

ANNUAL REPORT 2023

The Norwegian Renal Registry (Norsk Nyreregister)

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

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Introduction

During 2023 the registry has worked intensively to get the new MRS-platform ready for launch in January 2024. This new digital platform replaced the old paper-form reporting, and all local centers were able to report annual data to the registry electronically this year. The new platform also gives each center local access to all registered data on their own patients. In this local registry the centers themselves can make center-specific analyses.

In this report we have made some layout changes, moving many of the survival curves etc. to the appendix for a better overview. Remember that by contacting the registry or the local center contact it is also possible to get even more figures with results from the registry.

The section of biopsy presents this year the development over the last six years of the percentage of all biopsies that show a specific diagnosis (**Figures 3-7**). We have also performed an analysis of biopsy coverage for the period 2019-2022 together with NPR (Norwegian Patient Registry).

The reporting of patients in CKD5 before kidney replacement therapy is still too low from many centers. The registry hopes that the new MRS-platform will make it easier for the centers to keep track of these patients and accordingly also report them.

With regards to the dialysis population, we continue to see a steady increase in home treatment. For Norway as a whole, we are still a few percentage points below the target of 30%, but with a high inter-center variation. Five centers are above the 30%-target. The upcoming reporting of annual data will also collect the information if patients receive treatment that is considered life-prolonging or not. This information has been included in the analyses of the quality indicators to give a more relevant presentation of the degree of "high quality treatment". With the new MRS-platform we will also from 2025 be able to include PROMs and get information from the patients about how they rate their treatment.

In this report we have included an analysis on sex differences. There are no signs of any differences in treatment or outcomes between sexes. The specific reasons for the decreased incidence are not known but steady improvement in individualized immunosuppressive therapy and follow-up of these patients contribute. Somewhat linked to this is the quality indicator of *at least 4 follow-up visits per year*, which also has been improved during the last years.

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 kidney 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. Together with the 5,600 non-neoplastic kidney biopsies collected in the new registry, the total amount of biopsies is about 17,500.

National organization and policy

Norway had 5.550 mill. inhabitants (December 2023). Each county has at least one central renal unit and some central units have satellite units run in close collaboration. 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 do not always coincide with the area that the different kidney units cover, and this report presents data based on county boarders as well as divided in RHF and HF levels, whenever appropriate.

During 2017 Finnmark was separated from Tromsø and in March 2022 Lovisenberg started to treat patients with severe renal disease. So now there are 27 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 ($eGFR < 15 \text{ mL/min/1.73 m}^2$ that is verified after three months. *The verification eGFR date is then the CKD5 start date*). Progression to need of kidney replacement therapy (dialysis, transplantation), changes between dialysis modality (PD, “center HD”, “home HD”), transfer between centers or immigration/emigration, graft loss

and deaths are reported on a continuous basis. For 2023, data from the visit *closest to December 31st* 2023 was to be reported for all CKD5 patients, either if they were not treated with kidney replacement therapy or if they received dialysis or had a functioning kidney graft. The overall report rate by the finalization of this report was 95.6%.

Transplantation has always been considered the kidney replacement treatment of choice, if possible, with a living related donor. Since 1984, also unrelated living 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 90%. Transplanted patients are crosschecked continuously against the transplantation lists at OUS-Rikshospitalet and annual crosschecks against each of the 27 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%. CKD5 patients not treated with kidney replacement therapy have been included in the registry since 2016. Based on prevalence data from the literature it is expected that there is between 550-600 prevalent CKD5 patients not on KRT in Norway. For 2023 this results 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 60%. A coverage analysis of non-neoplastic kidney biopsies for the period 2019-2022 has been performed (against Norwegian Patient Registry). The average coverage in the period was 77%. At regular intervals, reporting of deaths to the registry is checked against the Norwegian National Registry (NO: *Folkeregisteret*).

