ANNUAL REPORT 2018

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.

The current version of NRR is a merge of the Norwegian Nephrology Registry and the Norwegian Renal Biopsy Registry in 2016 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 formalised manner, and the transplant centre 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 5.312 mill. inhabitants (July 2018) and 18 counties (not including Svalbard) with populations ranging from 75,997 to 676,462 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 centre (two during 1963-82). Pre-transplant work-up, as well as post-transplant follow-up beyond 2 months, is handled by the county-centres. 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 m^2 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 2018, data from the last visit before December 31st 2018 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 96.2%.

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 95%. 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 42 alive without consent). CKD5 patients not treated with renal replacement therapy have only been included in the registry since 2016 and the coverage is still suboptimal. Based on prevalence data from the literature a conservative estimate of coverage of this group is at least 60%. 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*).

NRR 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: http://www.nephro.no/nnr.html.

Incidence data 2018

During 2018 a diagnostic kidney biopsy with clinical data was available from 622 patients, 320 were reported as new patients established in CKD5 (without RRT) and 544 patients started renal replacement therapy (i.e. 100.5 per mill. inhabitants). The incidence of new patients in renal replacement therapy has been stable on this level for the last 10 years.

Biopsy

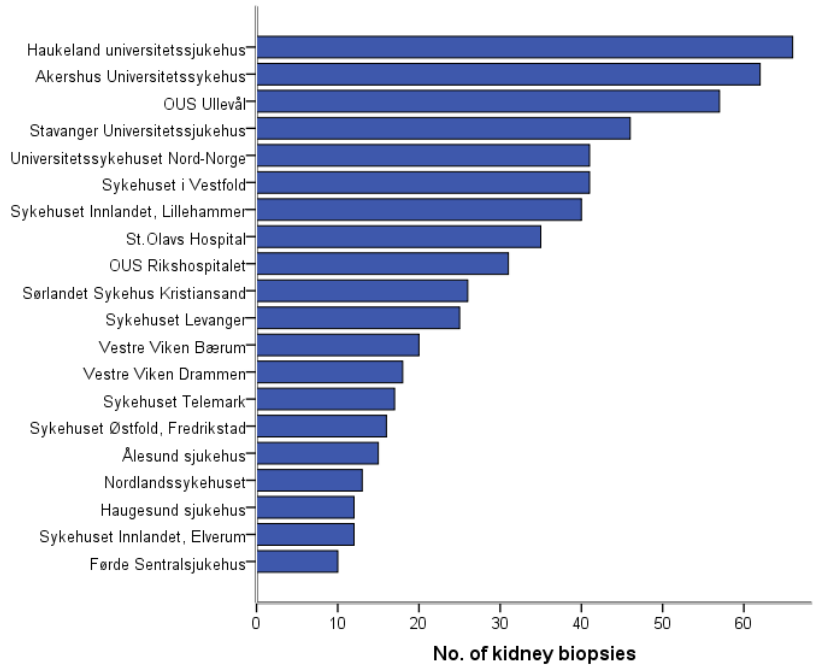
Table 1. Number of kidney biopsies per regional health authority

	2015	2016	2017	2018
Helse Sør-Øst	320	297	305	353
Helse Vest	172	126	134	137
Helse Midt	64	62	54	78
Helse Nord	40	47	52	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 kidney biopsies per hospital in 2018



This figure shows the number of kidney biopsies performed per hospital in 2018. Five hospitals were excluded from the analysis, as they reported less than ten native kidney biopsies in 2018.

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

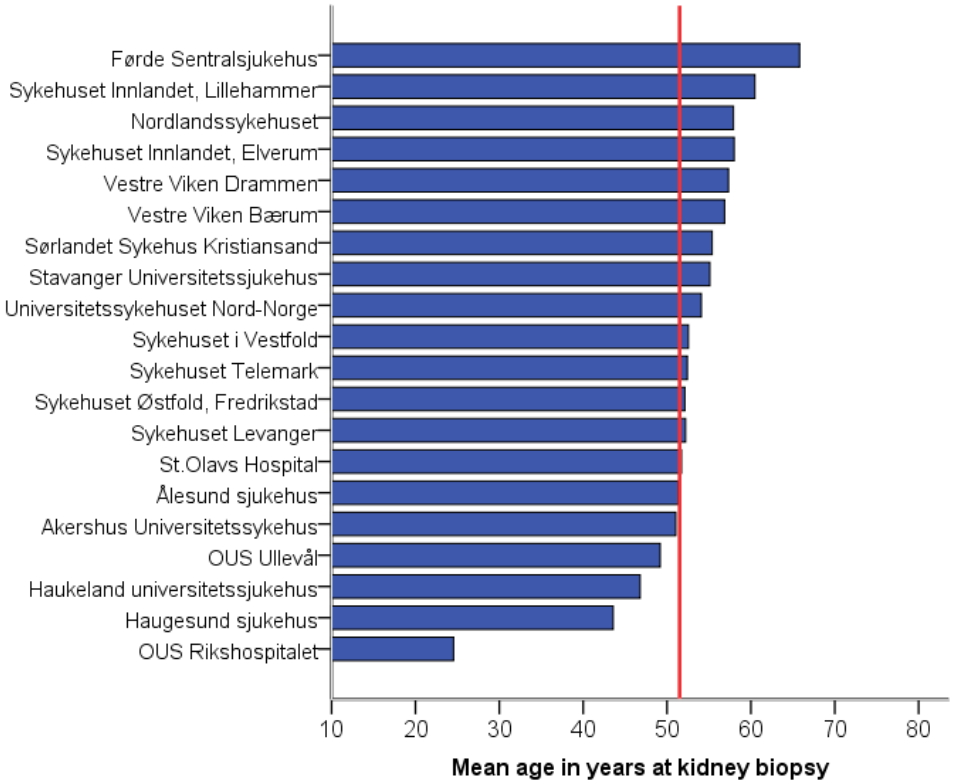
	Helse Sør-Øst N=353	Helse Vest N=137	Helse Midt N=78	Helse Nord N=54	Total N=622
Mean age in years (±SD)	51.1 ± 19.8	50.7± 20.1	52.0 ±18.7	55.0 ± 18.3	51.5 ± 19.6

Mean age at kidney biopsy in 2018 was 51.5 (±19.6) years, which is relatively unchanged from 2017. As in the two 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 unchanged from 2017; 5.5 % 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 (61.8 %) in Helse Sør-Øst and Haukeland University Hospital (23.5 %) in Helse Vest.

4.0 % of all reported kidney biopsies were performed in patients above 80 years of age, which is an increase from 2.9 % in 2017. As in 2017, most octogenarians were biopsied in the South-Eastern Regional Health Authority (Helse Sør-Øst).

Figure 2. Average age at kidney biopsy per hospital in 2017



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(%)	Total N(%)
Nephrotic syndrome	70 (19.8 %)	21 (15.3 %)	13 (16.7 %)	11 (20.4 %)	115 (18.5 %)
Nephritic syndrome	57 (16.1 %)	35 (25.5 %)	12 (15.4 %)	9 (16.7 %)	113 (18.2 %)
Acute kidney failure	52 (14.7 %)	29 (21.2 %)	11 (14.1 %)	7 (13.0 %)	99 (15.9 %)
Chronic kidney failure	81 (22.9 %)	21 (15.3 %)	14 (17.9 %)	14 (25.9 %)	130 (20.9 %)
Proteinuria	182 (51.6 %)	61 (44.5 %)	34 (43.6 %)	30 (55.6 %)	307 (49.4 %)
Hematuria	114 (32.3 %)	47 (34.3 %)	36 (46.2 %)	17 (31.5 %)	214 (34.4 %)
Other	8 (2.3 %)	18 (13.1 %)	1 (1.3 %)	0 (0%)	27 (4.3 %)

It is possible to report more than on clinical indication for biopsy. As a result, the total number of clinical indications exceeds the total number of reported kidney biopsies for 2018. Some regional differences are apparent. Nephritic syndrome was more frequently reported in Western Norway, whereas chronic kidney failure was reported more frequently in Northern Norway. Compared to 2017, acute and chronic kidney failure was less frequently reported as an indication for kidney biopsy in 2018. In 2017, 30.5 % of all reported kidney biopsies were performed due to chronic kidney failure, as compared to 20.9 % in 2018. Similarly, 23.9 % of reported kidney biopsies in 2017 were performed due to acute kidney failure, as compared to 15.9 % in 2018.

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

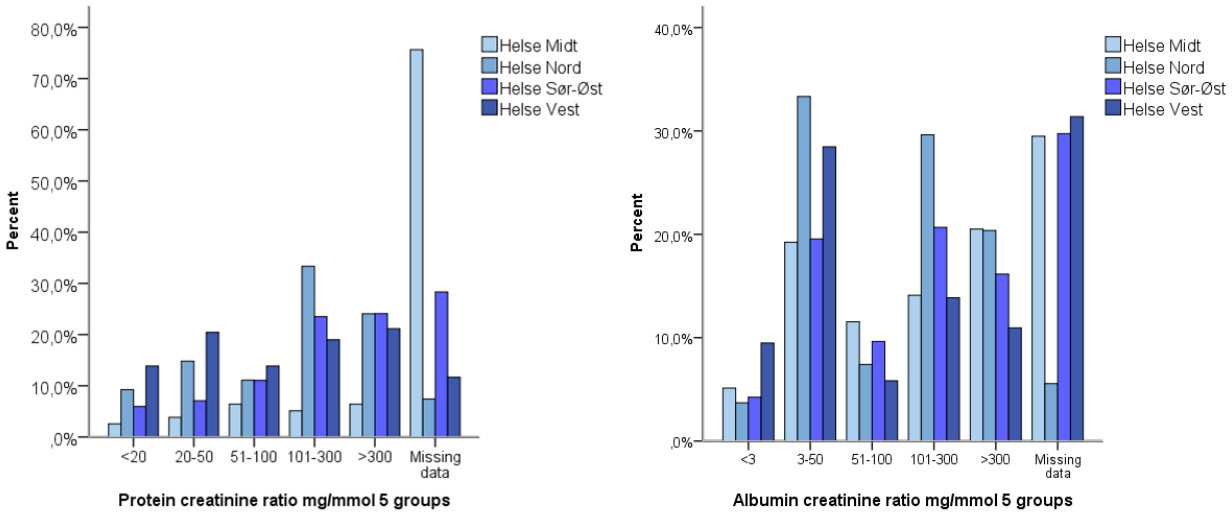


Figure 4. Serum creatinine (µmol/liter) at the time of kidney biopsy, per Regional Health Authority

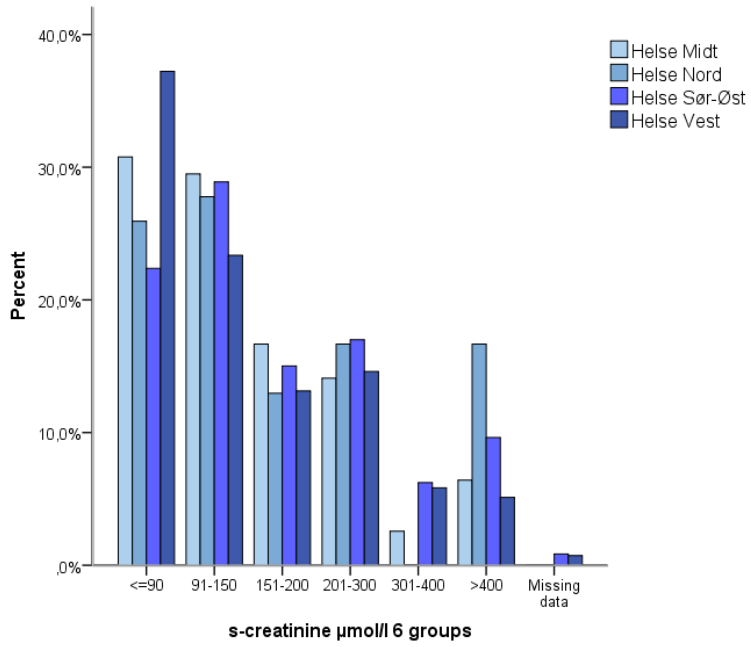
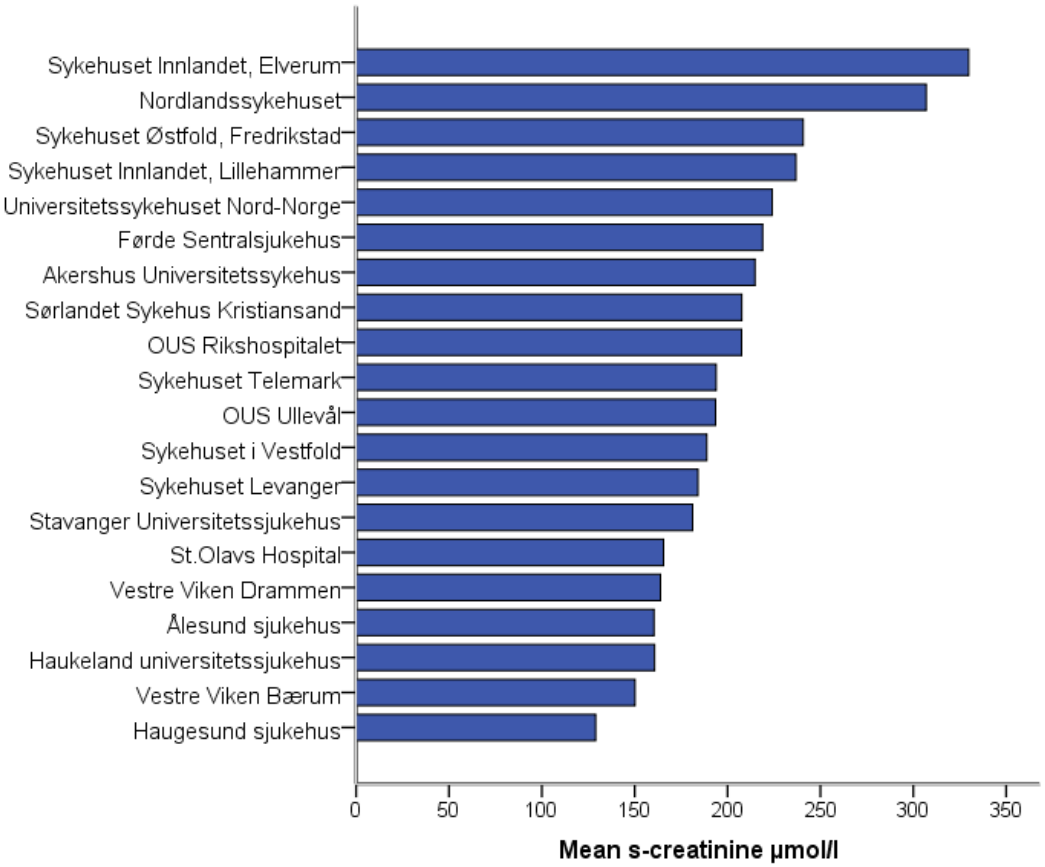


Figure 5. Mean s-creatinine at the time of kidney biopsy, per hospital



Only hospitals which reported 10 or more native kidney biopsies are included in the analysis.

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
No complications	74 %	82.9 %	78.3 %	81.1 %
Missing data	16.9 %	9.1 %	13.0 %	9.6 %

Most kidney biopsies are reported without complications, and very few biopsies are reported with serious complications, i.e. blood transfusions and/or interventions. However, 9.6 % of all biopsies are reported with missing data on this very important quality indicator. More effort should be placed in securing a more complete overview of this variable. Complications can be reported to the registry after the initial clinical data report has been submitted, if necessary.

Table 6. Reported complications in 2018 per Regional Health Authority

	Helse Sør-Øst N(%)	Helse Vest N(%)	Helse Midt N(%)	Helse Nord N(%)	Totalt N(%)
None	285 (80.7 %)	118 (85.5 %)	66 (84.6 %)	36 (66.7%)	505 (81.1 %)
Transfusion	2 (0.6 %)	0 (0 %)	1 (1.3 %)	0 (0 %)	3 (0.5 %)
Intervention	1 (0.3 %)	0 (0 %)	0 (0 %)	0 (0 %)	1 (0.2 %)
Other	19 (5.4 %)	4 (2.9 %)	6 (7.7 %)	4 (7.4 %)	33 (5.3 %)
Hematuria	8 (2.3 %)	5 (3.6 %)	3 (3.8 %)	4 (7.4 %)	20 (3.2 %)
Missing data	38 (10.8 %)	11 (8.0 %)	2 (2.6 %)	10 (18.5 %)	60 (9.6 %)

It is possible to report more than one complication per procedure. Clinical data were reported for 622 kidney biopsies in 2018, 81.1 % of which were reported without complications. Information on complications was missing in 9.6 % of cases.

Only four (0.6 %) serious complications were reported to the registry in 2018, three blood transfusions and one intervention. Thirty-three "other" complications were reported, most of these 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 (%)	Totalt N (%)
Biopsy performed by					
Nephrologis	2 (0.6%)	93 (67.9 %)	0 (0%)	3 (5.6 %)	98 (15.8 %)
Radiologist	338 (95.8 %)	31 (22.6 %)	73 (93.6 %)	47 (87.0 %)	489 (78.6 %)
Both	1 (0.3 %)	0 (0%)	1 (1.3 %)	1 (1.9 %)	3 (0.5 %)
Unknown	12 (3.4 %)	13 (9.5 %)	4 (5.1 %)	3 (5.6 %)	32 (5.1 %)
Biopsy needle					
14G	1 (0.3 %)	1 (0.7 %)	0 (0%)	0 (0%)	2 (0.3 %)
16G	24 (6.8 %)	116 (84.7%)	69 (88.5 %)	34 (63.0 %)	243 (39.1 %)
18G	289 (81.9 %)	18 (13.1 %)	4 (5.1 %)	11 (20.4 %)	322 (51.8 %)
Unknown	39 (11.0 %)	2 (1.5 %)	5 (6.4 %)	9 (16.7 %)	55 (8.8 %)
No. of passes					
1	23 (6.5 %)	38 (27.7 %)	0 (0%)	1 (1.9 %)	62 (10.0 %)
2	158 (44.8 %)	71 (51.8 %)	44 (56.4 %)	17 (31.5 %)	290 (46.6 %)
3	91 (25.8 %)	17 (12.4 %)	17 (21.8 %)	23 (42.6 %)	148 (23.8 %)
4 or more	49 (13.9 %)	3 (2.2 %)	9 (11.5 %)	5 (9.3 %)	66 (10.6 %)
Unknown	32 (9.1 %)	8 (5.8 %)	8 (10.3 %)	8 (14.8 %)	56 (9.0 %)
Level of care					
Out-patient	5 (1.4 %)	21 (15.3 %)	8 (10.3 %)	1 (1.9 %)	35 (5.6 %)
In-patient	232 (65.7 %)	59 (43.1 %)	36 (46.2 %)	35 (64.8 %)	362 (58.1 %)
Unknown	116 (32.9 %)	57 (41.6 %)	34 (43.6 %)	18 (33.3 %)	225 (36.2 %)

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 clincial 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.

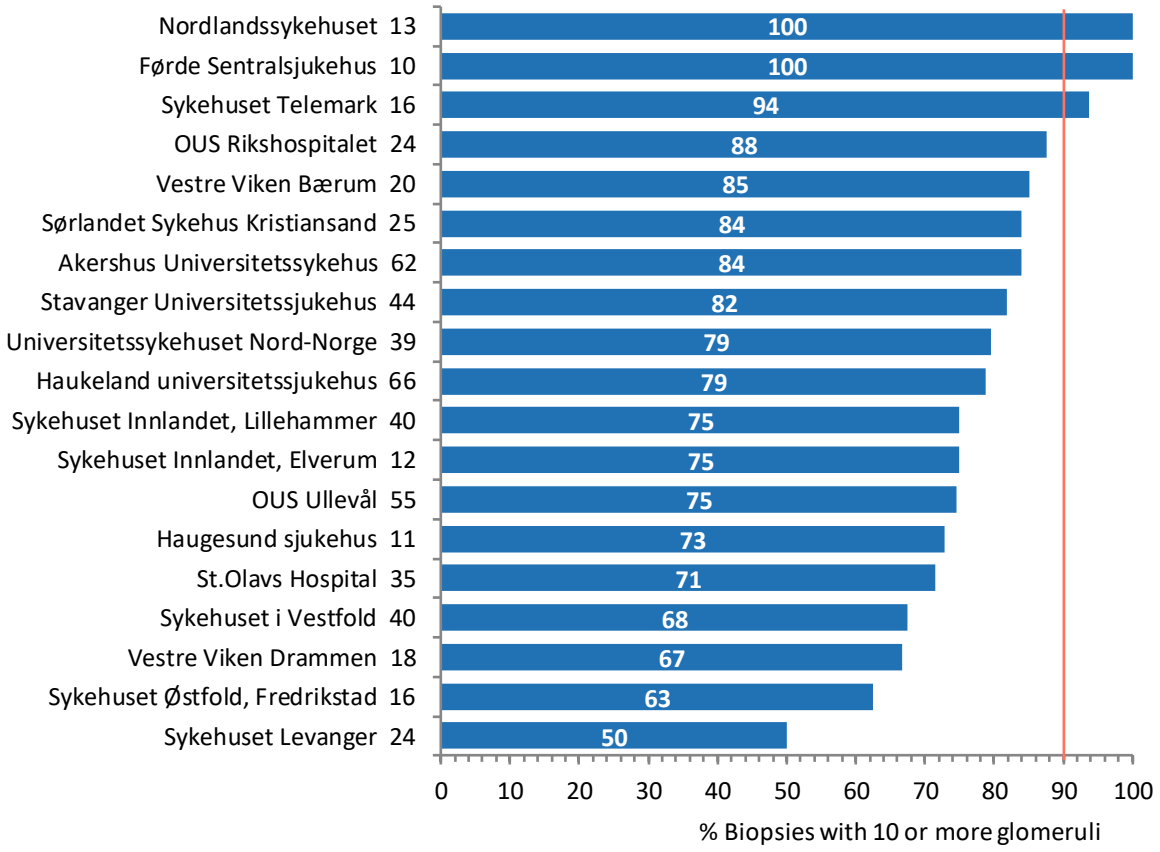


Figure 6: Percent biopsies with 10 or more glomeruli by hospital. The number behind the hospital name is the number of non-neoplastic kidney biopsies per year. The calculation is based on the number of glomeruli in the paraffin embedded biopsy tissue. Only hospitals with 10 or more non-neoplastic kidney biopsies are shown. Red line indicates quality indicator goal.

Figure 7 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 electronmicroscopy and immunofluorescence. If applying this assessment method, 8 hospitals achieved 10 or more glomeruli per biopsy in 90% of cases (see Figure 8).

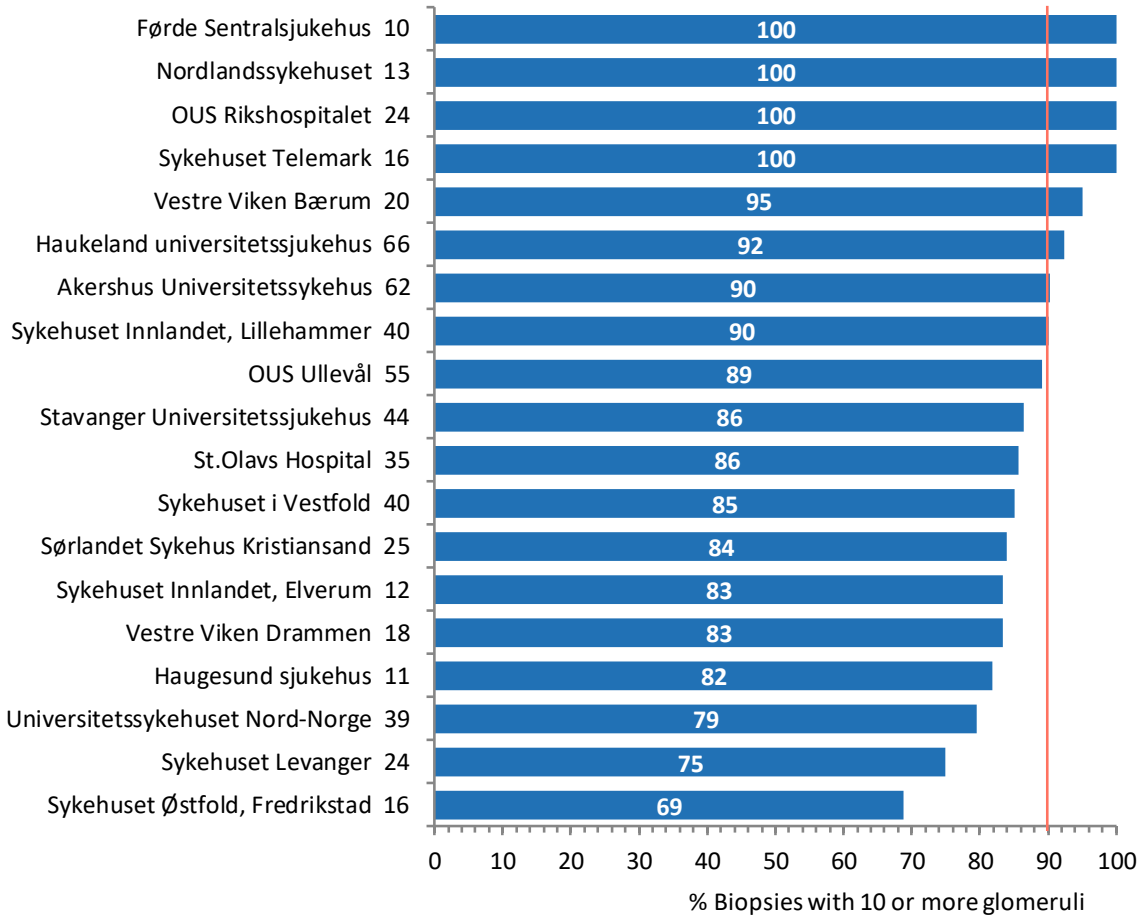


Figure 7: Percent biopsies with 10 or more glomeruli by hospital. The number behind the hospital name is the number of non-neoplastic kidney biopsies per year. The calculation is based on the number of glomeruli both in the paraffin embedded biopsy tissue, the frozen tissue for immunohistochemistry (only 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.

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.

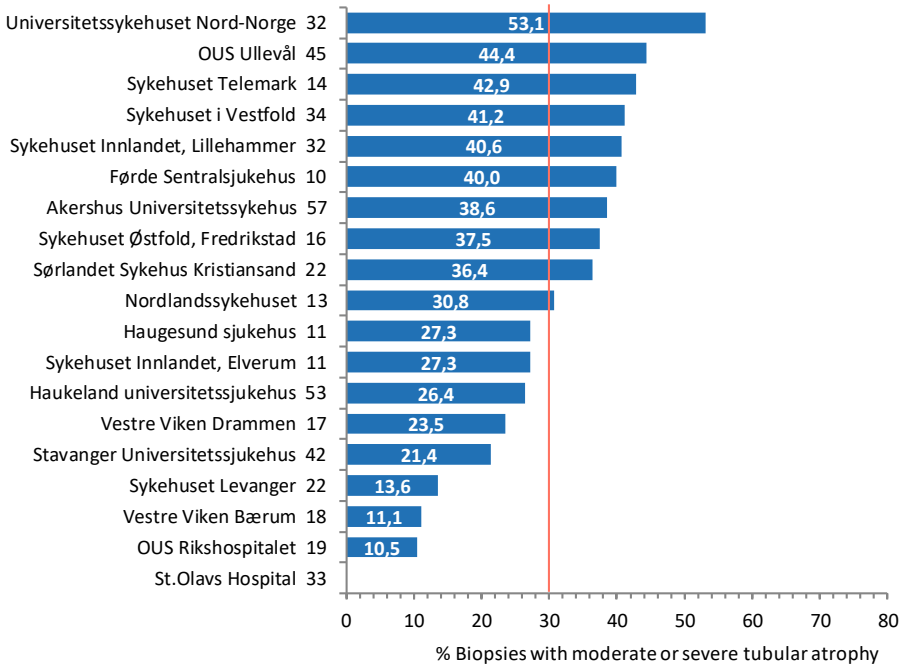


Figure 8: Percent biopsies with moderate or severe tubular atrophy by hospital. The number behind the hospital name is the number of primary non-neoplastic kidney biopsies per year. Only hospitals with 10 or more non-neoplastic kidney biopsies are shown. . Red line indicates quality indicator goal.

