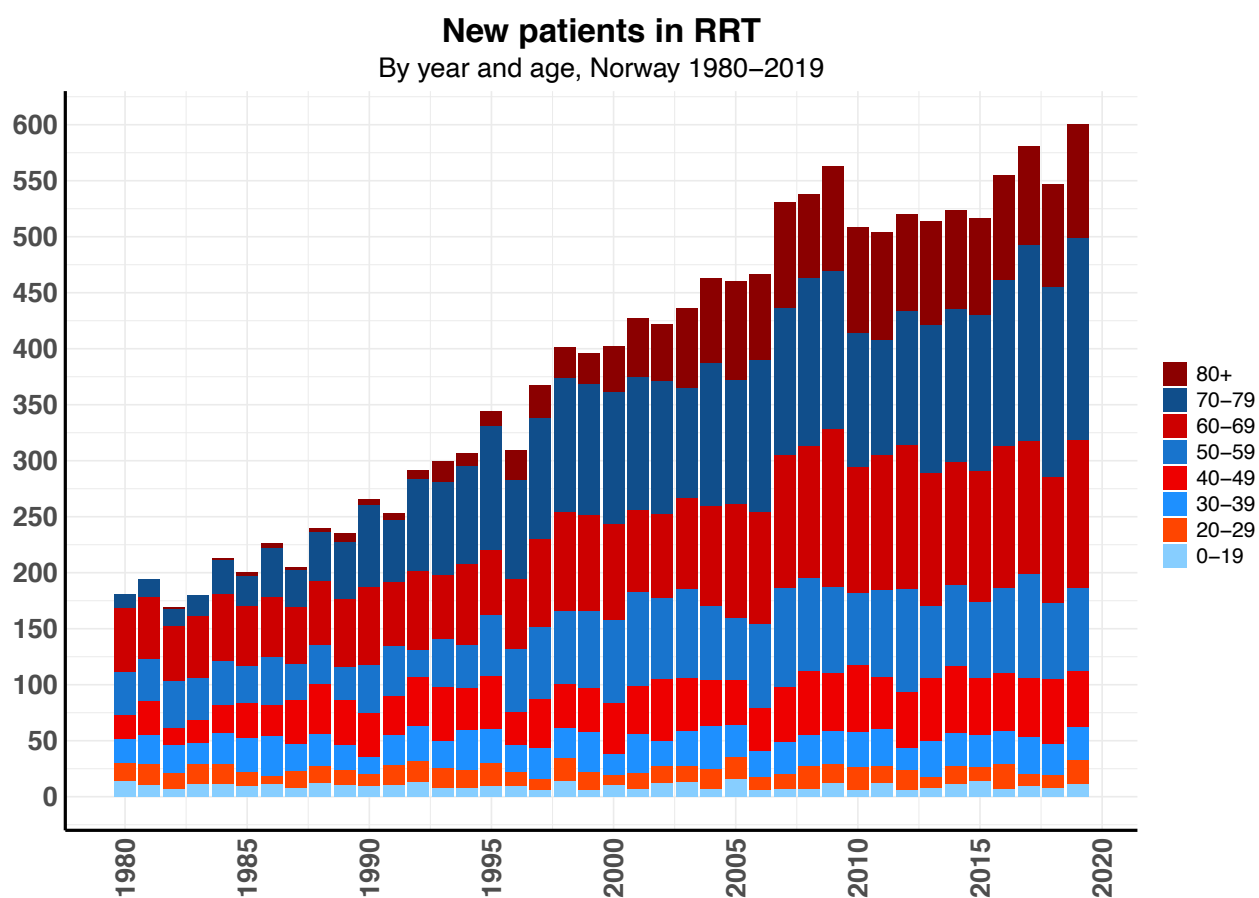
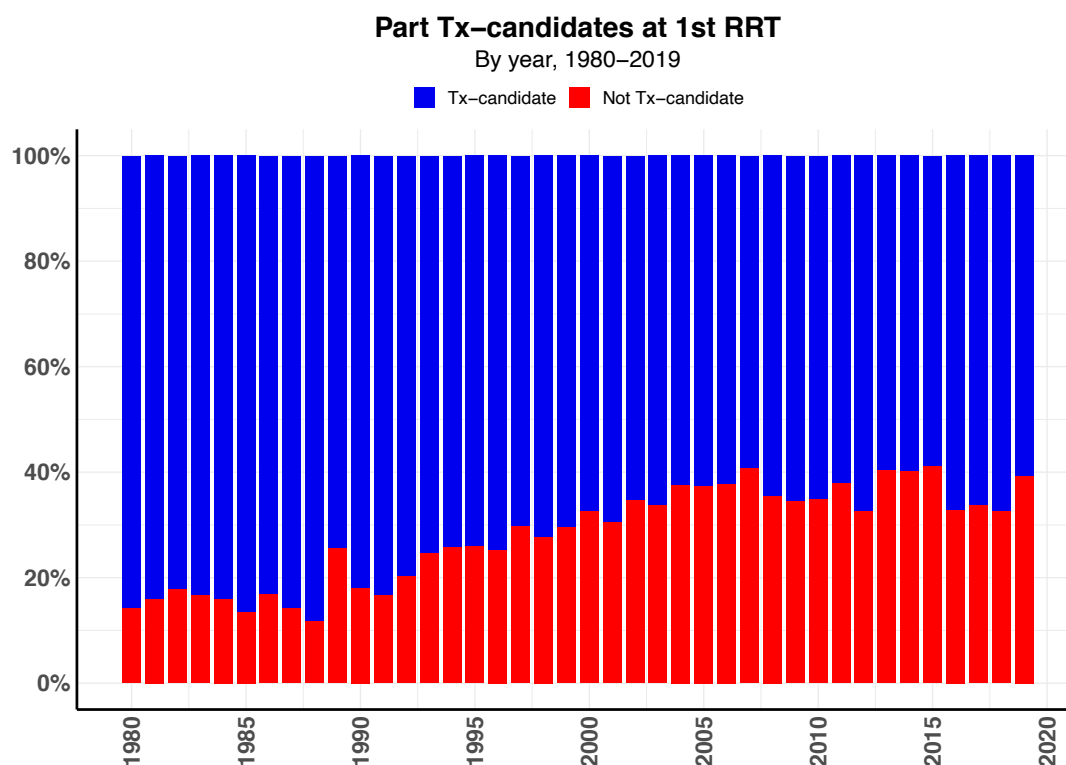


Figure 16:



Since registration started in 1980 there has been a continuous shift in patient age. (Figure 17) Both the maximum and the median age at start of RRT have increased. Also, the 5-percentile and 95-percentile values (i.e. including the majority of patients) have increased with a similar number of years. But also, younger children have been accepted; the youngest ever started PD in 2011 at age two days. Seven children below 16 years started RRT in 2019; transplantation (n=3), HD (n=2) and PD (n=2).

Figure 17:

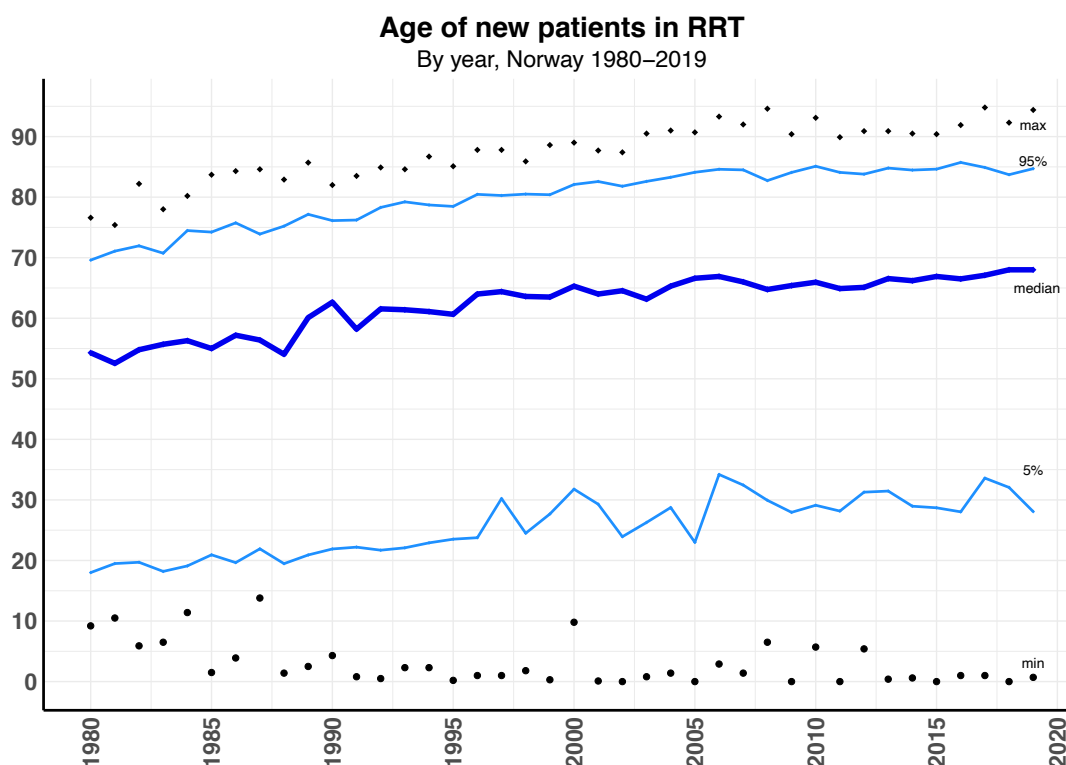


Table 11. Primary renal disease at start of RRT

	1980-89	1990-99	2000-04	2005-09	2010-14	2019
Glomerulonephritis	35%	27%	18%	18%	16%	14%
Pyelo/interstitial nephr.	15%	11%	11%	10%	9%	5%
Polycystic diseases	10%	9%	9%	8%	8%	8%
Diabetic nephropathy	13%	11%	15%	16%	17%	19%
Amyloidosis	6%	5%	3%	2%	2%	3%
Vascular/hypertensive	7%	21%	28%	31%	35%	34%
Immune/systemic	5%	5%	4%	4%	4%	4%
Kidney tumour	1%	1%	1%	2%	1%	0.5%
Myelomatosis	2%	2%	3%	3%	1%	1.5%
Other defined	4%	4%	3%	4%	4%	8%
Unknown	3%	3%	4%	4%	3%	3%
N:	2018	3234	2149	2556	2571	602

The main change over time has been an increase of vascular/hypertensive nephropathy and a relative reduction of glomerulonephritis. Whether this only reflects changed coding practice or a true shift is not known.

Diabetic nephropathy has stabilized on a higher levels as primary diagnosis cause for renal disease the last decade. In 2019, 21% of these were registered as having Type I diabetes mellitus. Including also patients with other primary diagnoses of renal disease a total of 222 patients were recorded as having diabetes mellitus at start of RRT (11% Type I), thus 37 % of new patients in RRT were diabetics.

The time from onset of diabetes to start of RRT differed considerably. For the patients with Type I diabetes the median time was 34 years, while for the patients with Type II diabetic nephropathy the median time was 18 years.

Cardiovascular disease is often present at start of RRT. Coronary heart disease was reported in 28% and 20% had anamnestic heart failure. Echo-verified left ventricular hypertrophy was reported in 29%. Cerebrovascular disease was reported in 15% and peripheral atherosclerotic disease in 15% while 13% had chronic obstructive lung disease.

Prevalence data CKD5 by December 31st 2019.

The national coverage of CKD5 patients not in RRT is in the range of 65% to 85%. The reported data on CKD5 patients not in RRT should hence be interpreted with caution.

There were 507 CKD5 patients in the registry that did not receive renal replacement therapy by the end of 2019 (494 in 2018). The median length of stay in this category, before being initiated in RRT during 2019 was 12 months, ranging from 0 to 124 months.

Prevalence data RRT by December 31st 2019.

By the end of 2019, 5,356 patients in Norway received renal replacement therapy, i.e. 1,001.9 per million inhabitants. This represents an increase of 100 patients or 1.9 % since 2018, similar as the year before.

Median age by the end of the year was 63.5 years, mean 61.2 years and range 1.5 to 97.4 years. Gender: 64.1 % males.

Figures 18 and 19 show prevalence per treatment modality, development over time and by center in 2019

Figure 18:

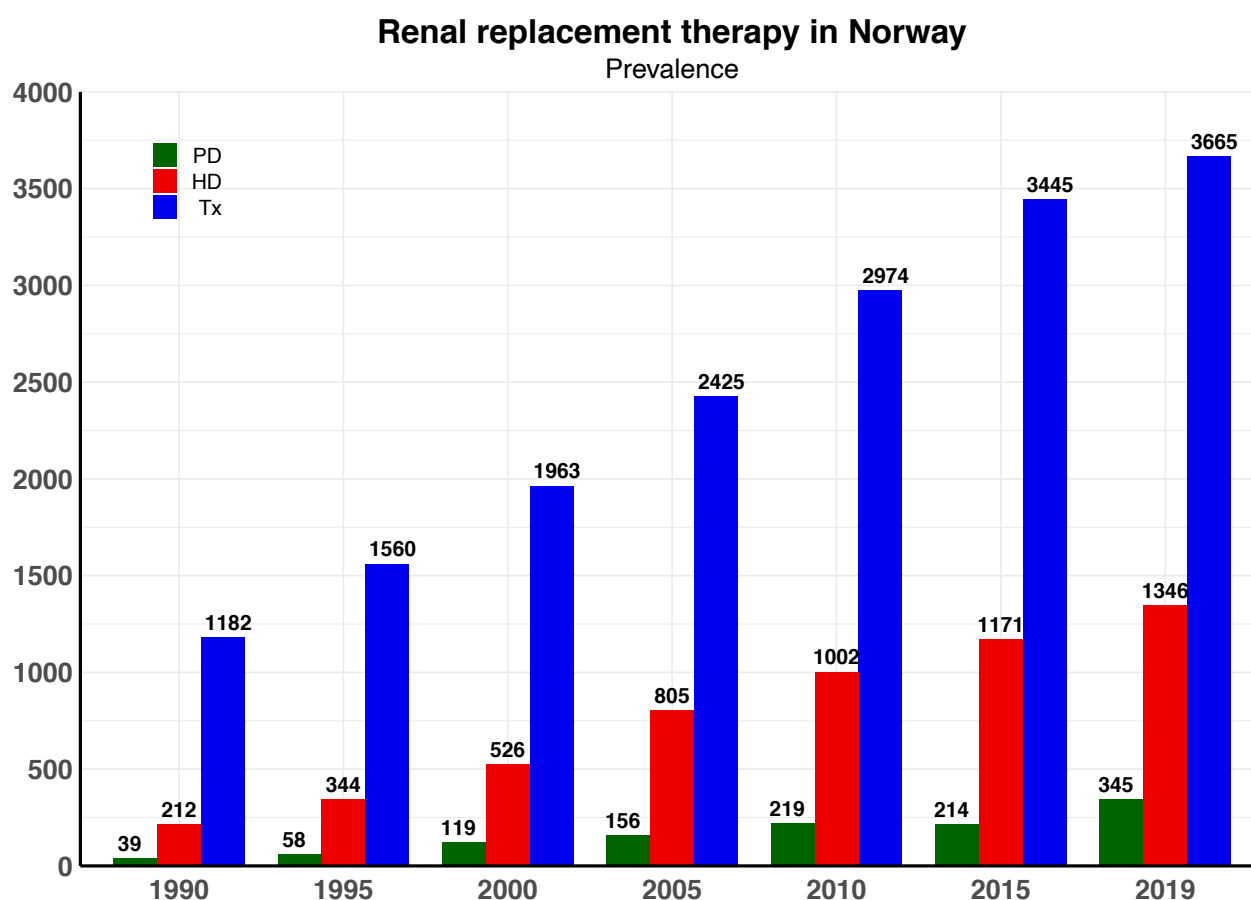
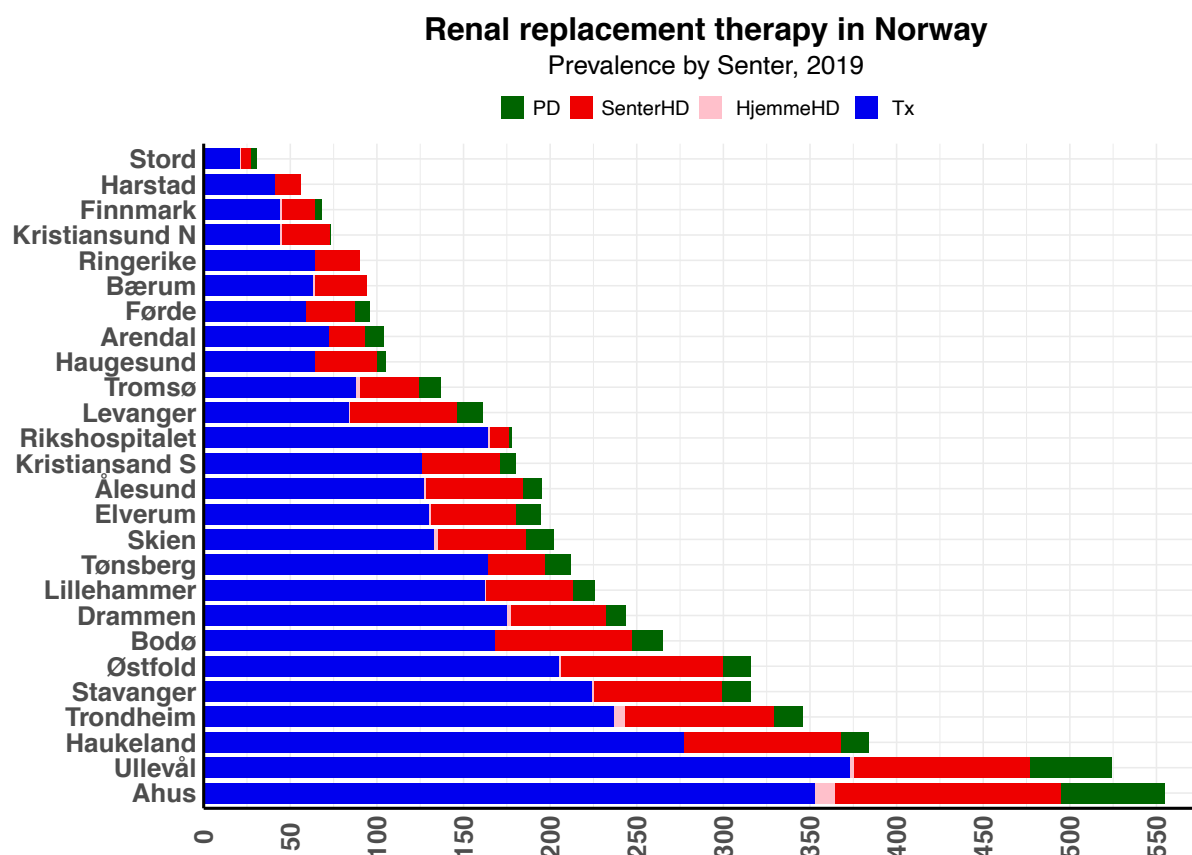


Figure 19:



New annual variables in the registry:

In 2019 annual data on assisted PD was captured for the first time. Of the 321 PD-patients with reported annual data, 94 were treated with “assisted PD”.

The registry started to capture data on use of warfarin and DOAK in 2016. The total usage of these two drug classes does not seem to have increased to any relevant degree during these years. However, there has been a switch toward more use of DOAK and in 2019 more transplanted patients were treated with DOAKs (7.9%) than warfarin (4.7%). For dialysis patients (6.1% vs. 6.6%) and CKD5 patients not on RRT (5.6% vs. 10.7%) there is still more warfarin users.

Transplantations and waiting list:

A total of 258 renal transplants were performed in Norway in 2019, i.e. 48.3 per million inhabitants, 16% were retransplantations. Preemptive transplantation was performed in 29% of all first transplantations in 2019. Those not preemptively transplanted had been in dialysis for a median of 1.9 years (mean 2.3 years), ranging from 1 week to 13.7 years. Distribution of transplantations with deceased and living donors, relation between recipient and donor etc. is presented in the figures below. Simultaneous pancreas and kidney (SPK) transplantation was performed in 5 patients and simultaneous liver and kidney transplantation in 2 patients.

In principle, transplantation is offered to all patients considered to profit from it, with no strict upper or lower age limit. The age of the 157 first-DD-graft recipients in 2019 ranged from 11 to 84 years, with a median age of 58 years. Out of these, 31% were above the age of 65 and 8 % were 75 or older. The 61 recipients of a first LD-graft were from 1 to 75 years, with a median age of 45 years. Re-graft recipients (n=41) were from 21 to 71 years, median 53 years.

The list of patients actively waiting for a kidney transplant at entry into 2019 consisted of 337 patients and at the end of 2019 it has increased to 364 patients.

Fun-facts Transplantation:

The oldest kidney transplant recipient ever was 84.1 year at time of transplantation (youngest 9.5 months). In total 930 recipients have been transplanted at an age older than 70 years, 40 older than 80 years. The oldest kidney transplant recipient became 93.8 years and the now living oldest recipient is 90.8 years. In total 13 patients have become older than 90 years (2 now living) and 542 reached an age over 80 years (134 now living).

The longest graft survival is 50.3 years, closely followed by a still functioning graft with 50.1 years survival. In total 44 (29 still working) grafts have functioned in a new body for over 40 years. The oldest transplanted kidney ever is 108.7 years and it is still working. In total 11 (6 still working) transplanted kidneys have reached a total age of over 100 years and 81 (39) over 90 years. As a comparison, in total 18 person in Norway have reached an age of over 110 years (1 still living).

Figure 20:

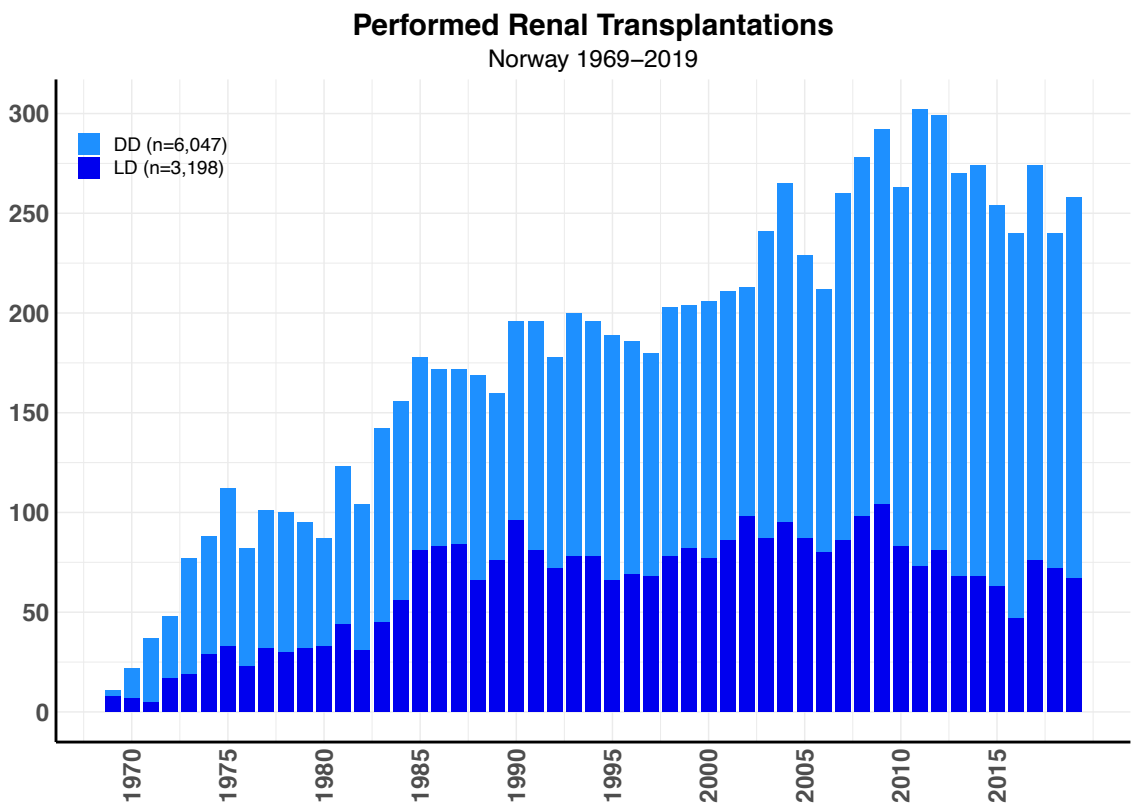


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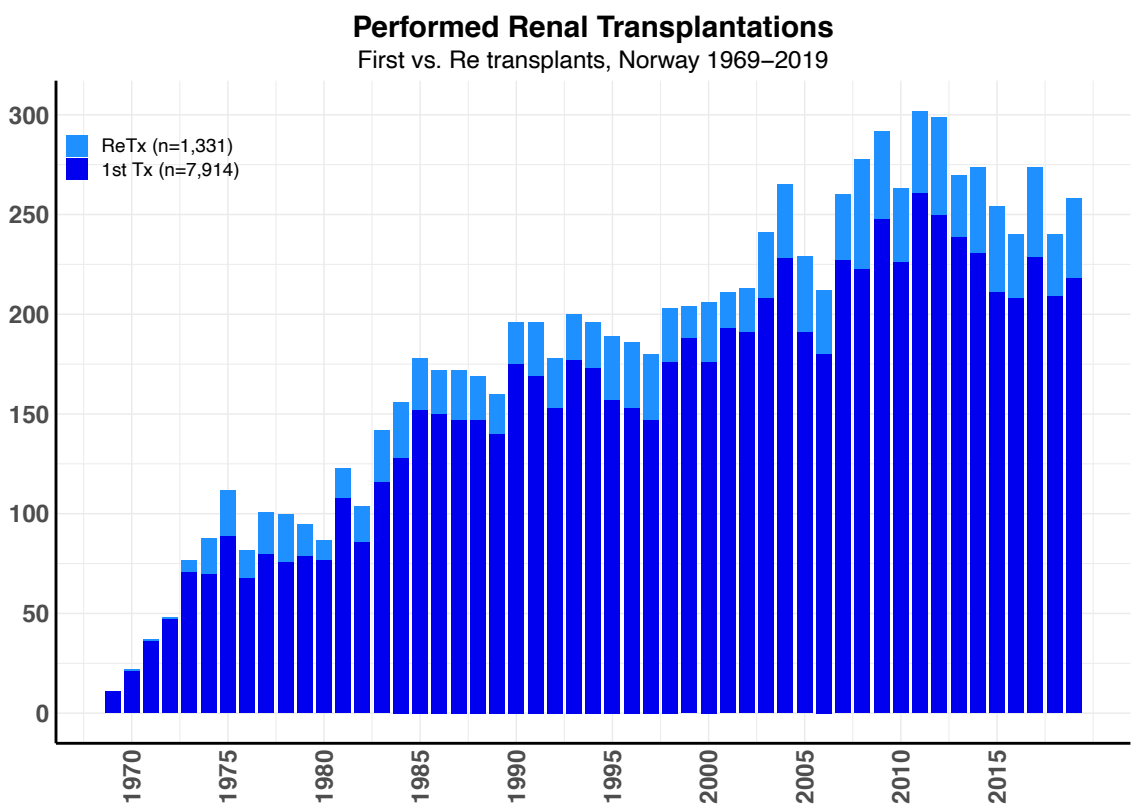