NRR is one of the national medicine quality registries (<https://www.kvalitetsregistre.no/registeroversikt>). NRR has identified 22 quality indicators to cover all relevant subgroups of patients in the registry. The quality indicators are reported annually (<https://www.kvalitetsregistre.no/register/nyre/norsk-nyreregister>). For the 2024 report the quality indicators have been revised and the new indicators are included in the present report on the 2023 data for comparison with the old versions.

Incidence Biopsy

During 2023, 690 diagnostic kidney biopsies with relevant clinical data were registered. Of these were 660 biopsies registered with complete pathology data. This is the highest number of biopsies per year ever registered. The increase has mainly been in the regions Helse Sør-Øst and Helse Midt (**Table 1**). For hospital level details, see **Figures 1a and 1b** where blue bars indicate the number of biopsies registered in 2023 and red line indicates the number of biopsies registered in 2022.

Table 1. Number of kidney biopsies per regional health authority previous six years

	2018	2019	2020	2021	2022	2023
Helse Sør-Øst	353	346	372	369	328	434
Helse Vest	137	113	115	101	97	107
Helse Midt	78	60	77	76	70	99
Helse Nord	54	54	48	49	44	50
Total	622	573	612	595	539	690

Neoplastic and transplant biopsies are not included

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

Figure 1a. Number of native kidney biopsies per hospital in 2023

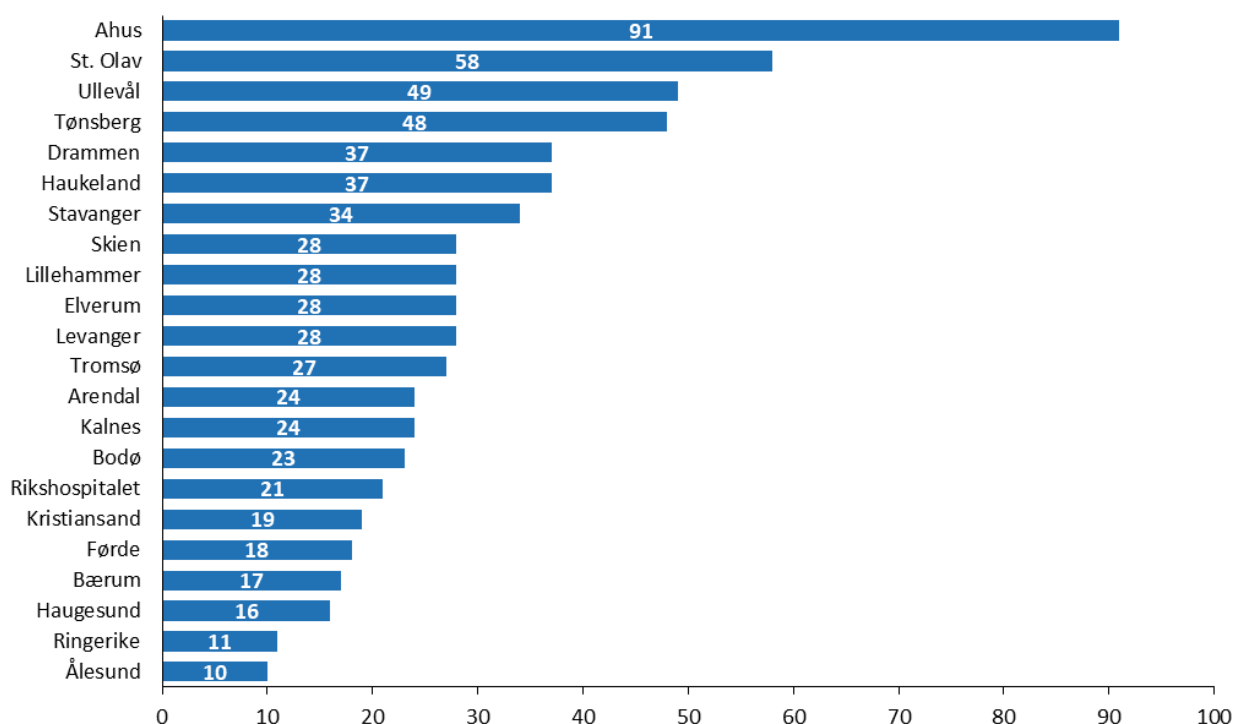
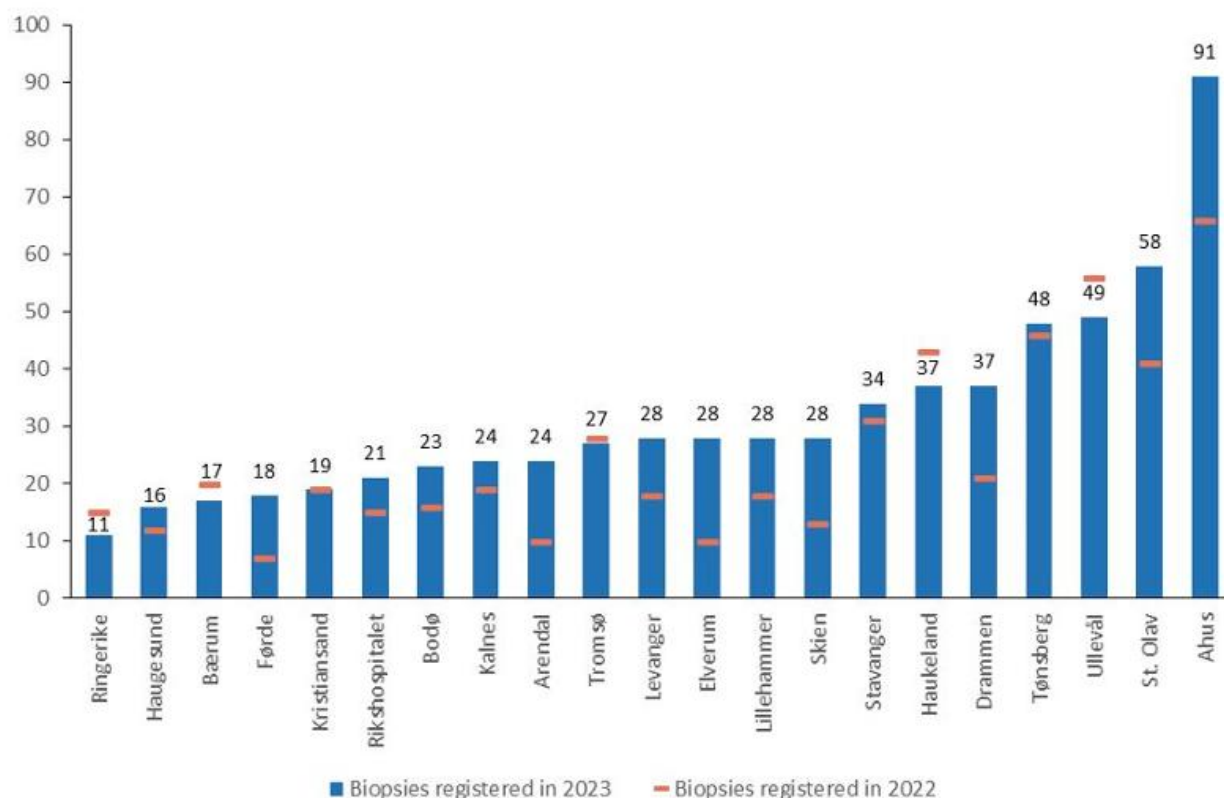


Figure 1b. Number of native kidney biopsies per hospital in 2023 compared to 2022.