Figure 9 shows, that 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, the figures in figure 9 should be considered with caution.

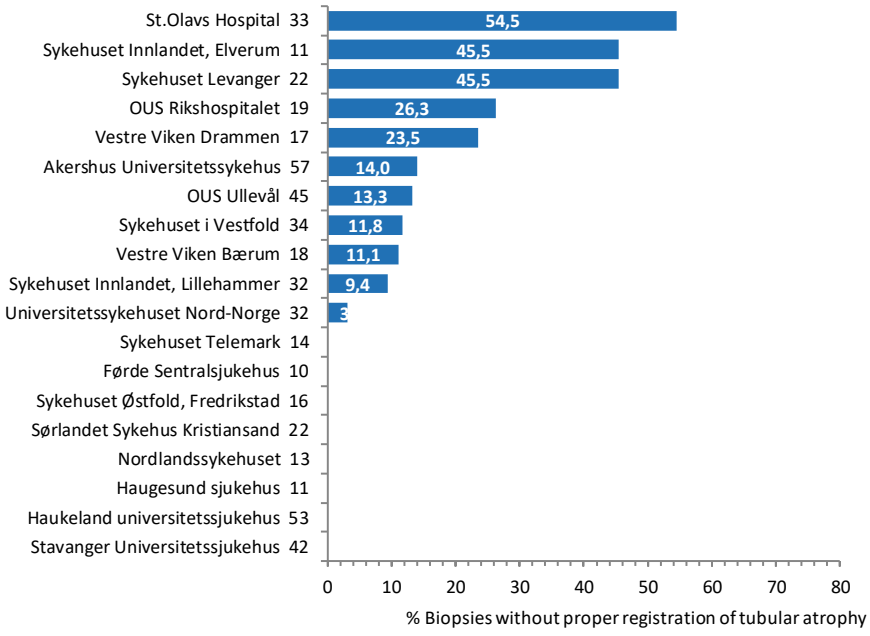


Figure 9: Percent biopsies without proper registration of tubular atrophy by hospital. The number behind the hospital name is the number of primary non-neoplastic kidney biopsies per year. Only hospitals with 10 or more non-neoplastic kidney biopsies are shown.

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 2 pathology departments met the quality standard of a final diagnostic report within 1 month (figure 10).

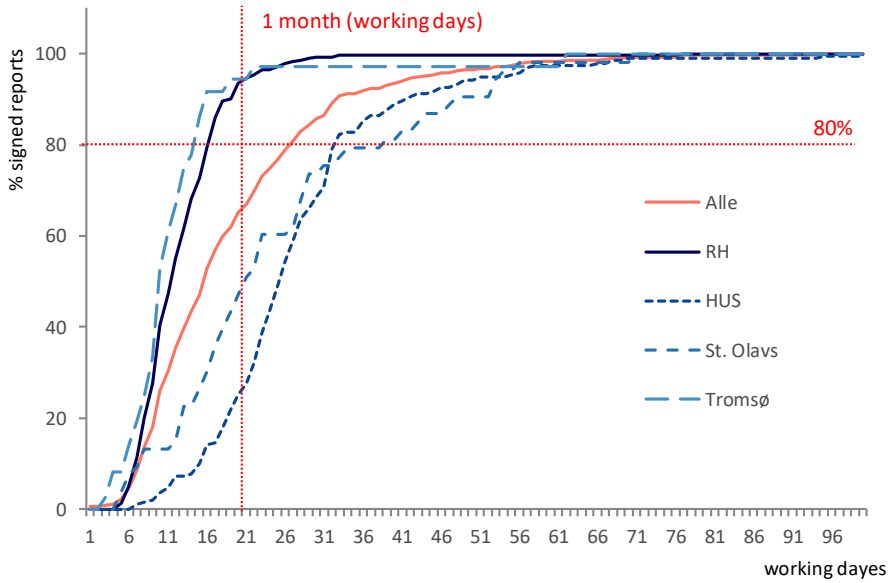


Figure 10: Percent kidney biopsies finally reported within one month (21 working days) by pathology department.

Over the years there has been a slightly negative overall trend towards longer reporting time (figure 11).

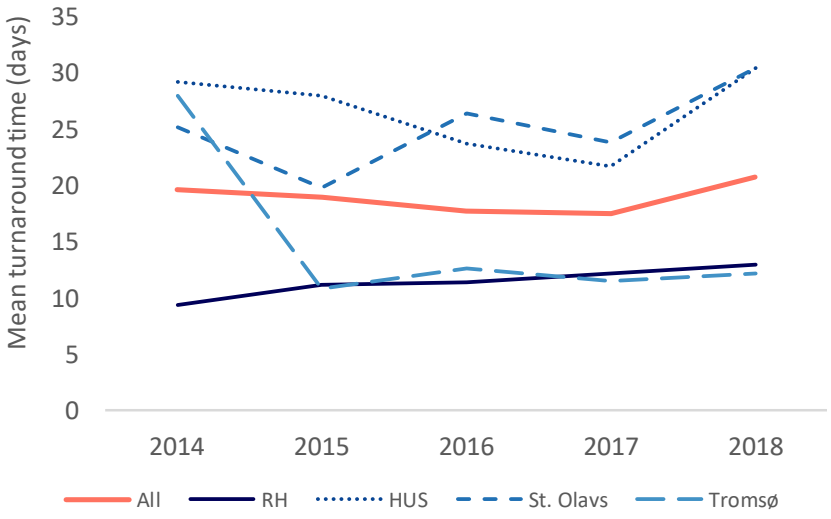


Figure 11: Mean turnaround time by pathology department from 2014 - 2018.

Table 8. Overview pathology diagnoses in Norway

	All	RH	HUS	St. Olavs	Tromsø	Førde	Ålesund
Minimal change nephropathy	23	15	3	5	0	0	0
FSGS[1] primary	10	5	2	0	3	0	0
FSGS secondary	14	8	4	0	2	0	0
Membranous GN[2]	34	18	11	0	3	1	1
IgA nephropathy	110	42	43	11	10	1	3
Mesangioprol. GN without IgA	5	2	2	1	0	0	0
Endokapillary prol. GN	5	5	0	0	0	0	0
Membranoproliferativd GN	16	5	3	4	3	0	1
ANCA associated GN	52	17	25	4	2	2	2
Anti-GBM nephritis	4	1	1	1	1	0	0
GN with crescents not ANCA	8	3	3	1	0	1	0
HSP[3]	5	3	2	0	0	0	0
Lupus nephritis - I	0	0	0	0	0	0	0
Lupus nephritis - II	4	2	2	0	0	0	0
Lupus nephritis - III	7	2	4	0	1	0	0
Lupus nephritis - IV	9	6	1	2	0	0	0
Lupus nephritis - V	5	4	1	0	0	0	0
Lupus nephritis - VI	0	0	0	0	0	0	0
Lupus nephritis - not classified	1	0	0	1	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	3	0	2	1	0	0	0
Immunotactoid GP[4]	0	0	0	0	0	0	0
Cryoglobulinemia	0	0	0	0	0	0	0
Pre-eclampsia-ass. GN	0	0	0	0	0	0	0
Sclerosing GN	0	0	0	0	0	0	0
GN unclassified	6	4	1	1	0	0	0
Alport syndrome	1	0	0	1	0	0	0
Thin basement membrane GP	10	5	2	2	0	0	1
Fabry's disease	13	0	12	1	0	0	0
Other hereditary diseases	1	1	0	0	0	0	0
Diabetic nephropathy	44	27	8	4	2	1	2
Benign nephrosclerosis	44	26	9	2	5	1	1
Malign nephrosclerosis	3	0	3	0	0	0	0
Cholesterolemboli	0	0	0	0	0	0	0
Vasculitis other	0	0	0	0	0	0	0
TMA[5]	4	3	0	1	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	2	1	0	0	0	1	0
Amyloidosis - AA	6	4	0	0	2	0	0
Amyloidosis - AL	6	1	3	1	1	0	0
Amyloidosis other	0	0	0	0	0	0	0
Myeloma kidney	4	2	1	0	0	1	0
Ig[7] deposition disease	1	0	1	0	0	0	0
ATN[8]	10	5	4	1	0	0	0
Acute interstitial nephritis	0	0	0	0	0	0	0
Tubulointerstitial nephritis	27	13	9	3	2	0	0
Granulomatous TIN[9] / Sarc.	2	0	1	0	0	0	1
TIN - drug associated	7	6	1	0	0	0	0
Lithium nephropathy	0	0	0	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	2	0	2	0	0	0	0
TIN aminoglycosides ass.	0	0	0	0	0	0	0
TIN autoimmune disease ass.	1	0	0	0	1	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	3	3	0	0	0	0	0
Normal	26	10	8	6	0	0	2
Uncharacteristic atrophy	34	22	7	4	0	1	0
End stage kidney	1	1	0	0	0	0	0
No code - free text	17	6	9	0	1	0	1
Not representative	13	6	5	2	0	0	0
All	603	284	195	60	39	10	15

Abbreviations in the table:

1	Focal and segmental glomerulosclerosis	RH	Rikshospitalet
2	Flomerulonephritis	HUS	Haukeland univ.ersitetssjukehus
3	Henoch Schönlein's purpura		
4	Glomerulopathy		
5	Thrombotic microangiopathy		
6	Hemolytic uremic syndrome		
7	Immunoglobin		
8	Acute tubular necrosis		
9	Tubulointerstitial nephritis		

The table gives an overview about registered non-neoplastic kidney biopsies and the related pathology diagnoses in 2018. 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 were male (64.1%) and median age at time of entering CKD5 stage was 70.8 years (mean 66.8 years), ranging from 2.5 to 93.2 years. Patients had been know at the nephrology unit in 86% of the cases and a total of 81% were considered as RRT candidates and 8% were definitely not candidates for RRT treatment (11% unsure status). The main reason for not being RRT candidate was comorbidity, followed by patient/family whish not to start RRT.

Hypertension was the main cause of renal failure with 33% of the patients having this as their main diagnosis. Diabetes was the primary diagnosis in 21% of the patients, including diabetes as comorbidity a total of 37% patients was diabetic (90% Type II diabetes mellitus). Median time with a diabetes diagnosis before entering the CKD5 stage was 18 years.

Proteinuria (ACR>3 and/or PCR>15) was present in 88% of the patients at time of entering CKD5.

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

	Total (n:320)
CKD-EPI-GFR (mean) [mL/min/1.73m^2]	13
Creatinine (mean) [µmol/L]	405
Albumin (mean) [g/L]	37
Haemoglobin (mean) [g/dL]	11.4
Haemoglobin - % <10 g/dL	19 %
ESA use	31 %
Active D vitamin use	61 %
Statin use	61 %
Not on antihypertensive drugs	6 %
Using ACEi/ARB	44 %
Using >2 antihypertensive drugs	53 %

CKD5 in RRT (Dialysis or Transplantation)

A majority of the patients were male (64.3 %) and median age at start of RRT was 67.9 years mean 63.8 years), ranging from 9 days to 92.3 years. At time of start of dialysis 44 % were assessed by the treating physician to be a Tx-candidate. Of the patients starting haemodialysis and that had been know at the treating center for at least 4 months 48 % started dialysis using an AV-fistula as blood access.

Table 10. Status at start of RRT

	Total (n:542)	HD (n:325)	PD (n:158)	Preempt. Tx (n:59)
Creatinine (mean) [µmol/L]	588	632	538	421
Albumin (mean) [g/L]	38	35	42	42
Haemoglobin (mean) [g/dL]	10.5	10.2	10.7	11.3
Haemoglobin - % <10 g/dL	34 %	41 %	25 %	14 %
ESA use	44 %	47 %	46 %	29 %
Active D vitamin use	59 %	56 %	67 %	54 %
Statin use	53 %	52 %	60 %	53 %
Not on antihypertensive drugs	9 %	11 %	3 %	12 %
Using ACEi/ARB	36 %	35 %	36 %	31 %
Using >2 antihypert. drugs	69 %	53 %	57 %	44 %

As might be anticipated, pre-emptively transplanted patients had a somewhat lower serum creatinine, thus higher GFR, and a higher haemoglobin and albumin than those starting dialysis. Among patients known less than four months, 79% had haemoglobin <11 g/dL.

Figure 12:

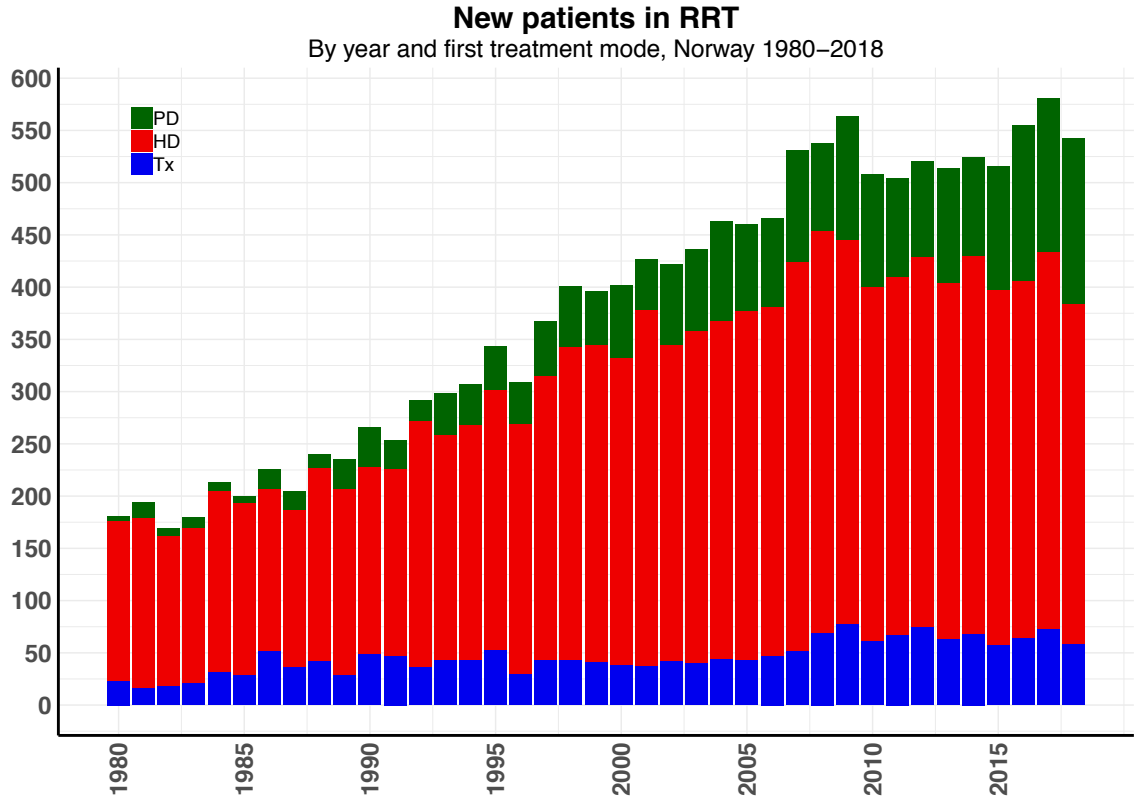


Figure 13:

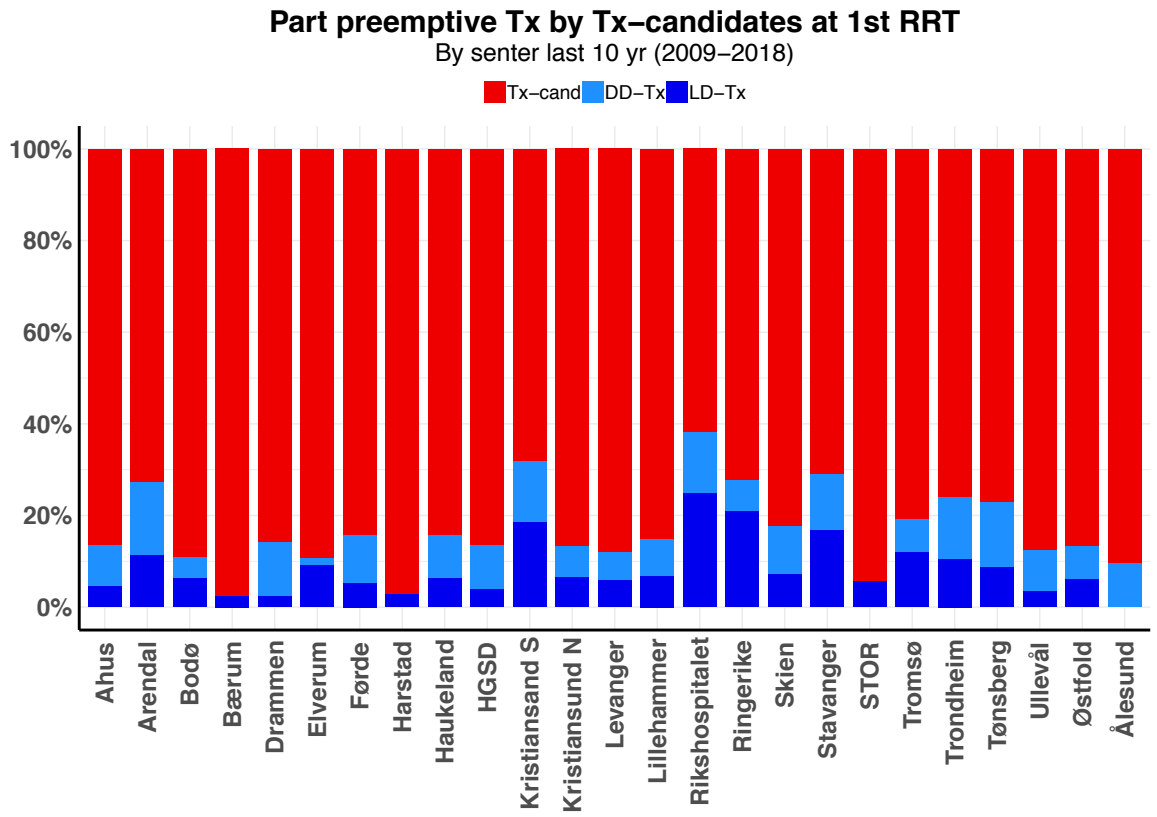
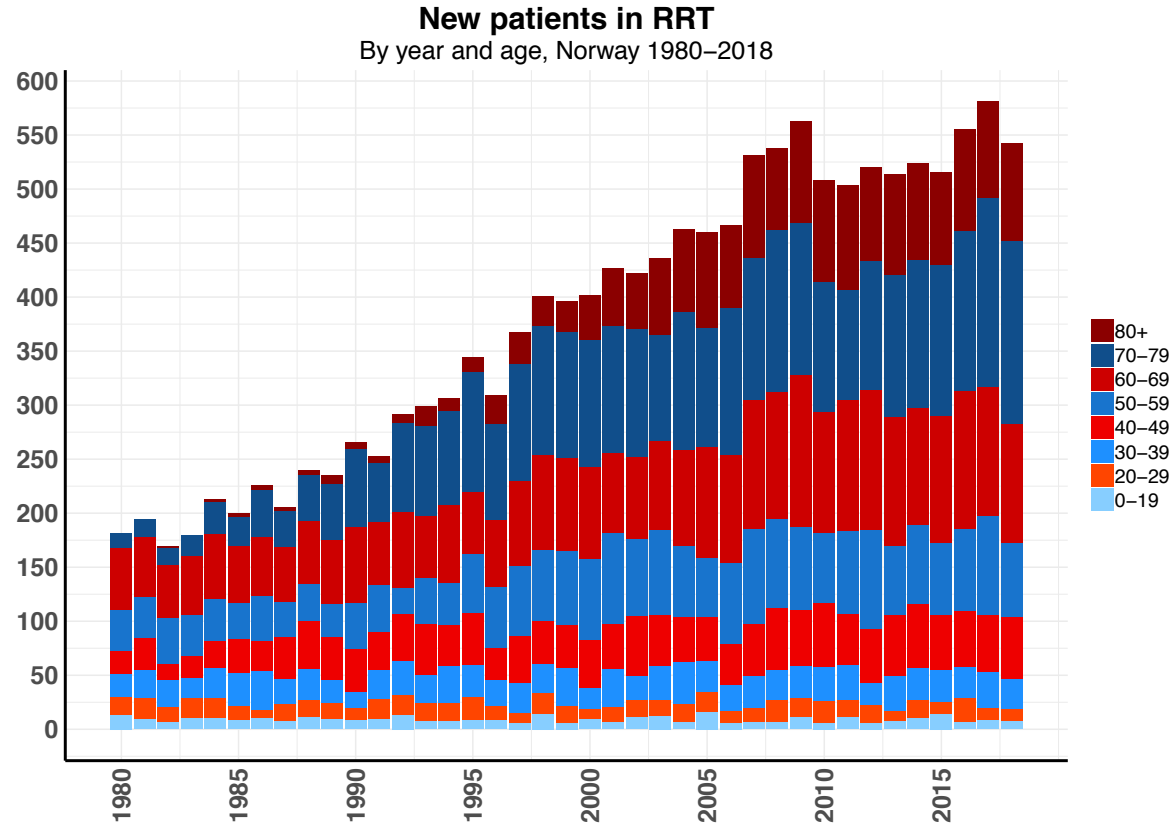


Figure 14:



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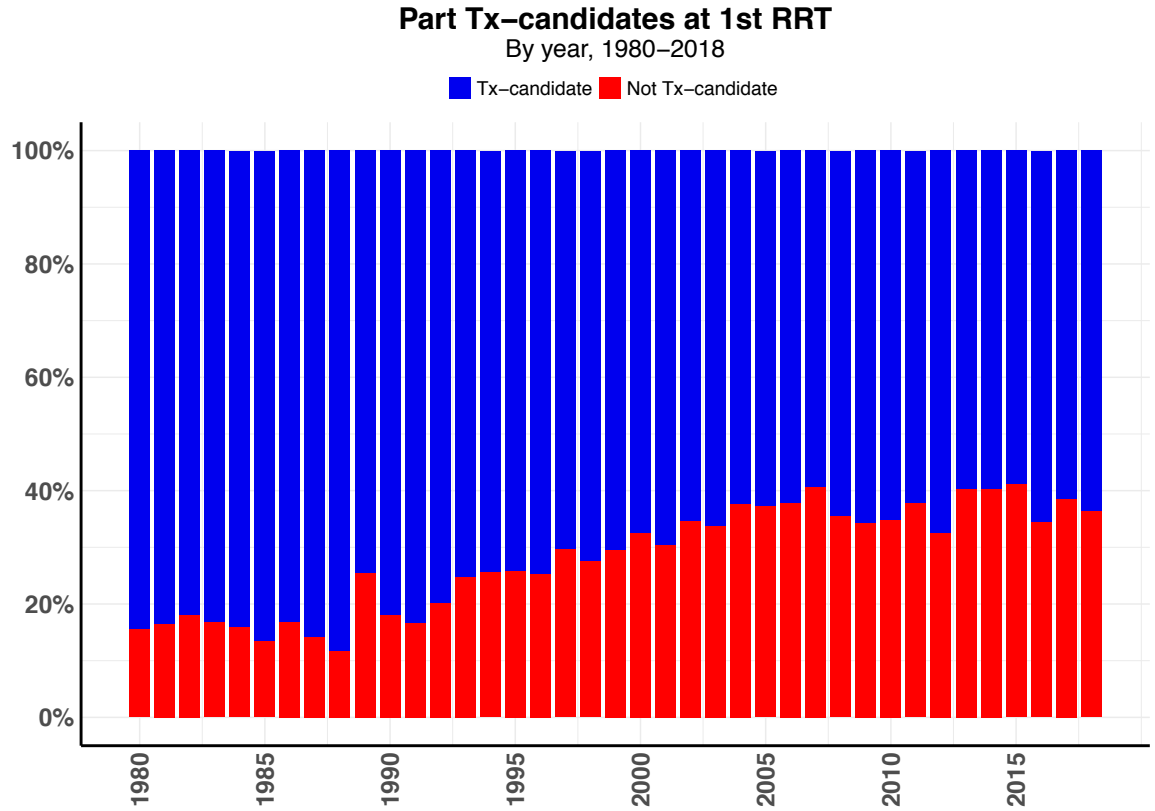


Since registration started in 1980 there has been a continuous shift in patient age. Both the maximum and the median age at start of RRT have increased. Also, the 5-percentile and 95-percentile values (i.e. including the majority of patients) have increased with a similar number of years. But also smaller children have been accepted; the youngest ever started PD in 2011 at age two days. Six children below 16 years started RRT in 2018.

Figure 16:

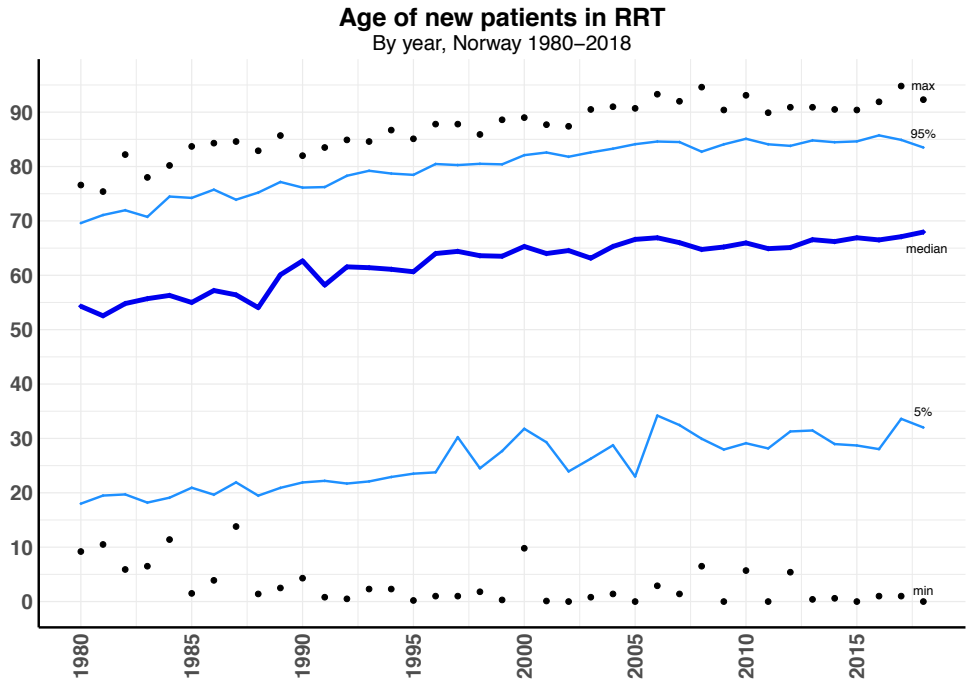


Table 11. Primary renal disease at start of RRT

	1980-89	1990-99	2000-04	2005-09	2010-14	2018
Glomerulonephritis	35%	27%	18%	18%	16%	8%
Pyelo/interstitial nephr.	15%	11%	11%	10%	9%	10%
Polycystic diseases	10%	9%	9%	8%	8%	10%
Diabetic nephropathy	13%	11%	15%	16%	17%	17%
Amyloidosis	6%	5%	3%	2%	2%	2%
Vascular/hypertensive	7%	21%	28%	31%	35%	27%
Immune/systemic	5%	5%	4%	4%	4%	10%
Kidney tumour	1%	1%	1%	2%	1%	1%
Myelomatosis	2%	2%	3%	3%	1%	2%
Other defined	4%	4%	3%	4%	4%	9%
Unknown	3%	3%	4%	4%	3%	4%
N:	2018	3234	2149	2556	2571	544

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 3-4 years. In 2018, 20% of these were registered as having Type I diabetes mellitus. Including also patients with other primary diagnoses of renal disease a total of 171 patients were recorded as having diabetes mellitus at start of RRT (12% Type I), thus 31 % 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 32 years, while for the patients with Type II diabetic nephropathy the median time was 16 years.

Cardiovascular disease is often present at start of RRT. Coronary heart disease was reported in 25% and 20% had anamnestic heart failure. Echo-verified left ventricular hypertrophy was reported in 25%. Cerebrovascular disease was reported in 14% and peripheral atherosclerotic disease in 14% while 11% had chronic obstructive lung disease.

Prevalence data CKD5 by December 31st 2018.

The data on CKD5 patients not in RRT is not complete as the register started to collect these data in 2016. The "best guess" is that the coverage of these patients is about 60%. The reported data on CKD5 patients not in RRT should hence be interpreted with caution.