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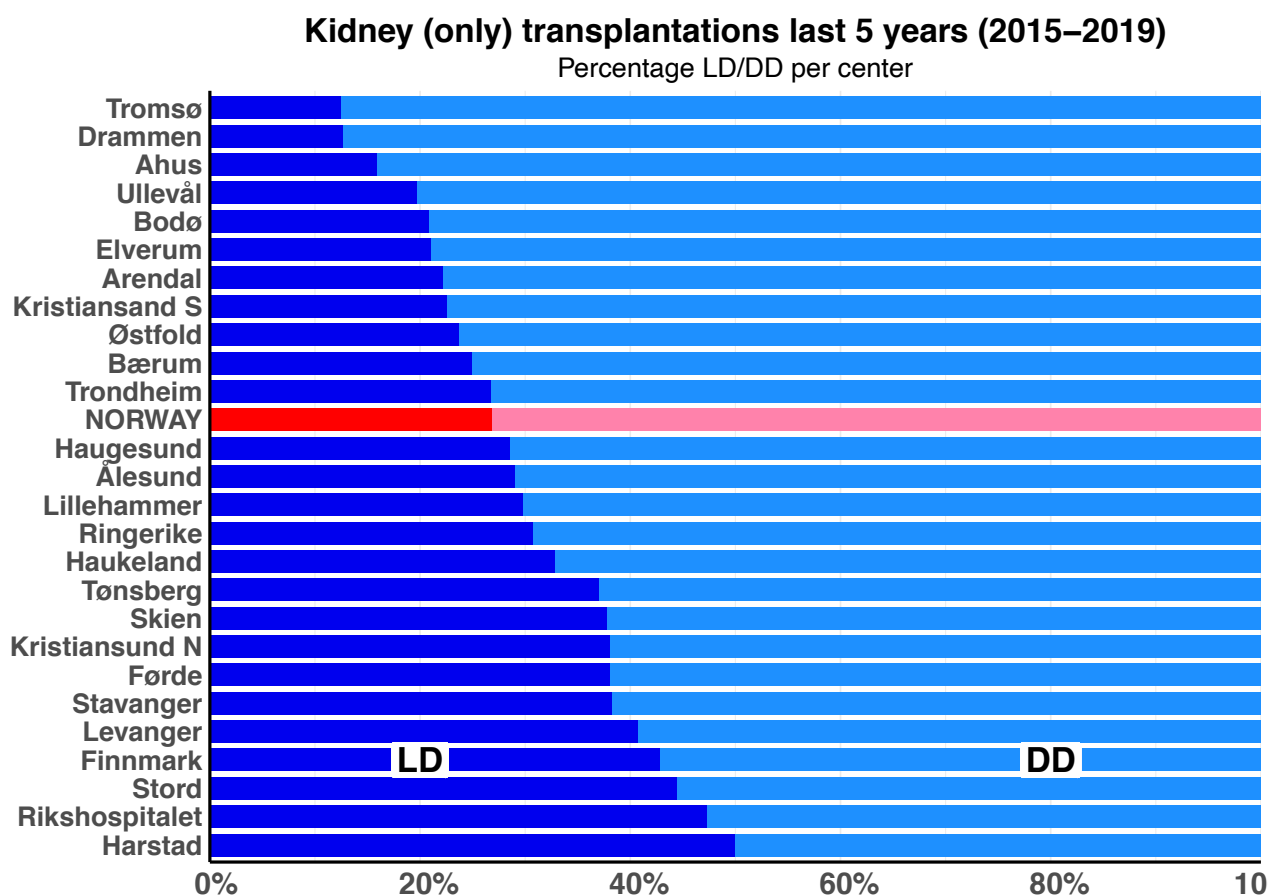


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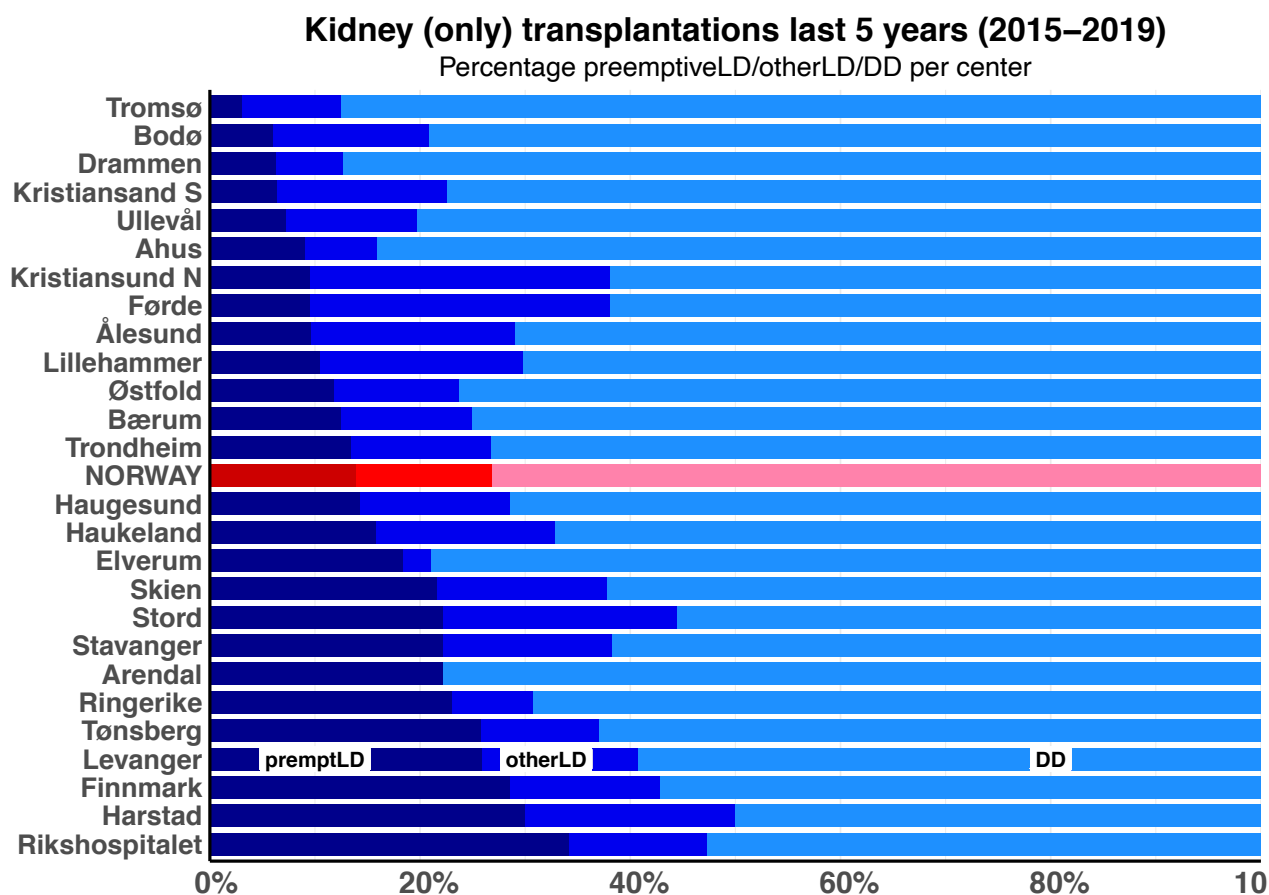


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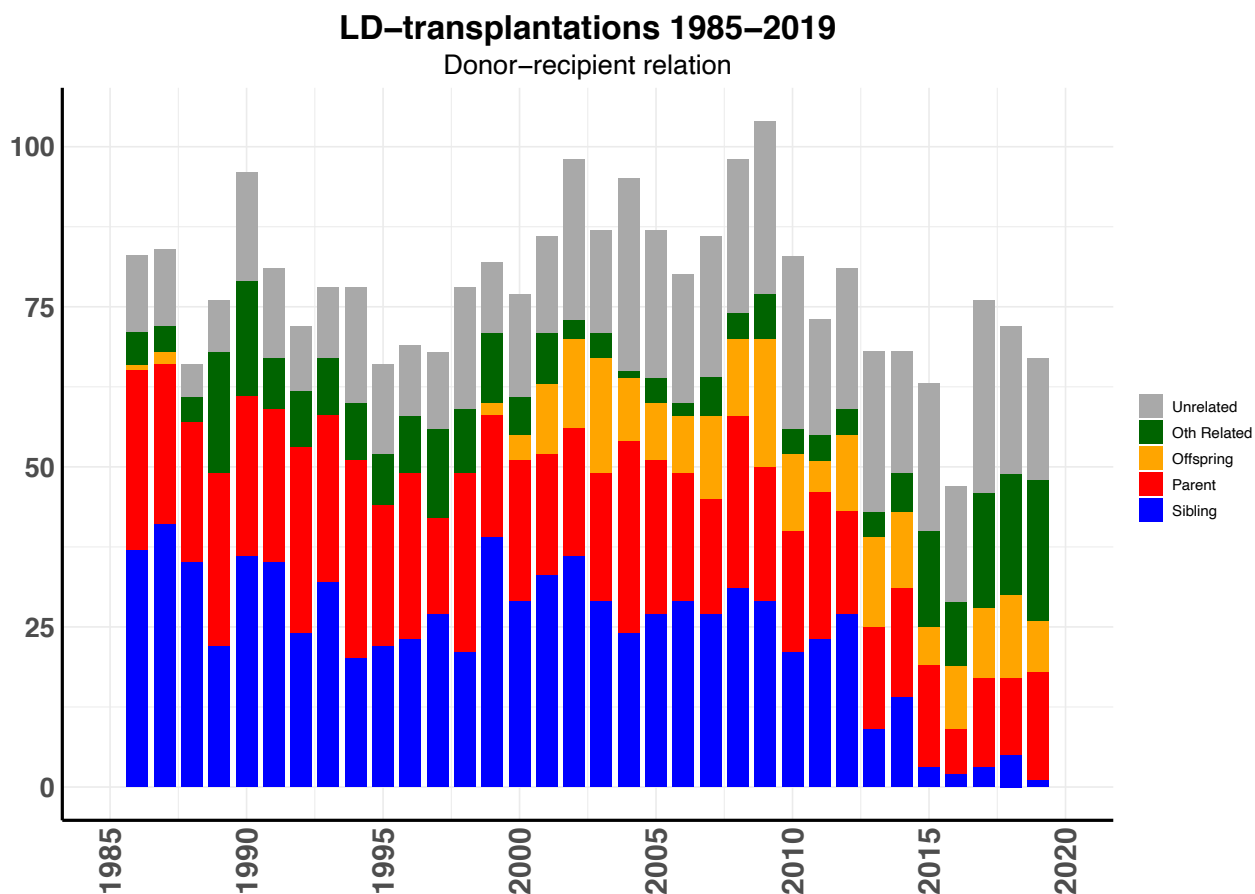
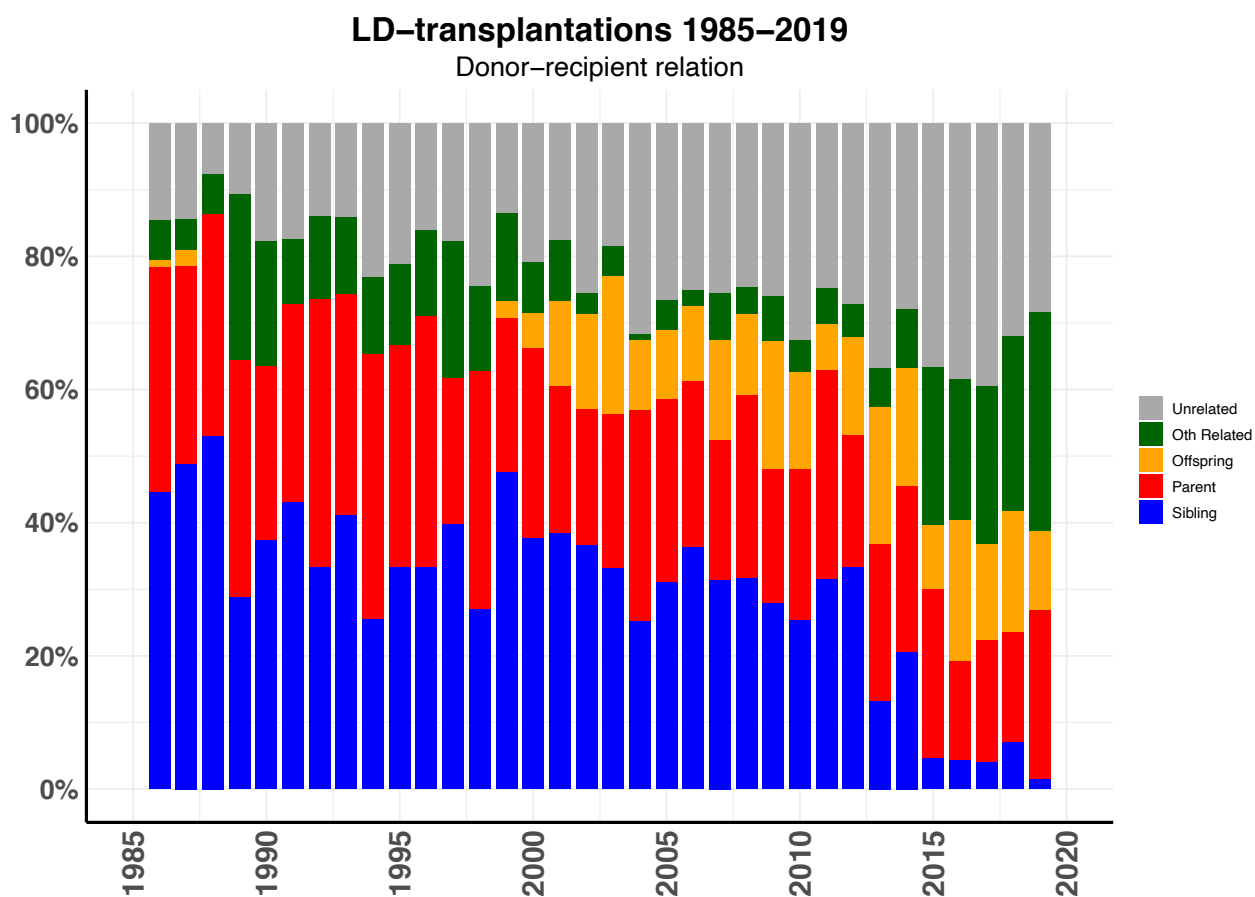
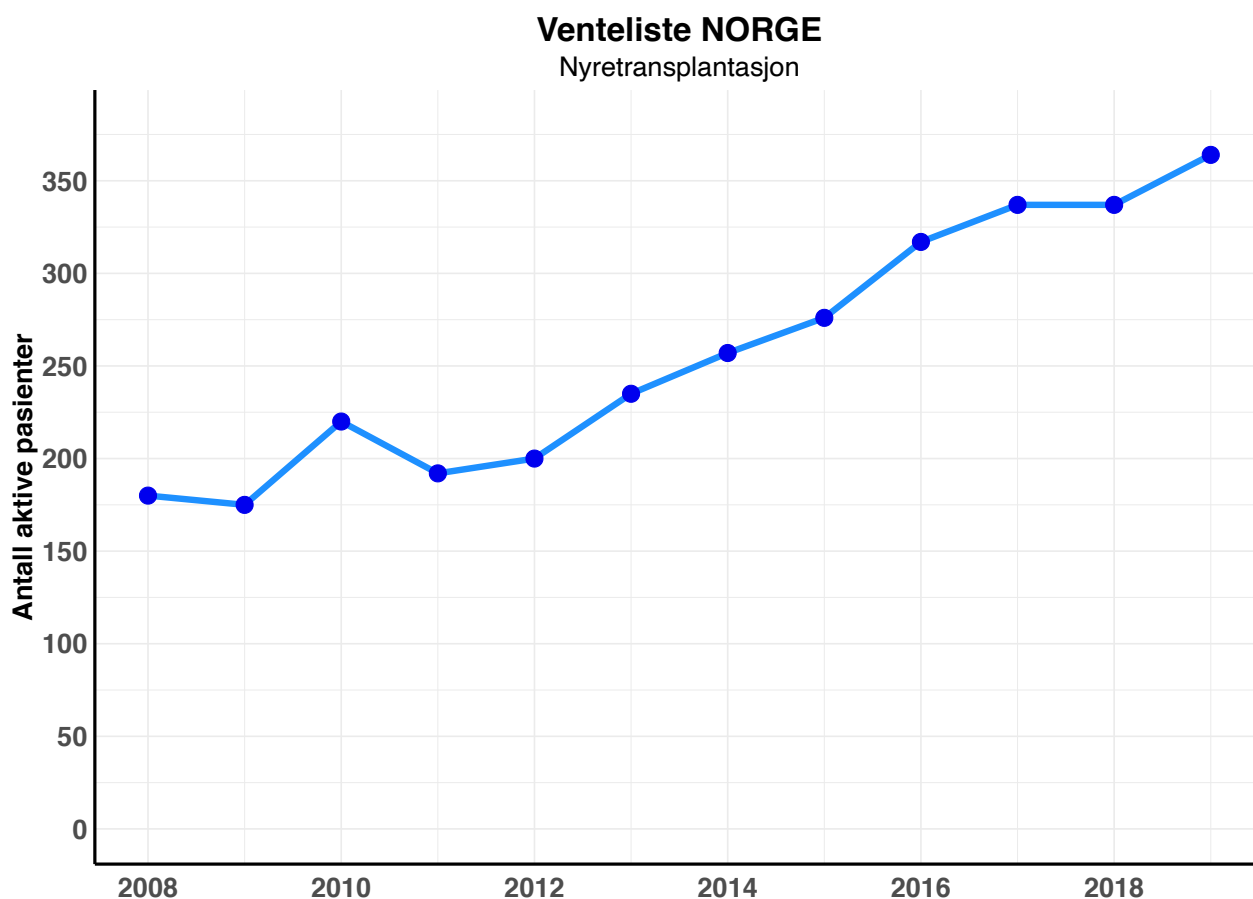


Figure 25:



By end 2019, 364 patients (68.1 per mill.) were on the active waiting list for a DD renal graft, an 8 % increase from 2018. Among those waiting by December 31st, median time on the list was 10 months for a first transplant. 54 % had waited less than one year and 22 % more than two years. The 184 recipients transplanted with a DD-graft in 2019 had a median waiting time of 13 months for a first transplant and 17 months for a retransplant and a maximum of 51 months at the time of grafting.

Figure 26:



Patient and graft survival:

Below different Kaplan-Meier analyses on graft (not death censored) and patient survival are presented, crude plots only. Changes in baseline characteristics should be taken into consideration, for example that median age when starting RRT is increasing by the year.

Figure 27:

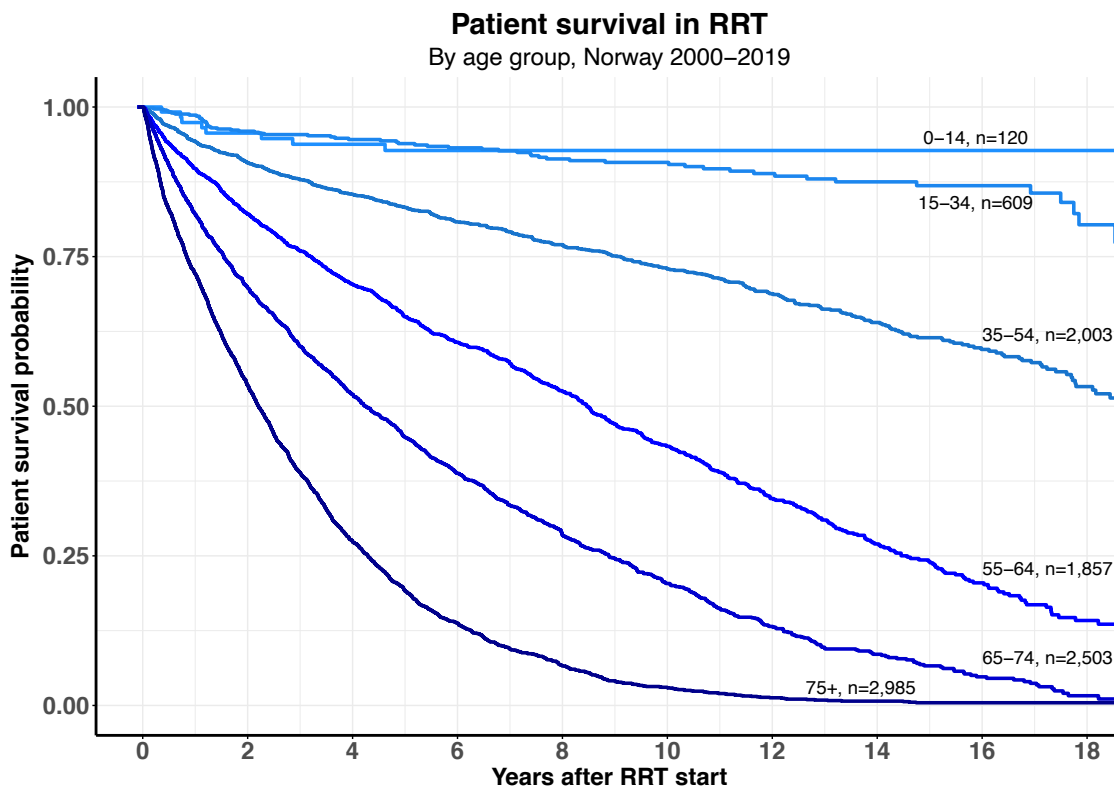


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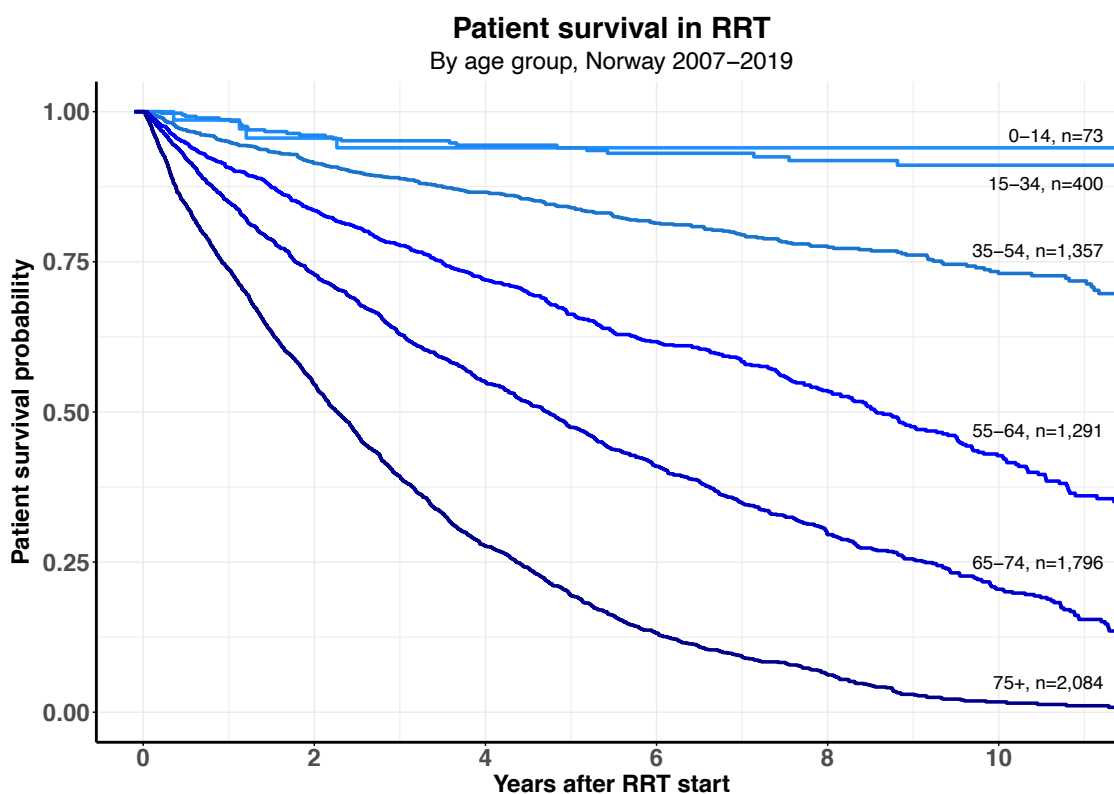