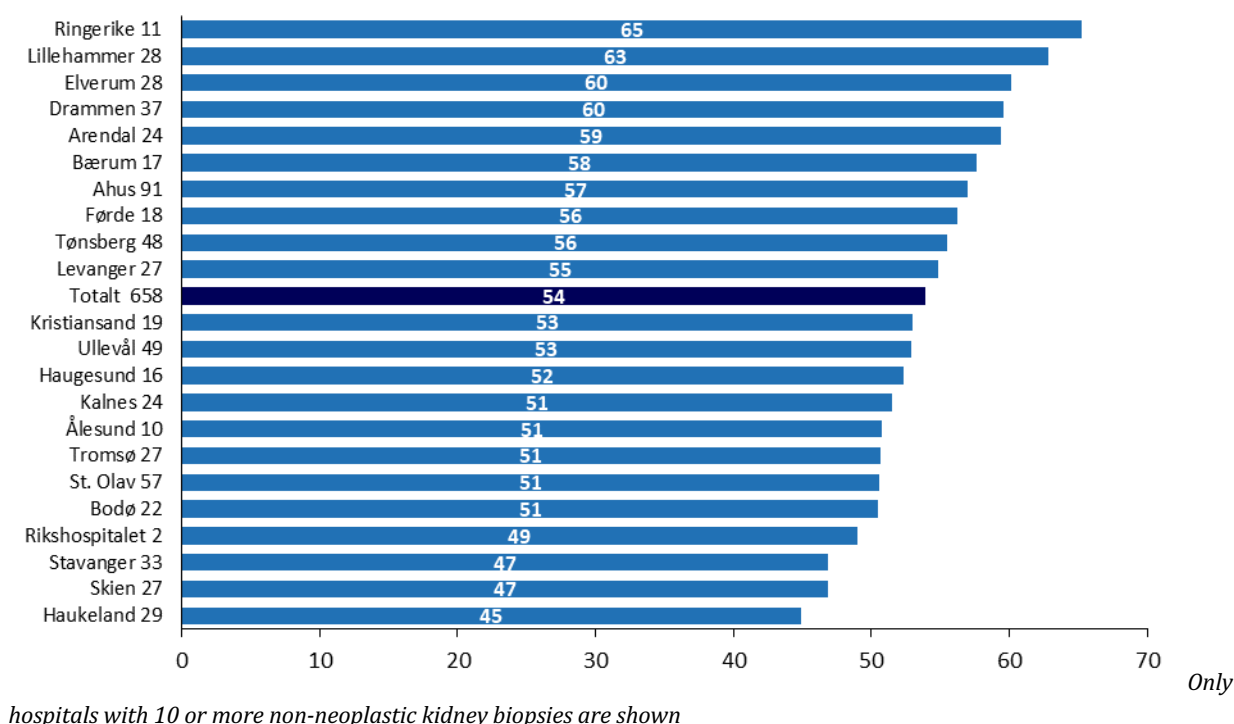
The mean age at kidney biopsy in 2023 was 51.9 (range 2-89) years (**Table 2**), which is a year lower compared to the mean age at kidney biopsy last year. The highest mean age at kidney biopsy was reported in Helse Sør-Øst (53.9), while the lowest mean age at biopsy was reported in Helse Vest (45.2).

Of all kidney biopsies reported to the registry in 2023, 32 biopsies (5 %) were performed in patients under the age of 18. The majority (59 %) of pediatric biopsies were performed at Rikshospitalet in Helse Sør-Øst. The percentage of kidney biopsies performed in patients above 80 years of age is 4 % (31 biopsies), compared to 3 % in 2022. Of these were 74 % biopsied Helse Sør-Øst.

Table 2. Mean age at kidney biopsy, per regional health authority in 2023.

	Total N=690	Helse Sør- Øst N=434	Helse Vest N=107	Helse Midt N=99	Helse Nord N=50
Mean age in years	51.9	53.9	45.2	51.1	49.9
Range	(2-89)	(3-89)	(2-85)	(16-87)	(16-79)

Figure 2. Mean age in years for patients over 18 years of age at kidney biopsy, total and per hospital in 2023.