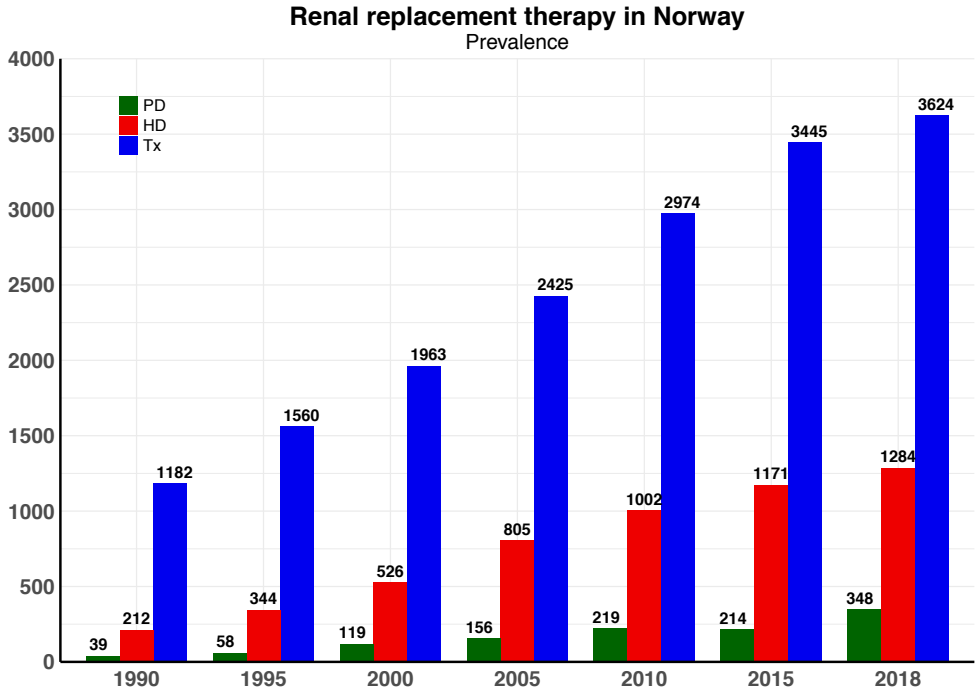
There were 494 CKD5 patients in the registry that did not receive renal replacement therapy by the end of 2018 (319 in 2017). The median length of stay in this category, before being initiated in RRT during 2018 was 13 months in the 250 patients where this had been registered, ranging from 0 to 103 months.

Prevalence data RRT by December 31st 2018.

By the end of 2018, 5,256 patients in Norway received renal replacement therapy, i.e. 986.5 per million inhabitants. This represents an increase of 108 patients or 2.1 % since 2017.

Median age by the end of the year was 62.0 years, mean 59.9 years and range 0.9 to 96.4 years. Gender: 64.5 % males.

Figure 17:



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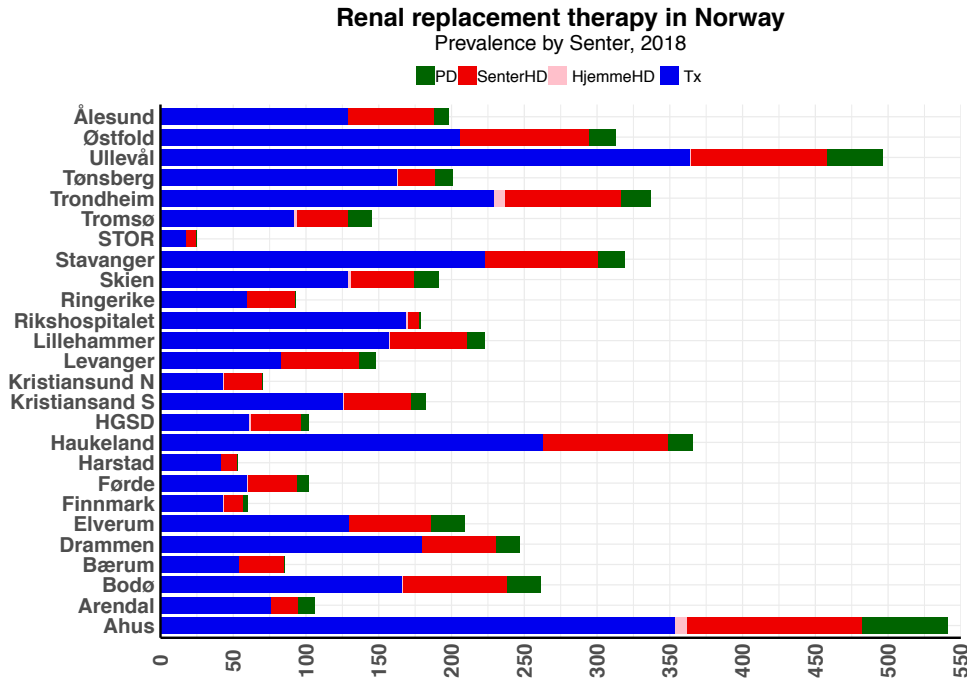


Transplantations and waiting list:

A total of 240 renal transplants were performed in Norway in 2018, i.e. 45.2 per million inhabitants, 13% were retransplantations. 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 7 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 144 first-DD-graft recipients in 2018 ranged from 3 to 81 years, with a median age of 58 years. Out of these, 33% were above the age of 65 and 9 % were 75 or older. The 65 recipients of a first LD-graft were from 3 to 74 years, with a median age of 51 years. Regraft recipients (n=31) were from 22 to 77 years, median 46 years.

Fun-facts Transplantation:

The oldest recipient was 82 years at time of transplantation and the oldest living recipient was 92 years by the end of 2018. Through the history there are 14 patients weith graft survival longer than 45 years! Eleven are still living. The longest graft survival ever in Norway is 50.3 years (patients dies in September 2019) and the longest living graft survival is 50.0 years. The oldest transplanted kidney in a now living recipient of 73 years is currently 108.5 years old (creatinine of 179 µmol/L).

Figure 19:

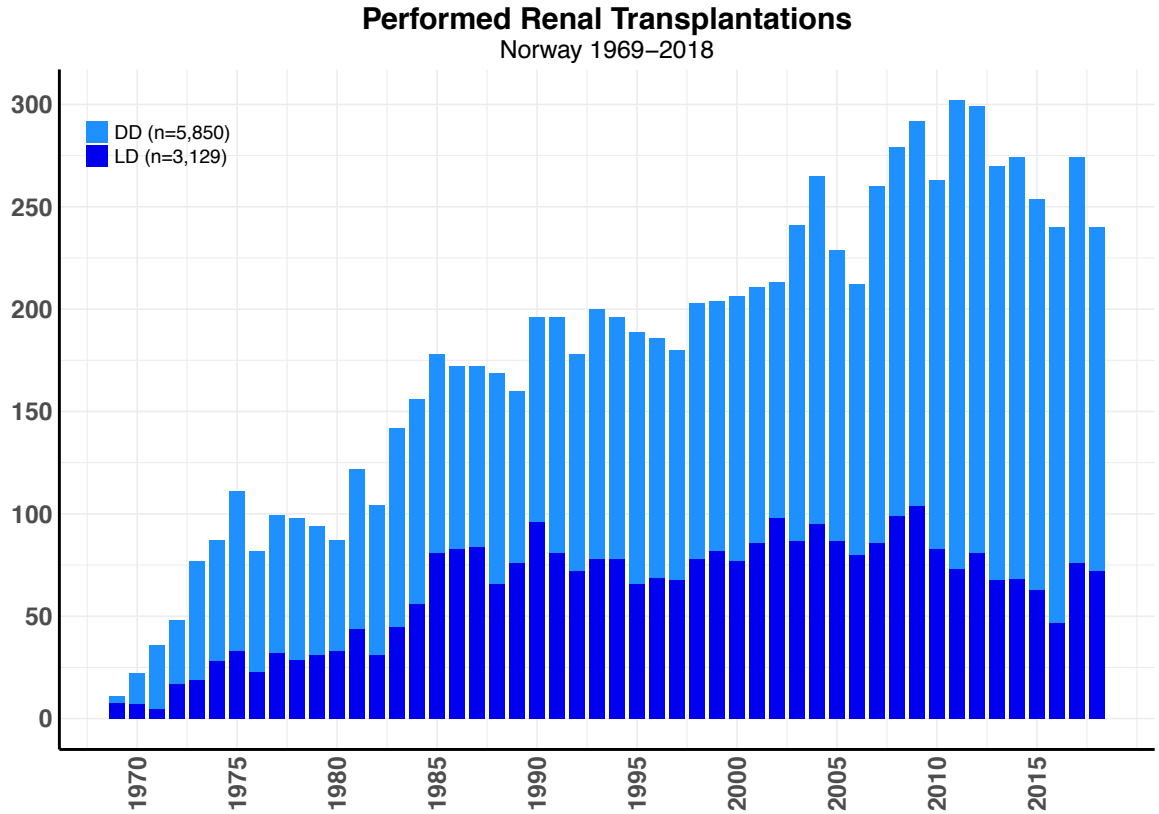
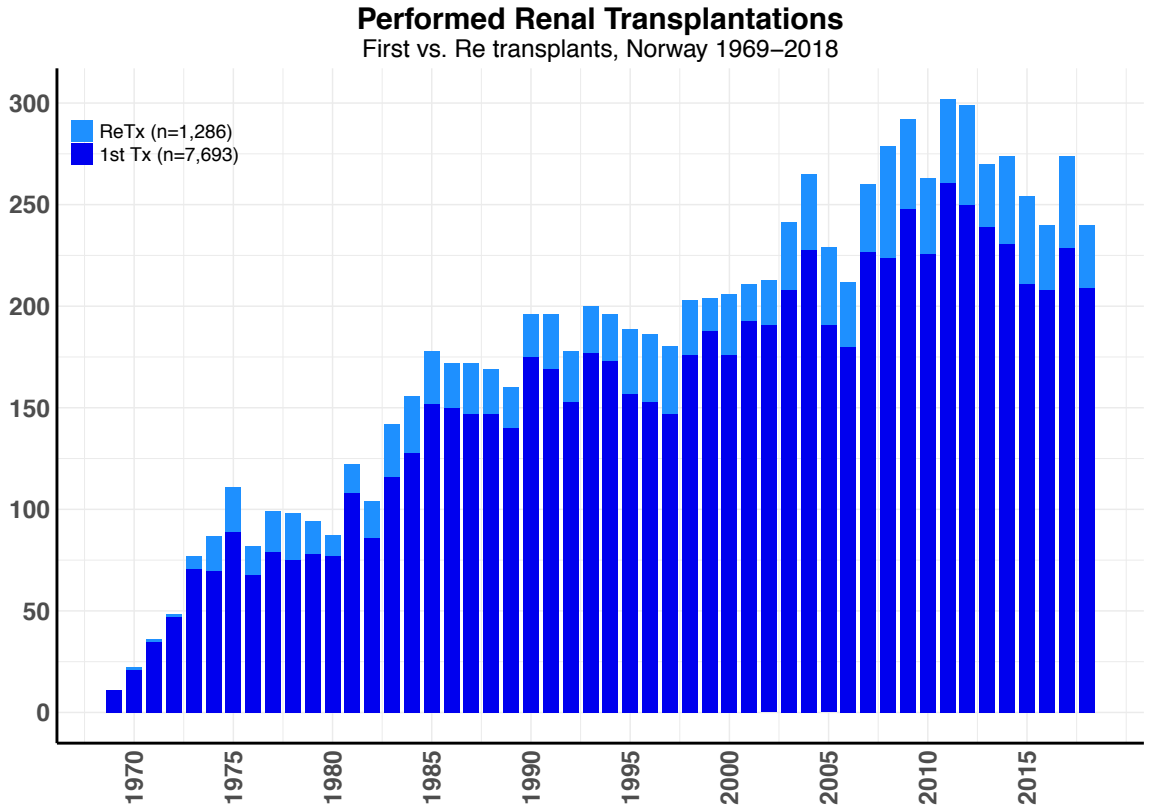


Figure 20:



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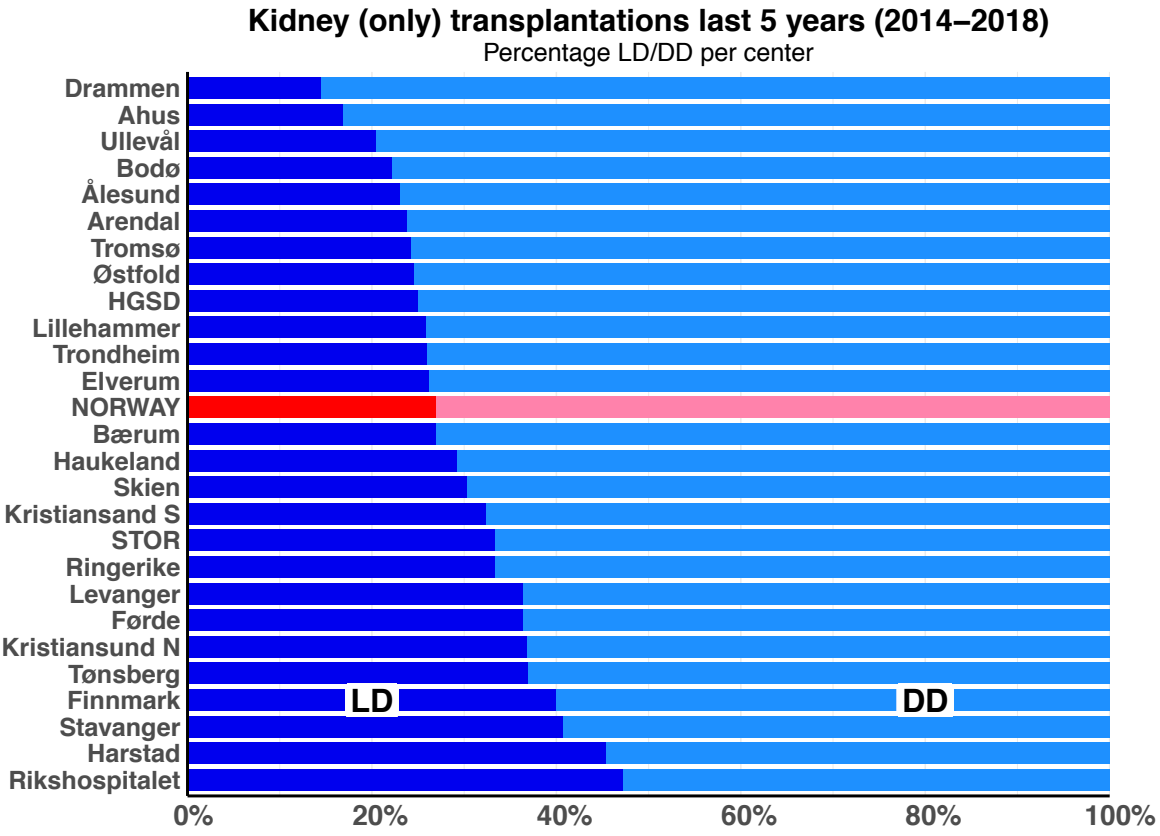

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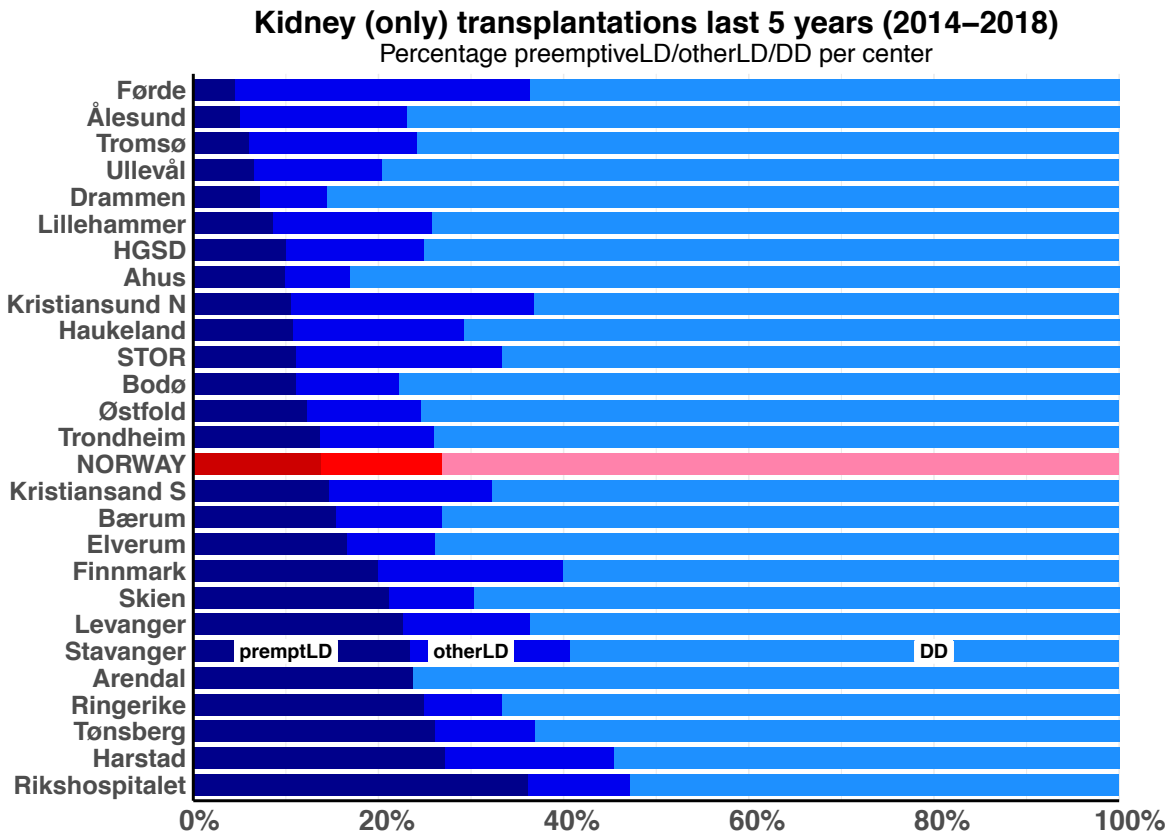


Figure 23:

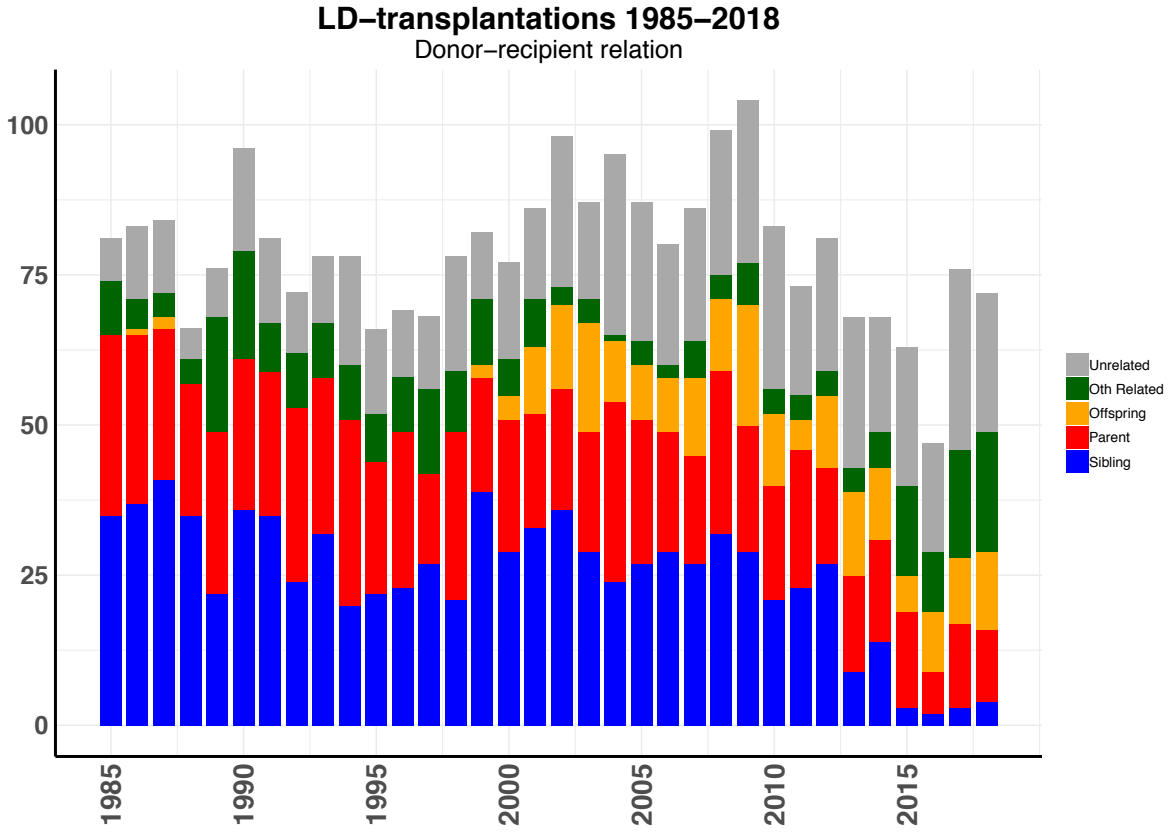
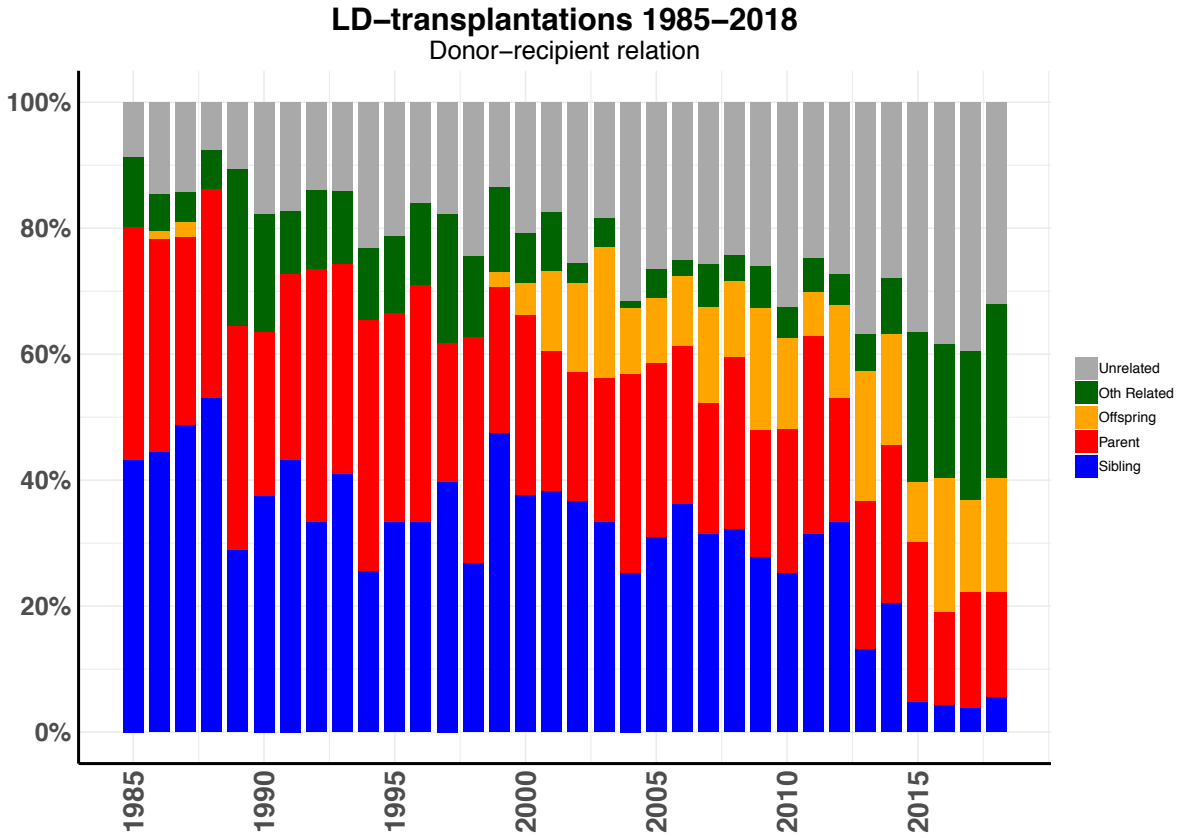
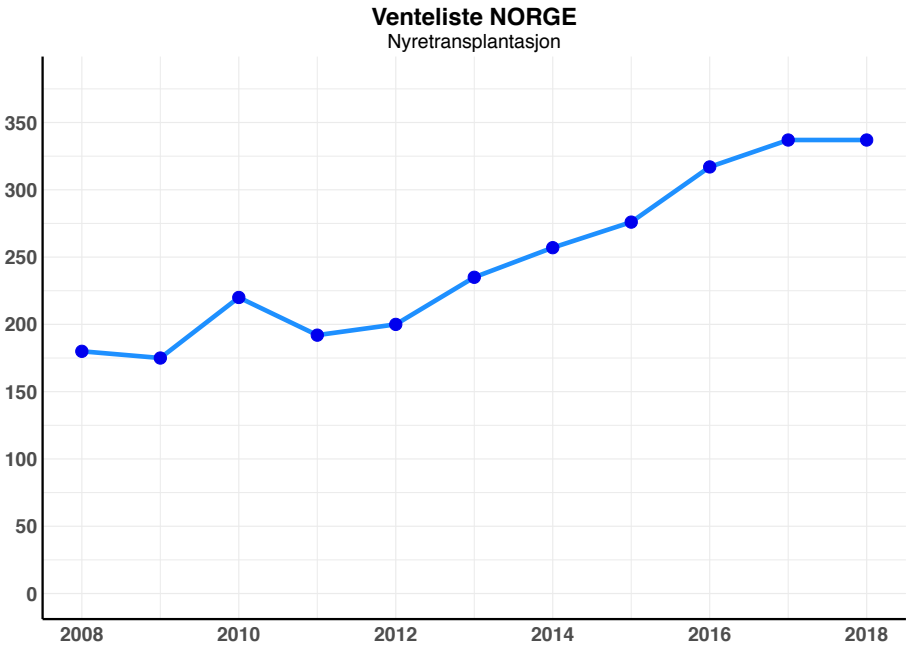


Figure 24:



By end 2018, 337 patients (63.4 per mill.) were on the active waiting list for a DD renal graft, similar as in 2017. Among those waiting by December 31st, median time on the list was 11 months for a first transplant. 52 % had waited less than one year and 20 % more than two years. The 168 recipients transplanted with a DD-graft in 2018 had a median waiting time of 15 months for a first transplant and 15 months for a retransplant and a maximum of 69 months at the time of grafting.