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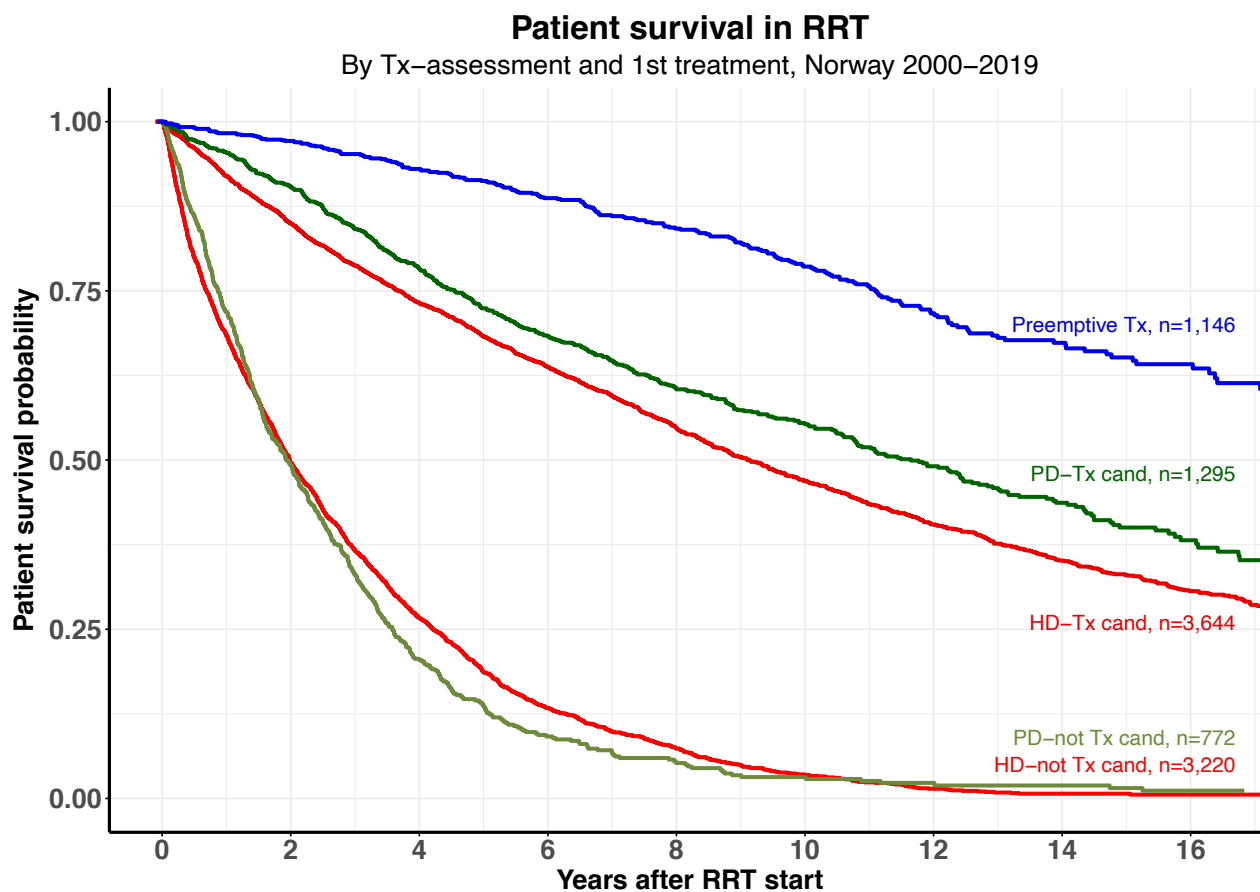


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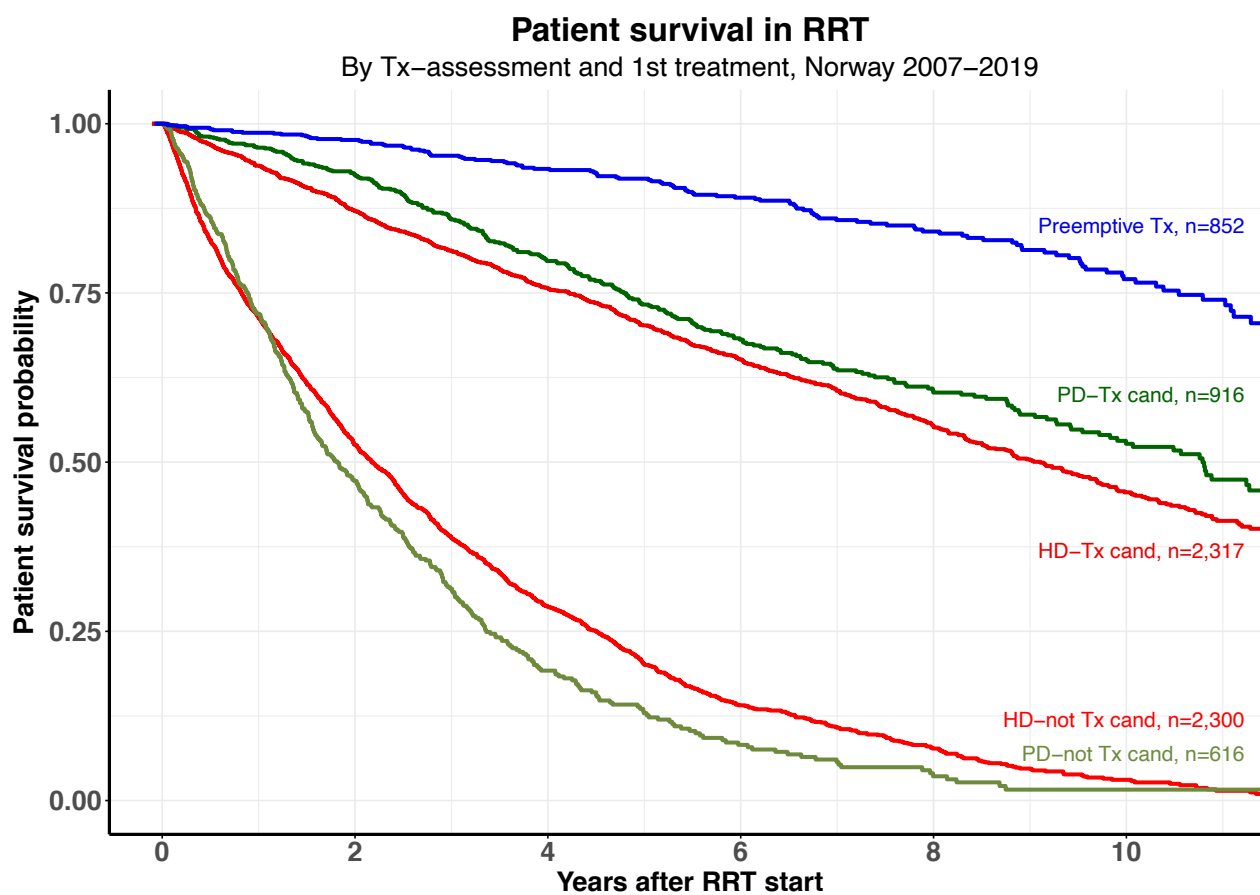


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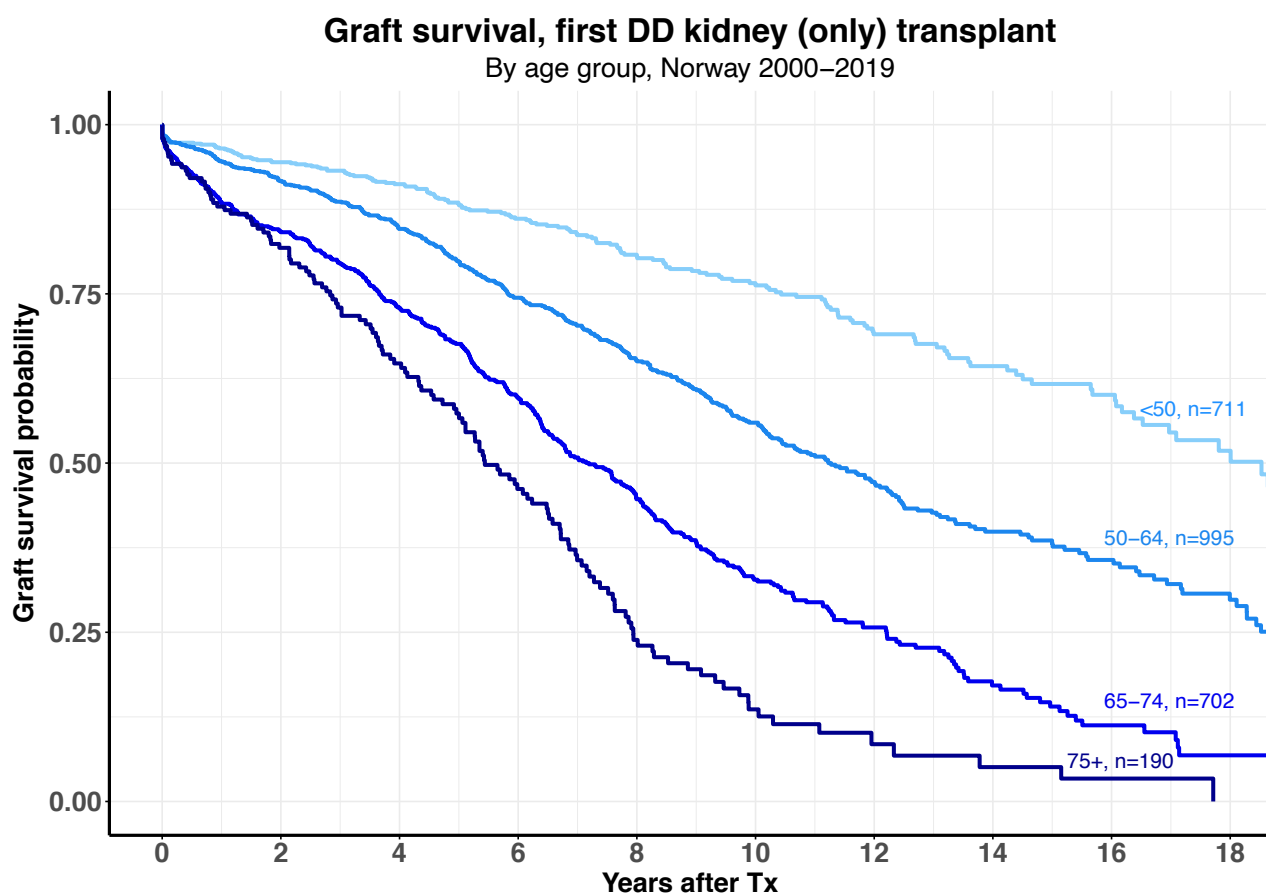


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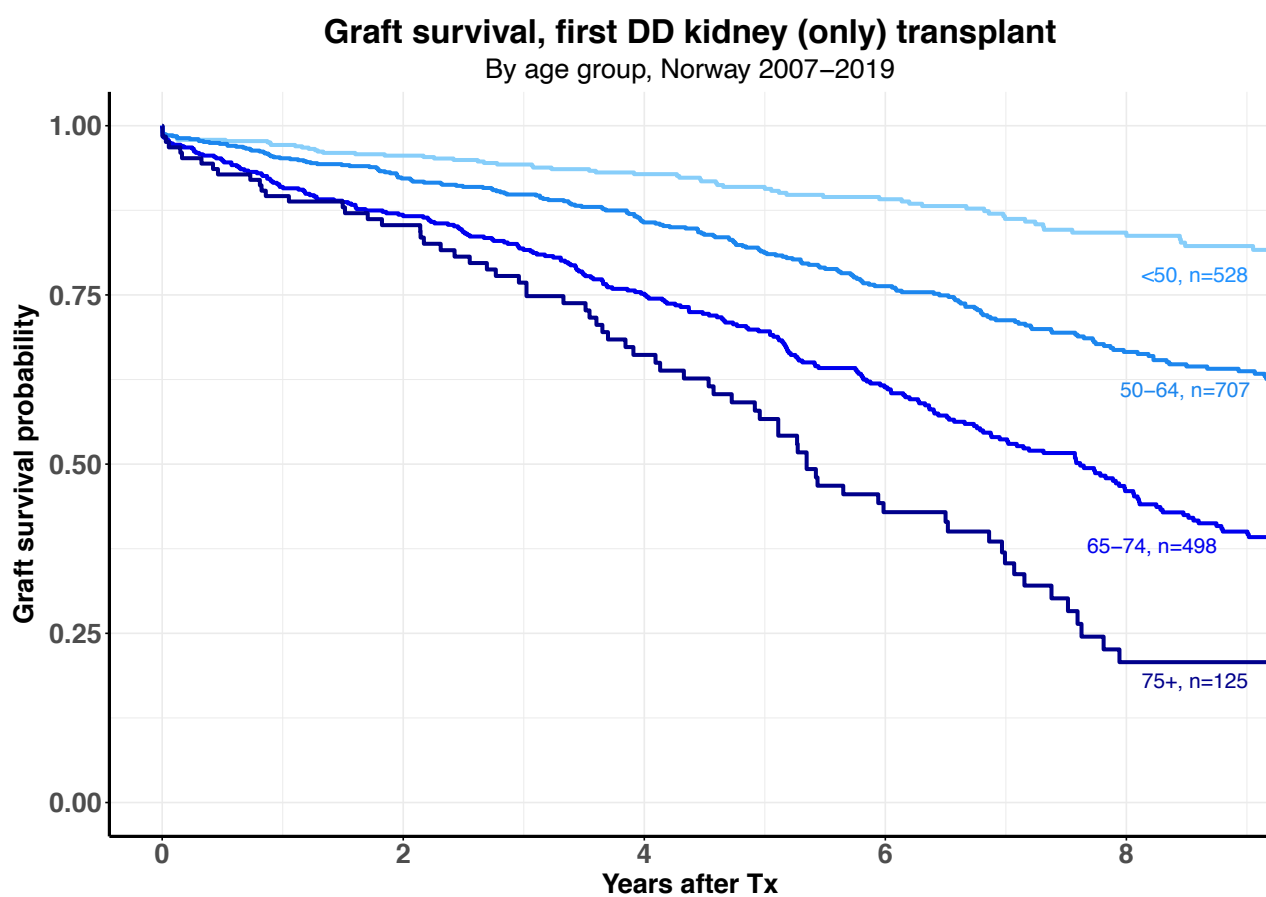


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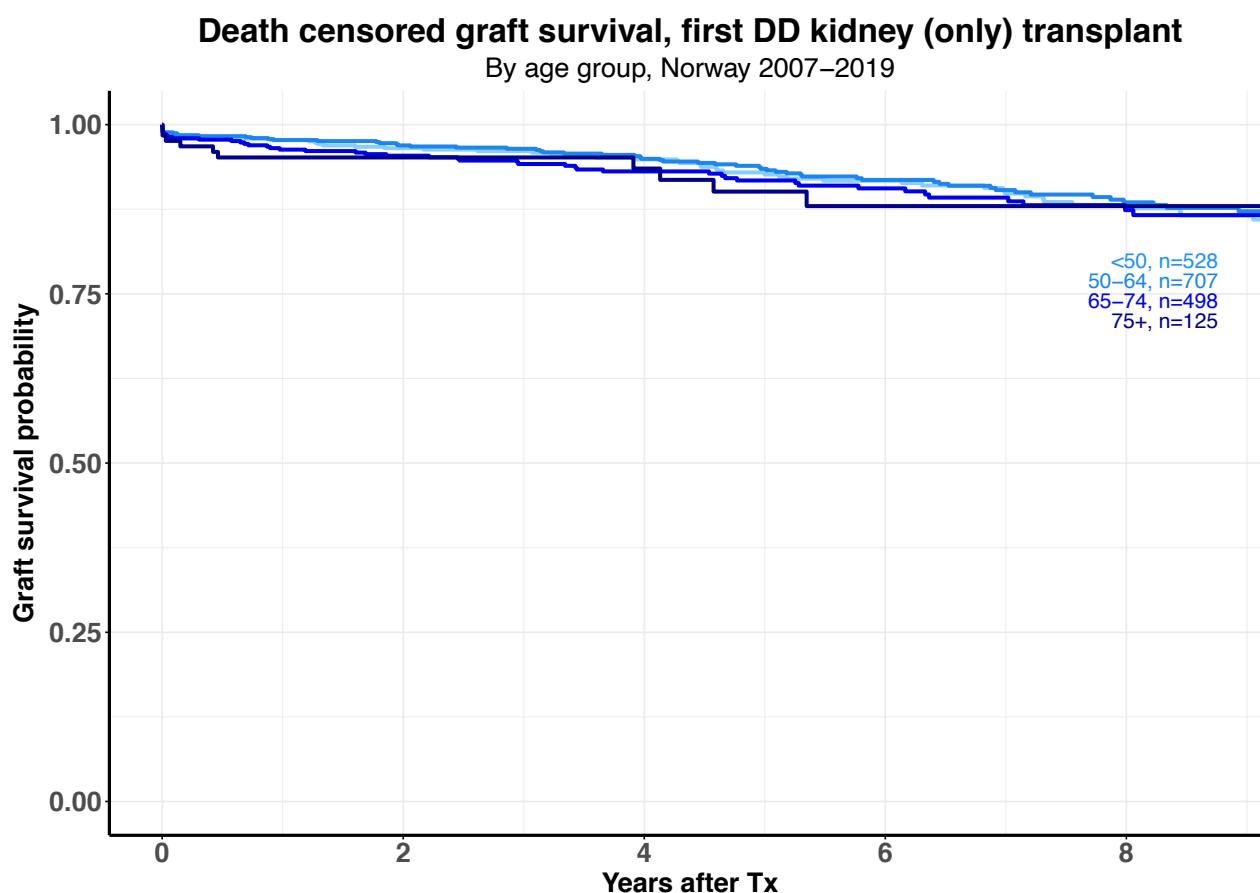


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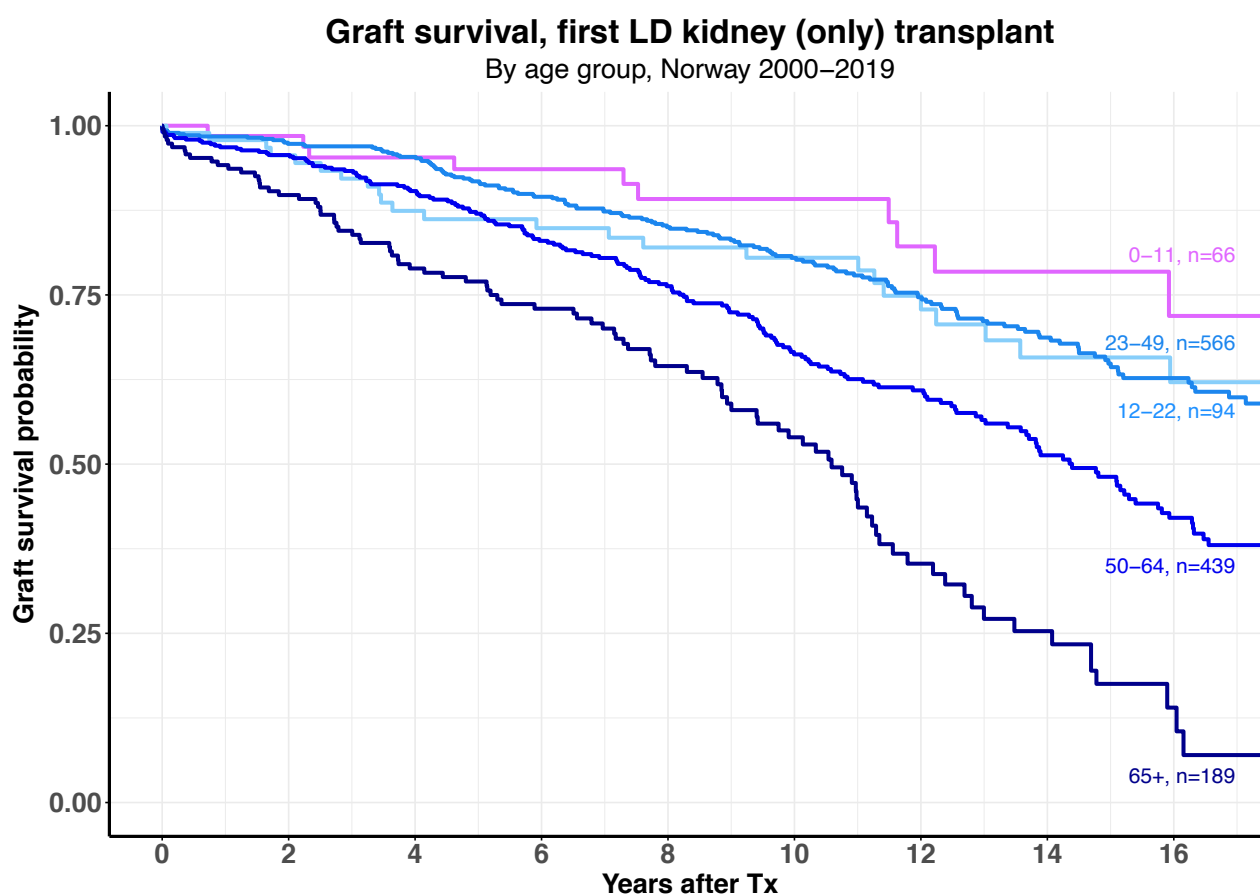


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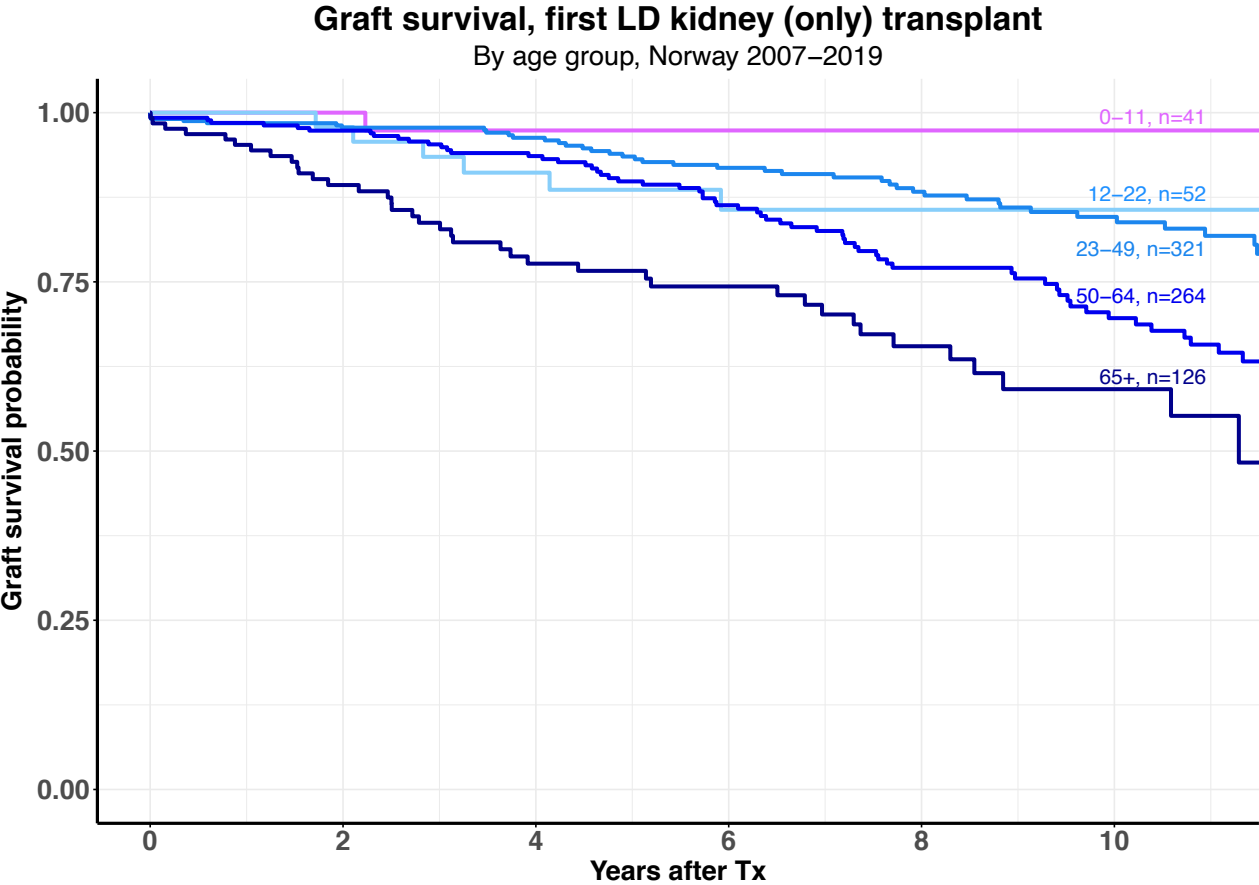