Indication for kidney biopsy

Table 3. Reported clinical indications for kidney biopsies in total and per regional health authority in 2023.

	Total N=690		Helse Sør-Øst N=434		Helse Vest N=107		Helse Midt N=99		Helse Nord N=50	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nephrotic syndrome	114	(16.5 %)	75	(17.3 %)	25	(23.4 %)	10	(10.1 %)	4	(8.0 %)
Nephritic syndrome	100	(14.5 %)	58	(13.4 %)	20	(18.7 %)	14	(14.1 %)	8	(16.0 %)
Acute kidney injury	201	(29.1 %)	135	(31.1 %)	37	(34.6 %)	16	(16.2 %)	13	(26.0 %)
Chronic kidney disease	241	(34.9 %)	157	(36.2 %)	23	(21.5 %)	42	(42.4 %)	19	(38.0 %)
Proteinuria	340	(49.3 %)	206	(47.5 %)	56	(52.3 %)	55	(55.6 %)	23	(46.0 %)
Hematuria	232	(33.6 %)	121	(27.9 %)	46	(43.0 %)	48	(48.5 %)	17	(34.0 %)
Proteinuria and hematuria	179	(25.9 %)	93	(21.4 %)	37	(34.6 %)	37	(37.4 %)	12	(24.0 %)
Other	1	(0.1 %)	0	(0.0 %)	1	(0.9 %)	0	(0.0 %)	0	(0.0 %)

It is possible to report more than one clinical indication for a kidney biopsy. As a result, the total number of clinical indications exceeds the total number of reported kidney biopsies for 2023.

Figure 3. Percentage of biopsies reported with nephrotic syndrome as a clinical indication, per health region, from 2017-2023

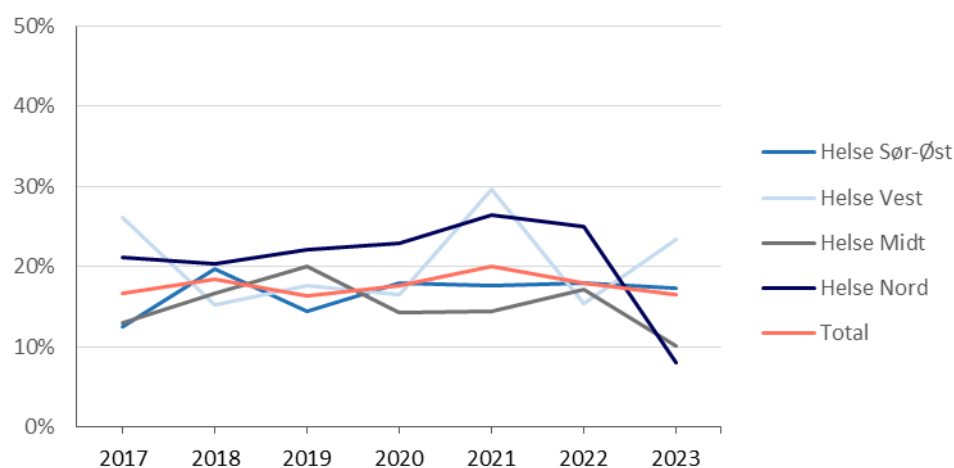


Figure 4. Percentage of biopsies reported with acute kidney injury as a clinical indication, per health region, from 2017-2023