Figure 25:



Patient and graft survival :

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

Figure 26:

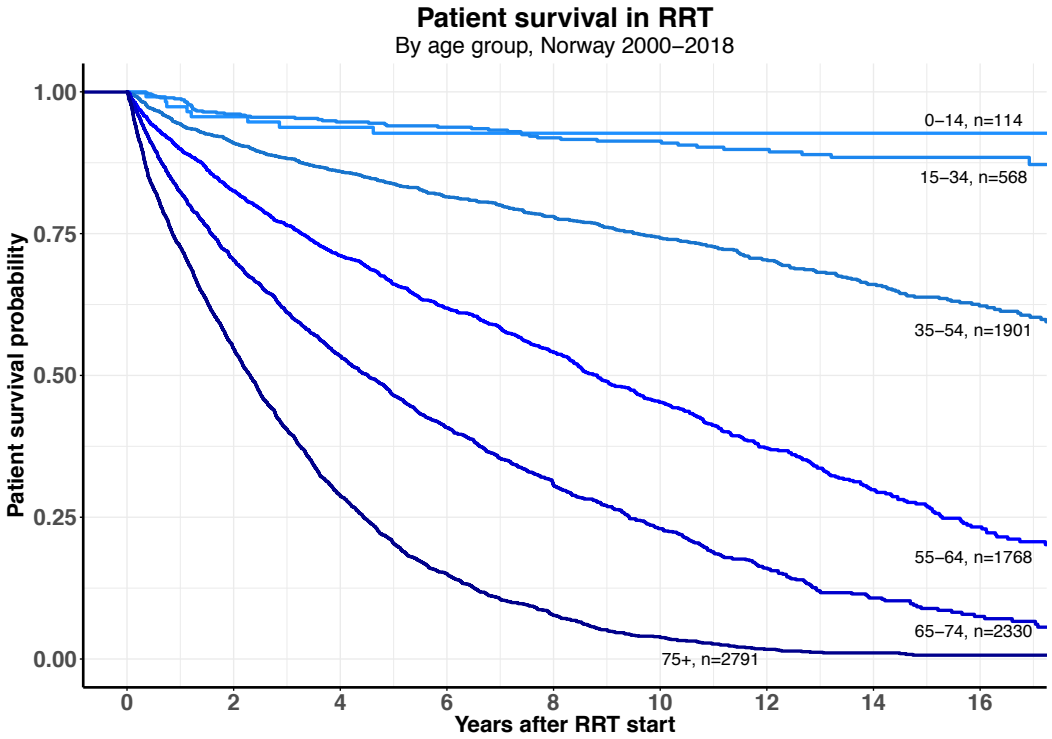


Figure 27:

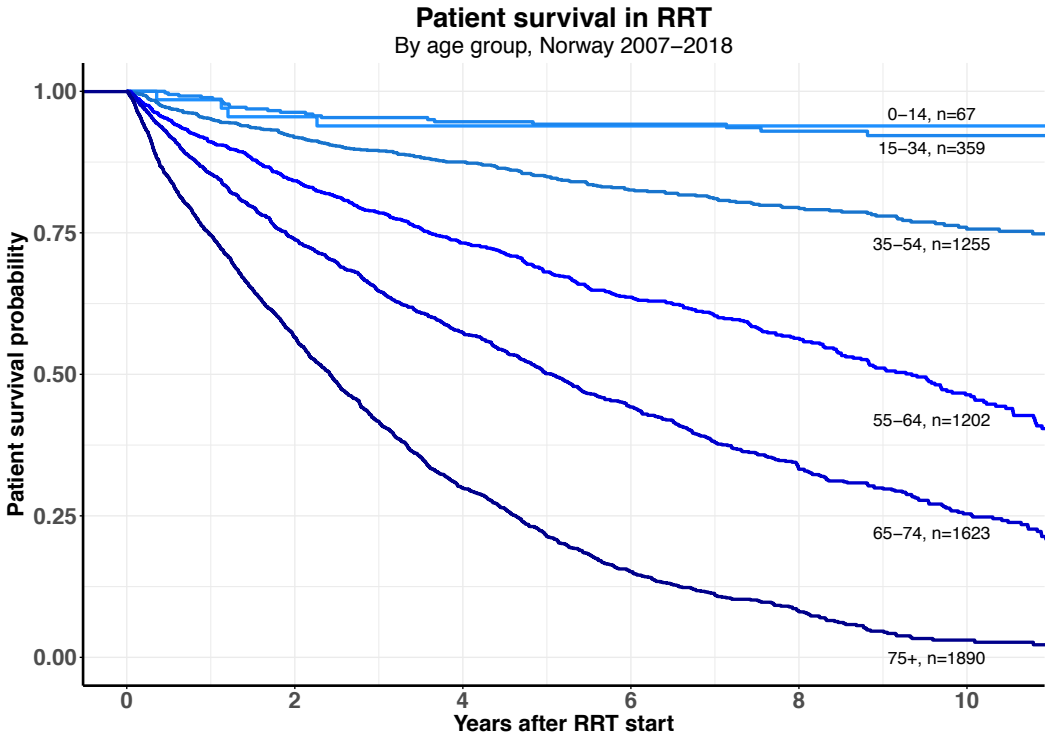
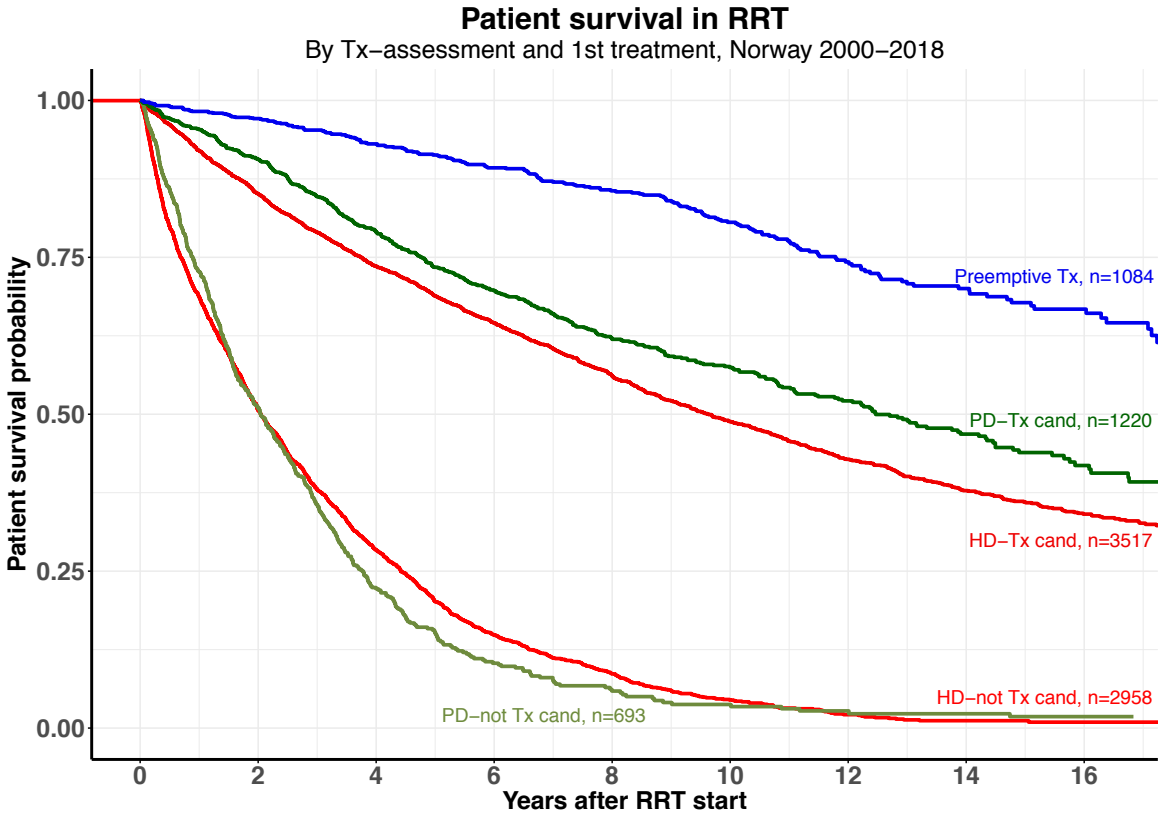


Figure 28:



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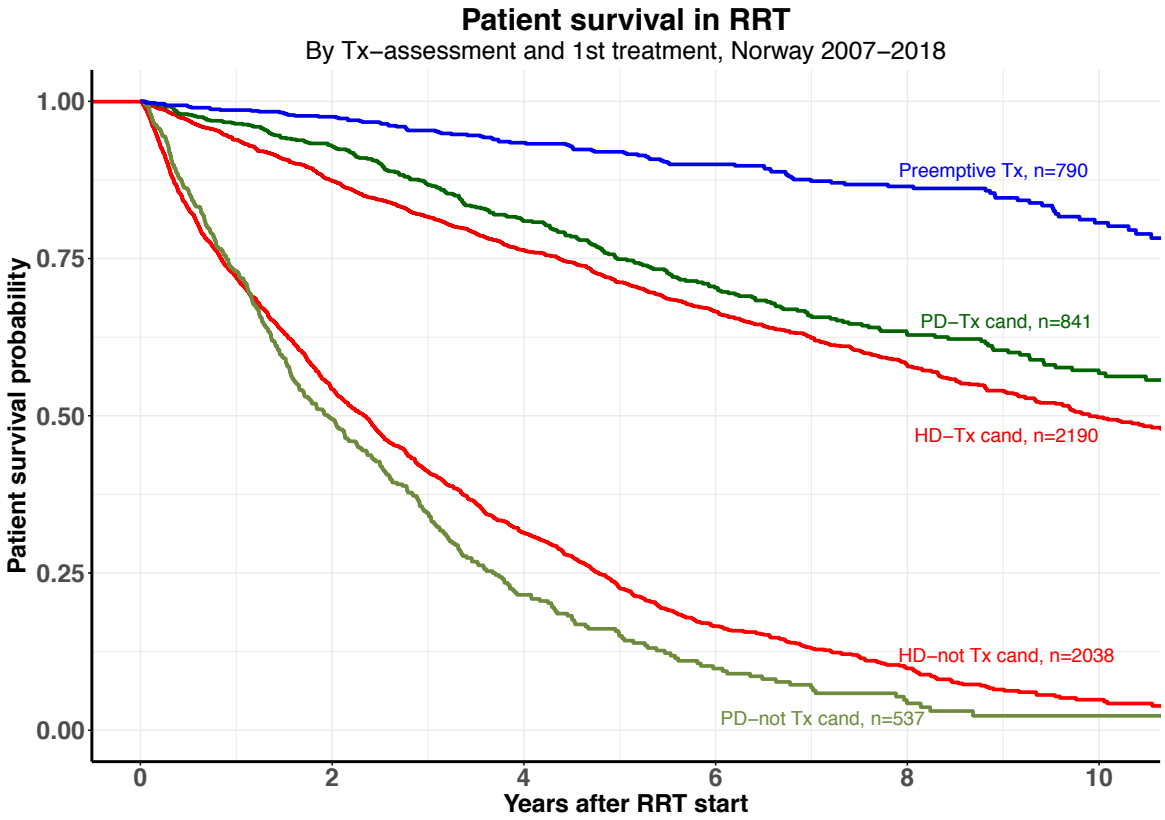
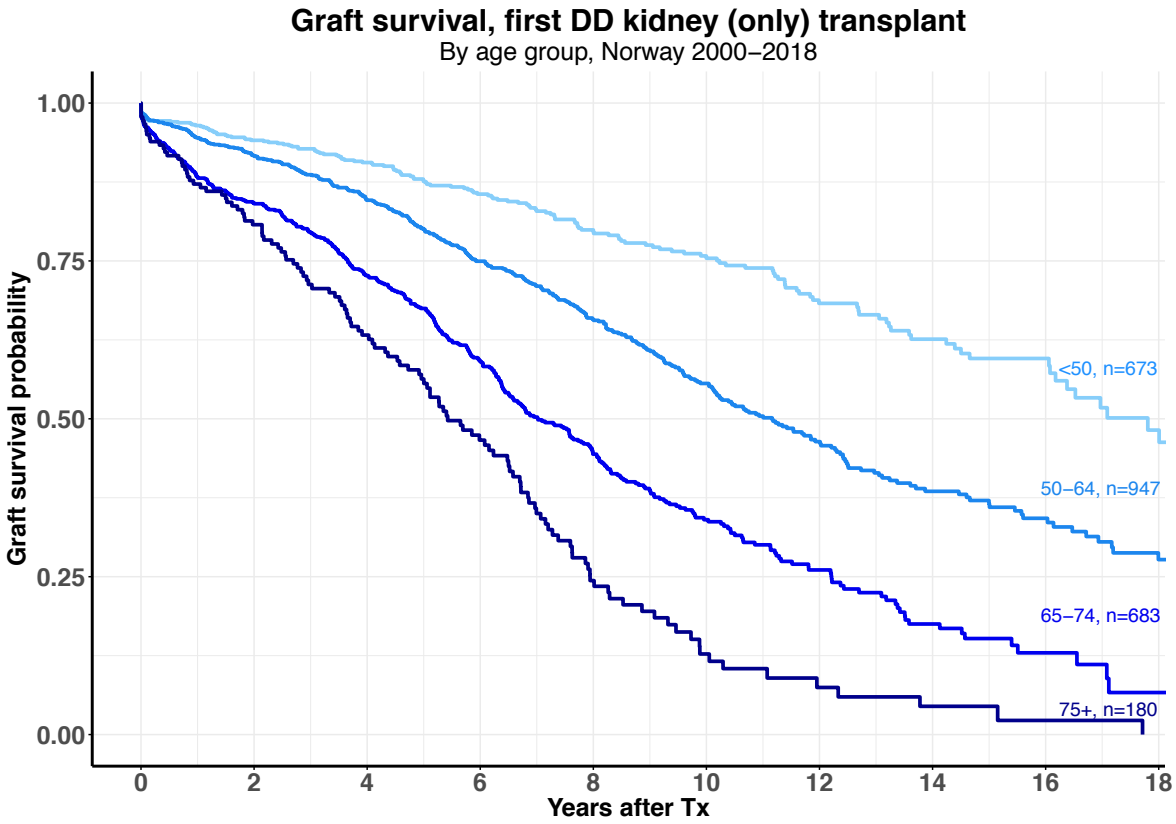


Figure 30:



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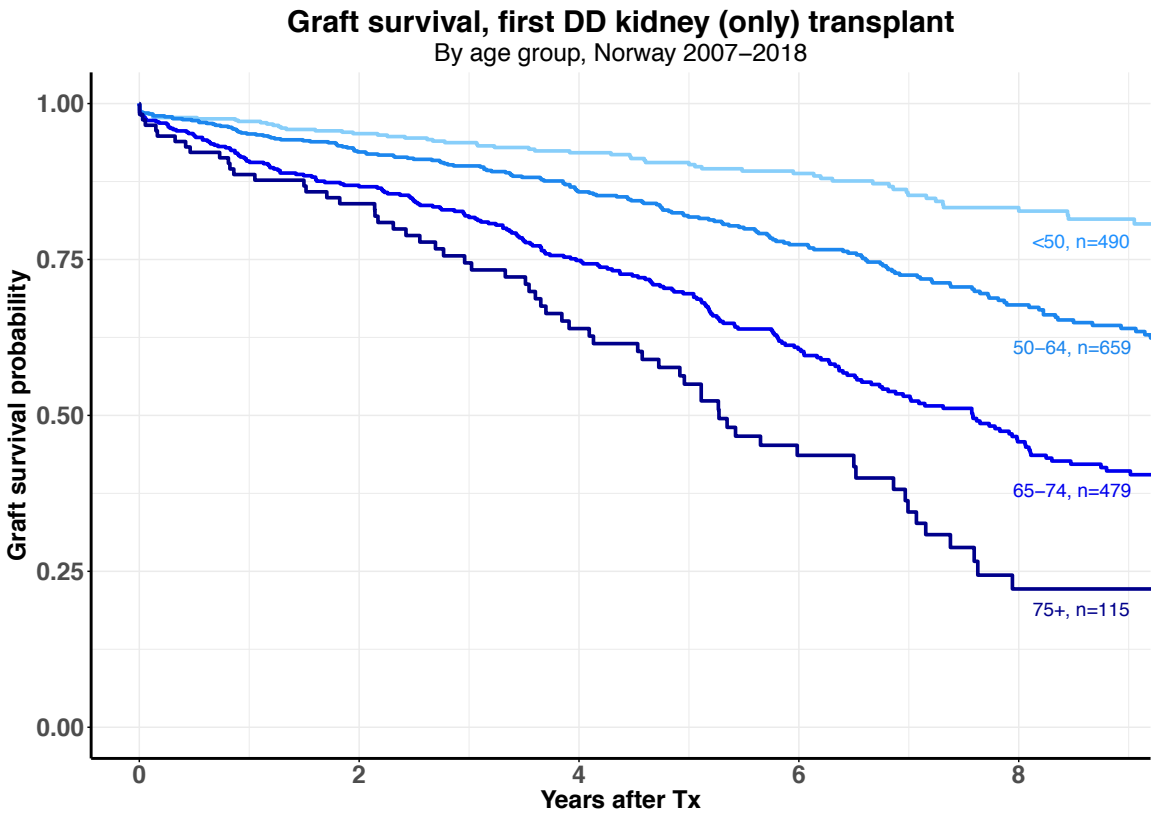
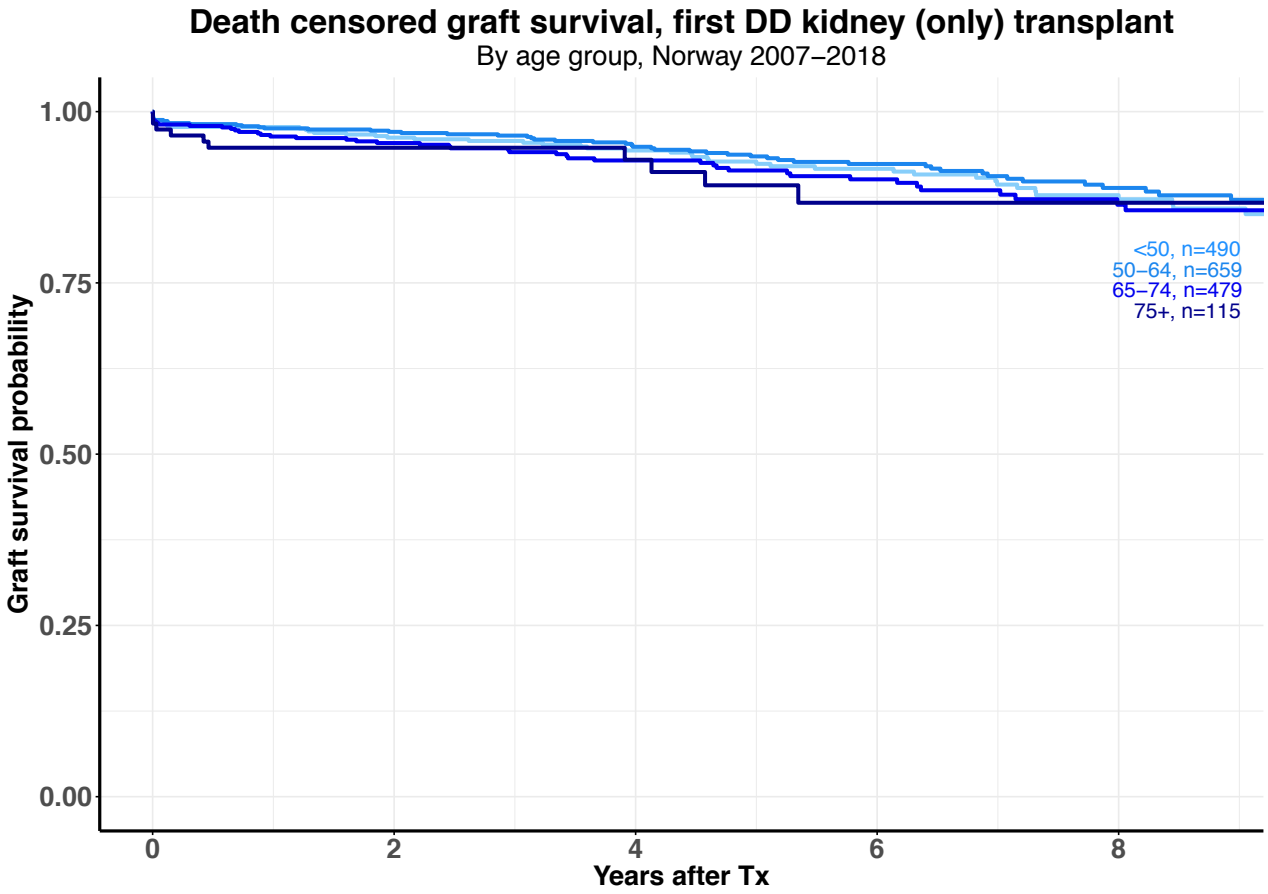


Figure 32:



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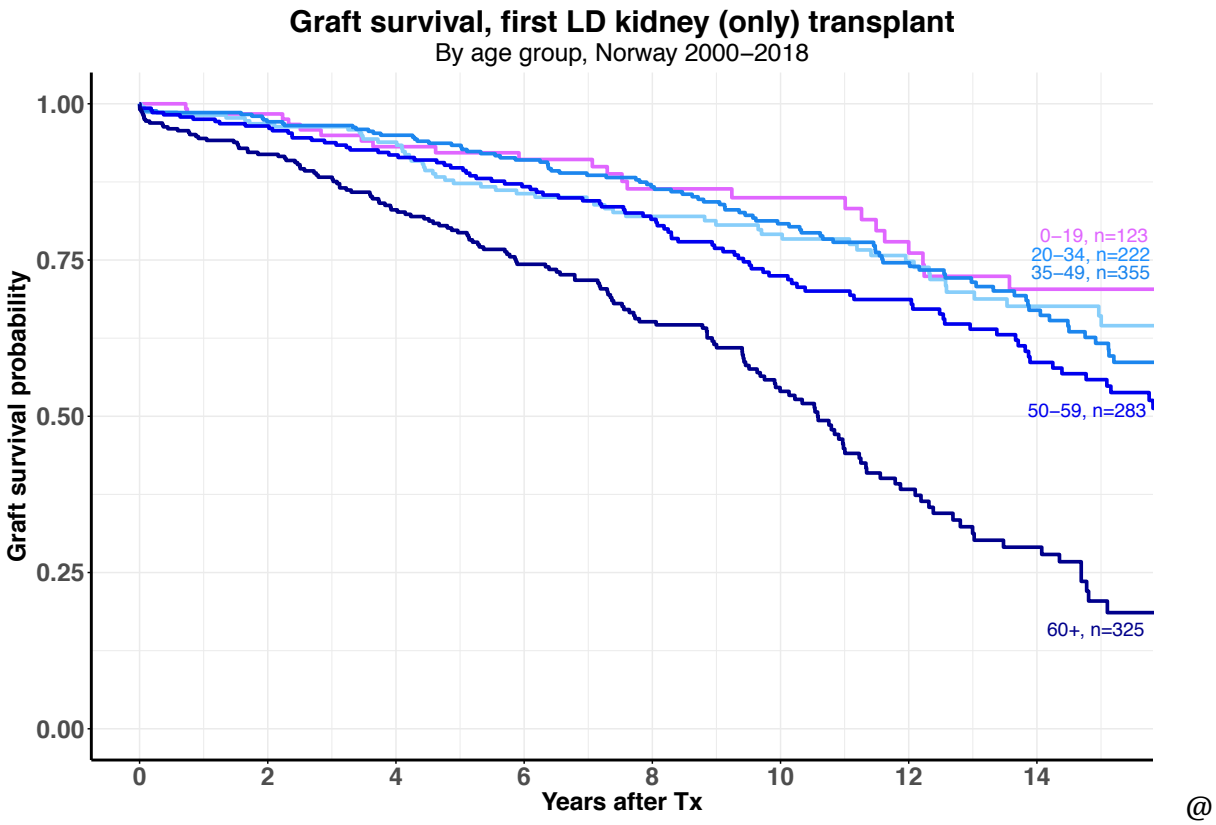

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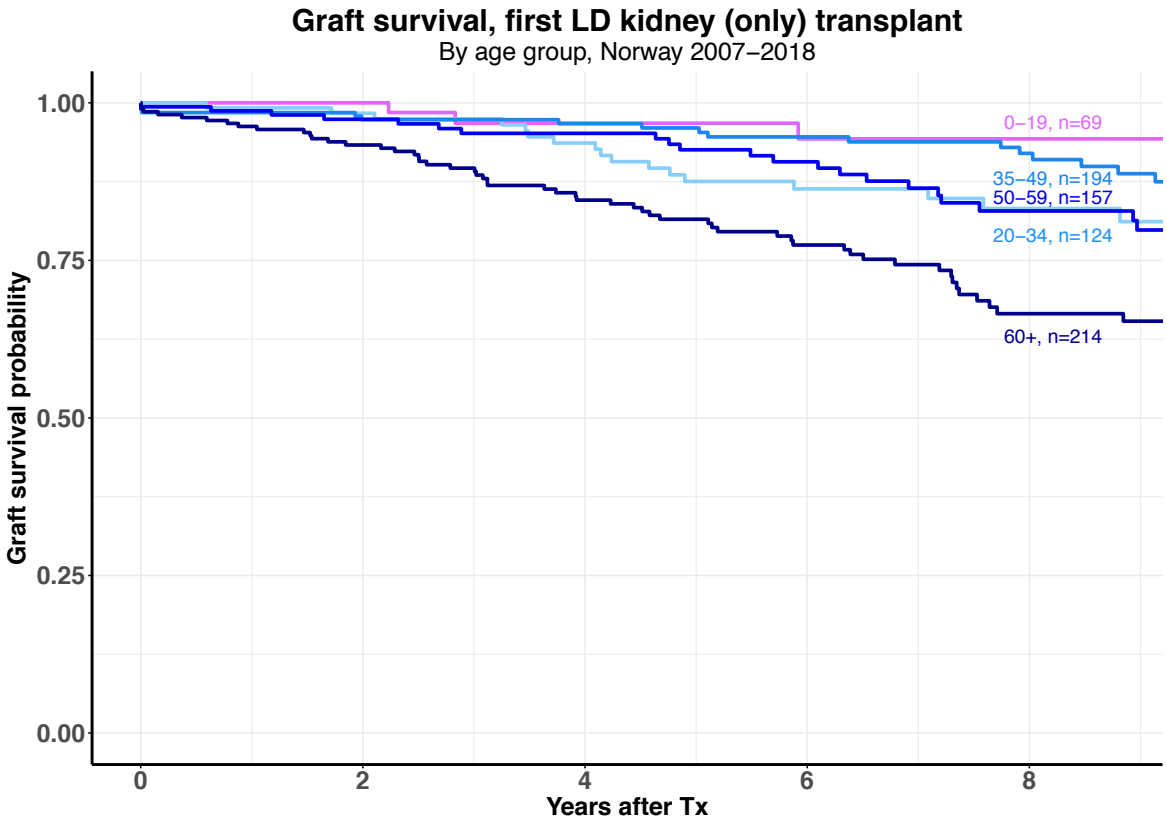
Figure 34:



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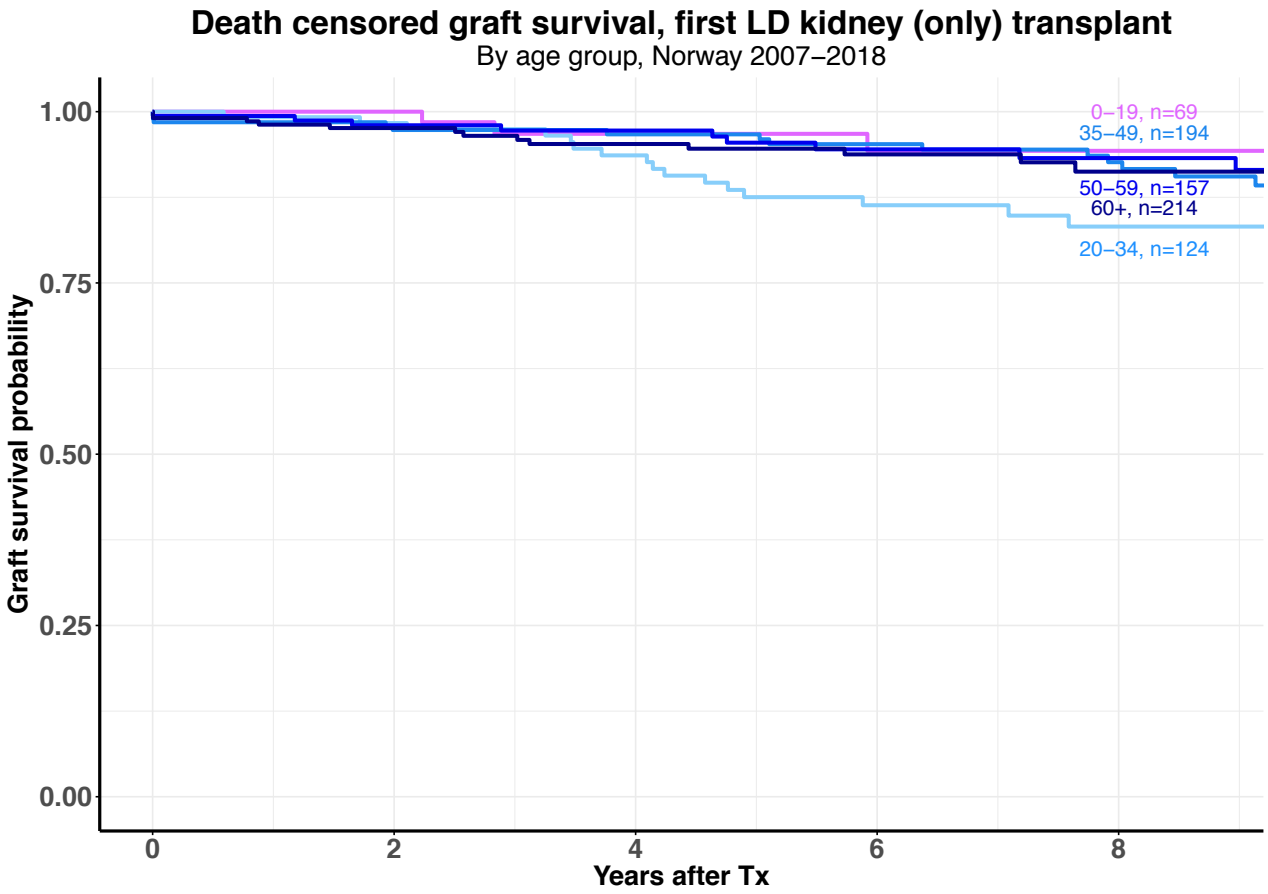