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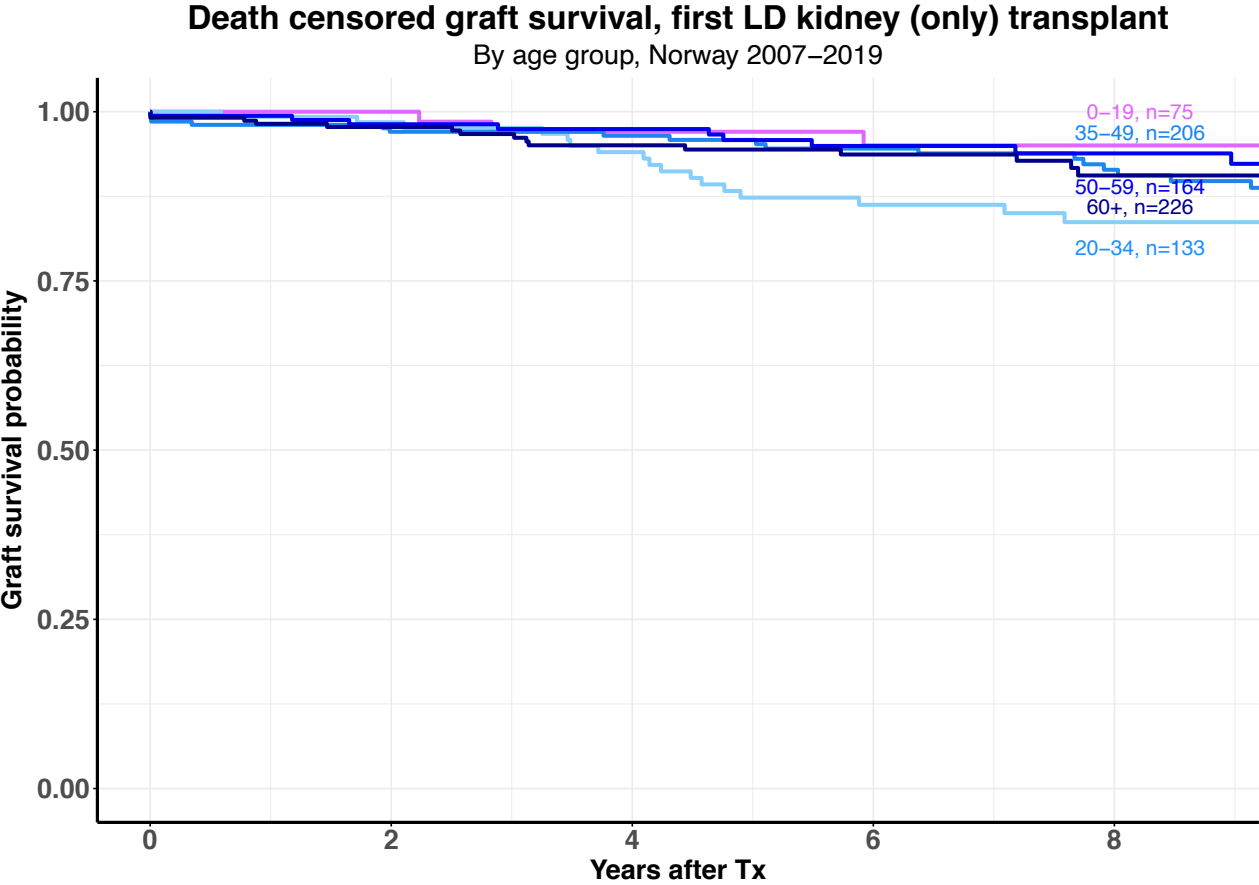


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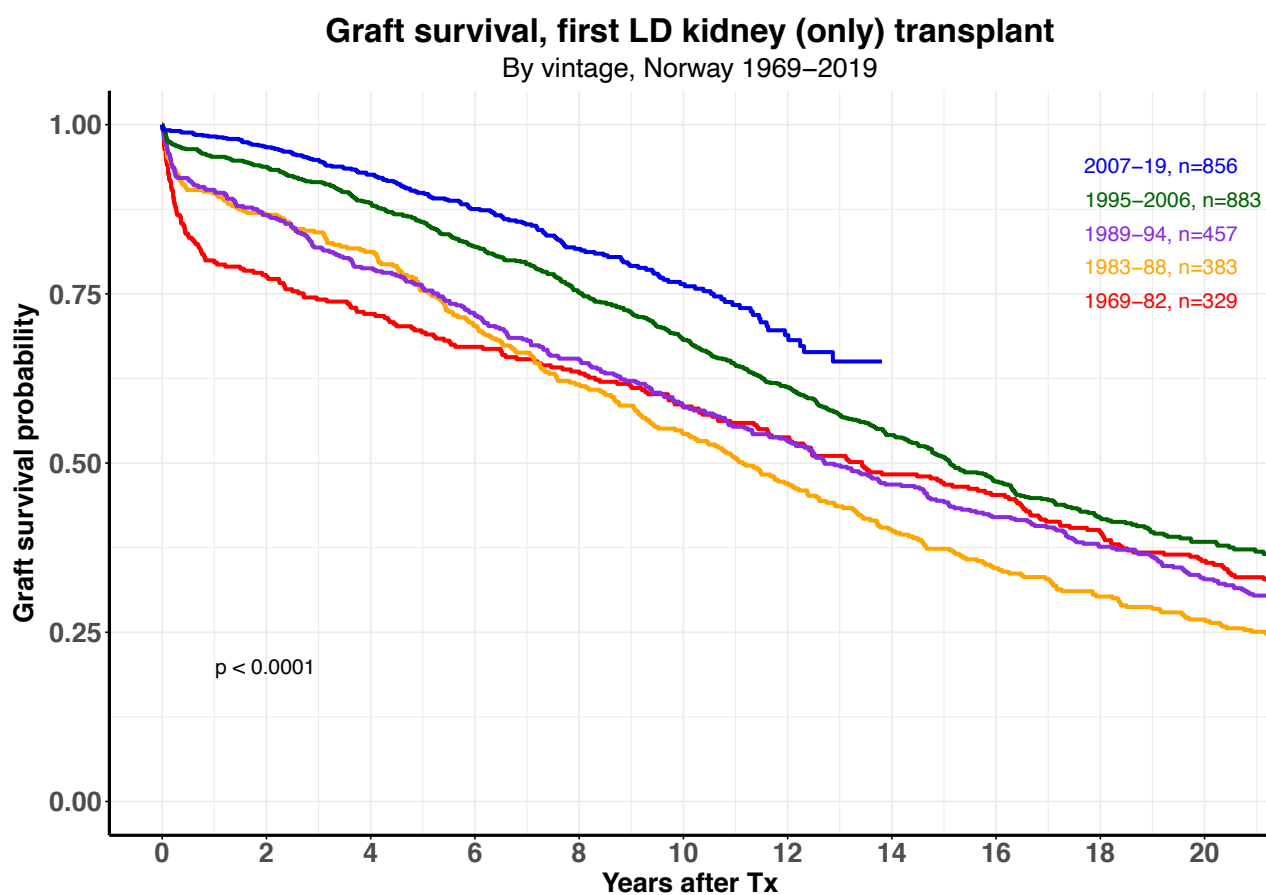


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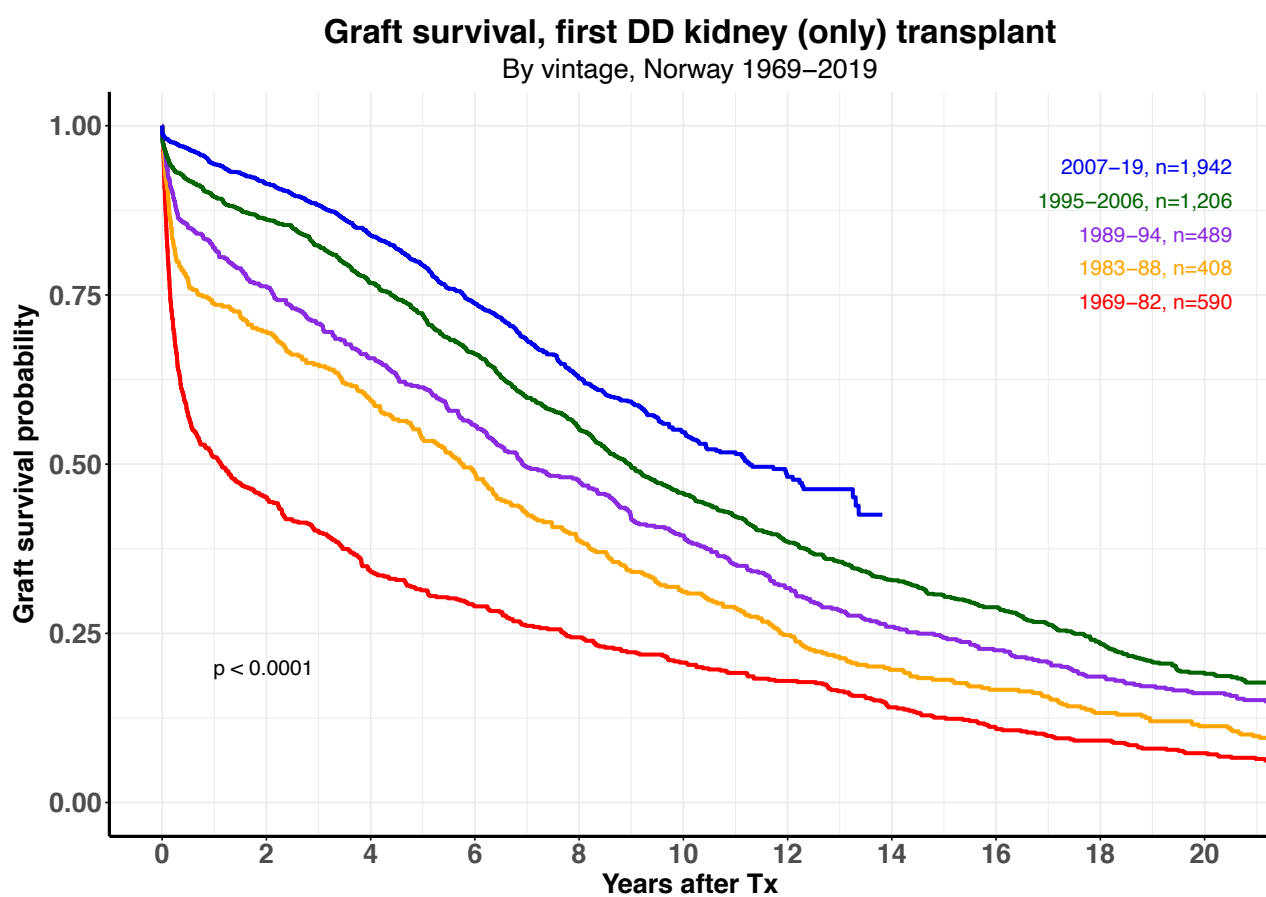


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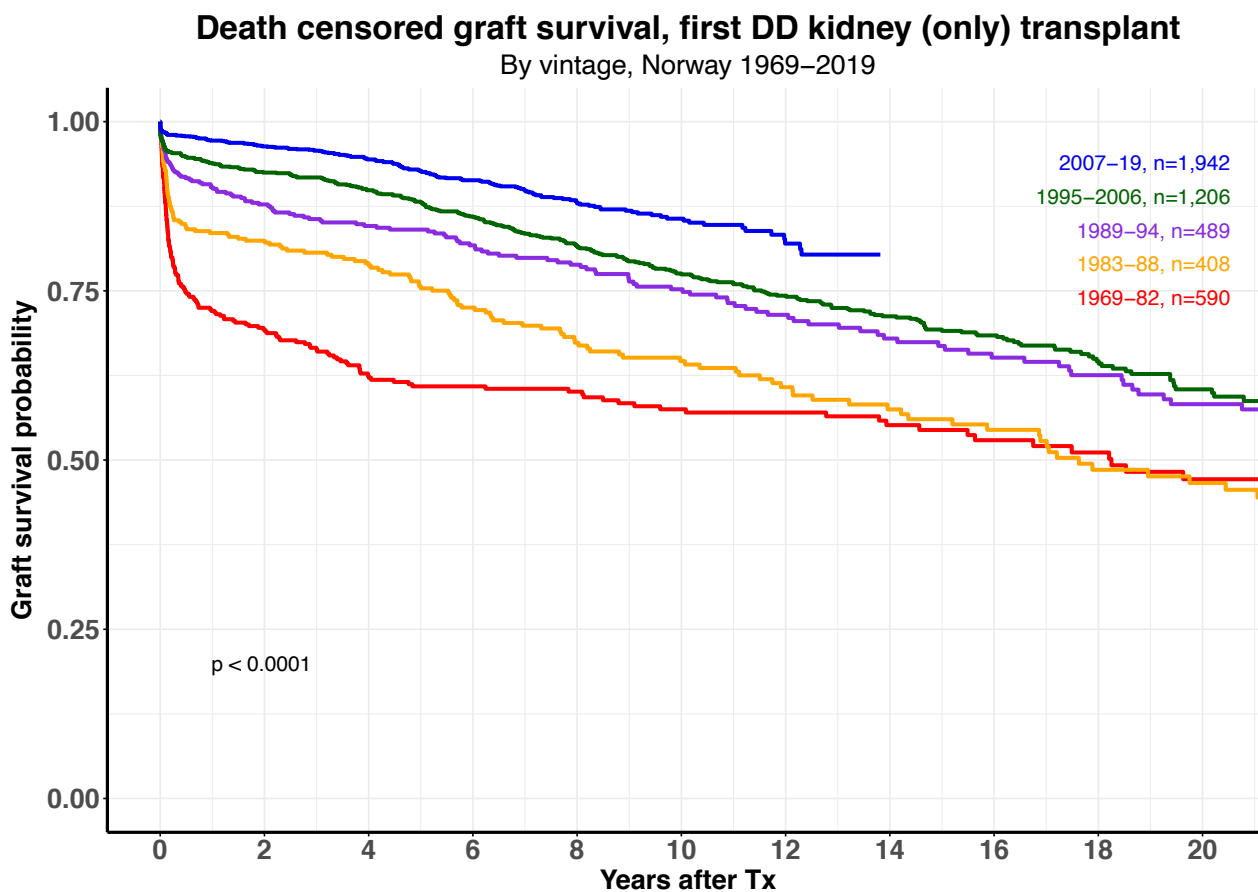


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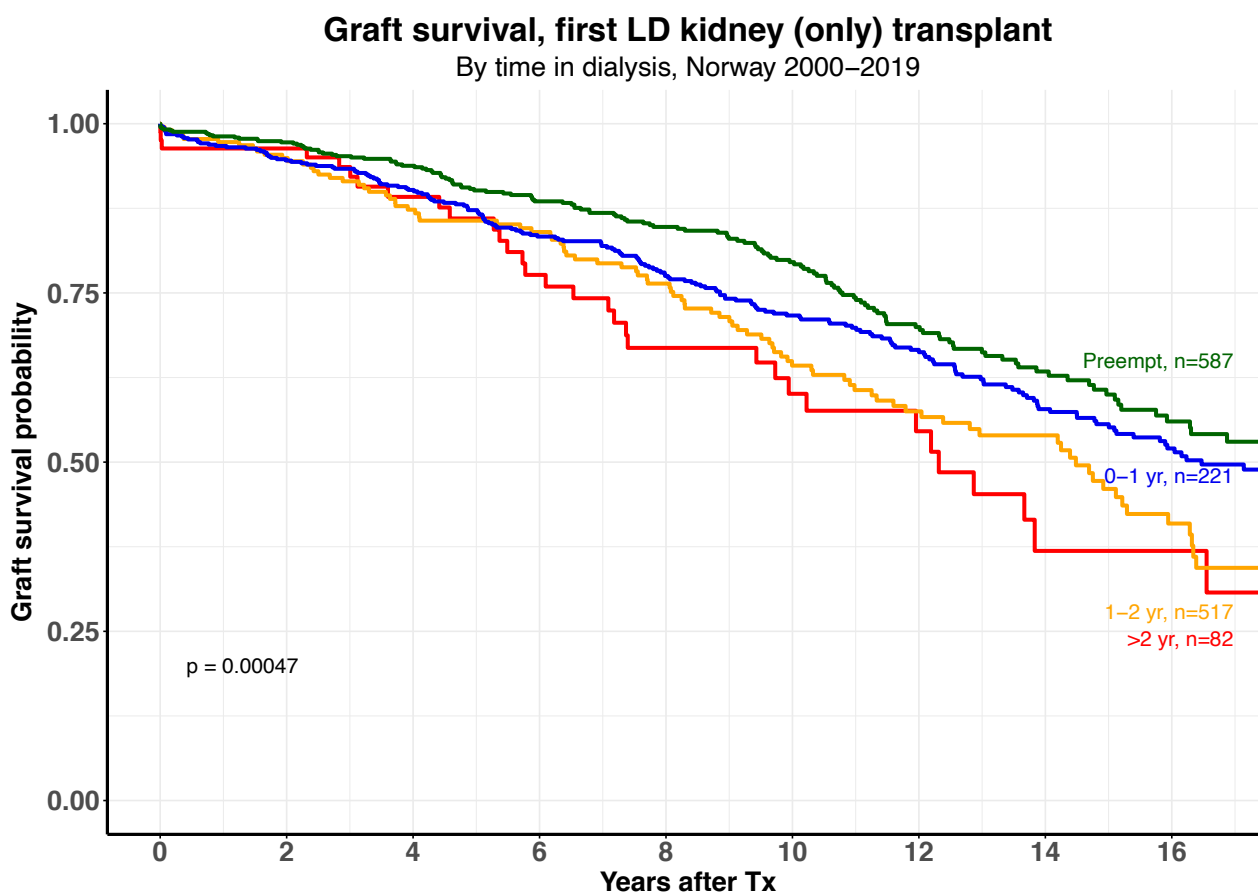


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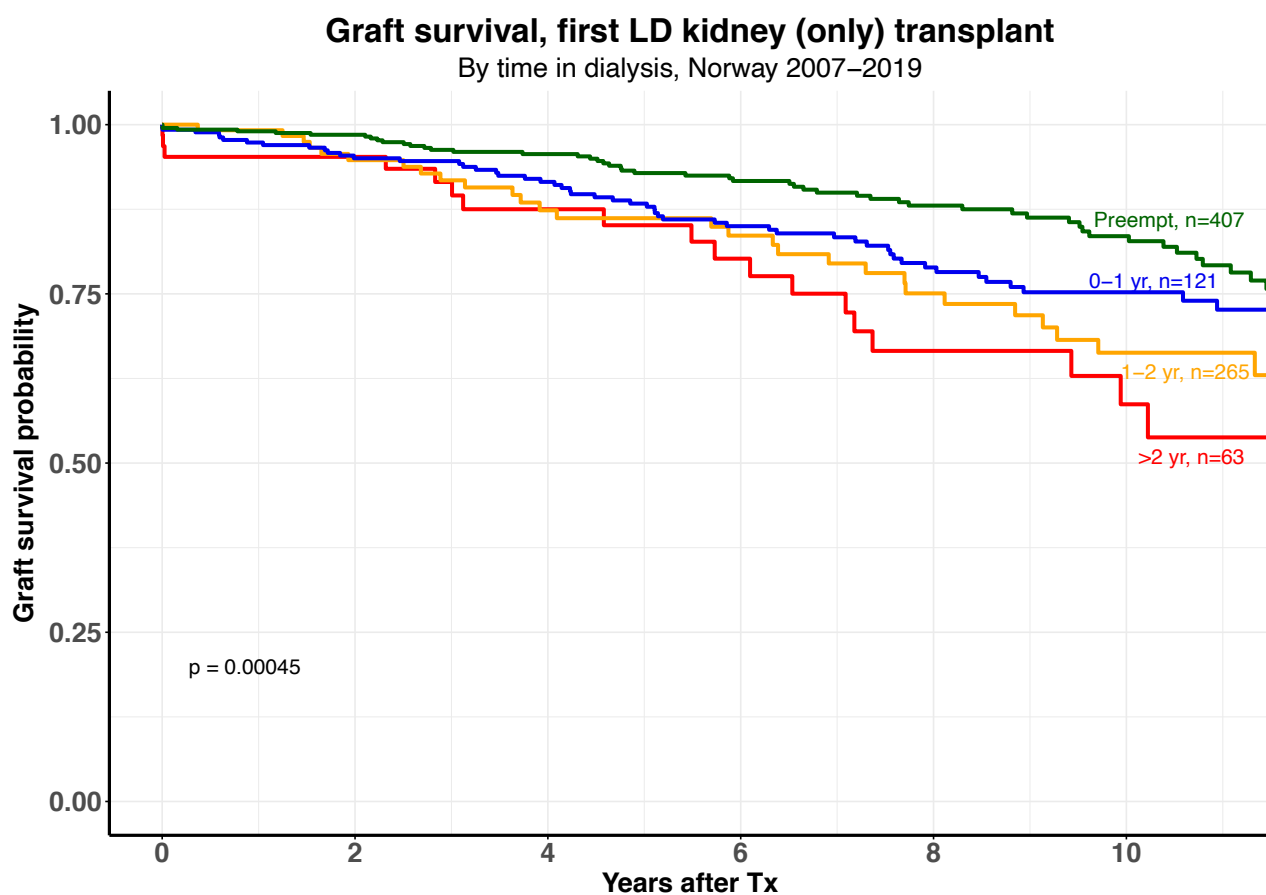


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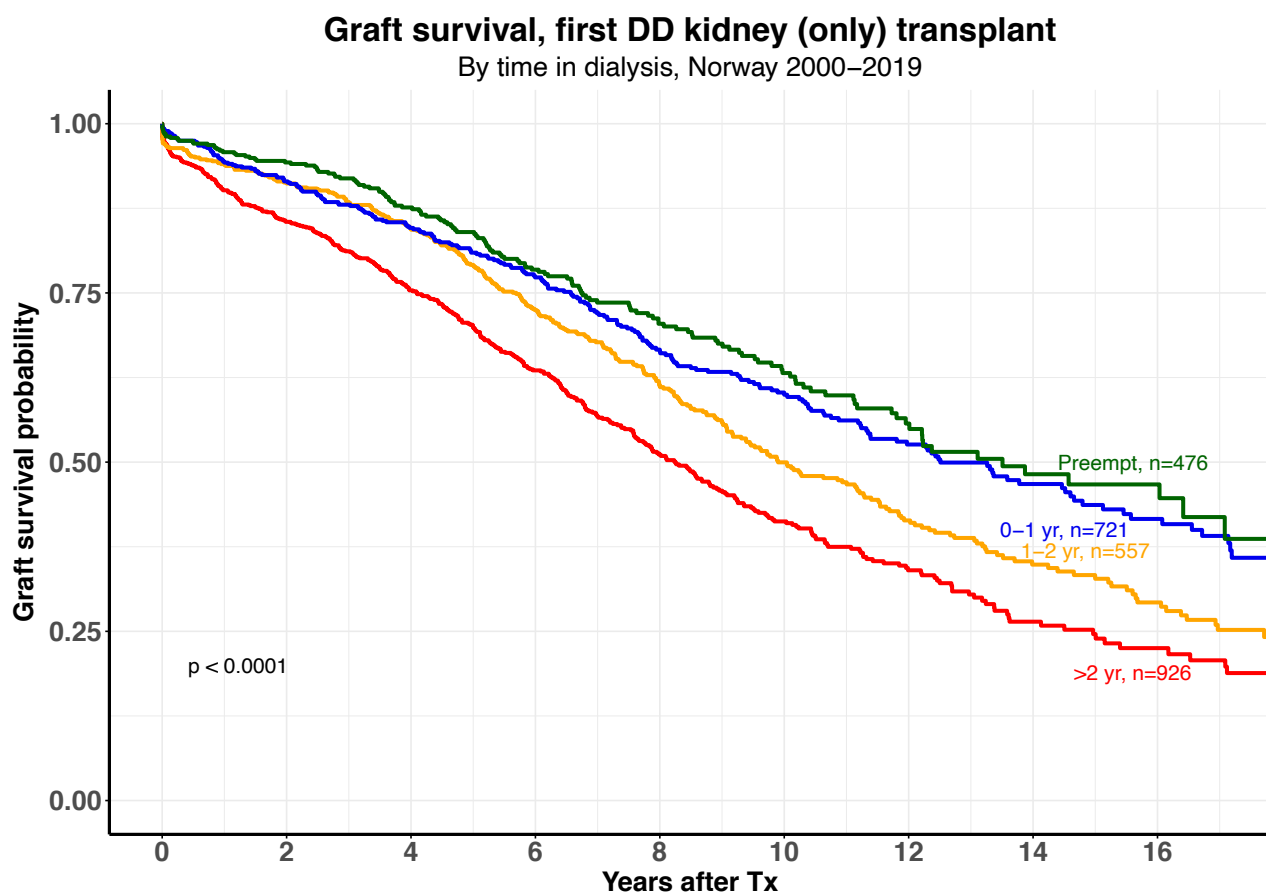