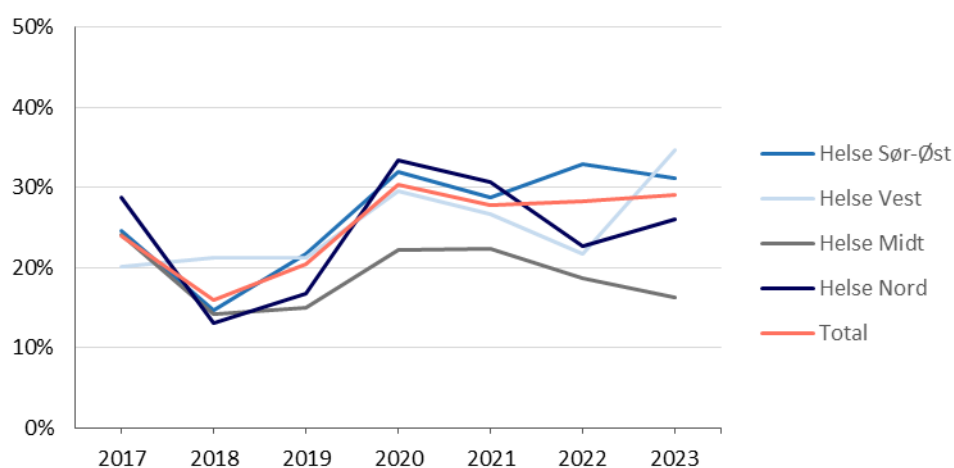


Figure 5. Percentage of biopsies reported with chronic kidney disease as a clinical indication, per health region, from 2017-2023

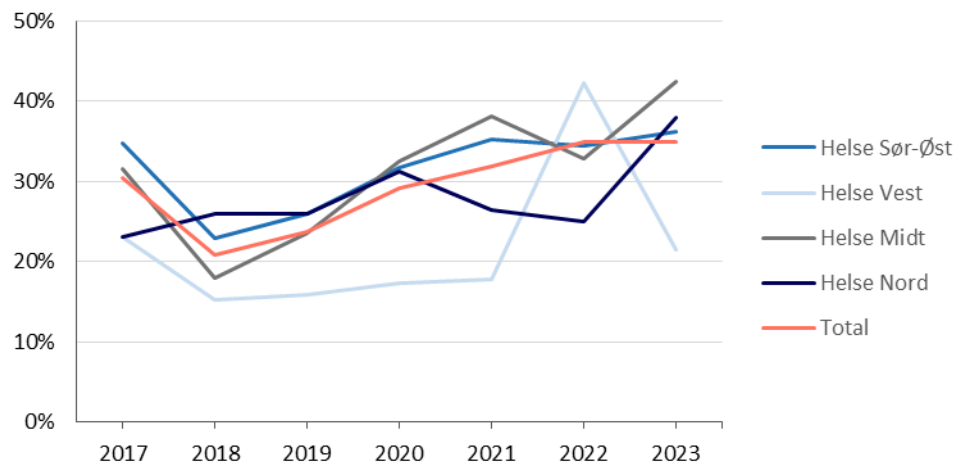


Figure 6. Percentage of biopsies reported with proteinuria as a clinical indication, per health region, from 2017-2023

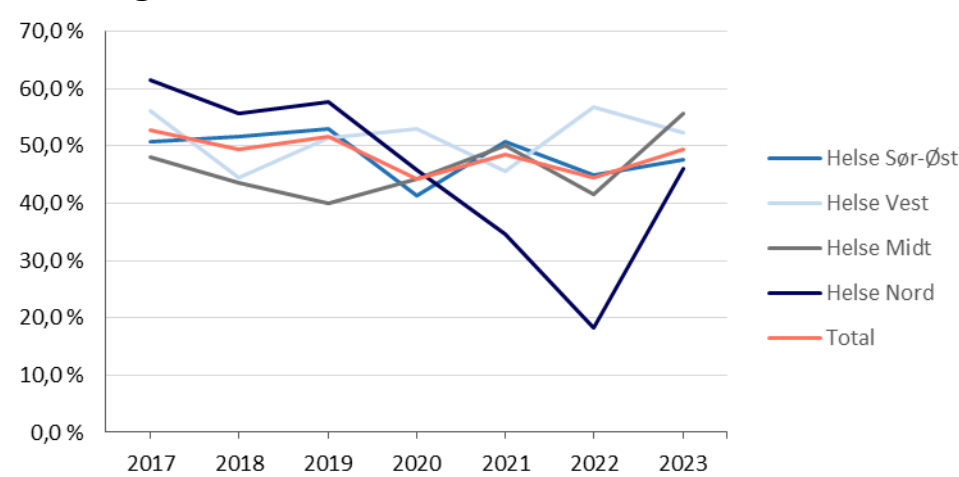


Figure 7. Percentage of biopsies reported with hematuria as a clinical indication, per health region, from 2017-2023