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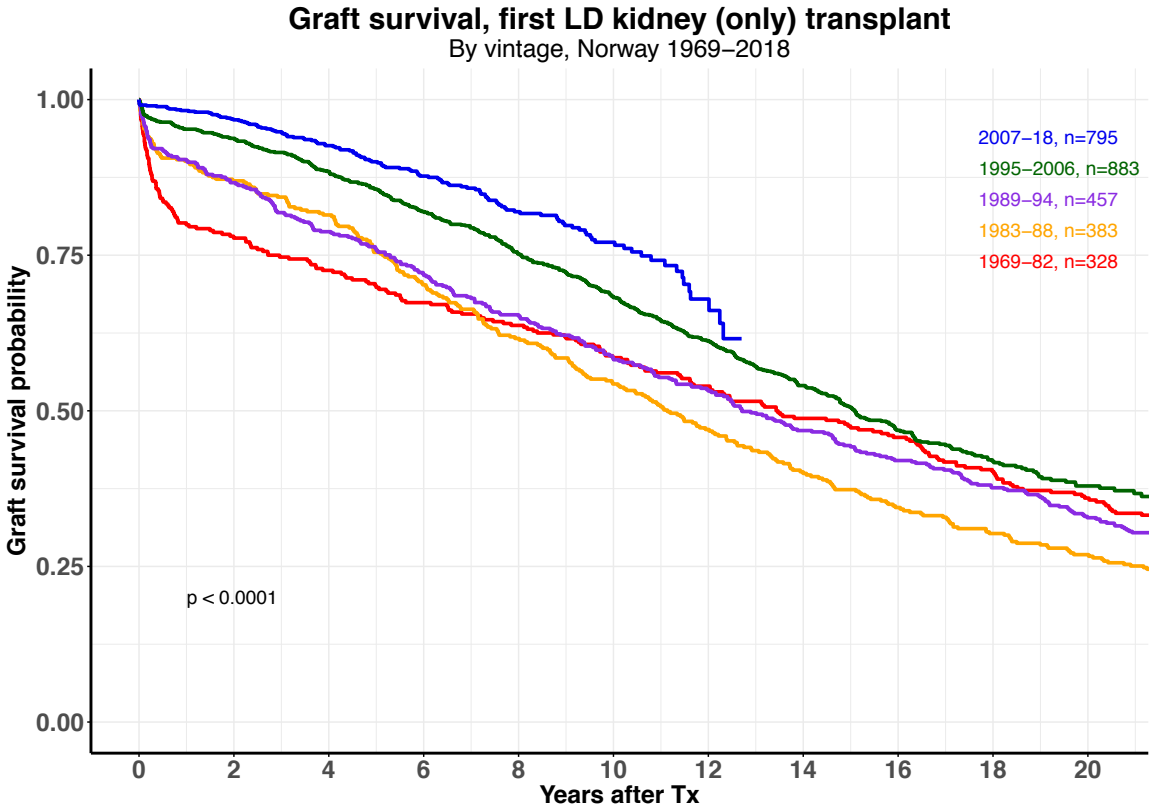

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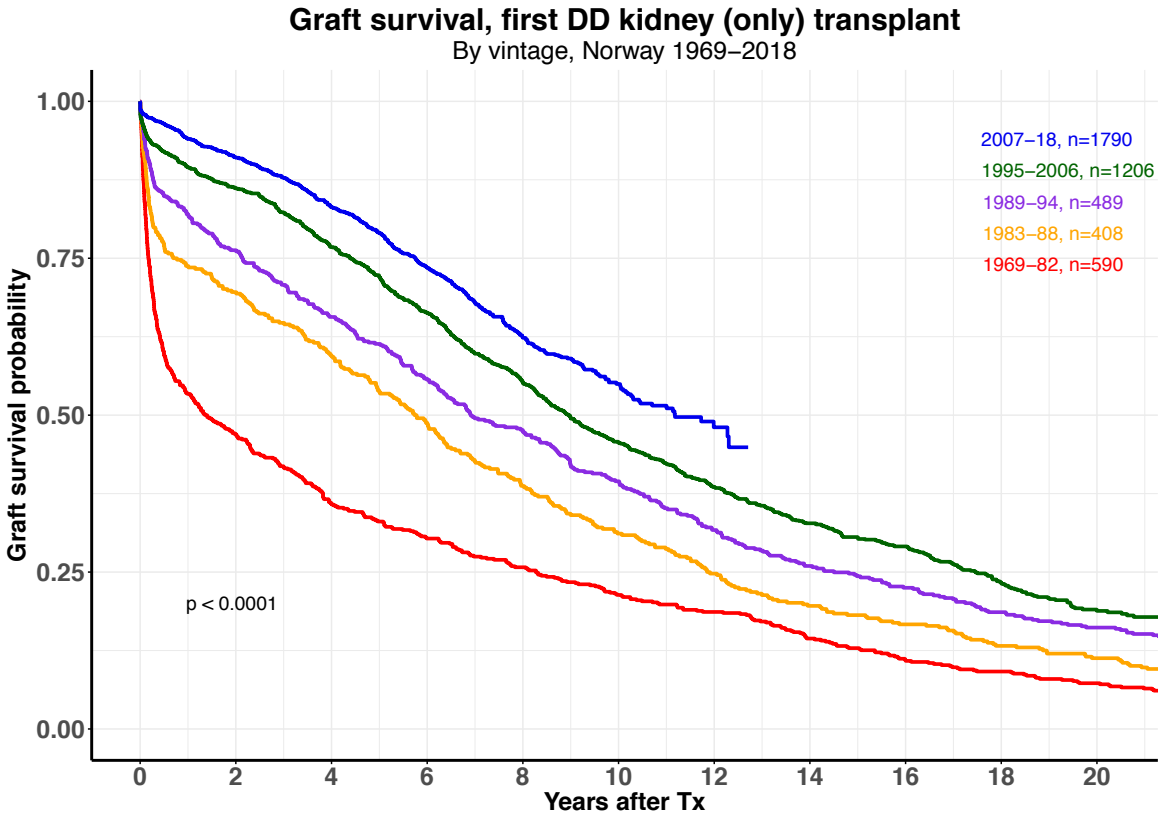

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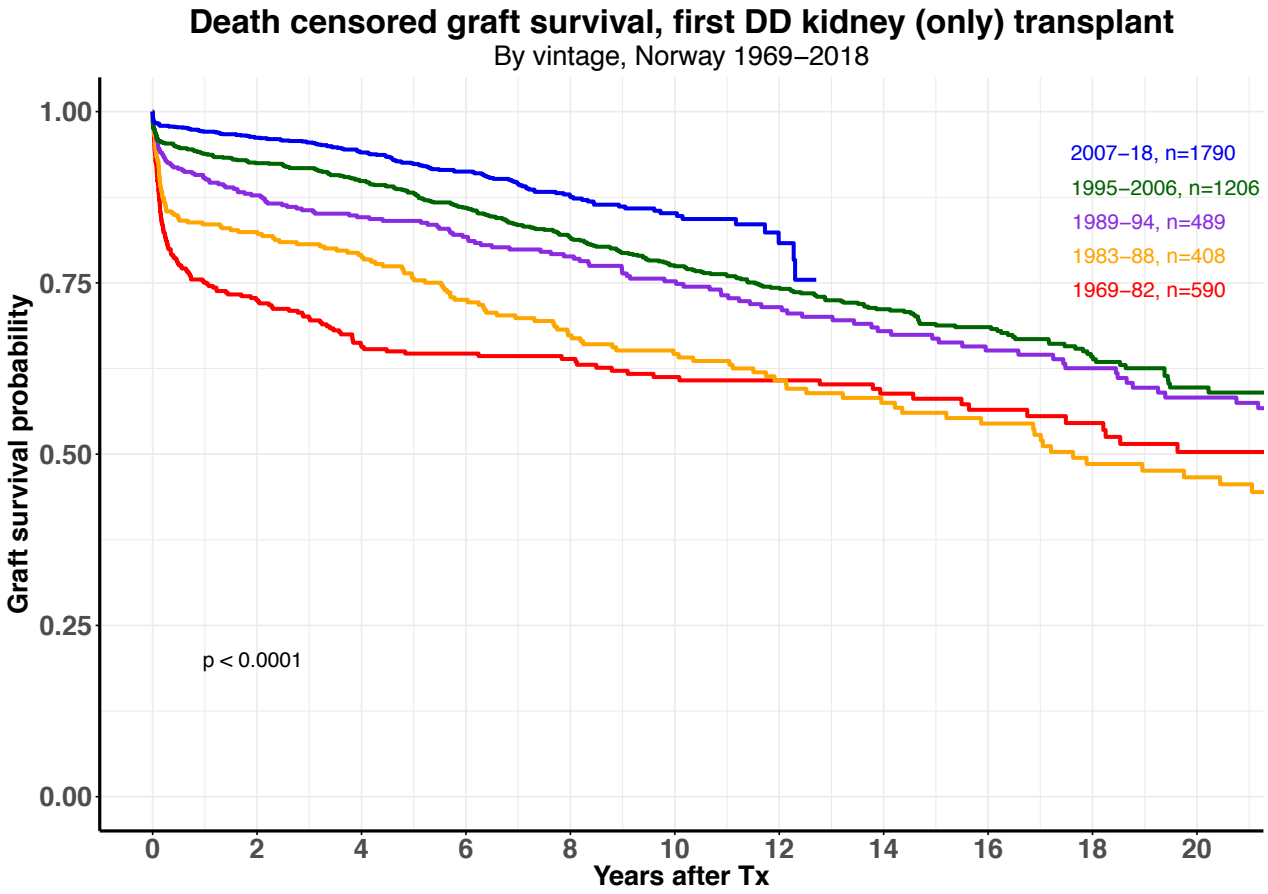

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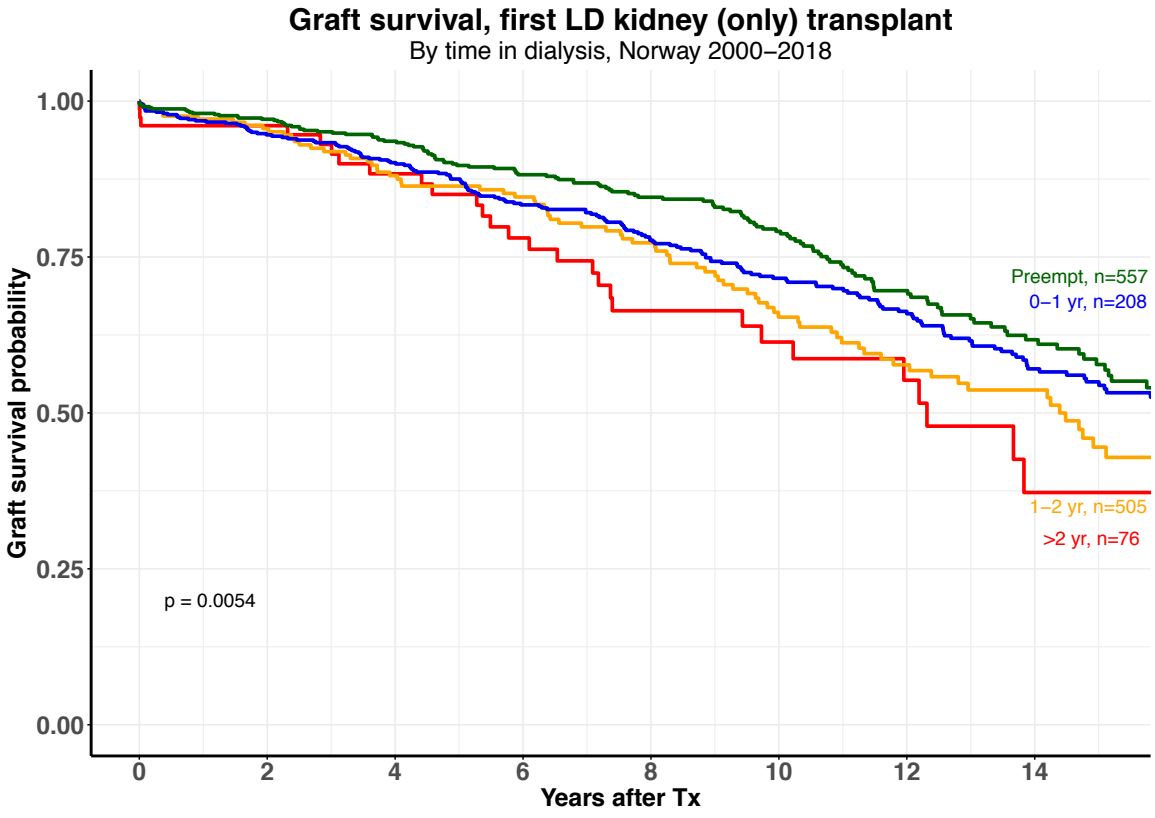

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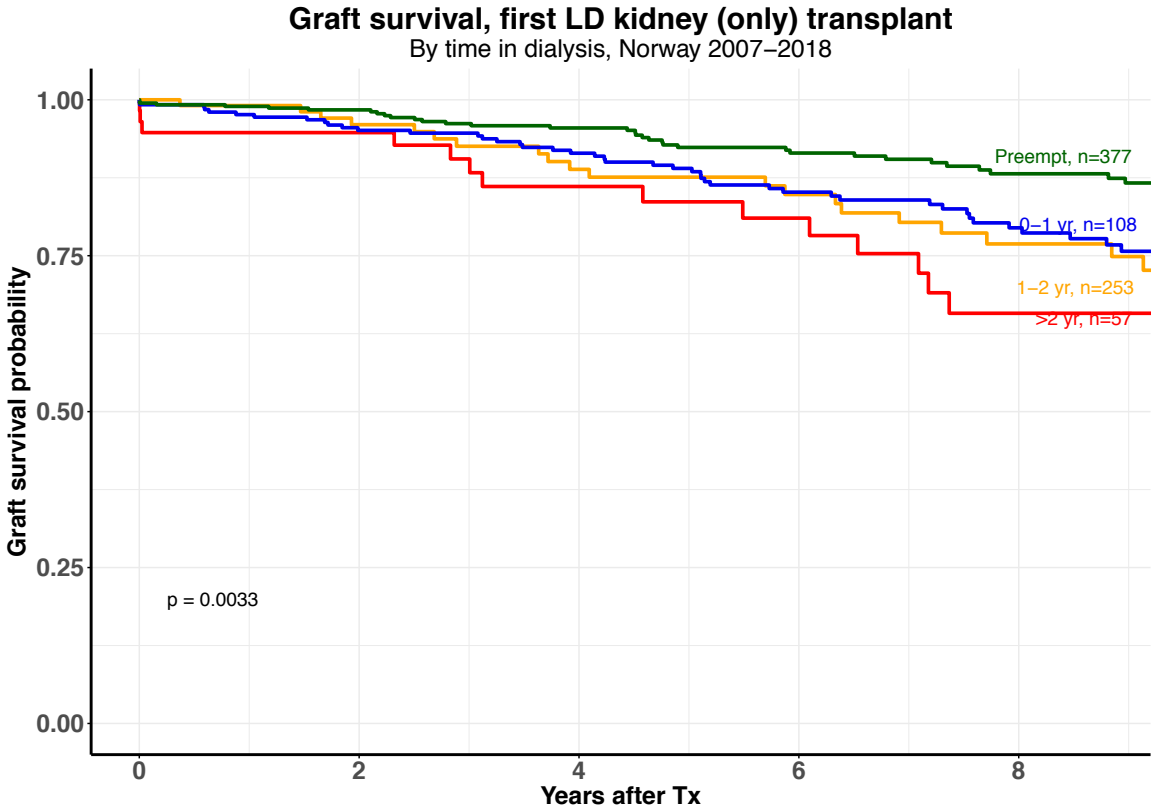

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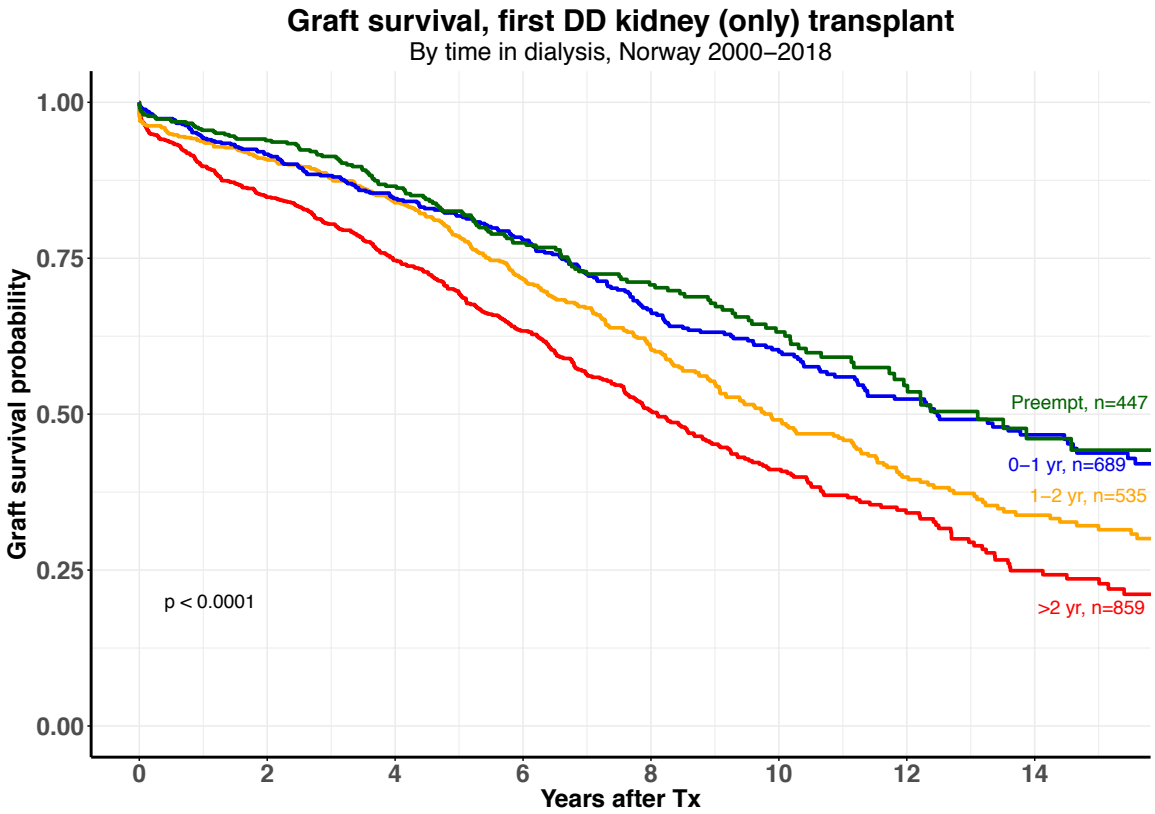

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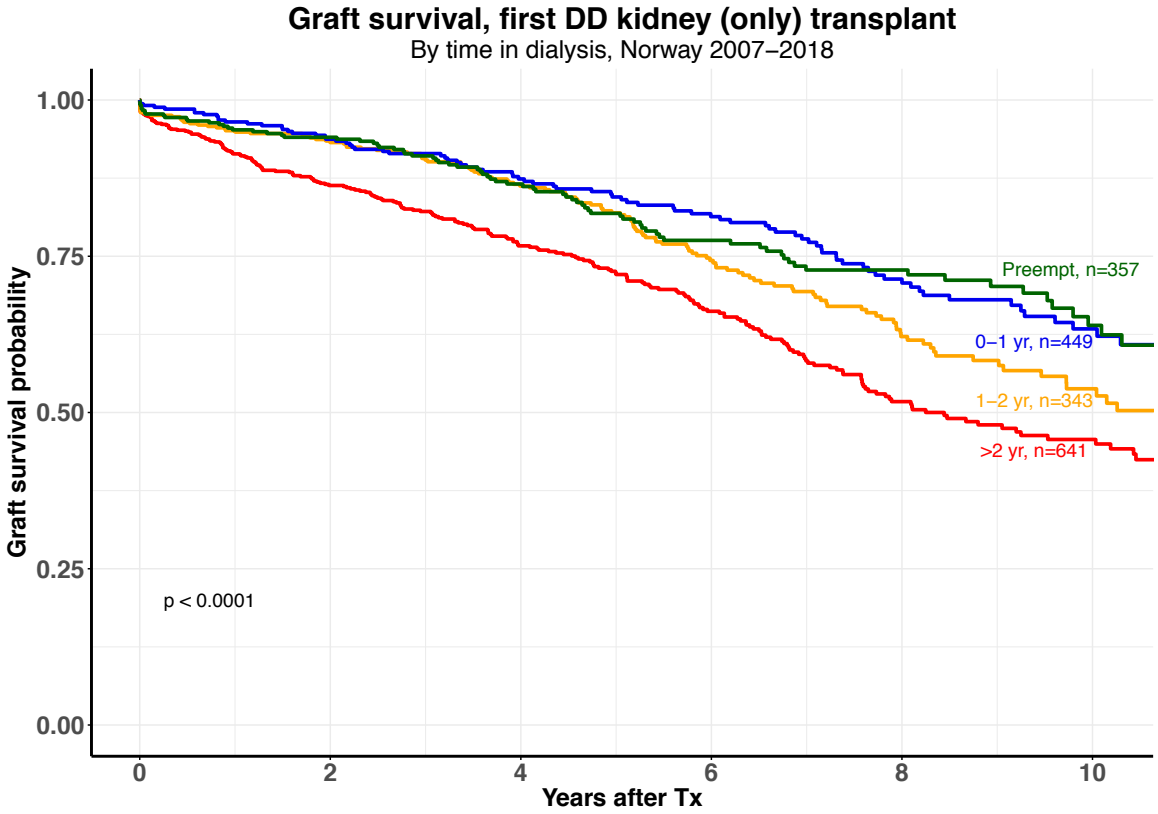

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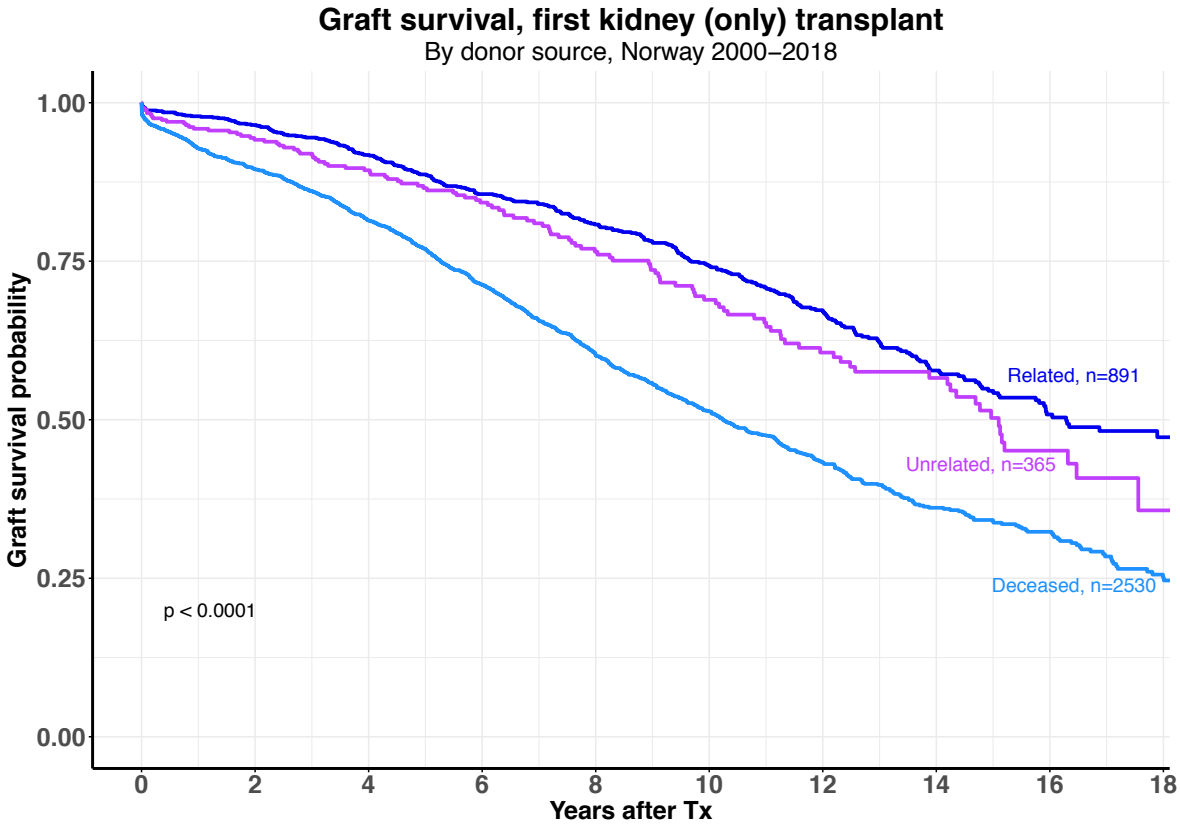

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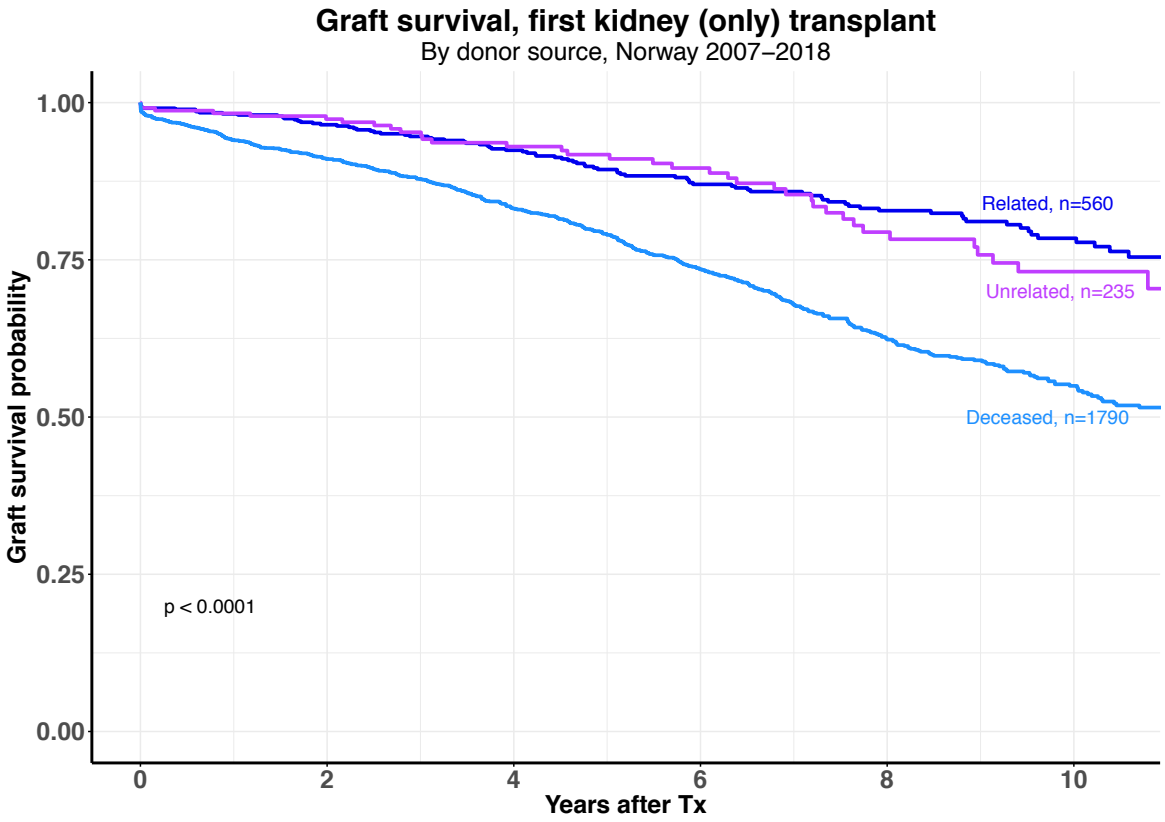


Death in CKD5:

A total of 488 patients in CKD5 died during 2018, 55 of patients had never started RRT, 304 of patients were in active dialysis and 129 transplanted. Dialysis treatment was terminated and followed by death in 47 patients.