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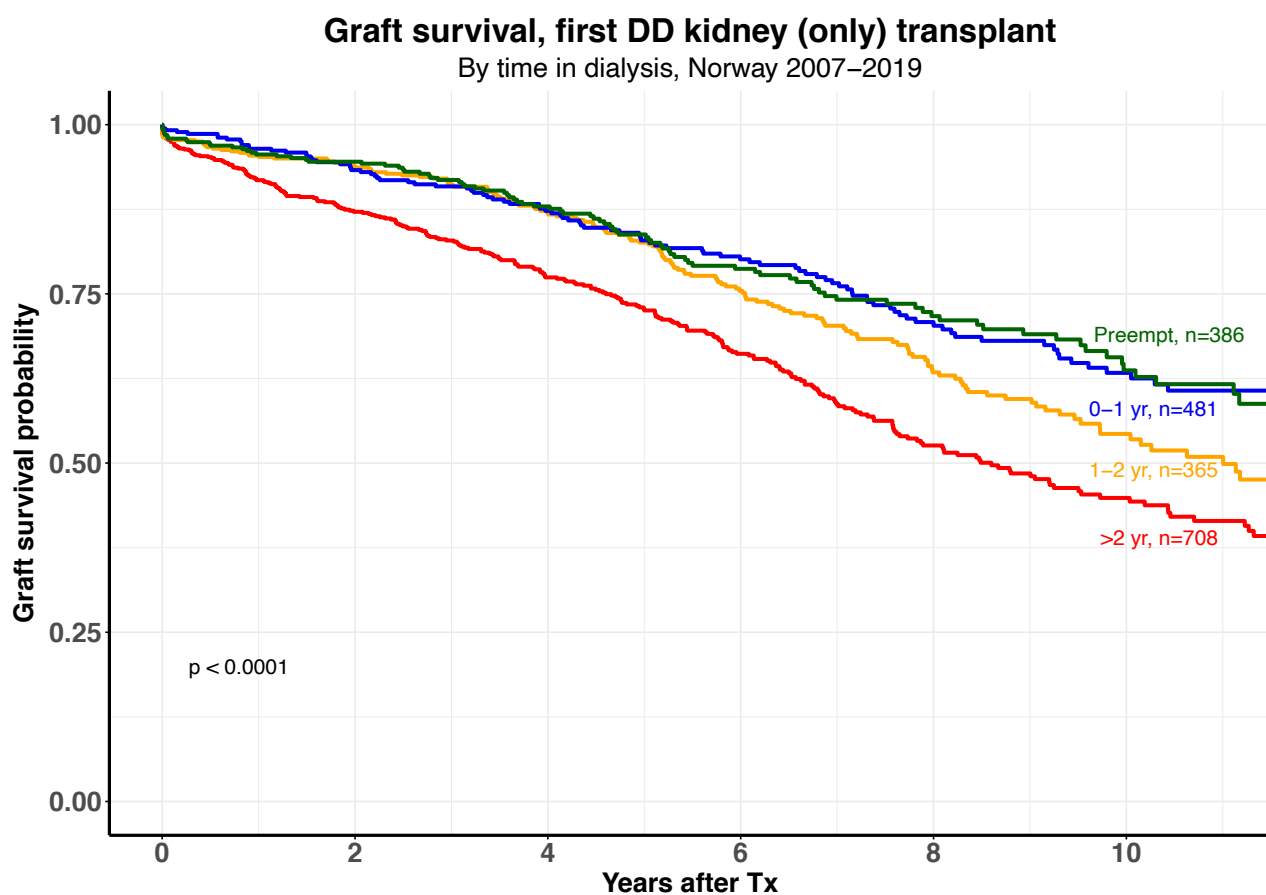


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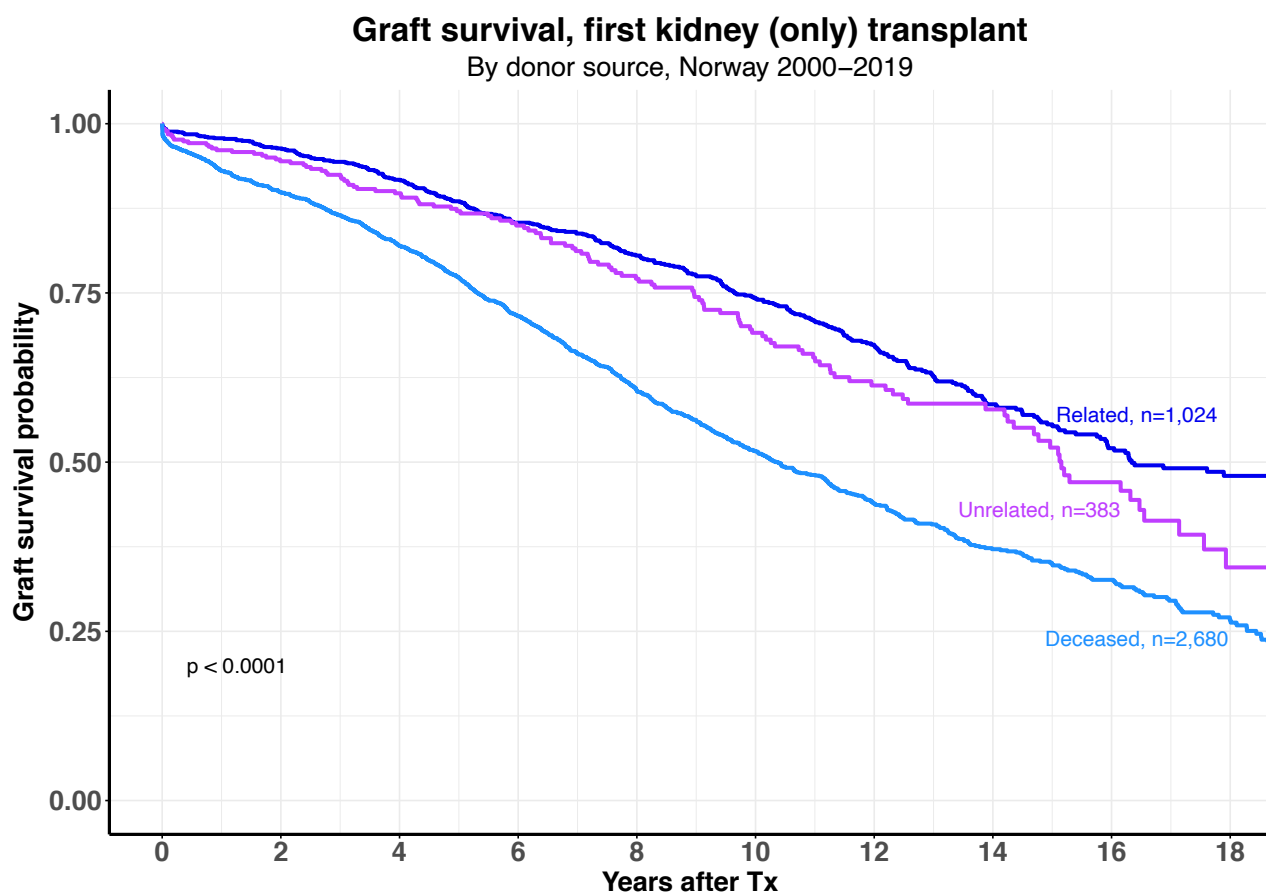
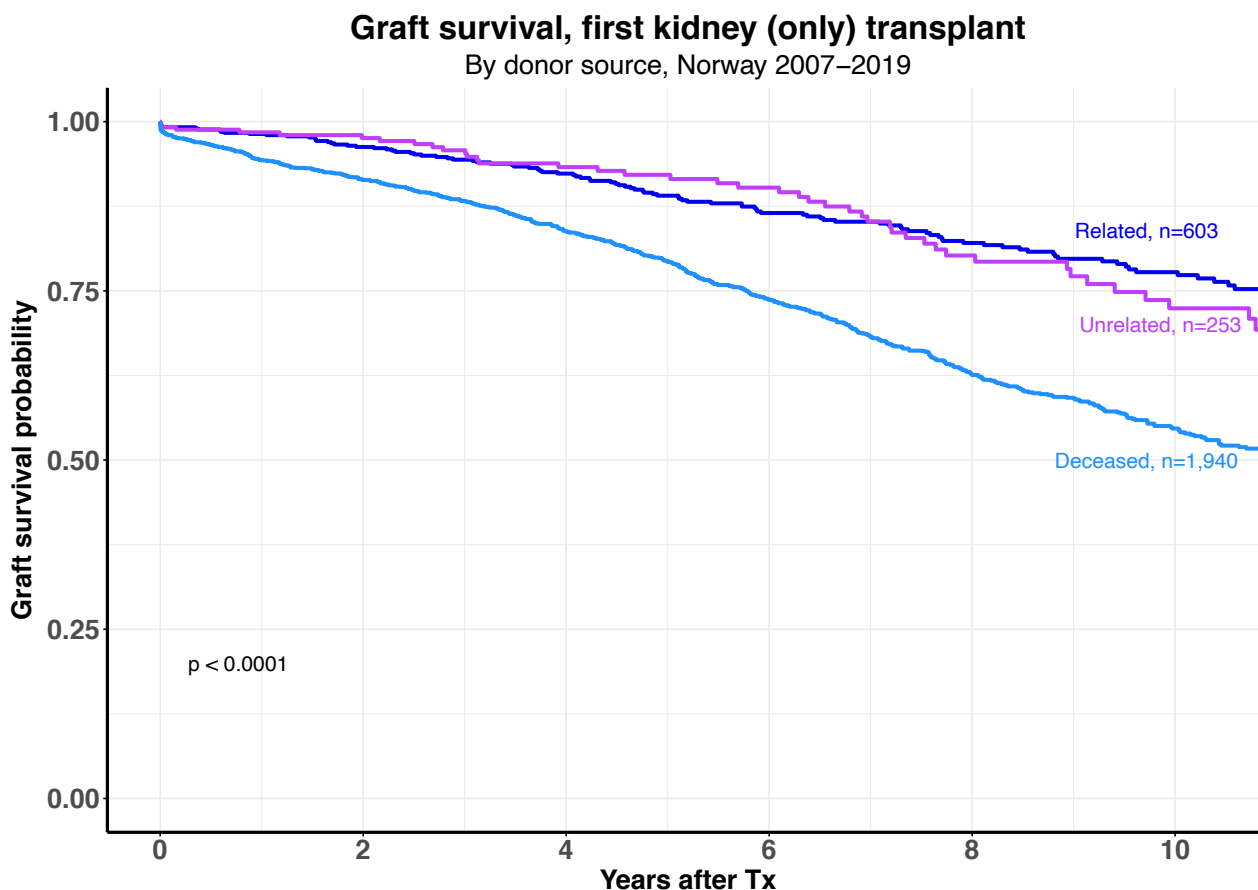


Figure 45:



Death in CKD5:

A total of 514 patients in CKD5 died during 2019, 67 of these patients had never started RRT (48% being RRT candidates), 315 of patients were in active dialysis (of which 27 were previously transplanted) and 132 transplanted. Dialysis treatment was terminated and followed by death in 35 patients.

Median age at death was 76 years (mean 74 years), ranging from 3 to 95 years. Median time from start of RRT until death was 4.1 years (mean 7.2 years), ranging from 1 week to 50 years.

Infections (26%) and cardiac complications (25%) were the most frequent causes of death, followed malignant tumors (11%).

Quality indicators:

The registry has implemented 22 quality indicators (see appendix) that will be followed year by year to assure the quality of the treatment the patients included in the registry is subjected to. These data are presented interactively at this site

(<https://www.kvalitetsregistre.no/registers/464/resultater>) and the national quality indicator of part in home dialysis is presented three times per year here

(<https://www.helsedirektoratet.no/statistikk/kvalitetsindikatorer/behandling-av-sykdom-og-overlevelse/andel-dialysepasienter-som-har-hjemmedialyse>). Only a short summary of the results is presented as figures in this report for completeness.

The registration of all cases of peritonitis during the year has not been complete and a change in collection procedure was implemented in 2017 to correct this. These data are hence only presented for the last three years in this report. Data on acute rejections are not possible to extract from the database where these are registered at OUS-Rikshospitalet why complete data is not available and this indication is not presented in the present report. The approximate acute rejection rate the first year after transplantation is in the range of 10% to 13%.

Data on part of the patients on the waiting list for a kidney transplant that has been in dialysis for more than 2 years (first kidney transplant only, excluding immunized patients, counting also time during temporary withdrawals) is not relevant to present on a center level. In 2019 the part decreased from 31% in 2018 to 28%.

In the figures below the red line indicate the target percentage, the black line the national average and shading in color the relative number of patients at respective center.

Figure 46:

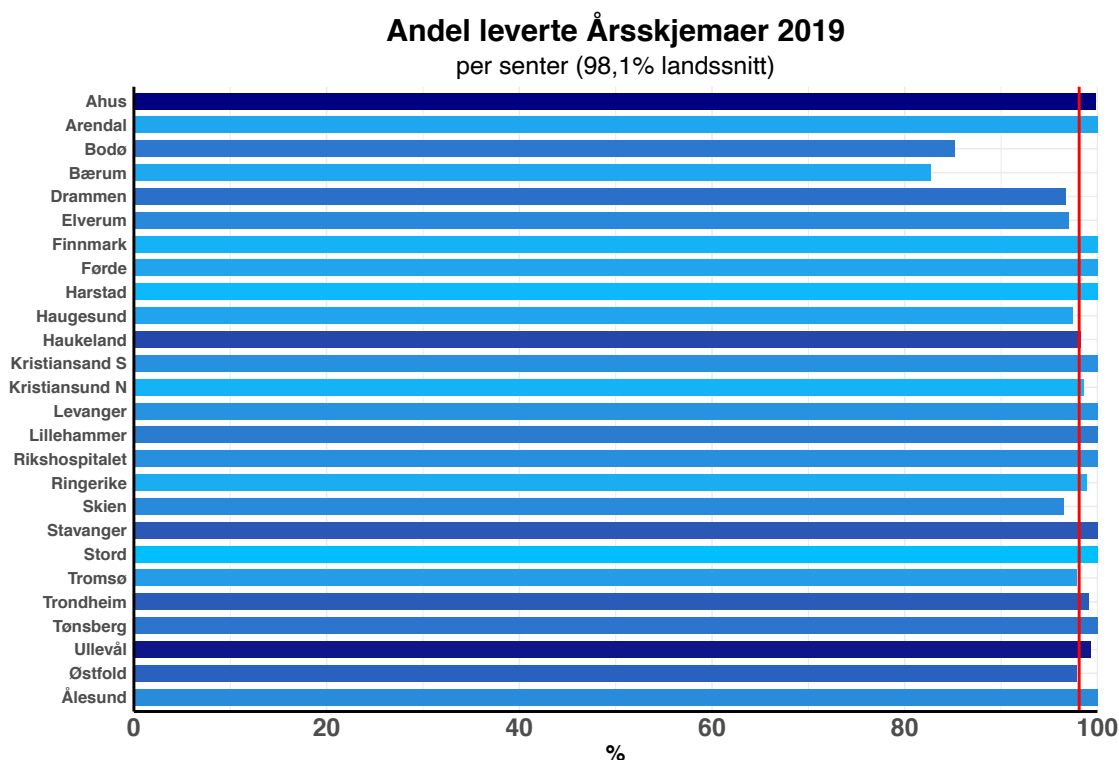


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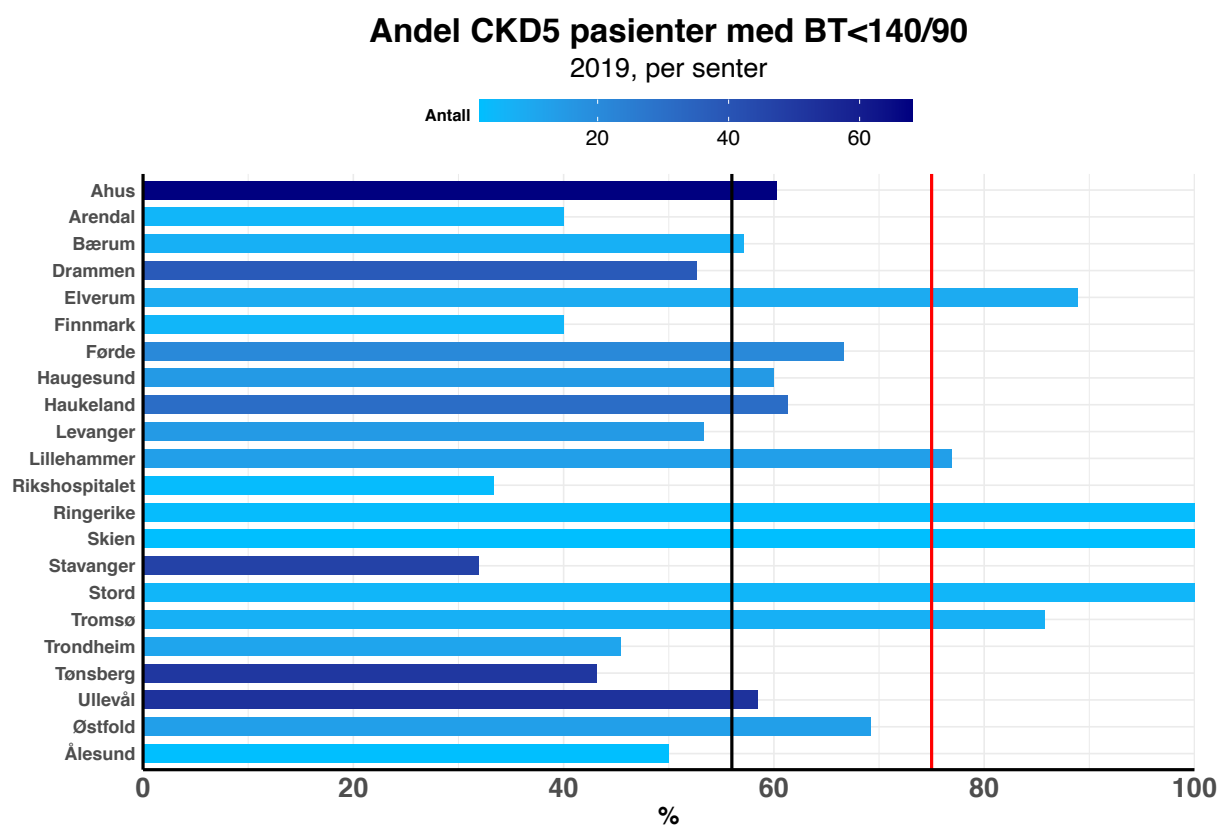


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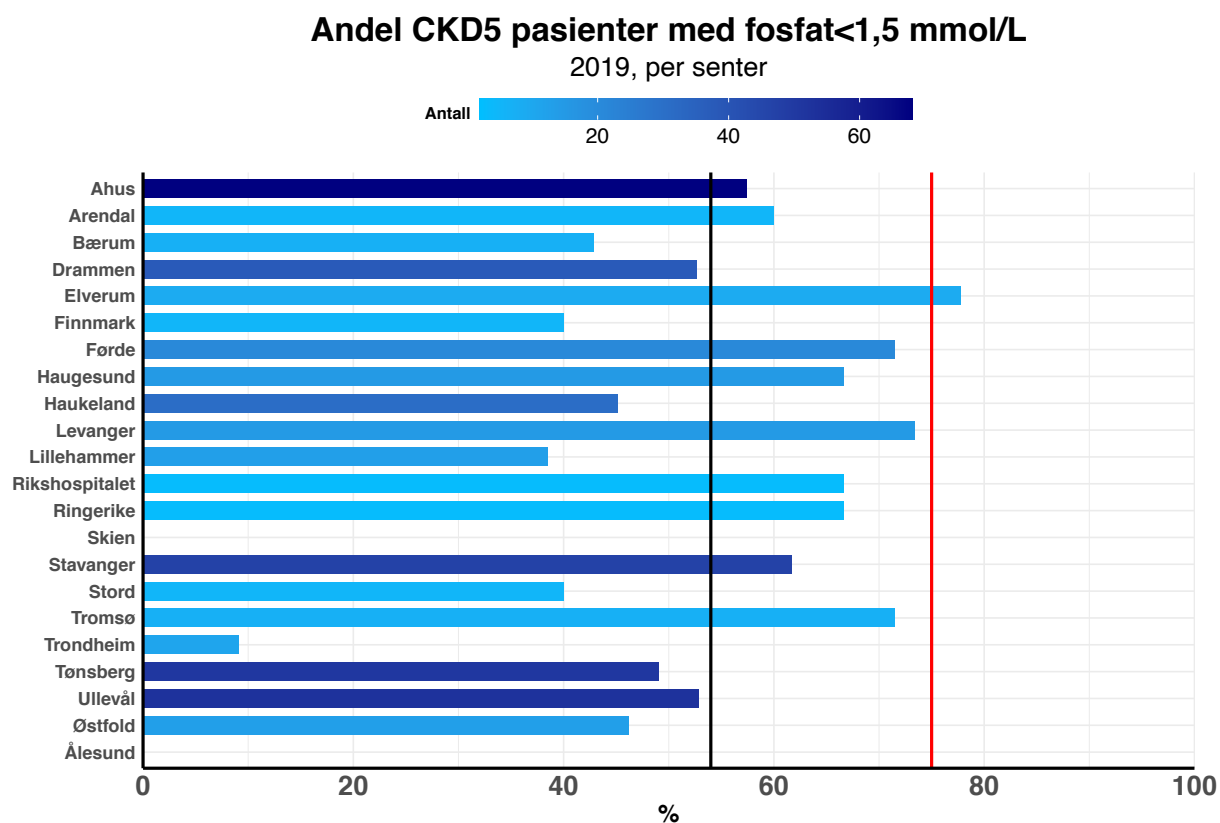


Figure 49

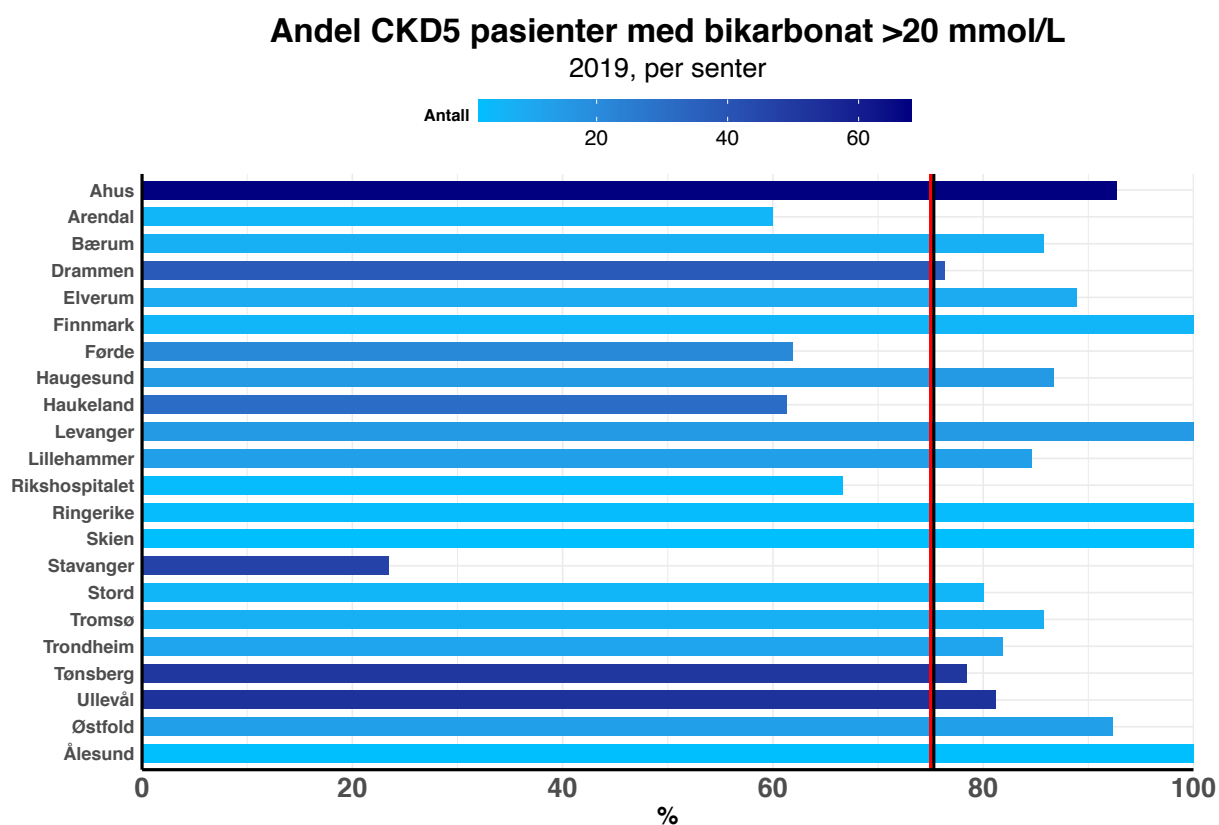


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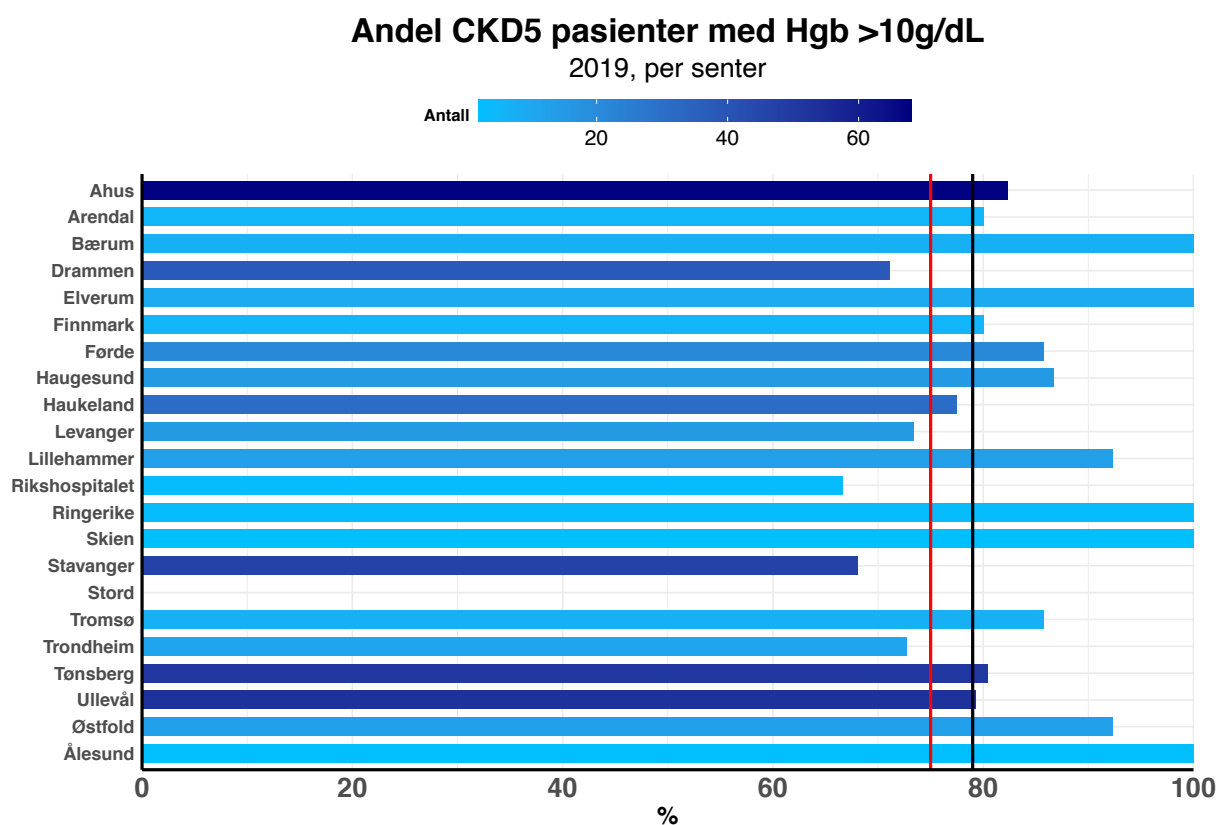