Median age at death was 76 years (mean 75 years), ranging from 34 to 95 years. Median time from start of RRT until death was 4.9 years (mean 7.3 years), ranging from 1 month to 40 years.

Cardiac complications (30%) were the most frequent causes of death, followed by infections (24%) and malignant tumours (12%).

Quality indicators:

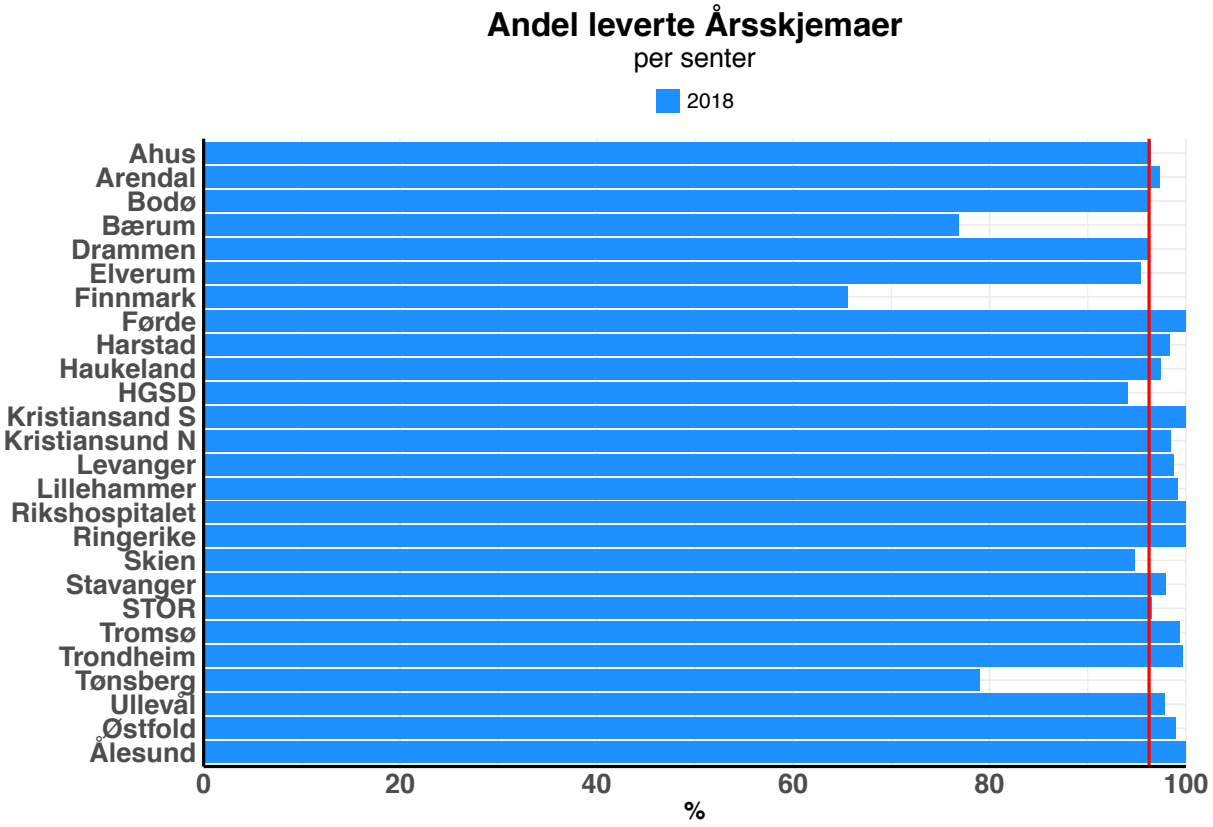
The registry has implemented 22 quality indicators (see appendix) that will be followed year by year to assure the quality of the treatment the patients included in the registry is subjected to. These data are presented interactively at this site (https://www.kvalitetsregistre.no/registers/464/resultater) and the quality indicator of part in home dialysis is presented three times per year here (https://helsenorge.no/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 two 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.

Data on part of the patients on the waiting list for a kidney transplant that has been in dialysis for more than 2 years is not relevant to present on a center level. In 2018 the part increased from 28.0% in 2017 to 31.2s % in 2018.

In the figures below the red line indicate the target percentage (if not other is described).

Figure 45:



Red line shows national average (96.2%)

Figure 46:

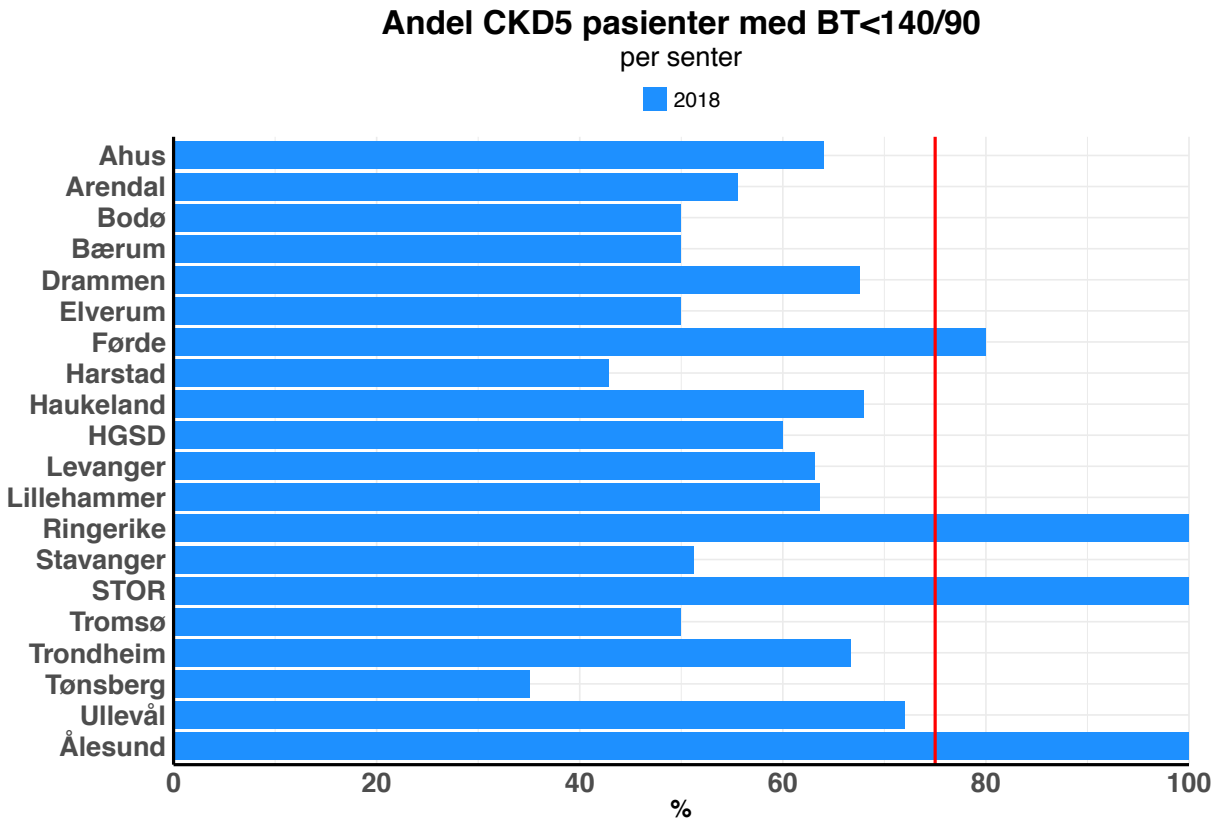


Figure 47:

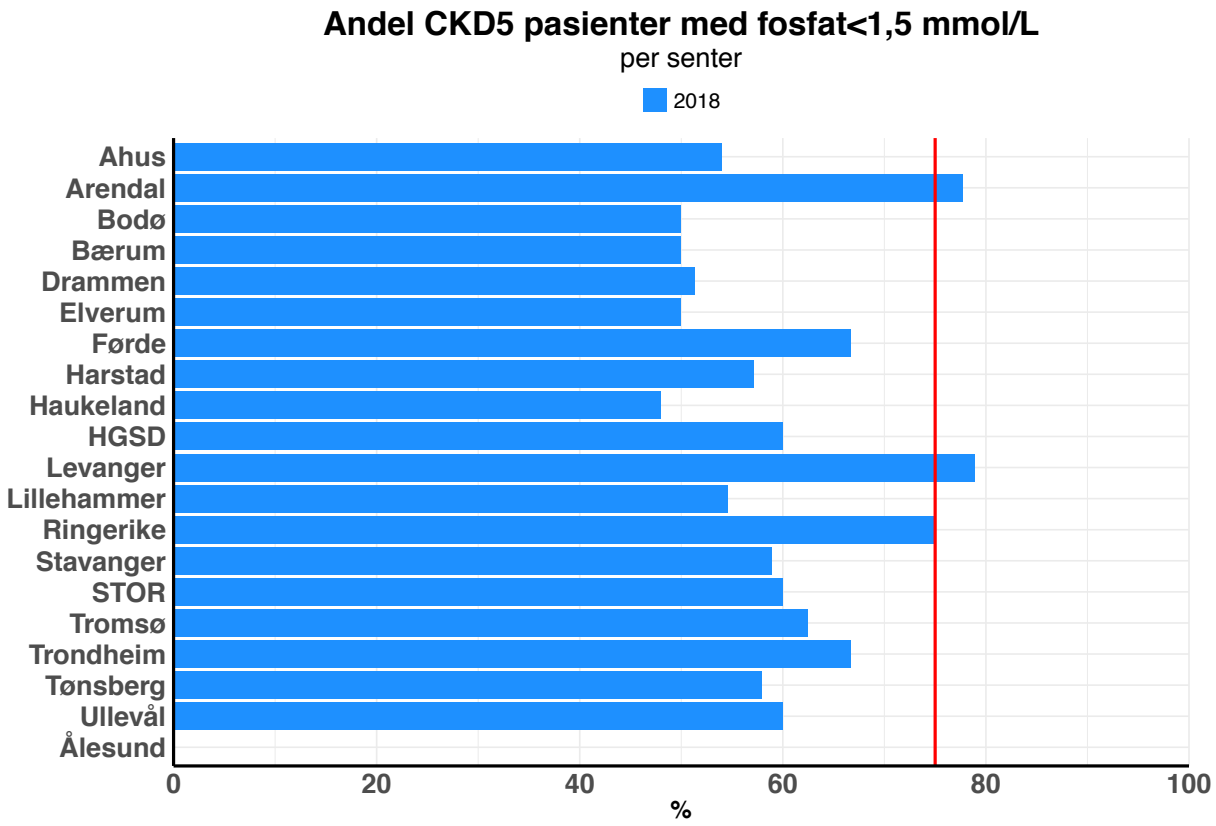
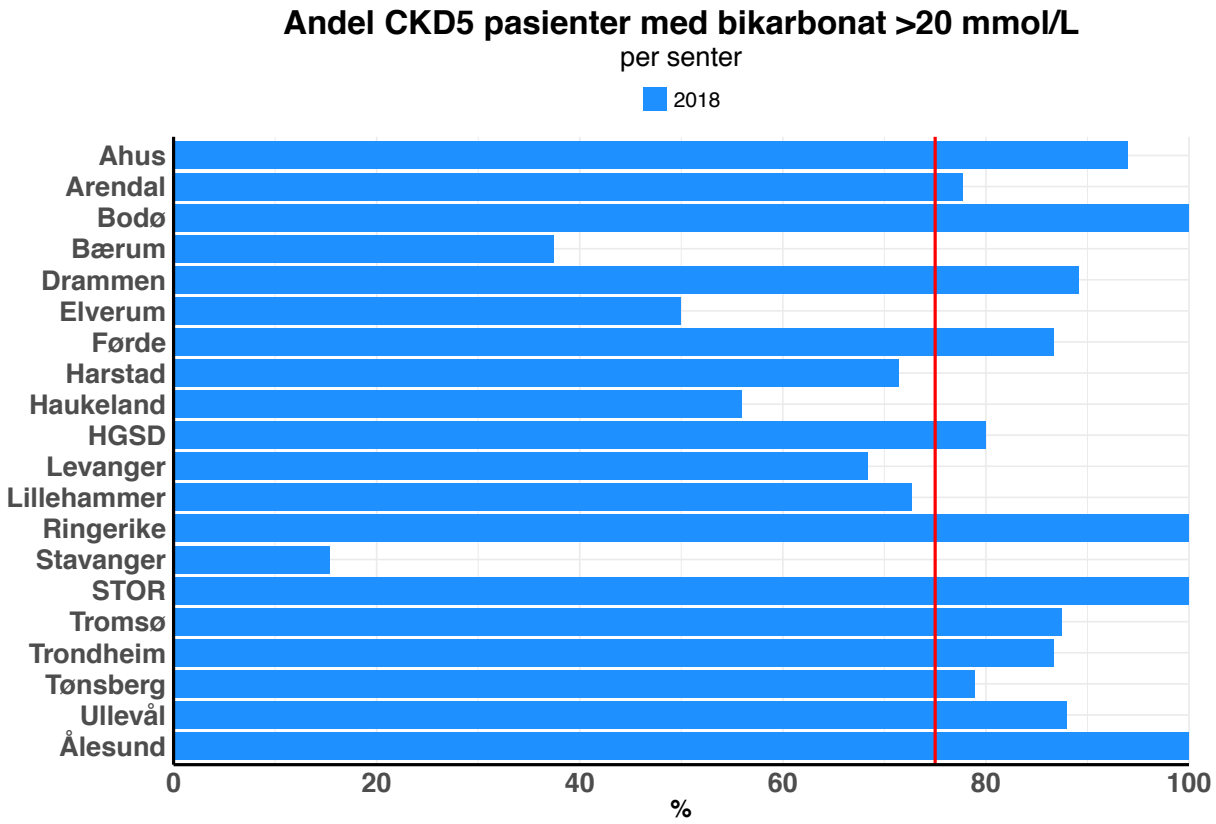


Figure 48



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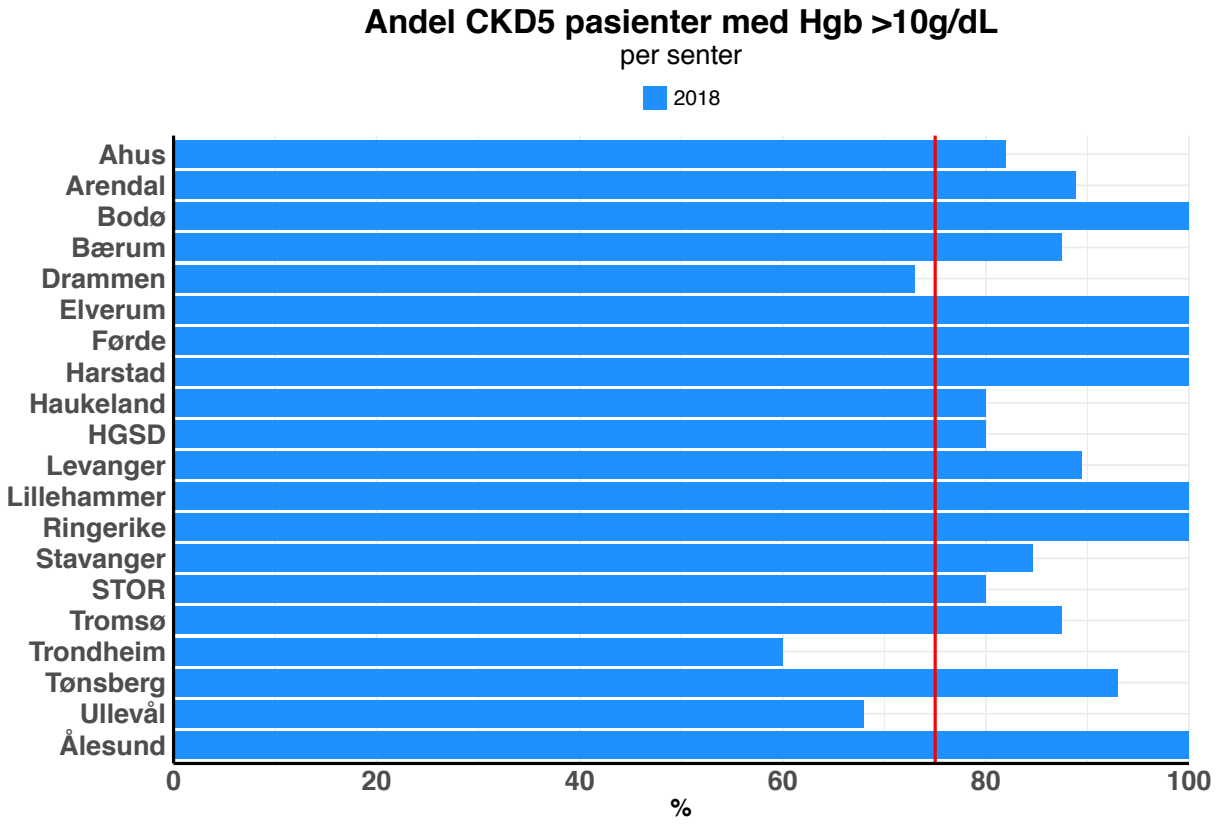

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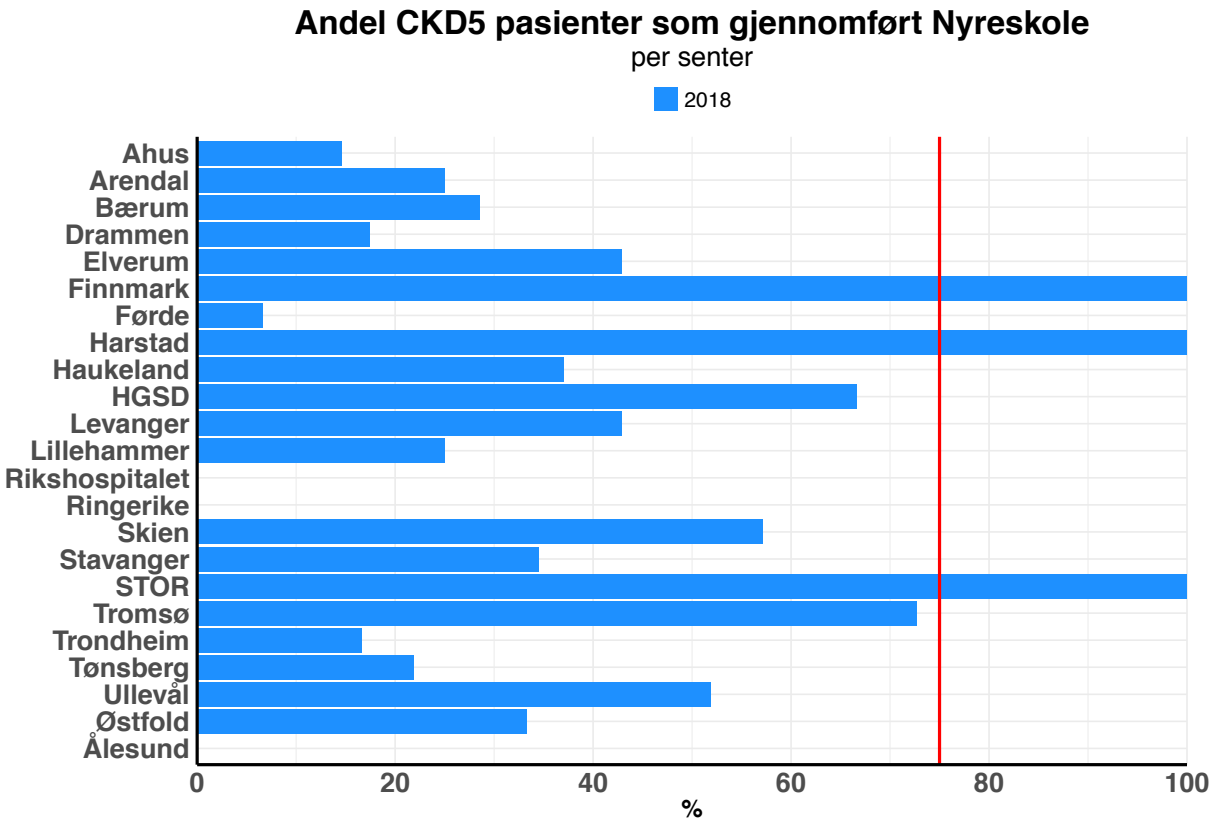

Andel CKD5 pasienter som gjennomført Nyreskole
per senter
2018
Ahus
Arendal
Bærum
Drammen
Elverum
Finnmark
Førde
Harstad
Haukeland
HGSD
Levanger
Lillehammer
Rikshospitalet
Ringerike
Skien
Stavanger
STOR
Tromsø
Trondheim
Tønsberg
Ullevål
Østfold
Ålesund
0
20
40
60
80
100
%

Figure 51:

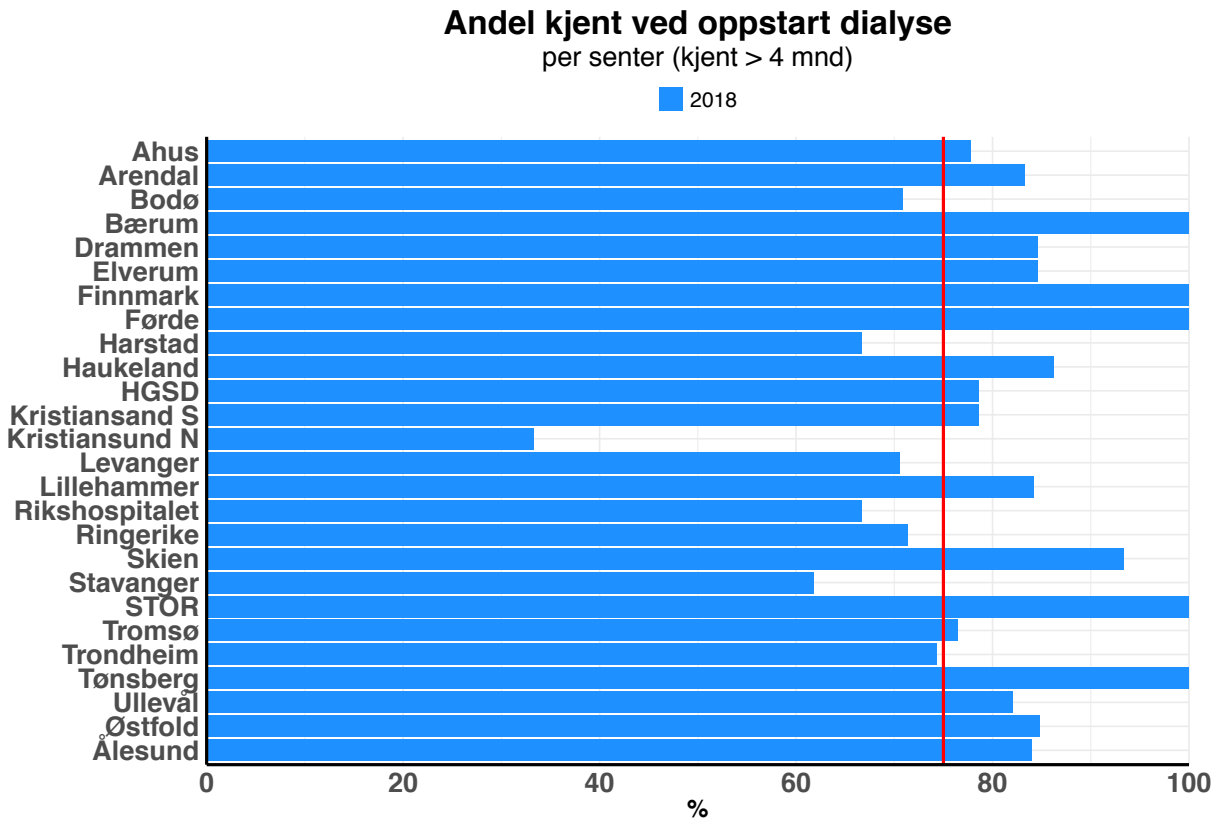


Figure 52:

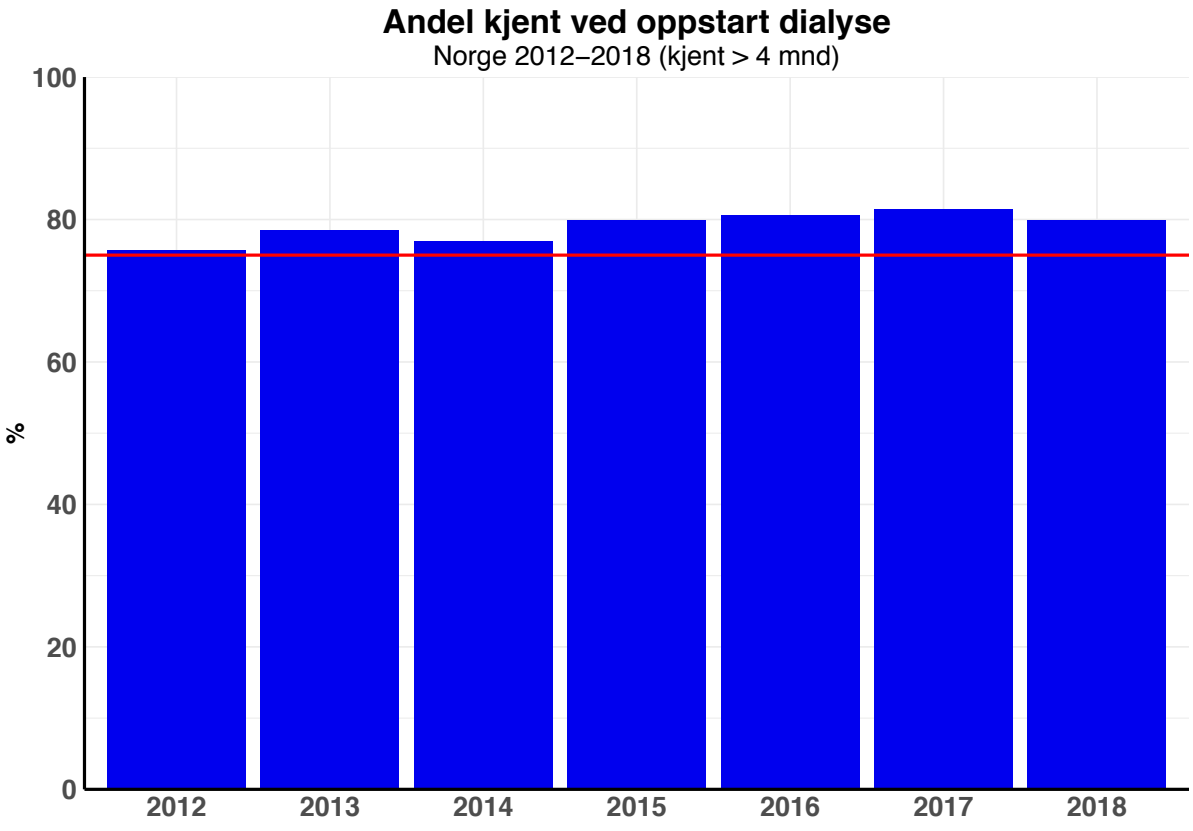


Figure 53:

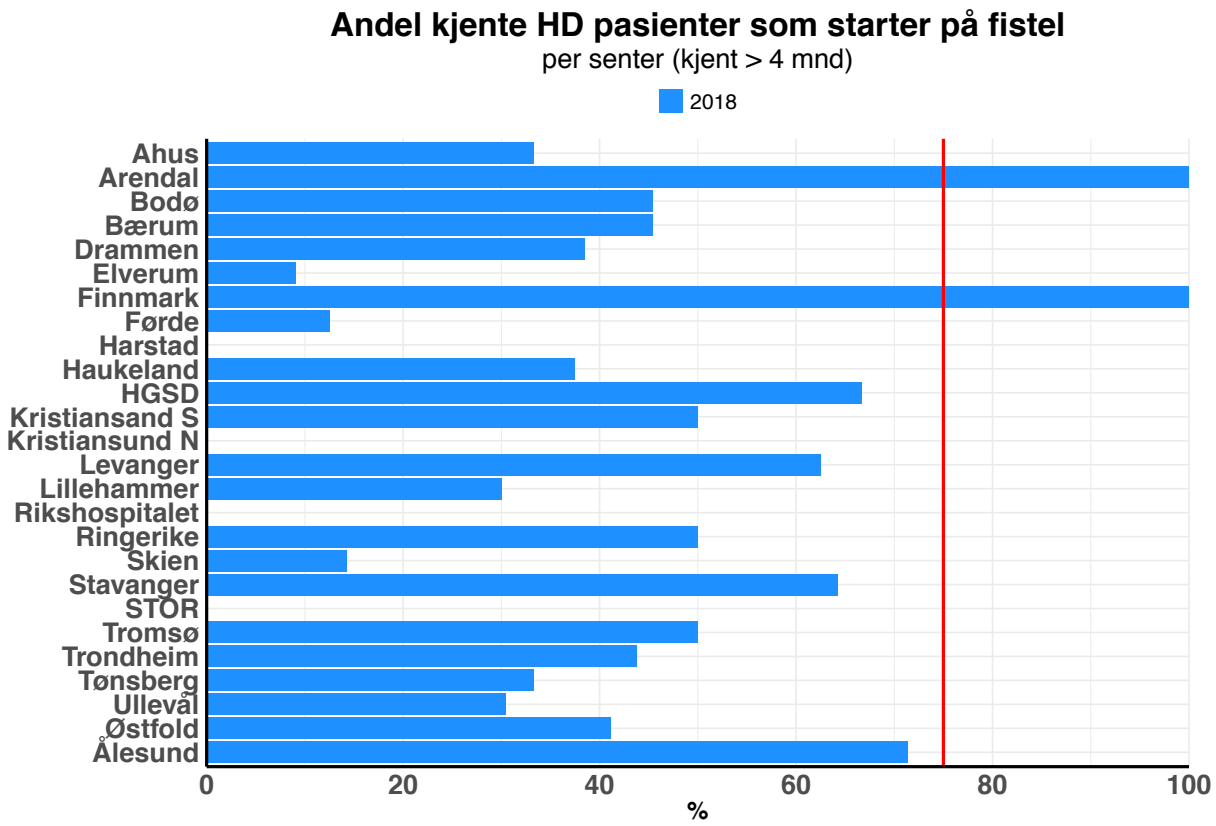
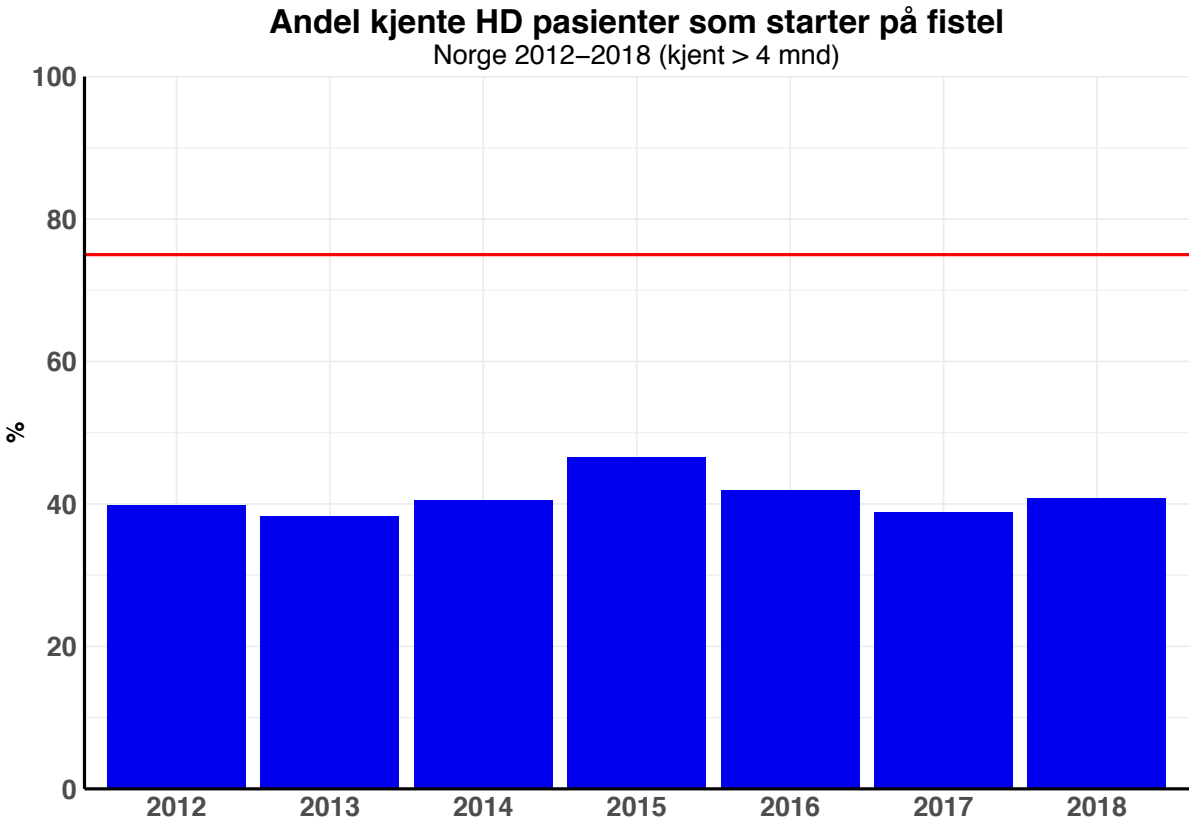


Figure 54:



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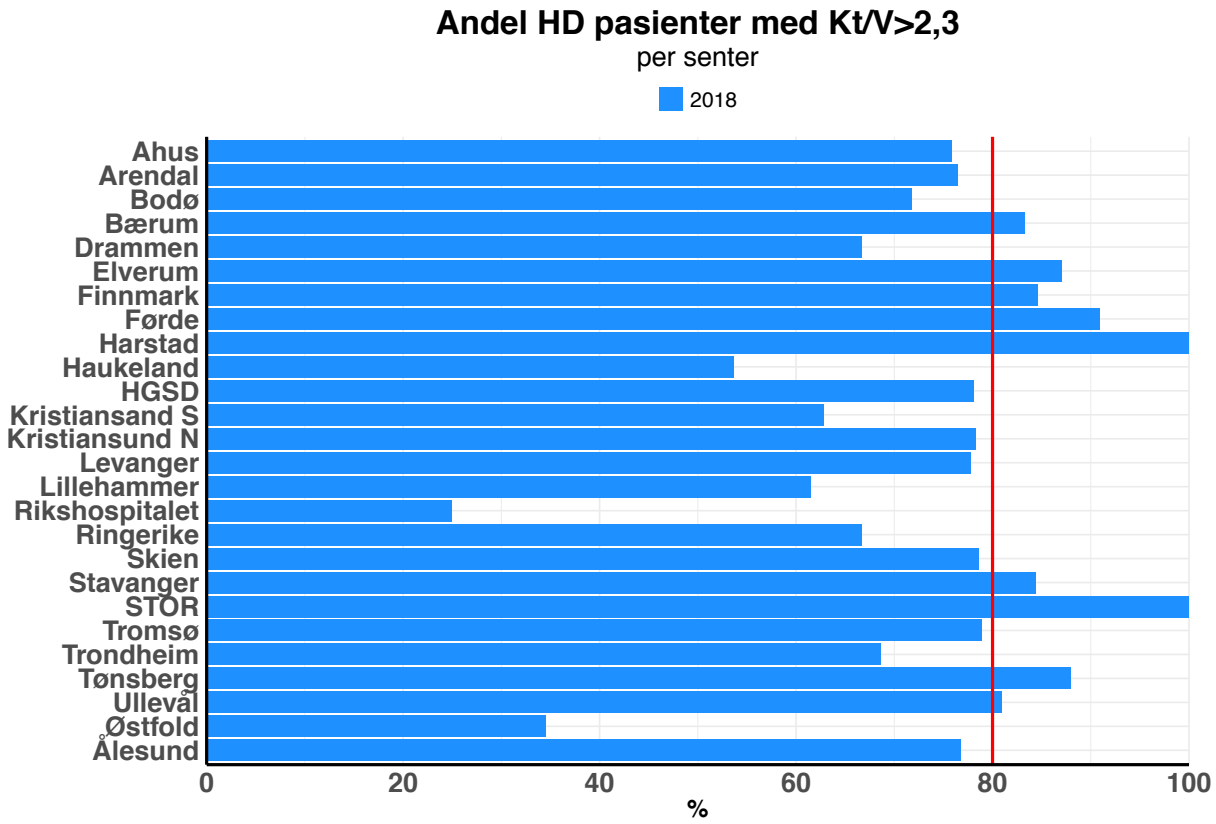
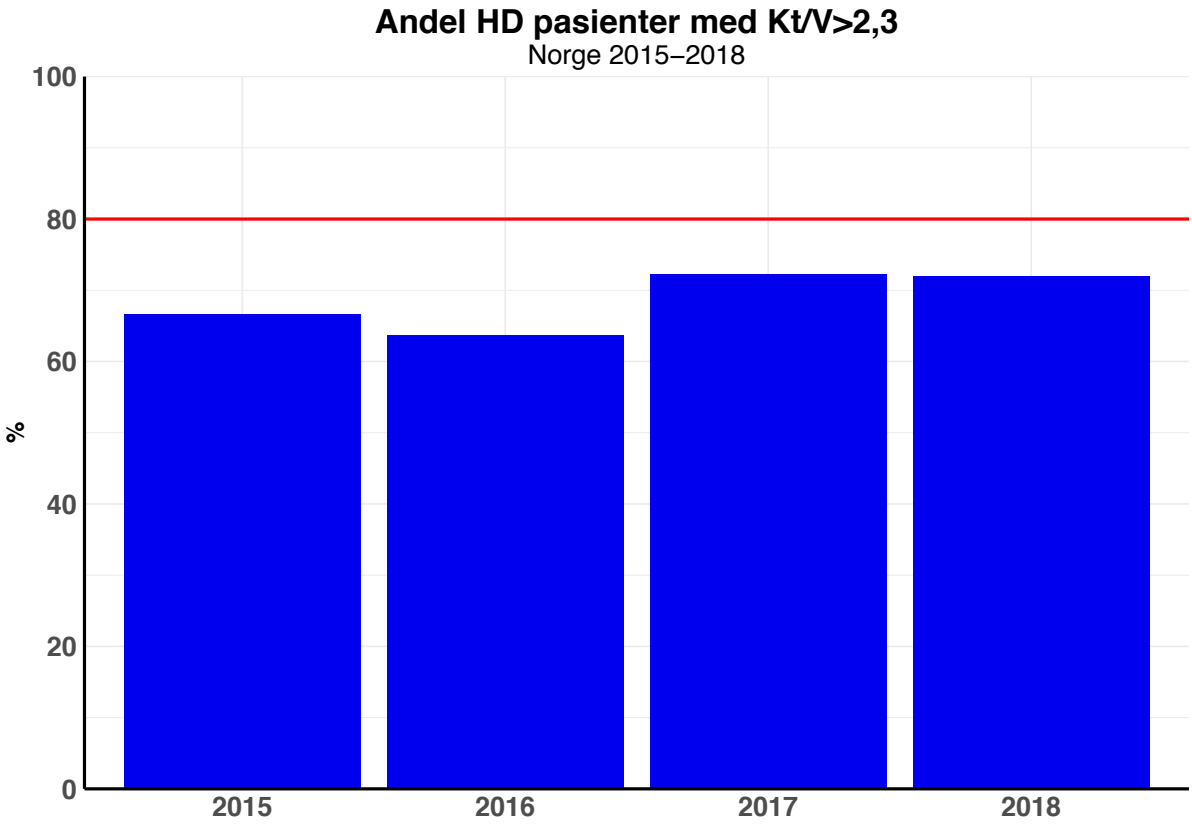


Figure 56:



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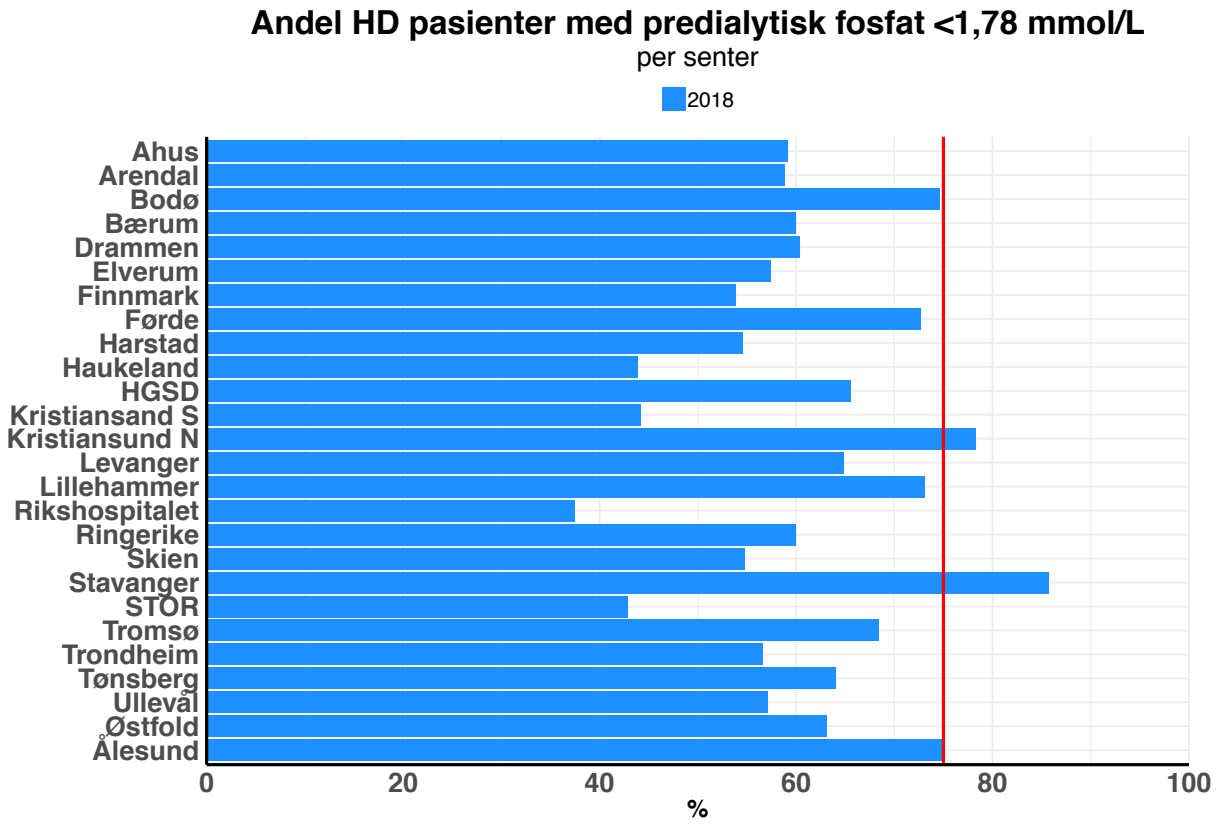
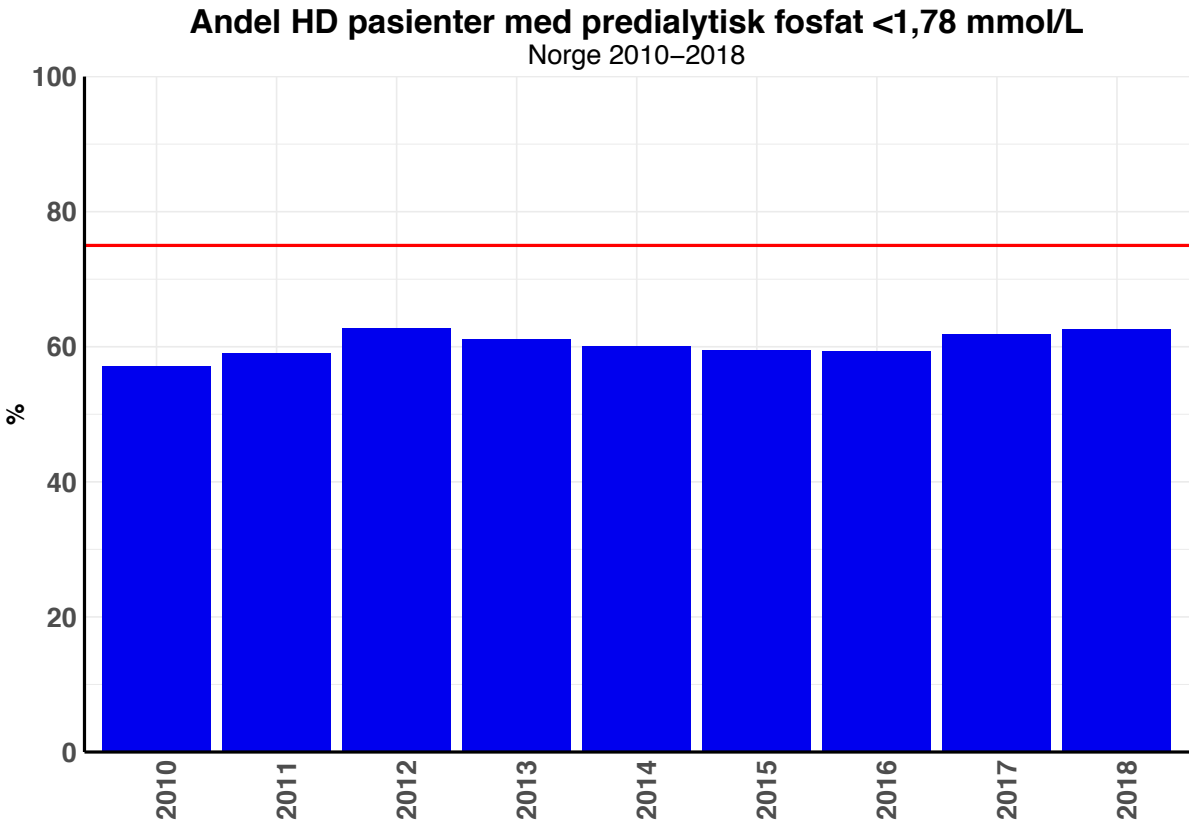


Figure 58:



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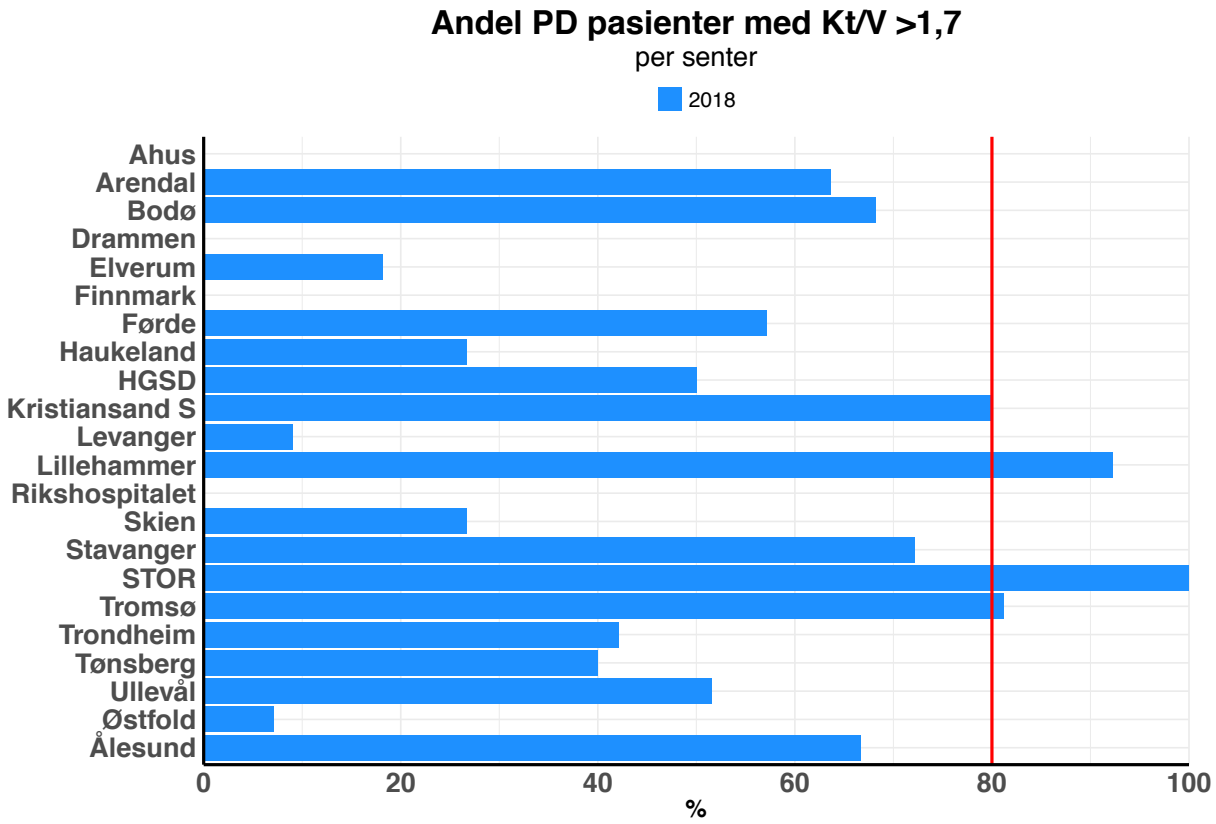


Figure 60:

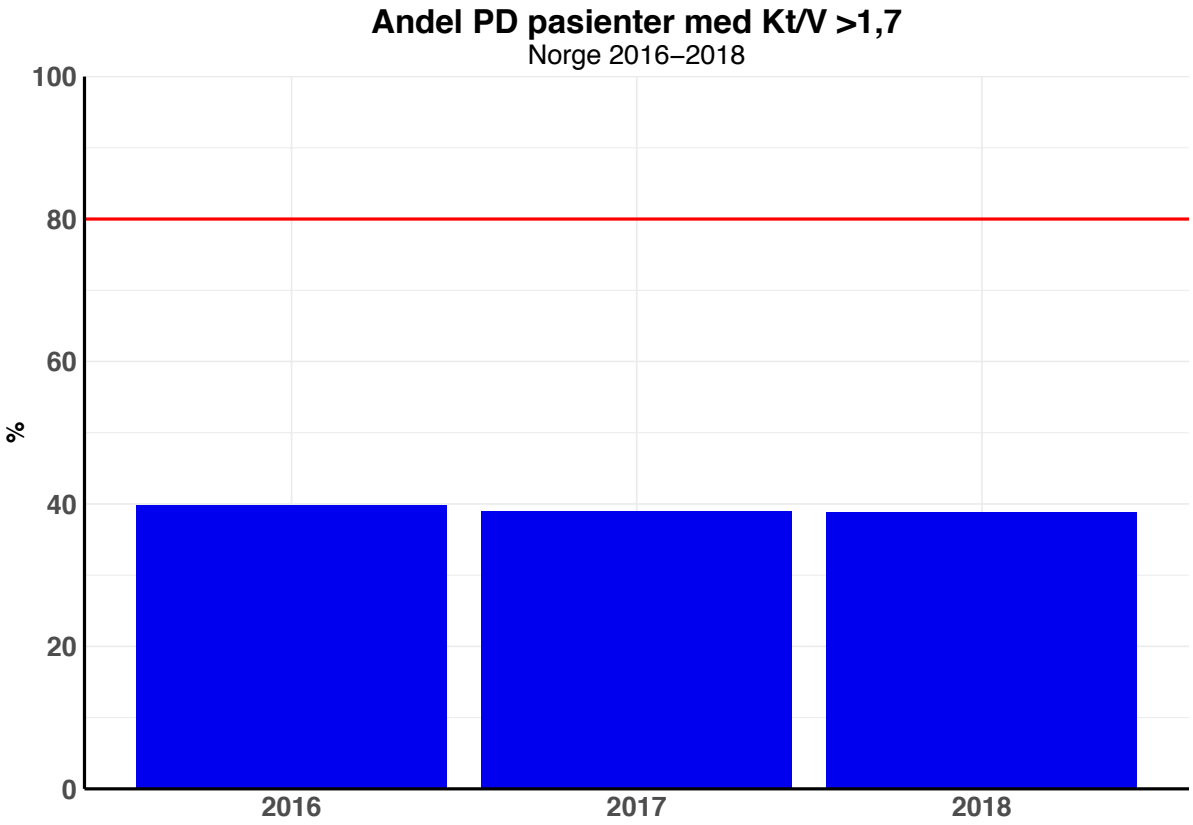


Figure 61:

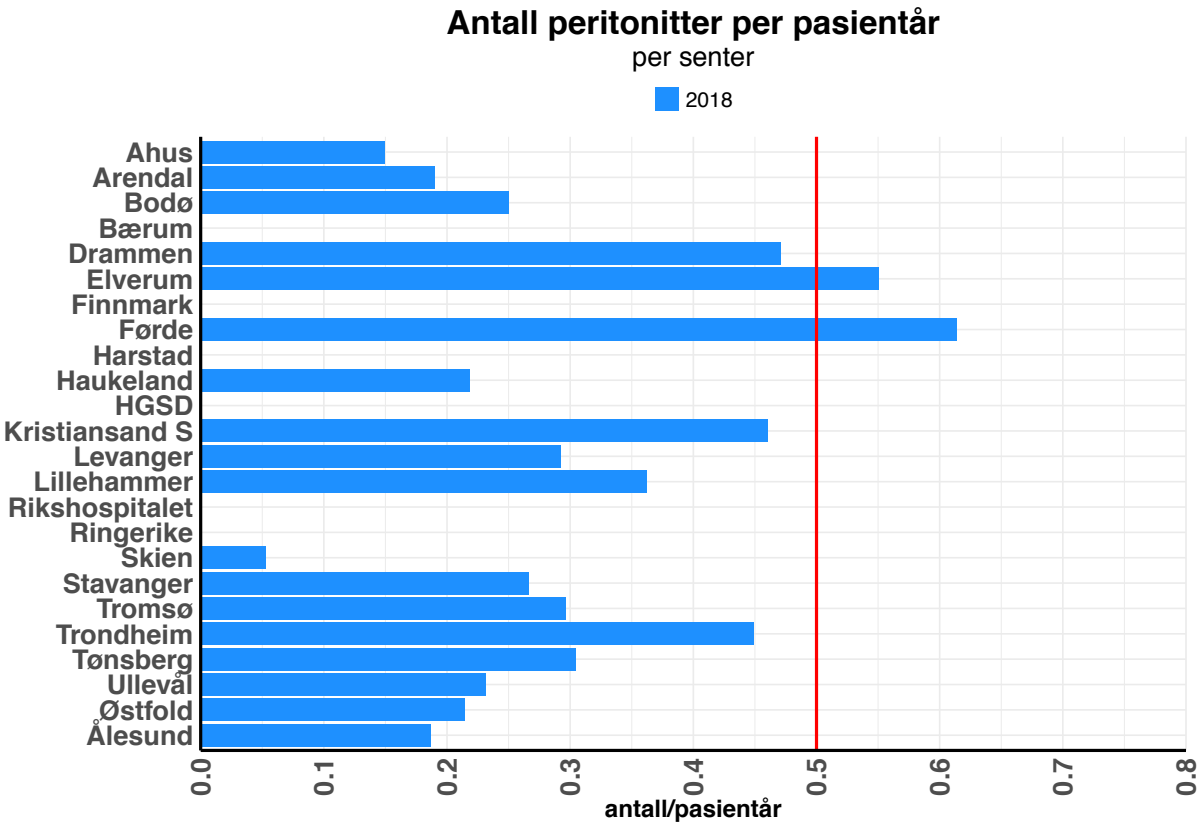

Antall peritonitter per pasientår
per senter
2018
Ahus
Arendal
Bodø
Bærum
Drammen
Elverum
Finnmark
Førde
Harstad
Haukeland
HGSD
Kristiansand S
Levanger
Lillehammer
Rikshospitalet
Ringerike
Skien
Stavanger
Tromsø
Trondheim
Tønsberg
Ullevål
Østfold
Ålesund
0.0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
antall/pasientår

Figure 62:

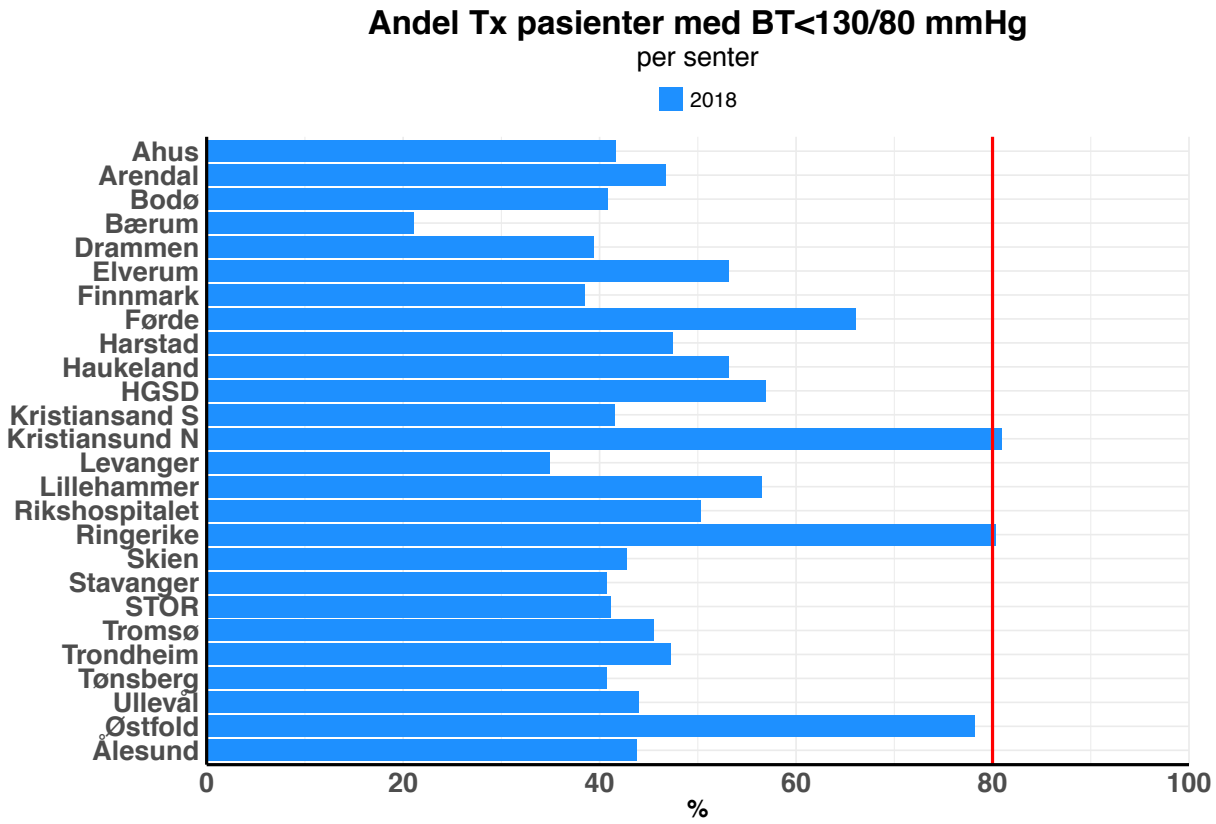


Figure 63:

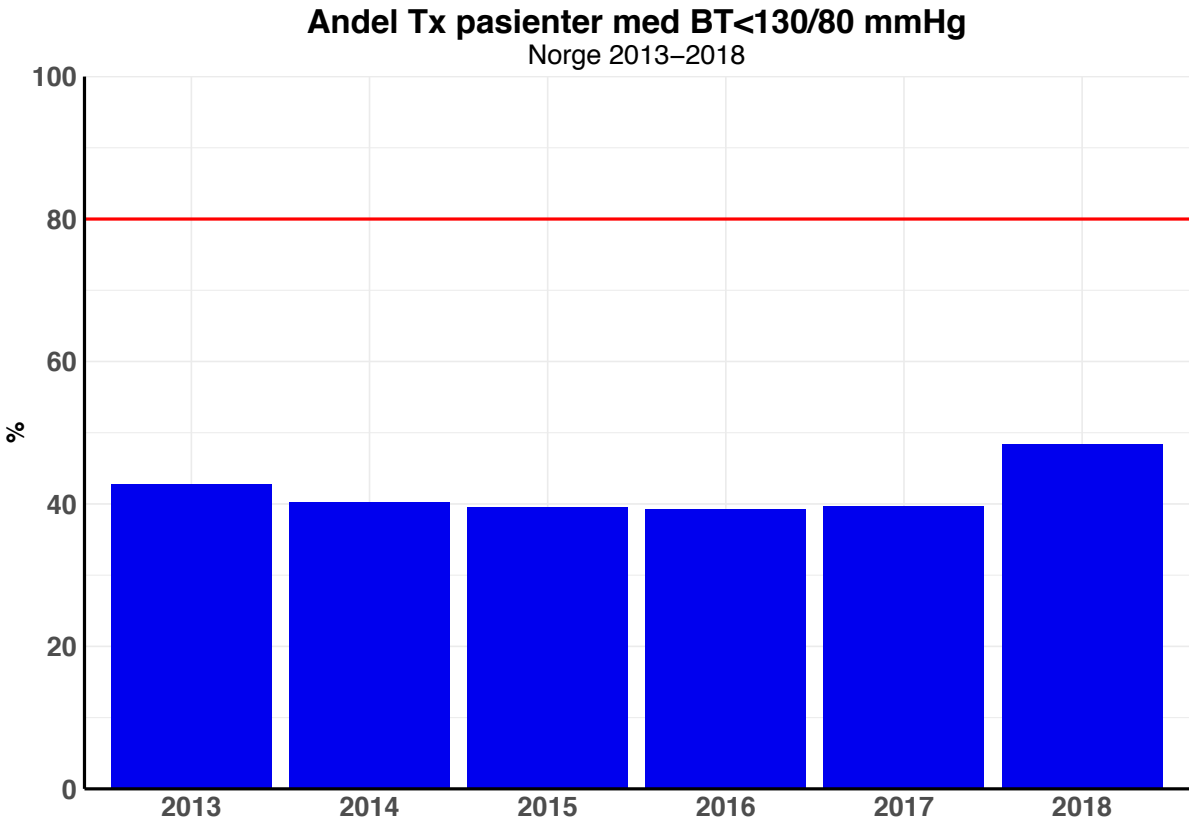


Figure 64:

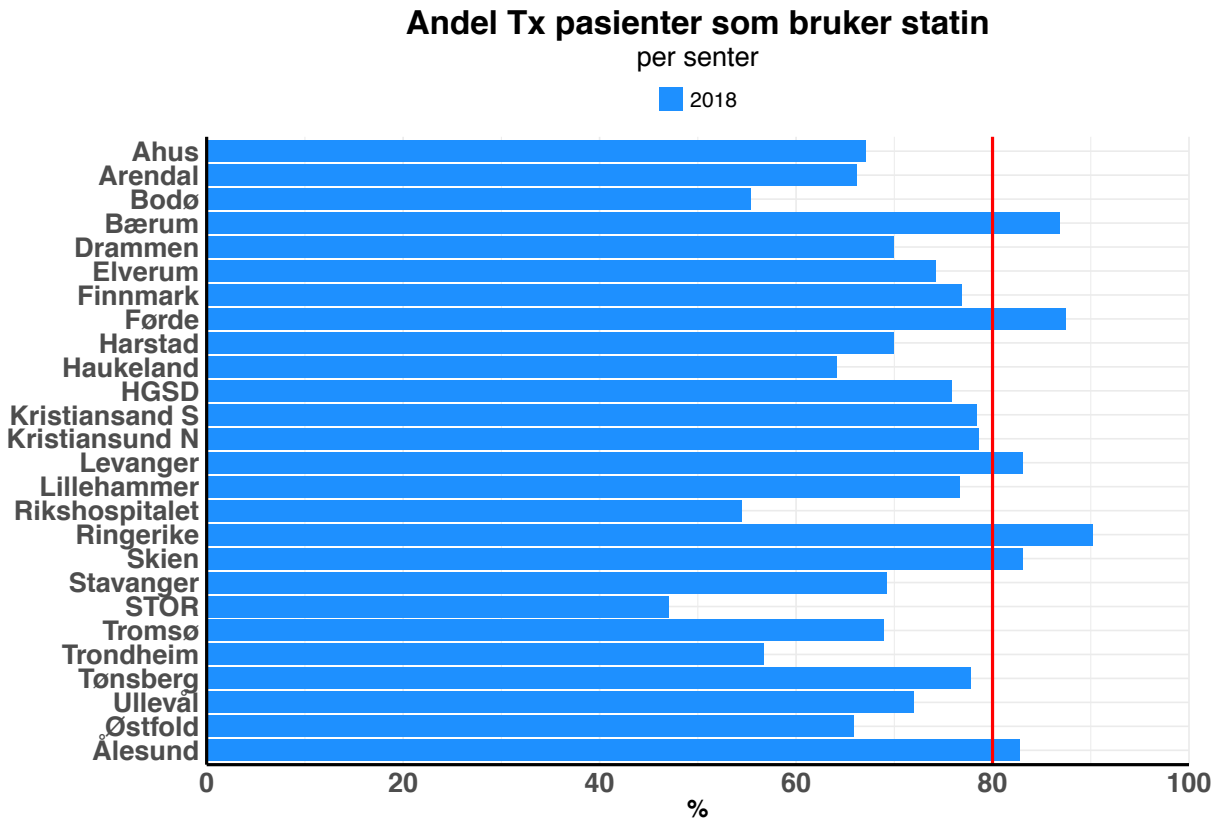


Figure 65:

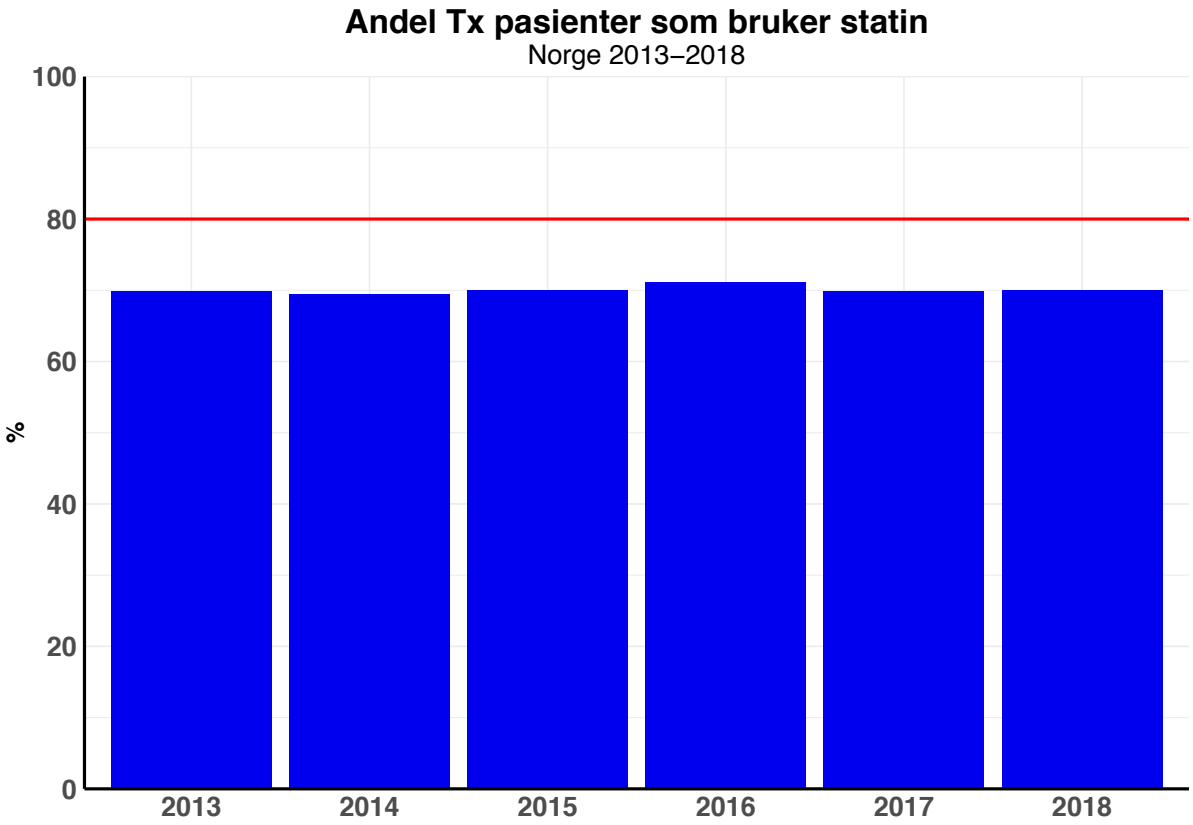


Figure 66:

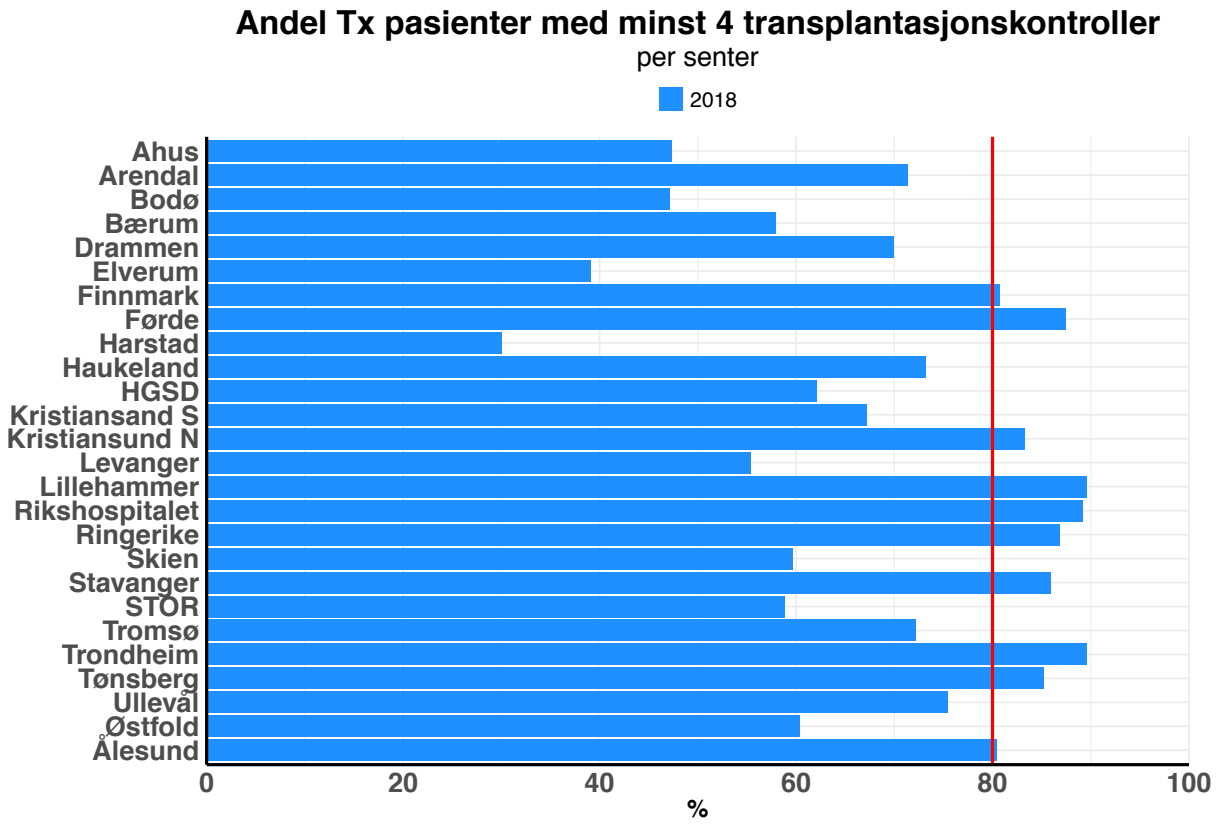
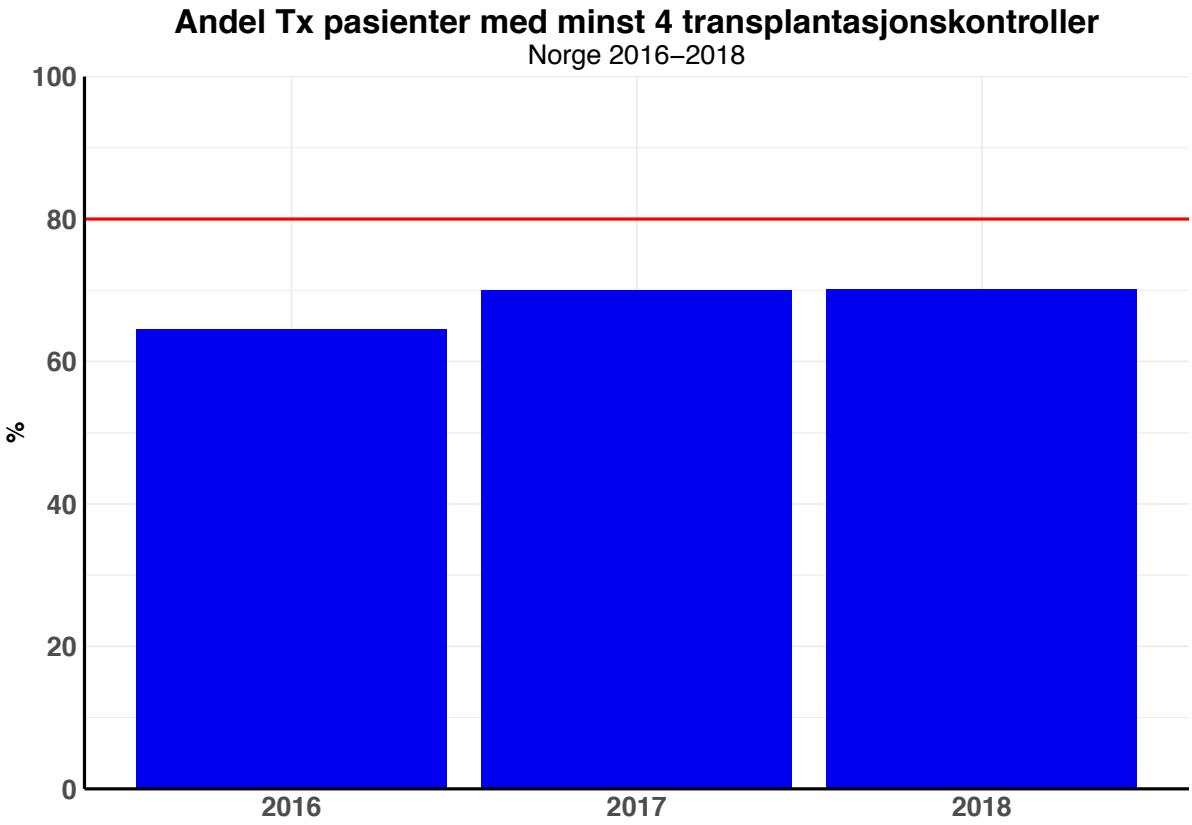


Figure 67:



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: .....

Of the 3,624 annual forms that should have been delivered to the registry in 2018, 3,442 was delivered (95%). Some forms did not include a blood pressure measurement resulting in 3,423 evaluable forms. Fifty-one percent of these patients had a blood pressure above the threshold (1,759 patients) and the questionnaire was submitted on 1,459 of these patients (83%). One third of these patients were considered by the treating physician to have an :acceptable blood pressure. One third of the patients were also on active anti-hypertensive treatment adjustment.

Figure 68 and 69 below show the binned diastolic- and systolic blood pressures of these patients.

Figure 68

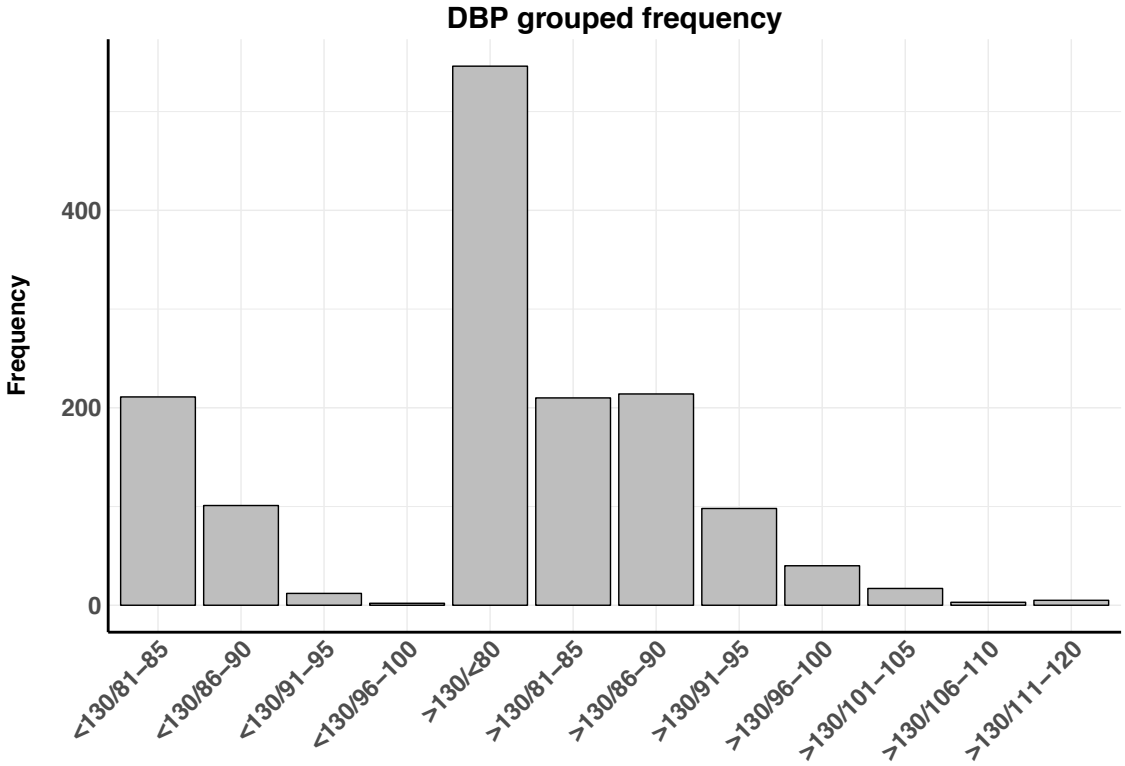
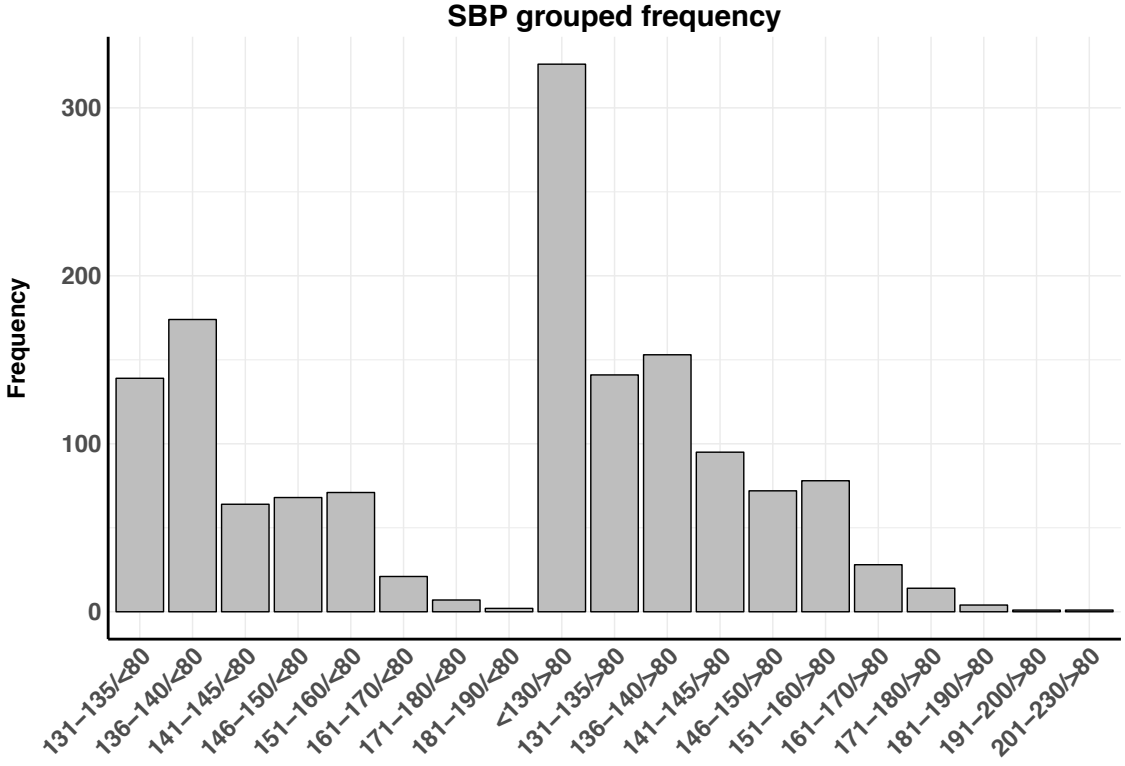


Figure 69:



Based on the preliminary results of this questionnaire it looks like the goal of 80% for this indicator is set a bit too high but also that there is potential for improving the anti-hypertensive treatment in Norwegian kidney transplanted patients.

Concluding remarks:

The incidence of patients in CKD5 seems to have stabilized during the last 10 years. 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. 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.

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 feed-back from the nephrology community the 80% goal will be revised.

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 2018 a total of 24 international peer reviewed papers and two 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 2018				Patients in RRT per 31.12.2018					Dialyses etc. in 2018			Died 2018		
	Satellites	HD/HDF	PD	Pre-emptive	Total	HD/HDF	Home HD	PD	Graft	Total	HD sessions	Plasma exchange	Other	Dialysis patients	Tx patients	Not Tx candidate
AHUS		26	28	2	56	120	8	59	354	541	20,137	17	0	31	13	94
Arendal		2	4	1	7	19	0	11	76	106	3,271	0	102	13	4	32
Bergen	4	19	10		29	86	0	17	263	366	14,260	44	46	16	7	39
Bodø	9	14	10	3	27	71	1	23	166	261	12,508	13	0	16	10	66
Bærum		11		3	14	31	0	0	54	85	4,123	0	0	3	1	25
Drammen	1	17	9	3	29	51	0	16	180	247	7,494	57	26	12	4	10
Elverum	1	15	11	3	29	56	0	23	130	209	8,755	0	27	18	4	53
Finnmark	4	1		2	3	13	1	3	43	60	2,092	0	0	5	1	9
Førde	2	8	5		13	34	0	8	60	102	5,450	5	0	5		34
Harstad		2	1		3	11	0	0	42	53	1,807	0	0	4	2	5
Haugesund	2	12	2		14	35	1	5	61	102	4,905	6	28	5	3	19
Hønefoss	1	7		1	8	33	0	0	60	93	4,439	0	0	4	3	18
Kristiansand S	2	11	3	1	15	46	0	10	126	182	7,050	34	0	6	5	38
Kristiansund N	1	6		2	8	26	1	0	43	70	3,981	0	0	6		14
Levanger	6	13	4	3	20	54	0	11	83	148	8,459	15	74	11	6	36
Lillehammer	3	13	6	1	20	53	1	12	157	223	8,033	15	74	18	3	36
Rikshospitalet		2	1		3	8	1	1	173	183	2,719	180	95		2	2
Stavanger		27	7	5	39	78	0	18	223	319	11,426	34	42	17	6	55
Stord		2			2	7	0	0	18	25	1,195	0	0	3		4
Telemark	4	8	7	4	19	43	2	17	129	191	7,564	51	0	19	7	37
Tromsø	3	11	6	1	18	35	2	16	92	145	6,649	9	0	8	3	25
Trondheim	4	25	10	5	40	80	8	20	229	337	14,802	166	482	16	5	56
Tønsberg		6	4	8	18	26	0	12	163	201	4,309	13	45	11	7	16
Ullevål		28	11	6	45	93	1	38	364	496	16,022	0	0	31	15	64
Østfold	2	22	11	3	36	89	0	18	206	313	14,481	15	0	20	13	52
Ålesund	1	17	8	2	27	59	0	10	129	198	7,969	92	0	6	5	42
SUM		325	158	59	542	1,257	27	348	3,624	5,256	203,900	766	1,041	304	129	881
Per mill. inhib.		61.0	29.7	11.1	101.7	235.9	5.1	65.3	680.2	986.5						165.4
% of total		60.0	29.2	10.9	100	23.9	0.5	6.6	68.9	100						16.8

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 patologiavdelingene 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≥80%)	< 10%	Mål på om behandlingstilbudet er godt nok
	Biopsipåvist akutt rejeksjon 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)