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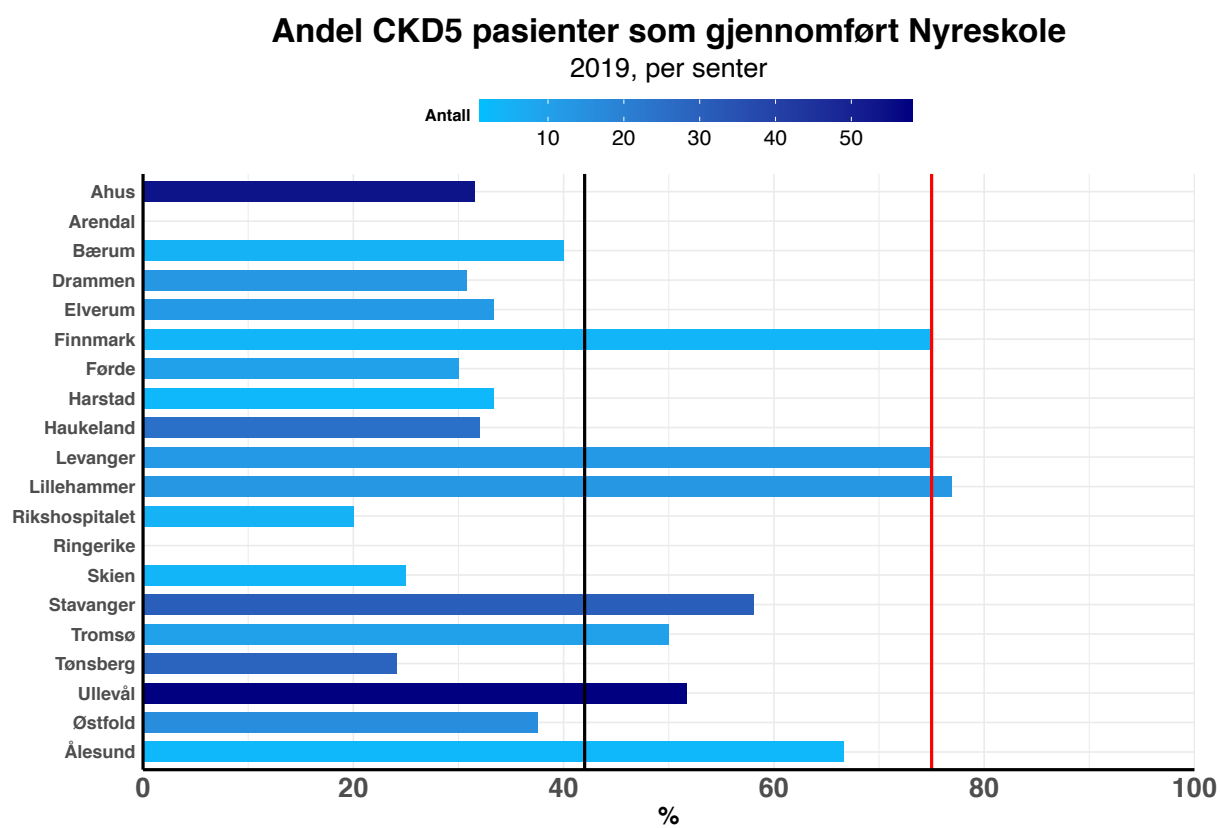


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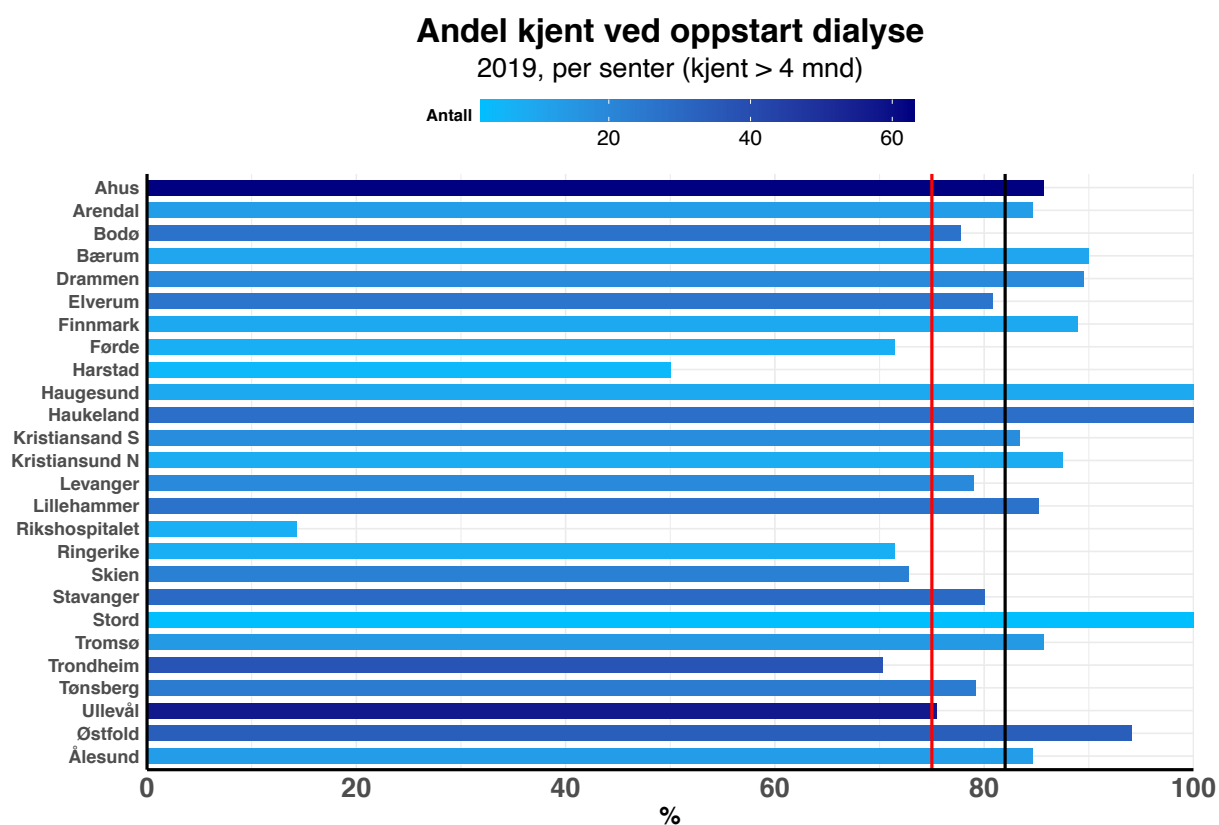


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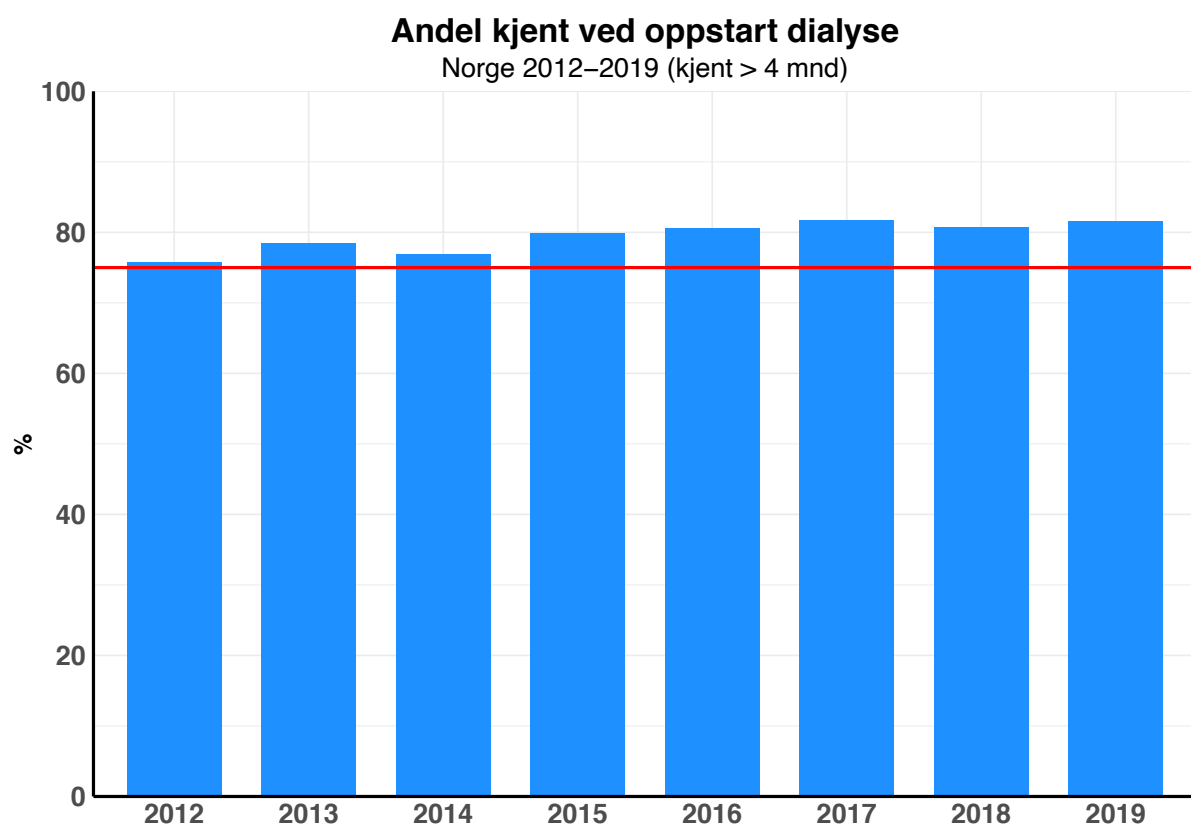


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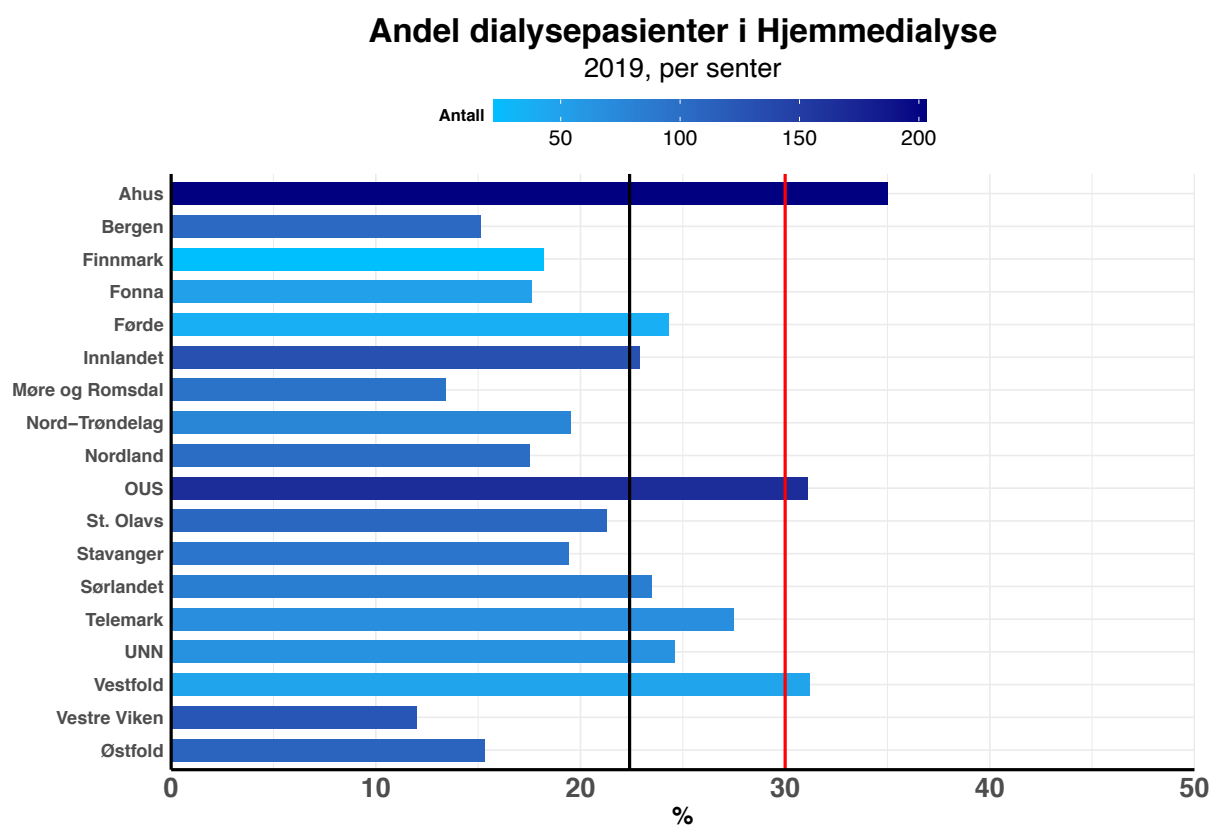


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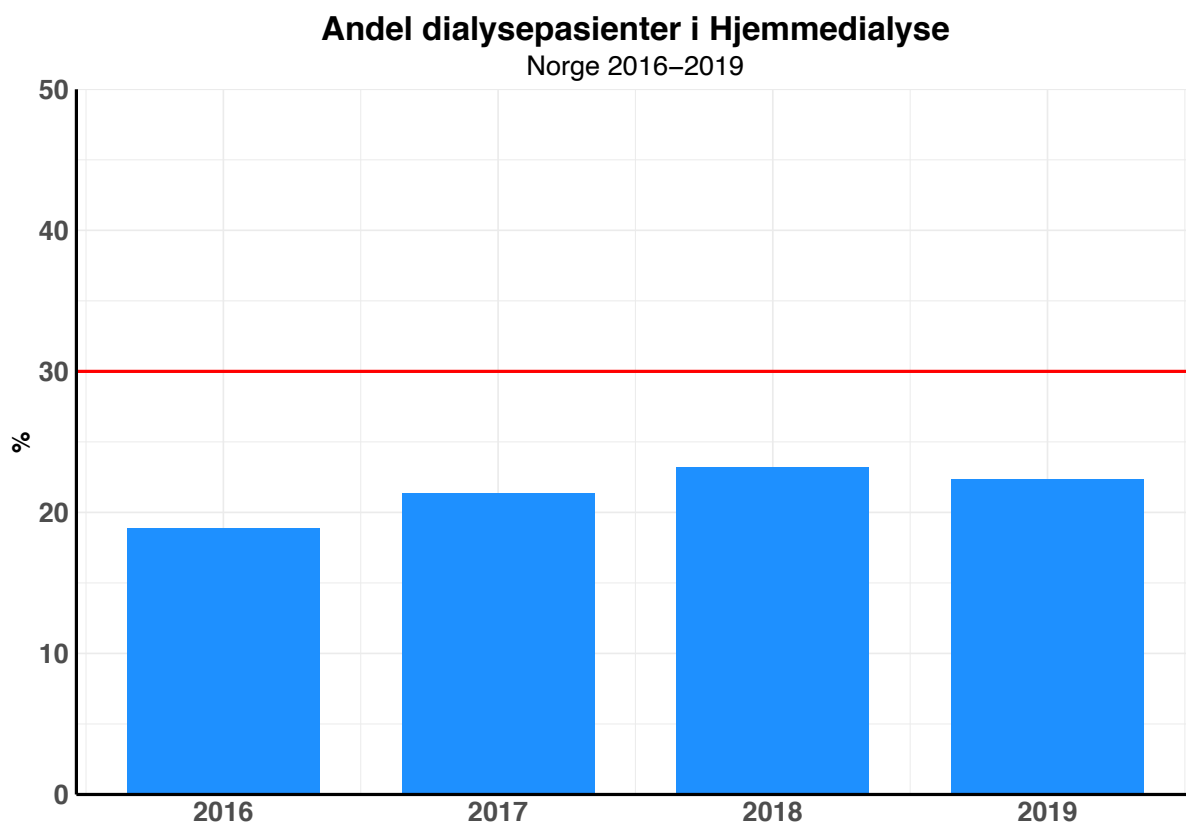


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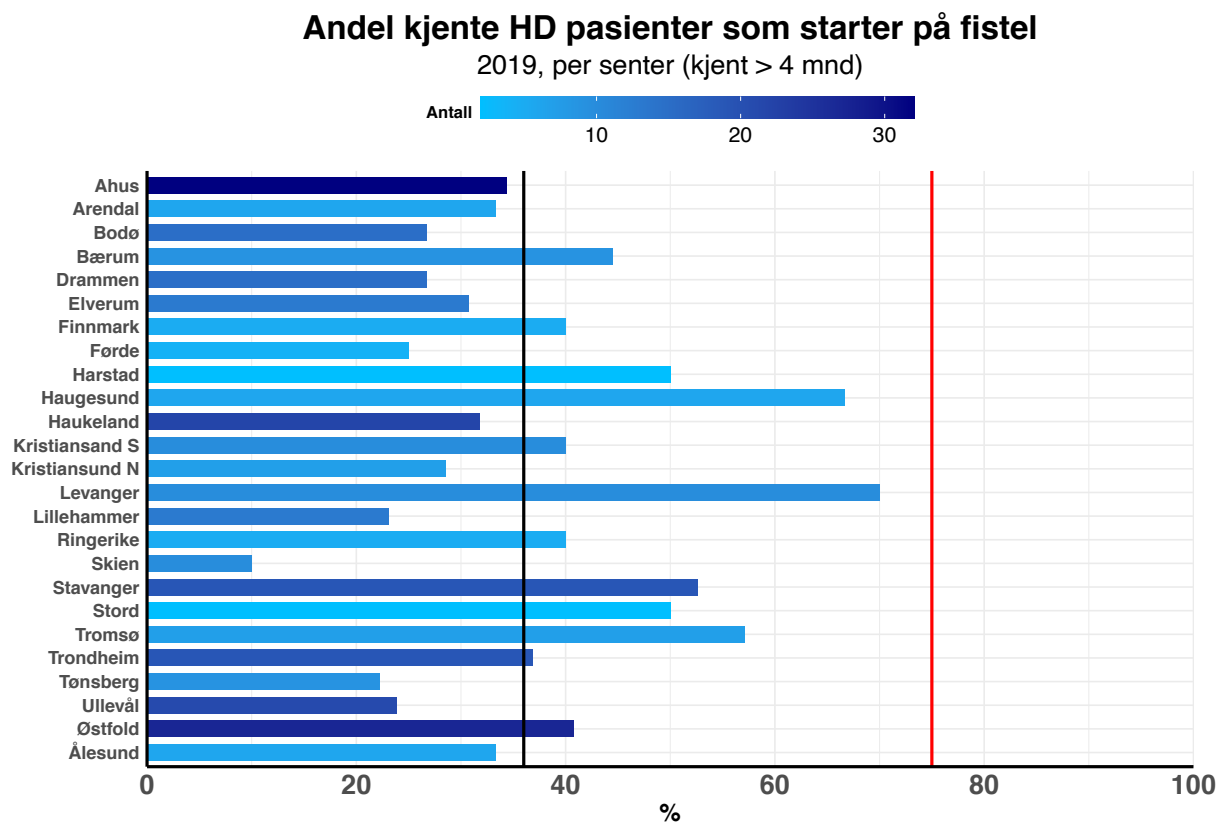


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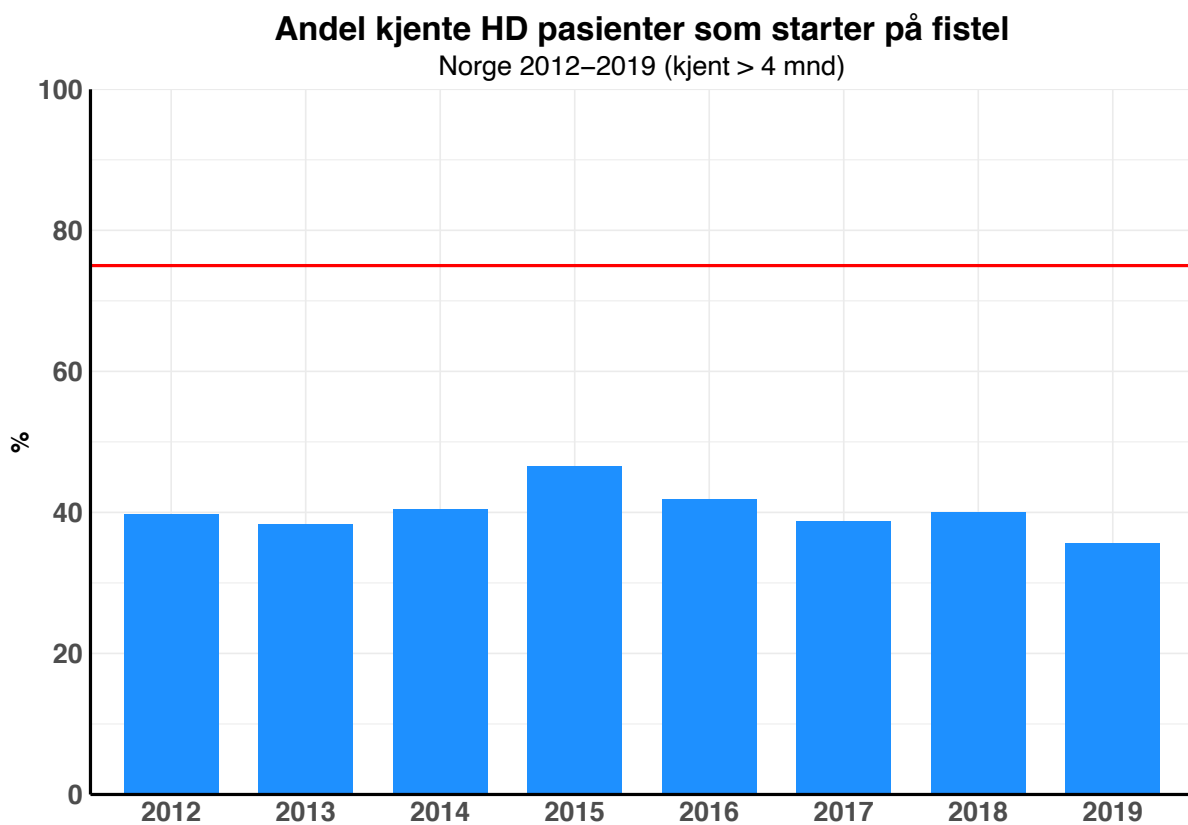


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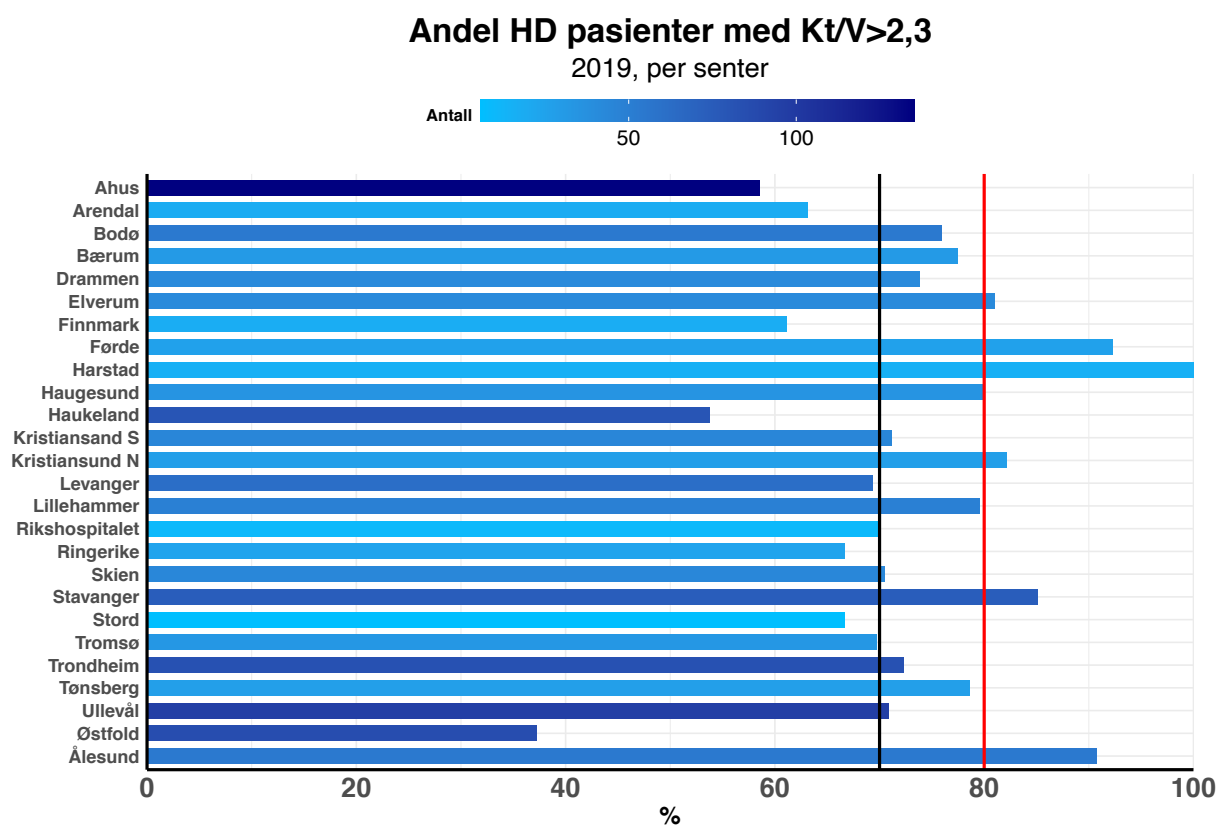


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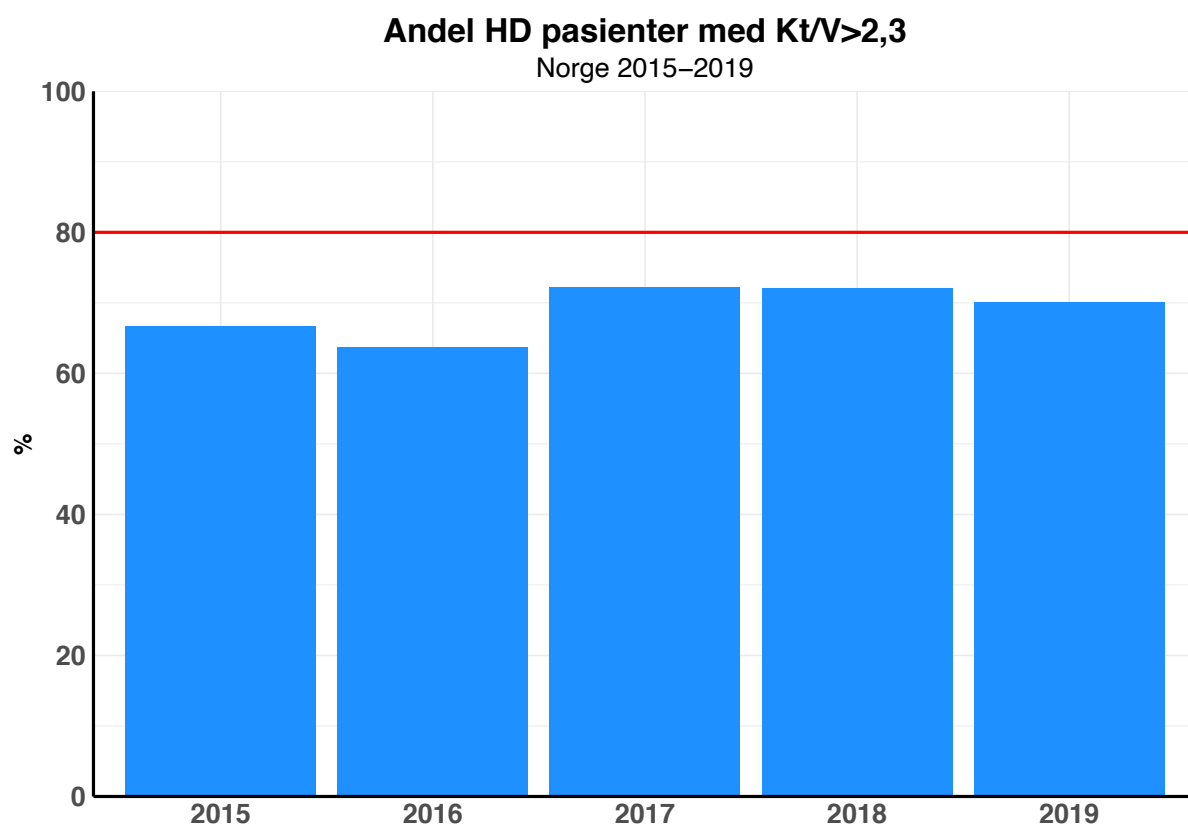


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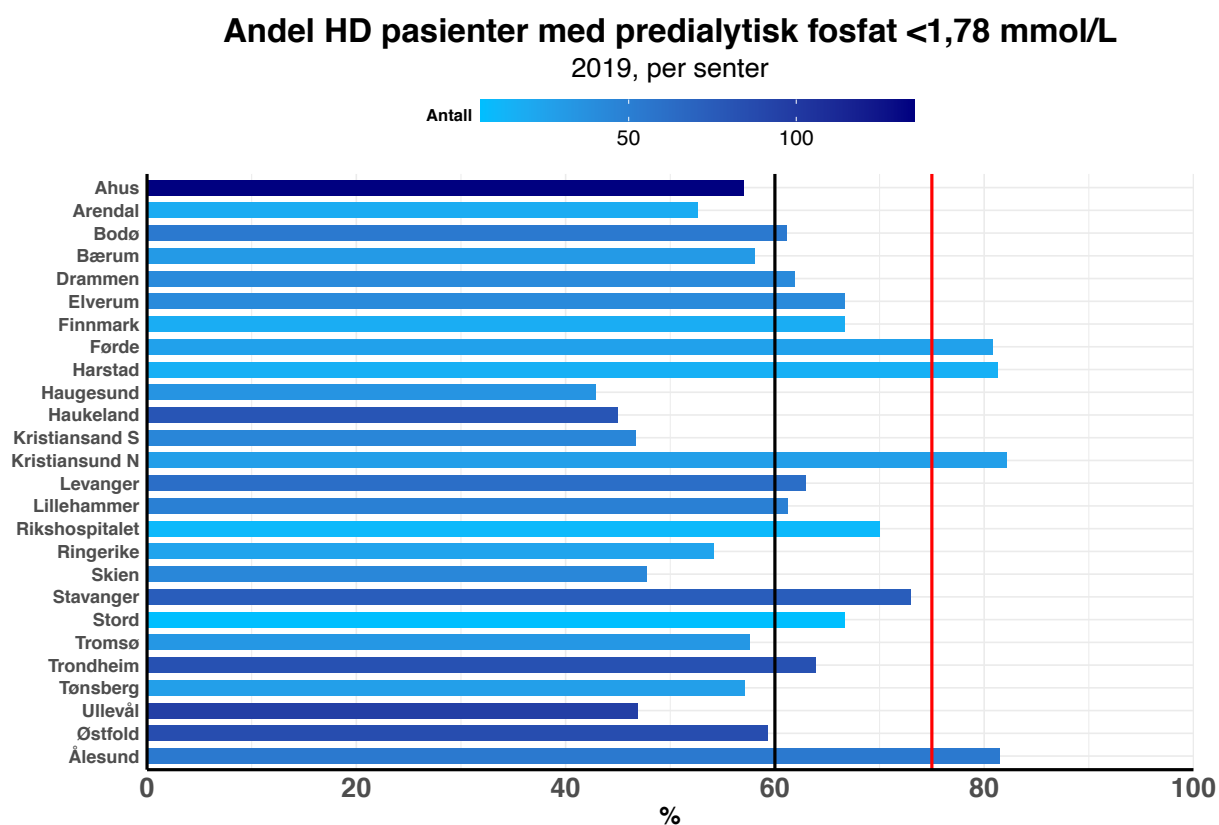


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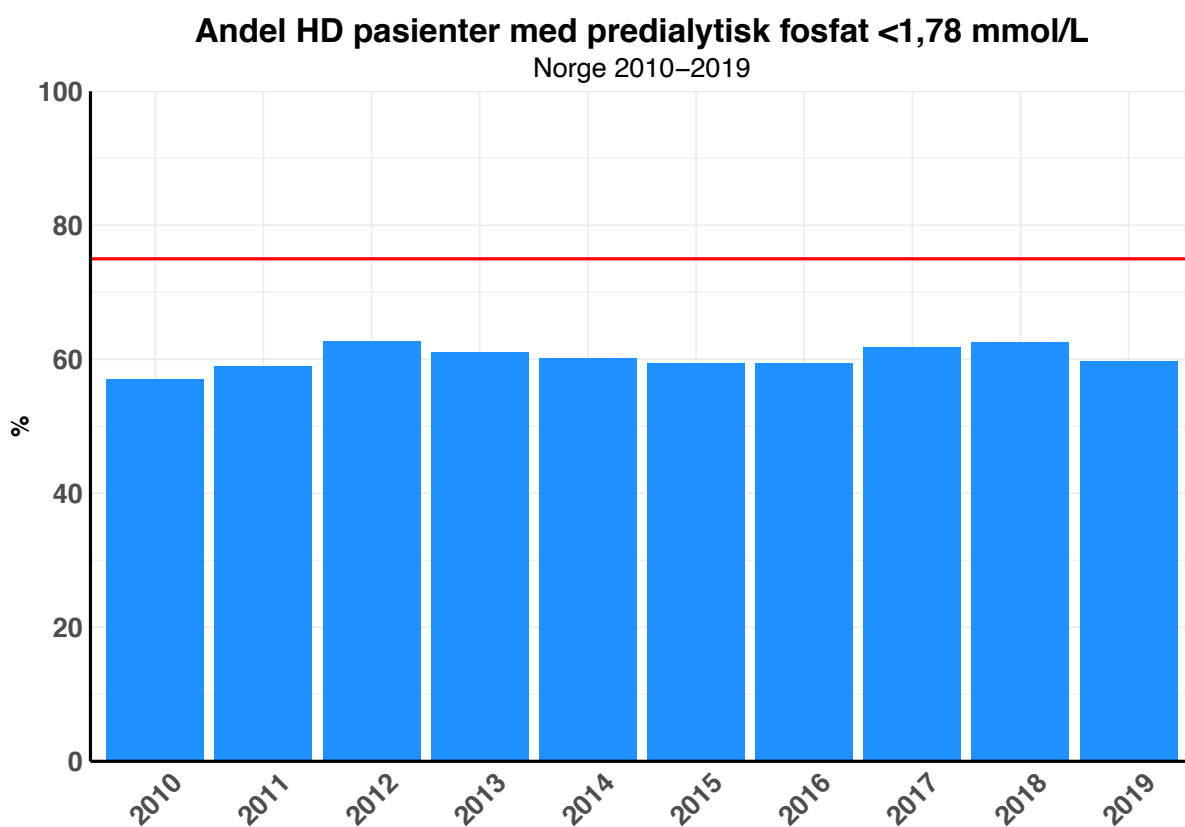


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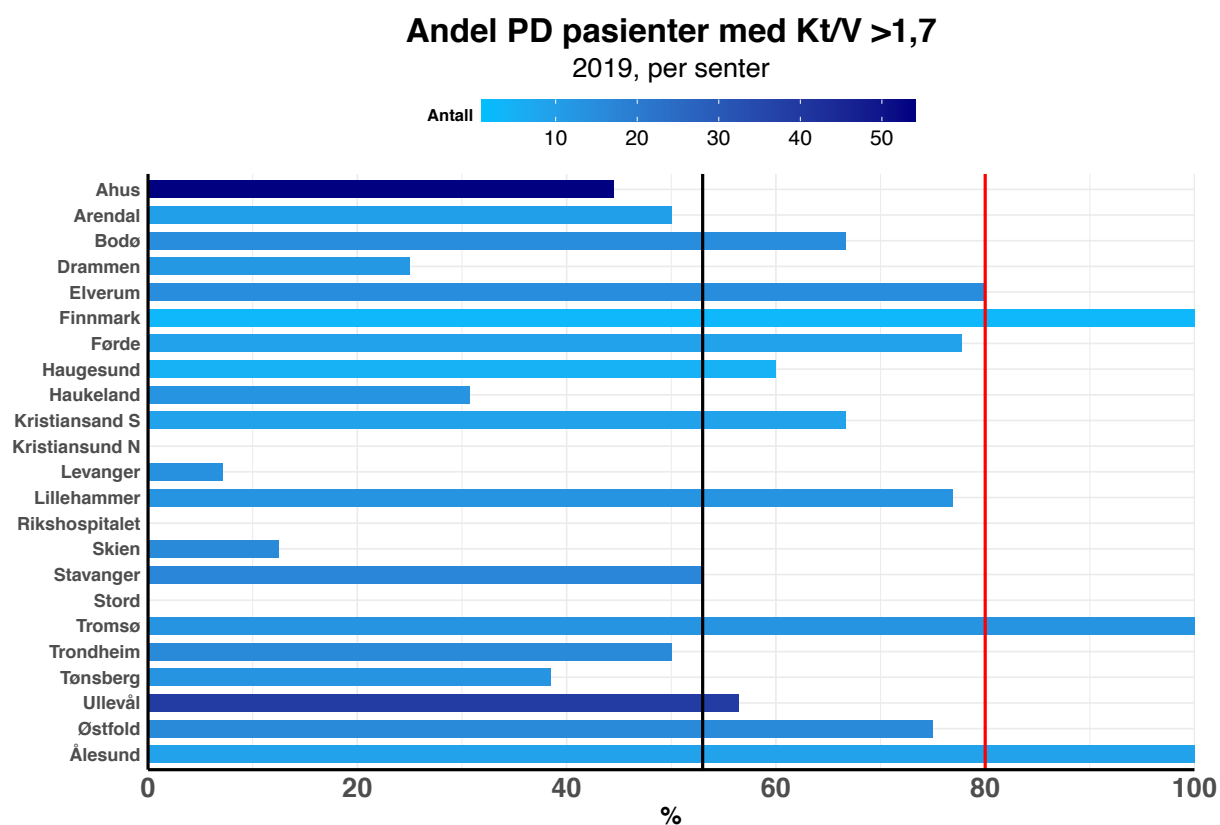


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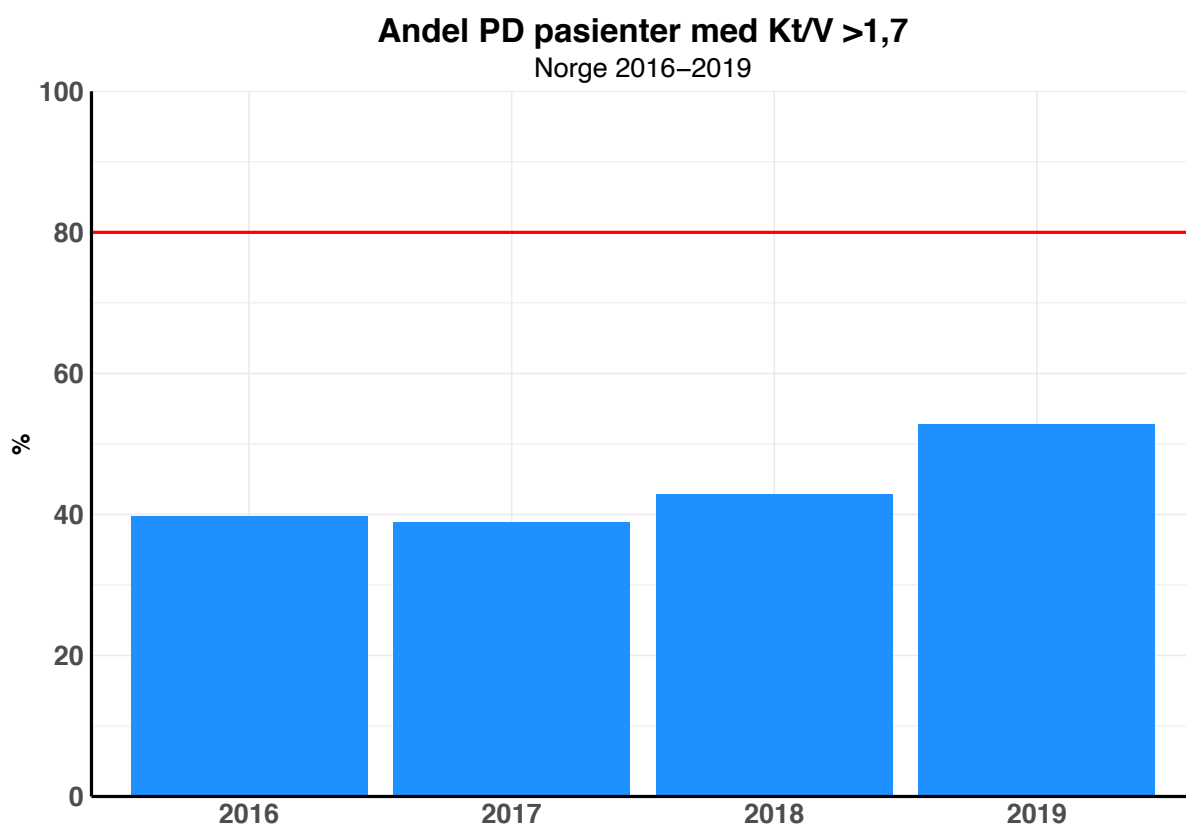


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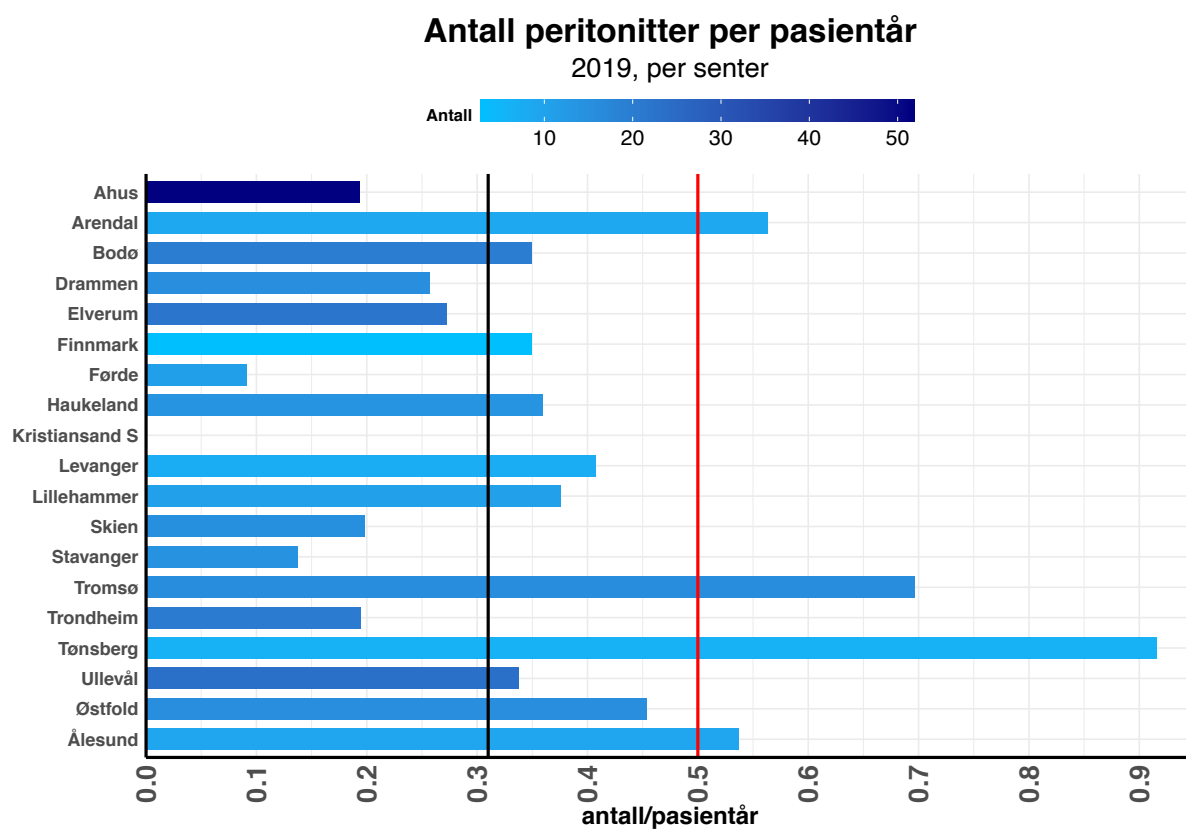


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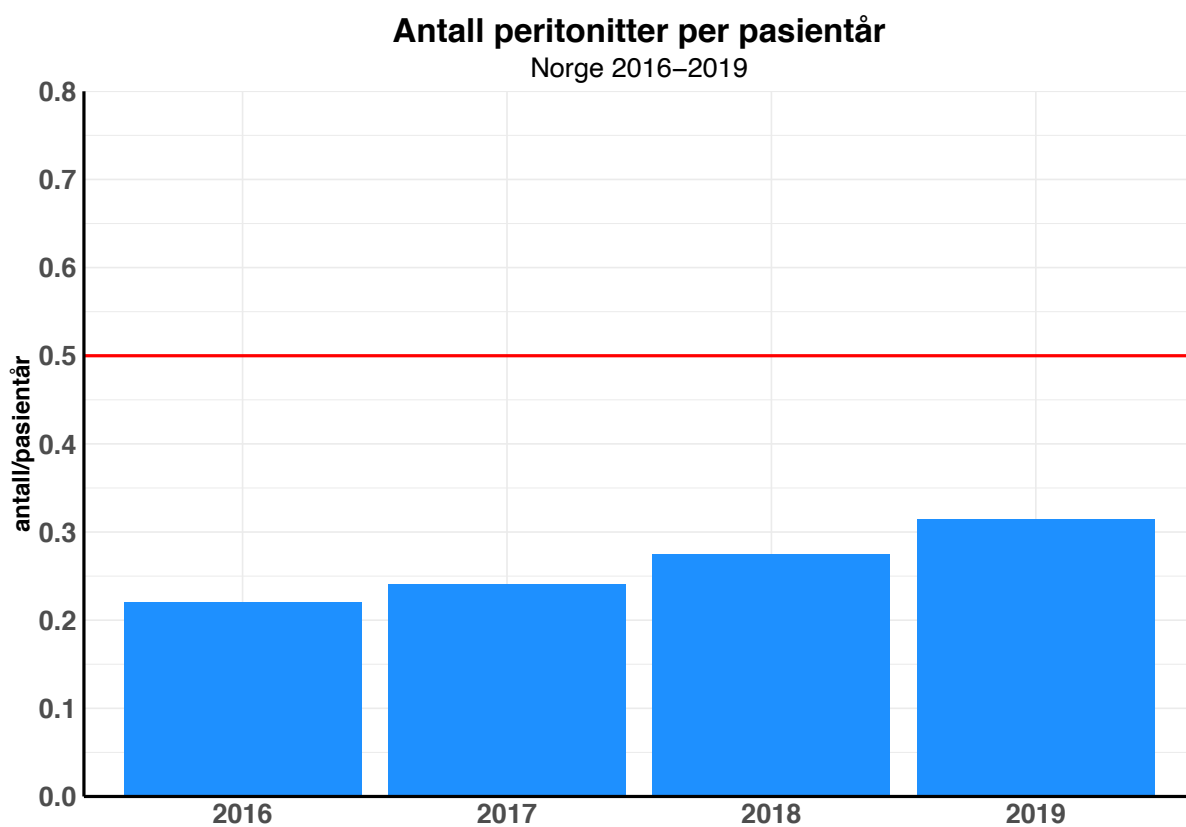


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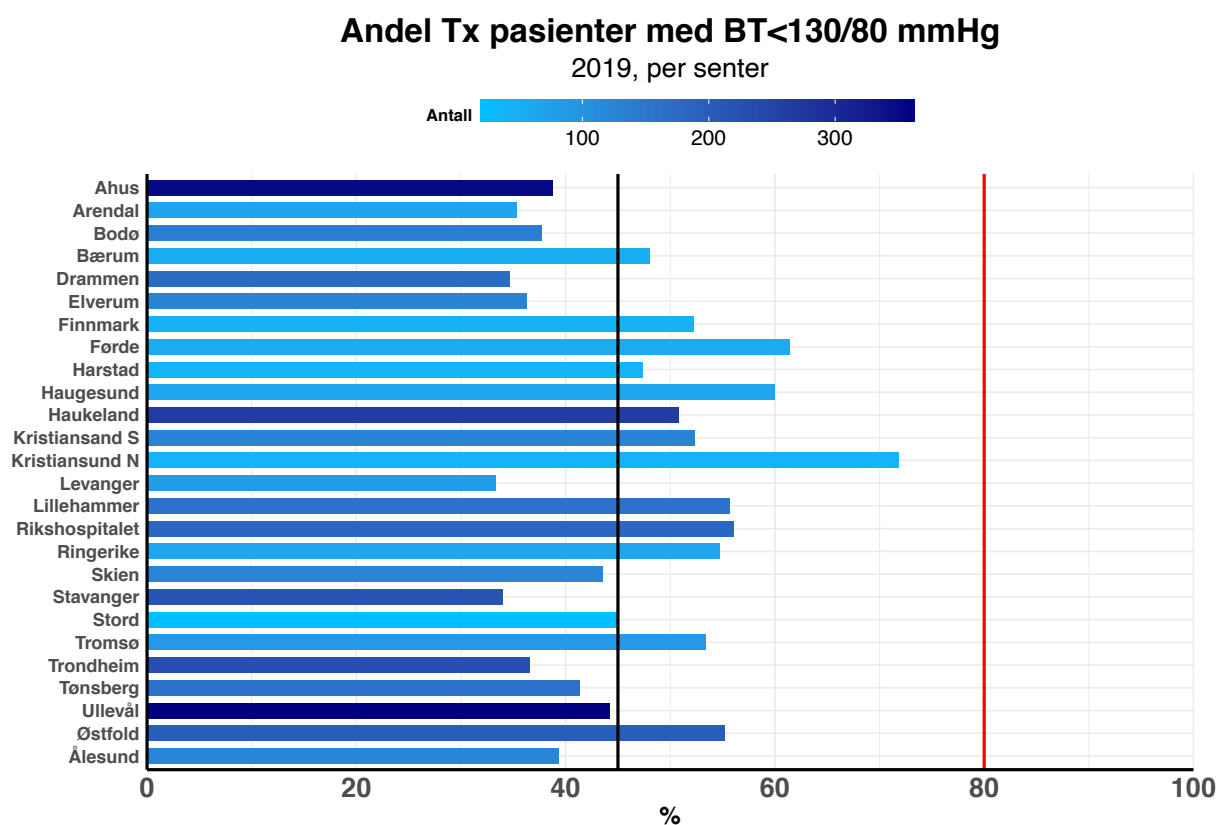


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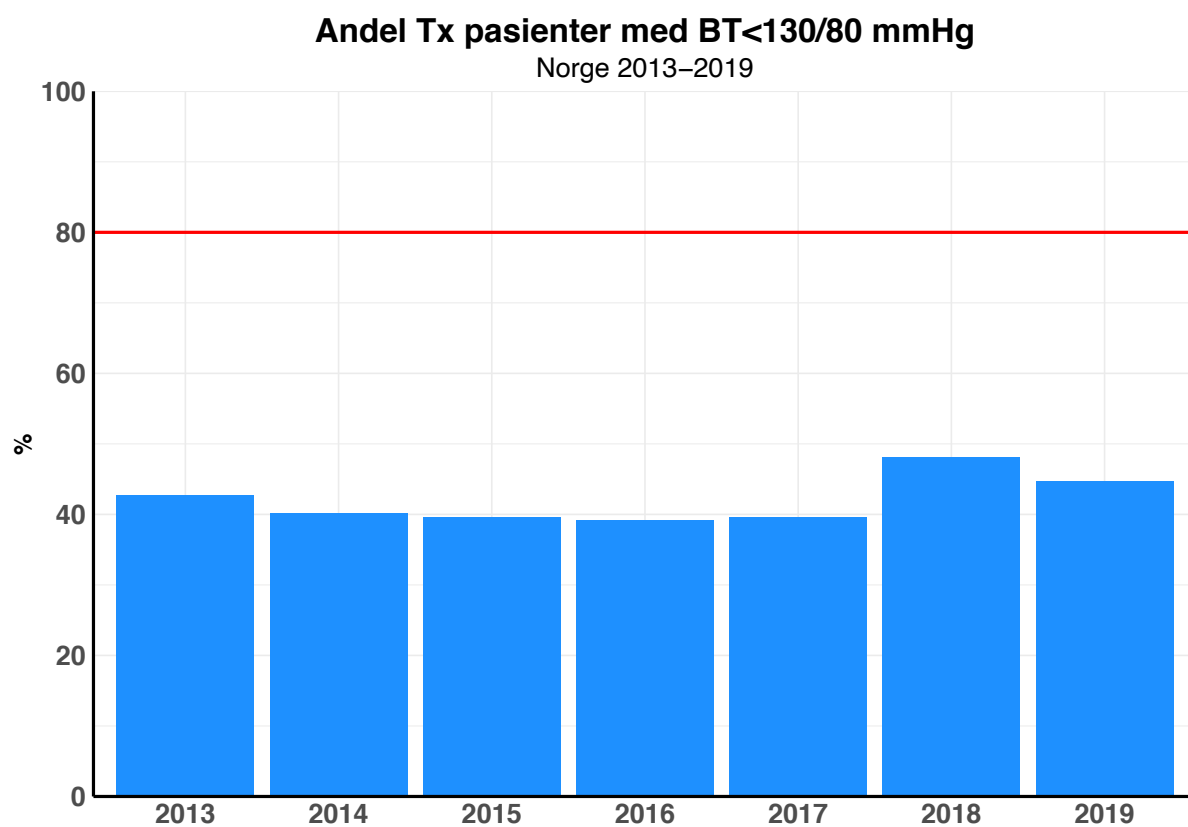


Figure 68:

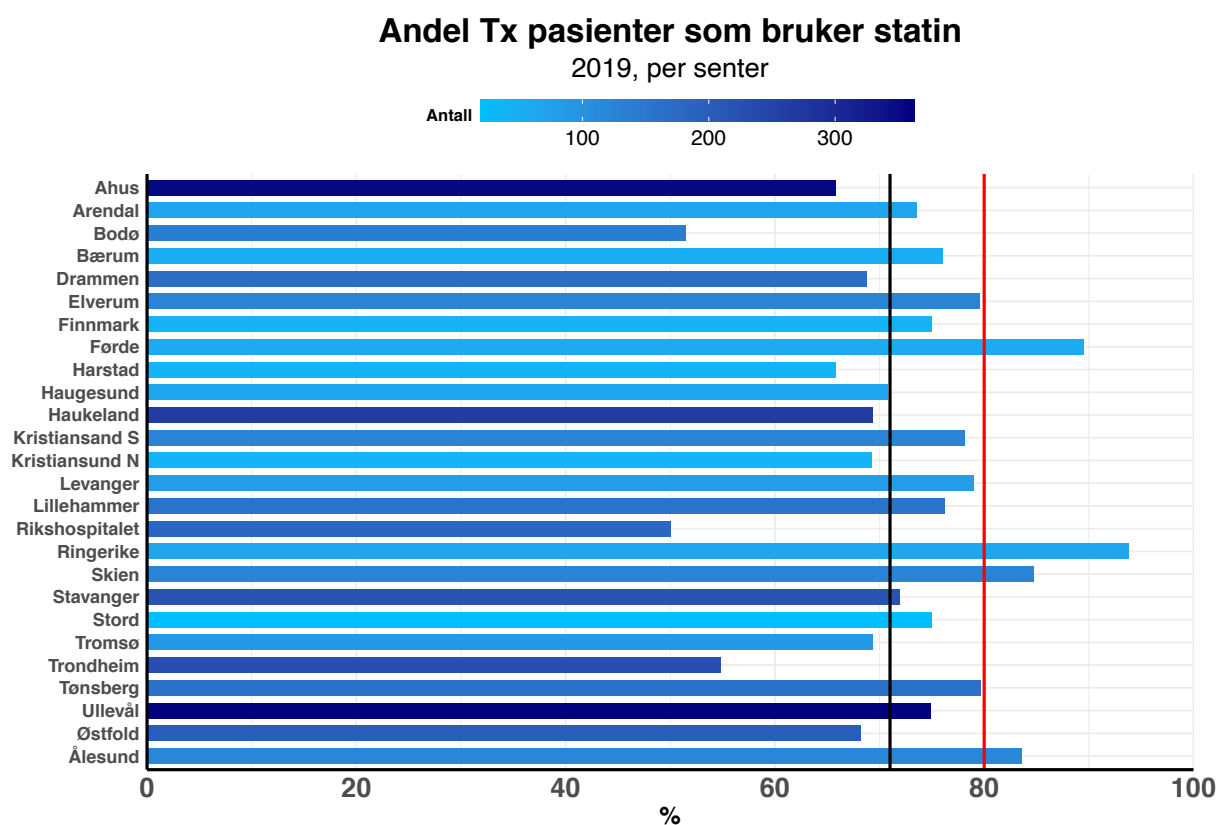


Figure 69:

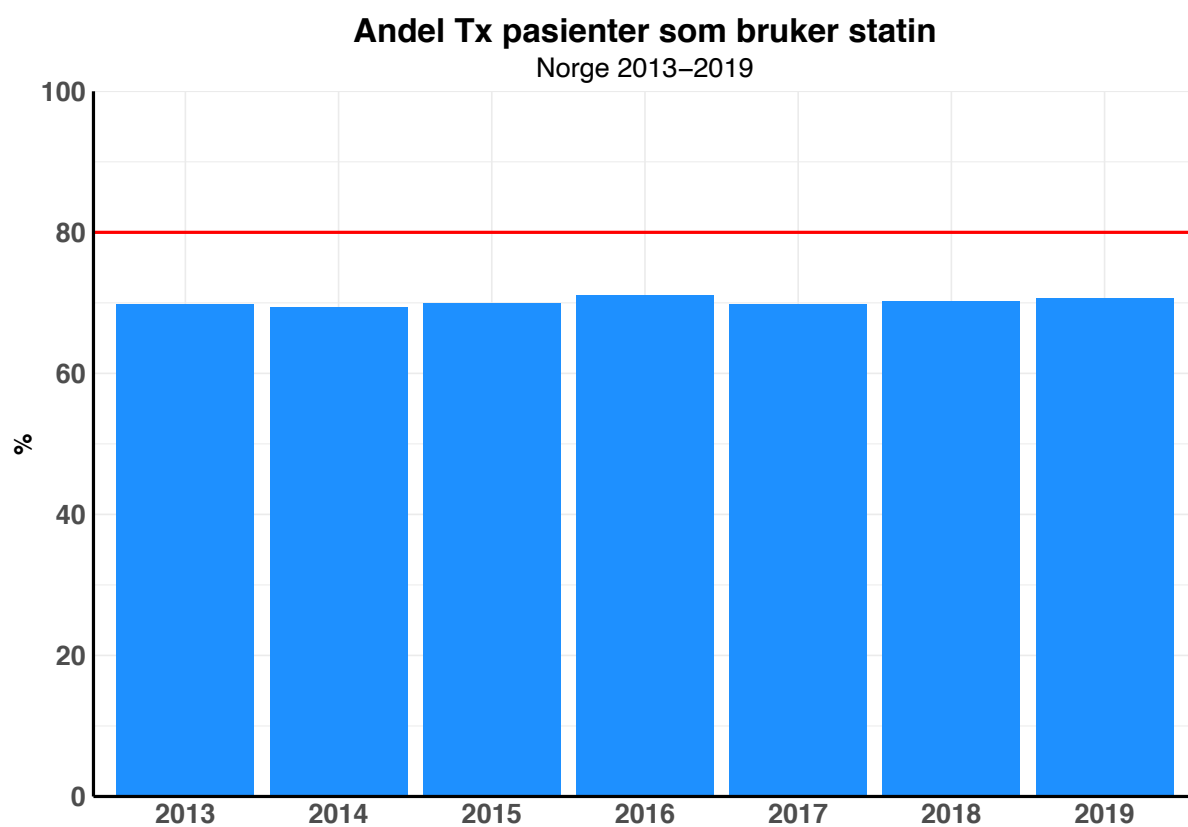
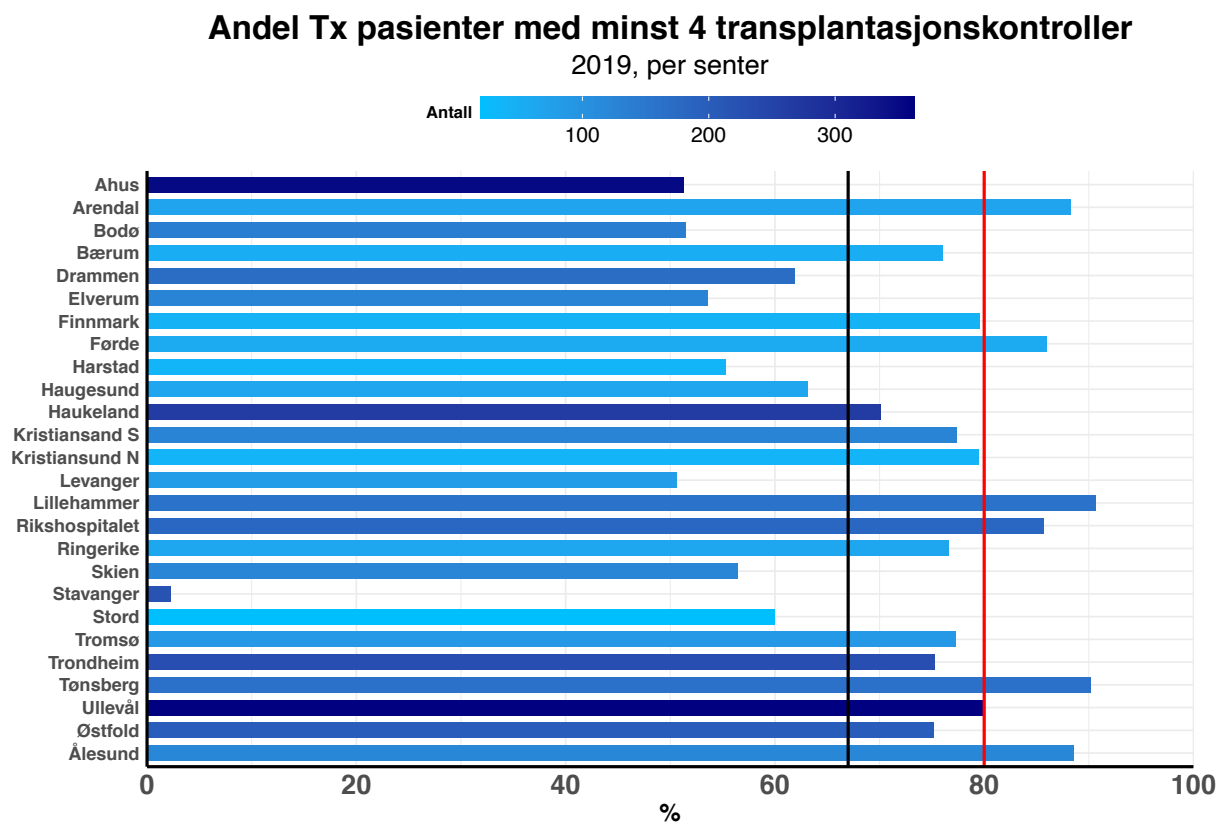
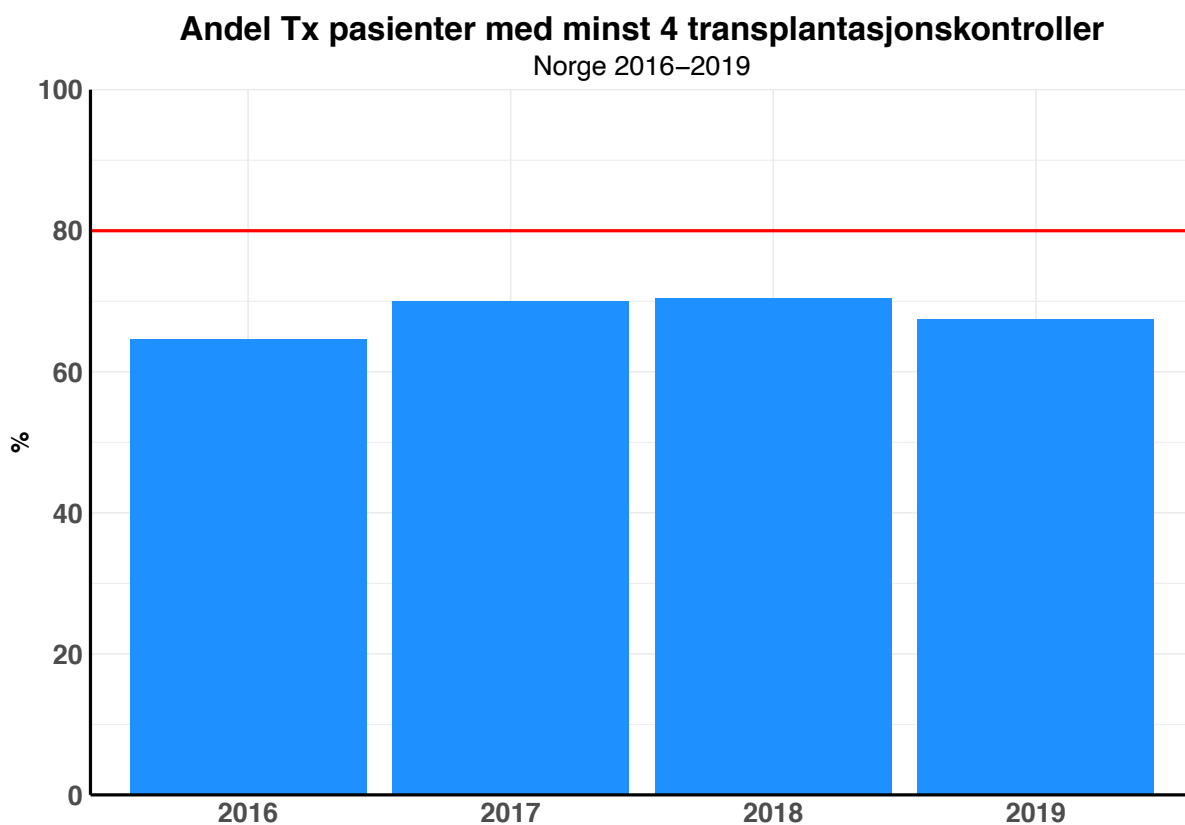


Figure 70:



Stavanger has not implemented this reporting in their electronic data extract yet.

Figure 71:



Quality projects

During the collection of the 2018 annual forms on transplanted patients an addition questionnaire was supposed to be filled out if the patient had a blood pressure above the defined target of less than 130/80 mmHg.

The questionnaire looked like this:

Hva er din kliniske vurdering av hva som bør være målblodtrykket for akkurat denne pasienten?

...../..... mmHg

Er medikasjonen fortsatt under opptrapping?

- ☐ ja
- ☐ nei

Hva er årsaken(e) dersom det registrerte BT er over målsettingen du har satt for pasienten og dersom det ikke er planer om å trappe opp medikasjonen ytterligere? (sett kryss i en eller flere ruter).

- ☐ registrert BT er ikke representativt for pasientens gjennomsnittlige BT-nivå
- ☐ problemer med adherence/compliance
- ☐ bivirkninger av antihypertensiva
- ☐ postural hypotensjon
- ☐ Annen årsak:

Målemetode

- ☐ manuelt
- ☐ automatisk; ☐ attended ☐ nonattended
- ☐ 24h

Kommentar:

Data was reported in the 2018 annual report and now a manuscript has been submitted to *Transplantation Direct*, November 2020.

Based on the results of this this analysis the goal of 80% for this indicator maintained for now.

Concluding remarks:

The flattening of the incidence curve for patients in CKD5 seen last year was just transient and this year it increased again. Patients starting RRT is steadily being older by the year. When interpreting the incidence rate, it should however be kept in mind that the true incidence first will be known when the coverage of CKD5 patients not in RRT reaches a higher level. A coverage analysis on the 2019 data is planned for in 2021. The prevalence is still increasing, majorly driven by an increased survival in RRT. Despite the increased age in patients starting RRT the survival is increasing.

A worrying trend is the increasing waiting list for kidney transplantation. Action has been taken to increase the number of living donors with a good result, but there is still need of more available organ for transplantation in order to meet the demand.

The quality projected performed in 2019 (2018 annual data), focusing on blood pressure treatment in transplanted patients, revealed a certain potential for reaching a higher level of goal achievement. Based on the latest analyses the 80% goal will be kept for now.

Registry data are also regularly used by Norwegian nephrologists as basis for scientific papers, congress presentations and PhD-thesis. A list of publications is published on www.nephro.no along with the annual reports. During 2019 a total of 17 international peer reviewed papers and one PhD-theses have been more or less based upon data from the registry.

Data delivered to the ERA-EDTA Registry in Amsterdam are included in its reports and publications; some data are also forwarded to the USRDS-reports (the chapter of "International Comparisons")

Regardless of status, the cooperation with all Norwegian nephrologists and nephropathologists, demanding their steady efforts to keep the registry updated, has always been, and will always be, a prerequisite for keeping a complete and reliable registry. All hard work over the entire country is GREATLY acknowledged!

Report completed 30.11.2019

Appendix:

		New patients in RRT 2019				Patients in RRT by 31.12.2019					Dialyses etc. 2019			Died 2019		
	Satellites	HD/HDF	PD	Pre-emptive Tx	Total	HD/HDF	HjemmeHD	PD	Graft	Total	HD sessions	Pl.exch.	Other	Dial.pat	Tx-pat	Not tx-cand.
AHUS	1	39	24	8	71	131	11	60	353	555	22 501	0	0	42	17	79
Arendal		9	5		14	21	0	11	72	104	3 263	10	47	6	4	20
Bergen	4	22	6	9	37	91	0	16	277	384	12 381	33	33	14	6	54
Bodø	9	20	7	2	29	79	0	18	168	265	13 095	13	0	9	8	60
Bærum		10		1	11	30	1	0	63	94	4 735	0	0	9	4	25
Drammen	1	16	3		19	55	2	12	175	244	8 140	41	7	13	6	15
Elverum		17	9	1	27	49	1	15	130	195	6 894	0	20	17	5	36
Finnmark	5	6	3	1	10	19	1	4	44	68	2 626	0	0	1	1	11
Førde	2	6	1	2	9	28	0	9	59	96	4 792	0	0	10	3	27
Harstad		4		2	6	15	0	0	41	56	1 830	0	0	2	1	6
Haugesund	2	6	3	1	10	36	0	5	64	105	5 033	50	26	6	1	20
Hønefoss	1	7			7	26	0	0	64	90	4 127	0	0	7	2	18
Kristiansand S	2	12	6		18	45	0	9	126	180	7 197	17	0	15	4	37
Kristiansund N	1	9		3	12	28	1	0	44	73	4 197	0	0	5	3	17
Levanger	6	14	6	4	24	62	0	15	84	161	9 927	10	73	7	6	50
Lillehammer	3	17	10	2	29	50	1	13	162	226	8 092	45	0	16	7	37
Rikshospitalet		5	2	1	8	11	1	2	167	181	2 744	158	73	1	3	4
Stavanger		23	7	7	37	74	1	17	224	316	11 839	7	31	24	12	62
Stord		2		1	3	6	0	4	21	31	952	0	0			5
Telemark	4	16	6	2	24	51	2	16	133	202	8 534	64	0	11	1	32
Tromsø	3	9	5	1	15	34	2	13	88	137	6 730	43	0	12	1	21
Trondheim	4	30	7	6	43	86	6	17	237	346	15 053	124	420	21	10	55
Tønsberg		14	10	1	25	33	0	15	164	212	4 823	23	87	7	6	22
Ullevål		32	25	6	63	102	2	47	373	524	15 856	23	0	22	10	79
Østfold	2	29	5		34	94	1	16	205	316	14 721	26	0	24	7	68
Ålesund	1	8	5	2	15	56	1	11	127	195	9 173	53	0	10	4	37
SUM	51	382	155	63	600	1 312	34	345	3 665	5 356	209 255	740	817	311	132	897
# Pr. mill innb.		71.5	29.0	11.8	112.2	245.4	6.4	64.5	685.6	1001.9						167.8
% of total		63.7	25.8	10.5	100,0	24.5	0.6	6.4	68.4	100,0						16.7

27-11-2017

Norsk Nyreregister -- Kvalitetsmål

Pasientgruppe	Kvalitetsmål	Måltall	Hva måler det?
Biopsi	Andel med alvorlige komplikasjoner i forbindelse med biopsitaking (definert som blodtransfusjon eller intervensjon)	<2%	Måler sikkerhet ved biopsitaking
	Andel biopsier med ≥ 10 glomeruli	90%	Måler kvalitet på selve biopsitakingen
	Andel biopsier endeligbesvart fra patologiavdelingen innen 1 mnd	80%	Måler rutiner og struktur i utredningsapparatet
	Andel primære biopsier med moderate til uttalte kroniske forandringer i biopsien	<30%	Mål på om pasientene utredes tidlig nok i forløpet av sin nyresykdom
CKD5	Andel med blodtrykk under 140/90 mmHg	75 %	Mål på om guidelines og anbefalinger følges
	Andel med fosfat < 1,5 mmol/L	75 %	Mål på om guidelines og anbefalinger følges
	Andel med bikarbonat > 20 mmol/L	75 %	Mål på om guidelines og anbefalinger følges
	Andel med Hgb > 10 g/dL (10-12 hvis ESA)	75 %	Mål på om guidelines og anbefalinger følges
	Gjennomført "Nyreskole" ved start i CKD5 (hvis kjent av nefrolog > 4 mnd.)	75 %	Fange opp at behandlingen for hver enkelt pasient tilpasse den enkelte pasient og er planlagt i god tid.

27-11-2017

Pasientgruppe	Kvalitetsmål	Måltall	Hva måler det?
Dialyse (felles)	Andel kjent >4 mnd før dialyseoppstart	75 %	Fanges pasientene opp av avdelingen? Henvisningspraksis, ressurser og opplæring av primærhelsetjeneste og kollegaer
	Andel i hjemmedialyse (hjemmeHD + PD)	30%	Mål på om individualisert behandling etterstrebes i stort nok omfang
Hemodialyse	Andel med ukentlig Kt/V >2,3 (inkludert restfunksjon)	80 %	Mål på bevissthet og kvalitet av dialysebehandlingen
	Andel pasienter, kjent > 4 mndr, som starter HD på fistel	75 %	Er det en plan for når og hvordan pasientene skal starte? Interne prosedyrer for å planlegge dialyseoppstart
	Andel med predialytisk fosfat < 1,78 mmol/L	75 %	Mål på fokus og behandling av metabolske forstyrrelser og komplikasjoner
Peritonealdialyse	Andel med ukentlig Kt/V >1,7 (inkludert restfunksjon)	80 %?	Mål på bevissthet og kvalitet av dialysebehandlingen
	Antall peritonitter per år	≤ 0.5 /pas.år	Mål på at behandlingen blir utført på tilfredsstillende måte
Transplantasjon	Andel med blodtrykk under 130/80 mmHg	80%	Mål på om guidelines og anbefalinger følges
	Andel som bruker statin	80%	Mål på om guidelines og anbefalinger følges
	Andel med ≥ 4 transplantasjons kontroller per år	80%	Mål på om pasientene blir tatt hånd om på en god nok måte
	Antall aktivt på Tx-venteliste med dialysetid > 2 år (unntatt PRA \geq 80%)	< 10%	Mål på om behandlingstilbudet er godt nok
	Biopsipåvist akutt reaksjon første år etter transplantasjon	< 20%	Overordnende mål på om behandlingen er godt nok tilpasset pasientene
	Graftoverlevelse	vs. ScandiTx	Sammenligner overordnede kvalitet på behandlingen i forhold til land som er naturlig å sammenligne med (Norden)