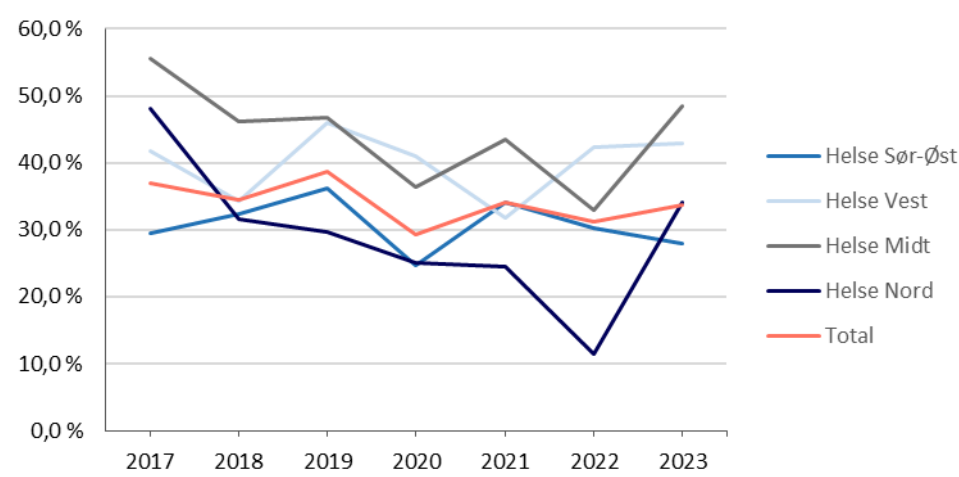


Figure 8. Albuminuria (mg/mmol creatinine) at the time of kidney biopsy in different Regional Health Regions in 2023

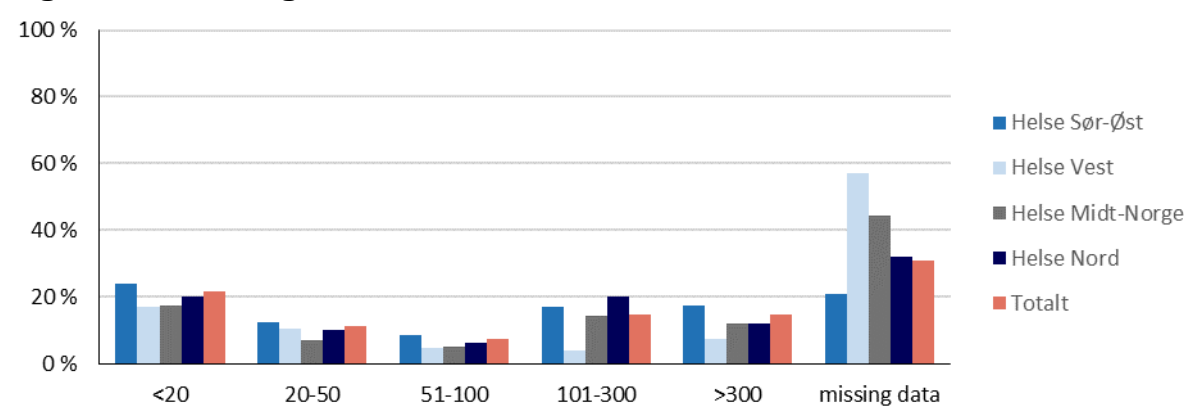


Figure 9. Serum creatinine ($\mu\text{mol/l}$) at the time of kidney biopsy in different Regional Health Regions in 2023

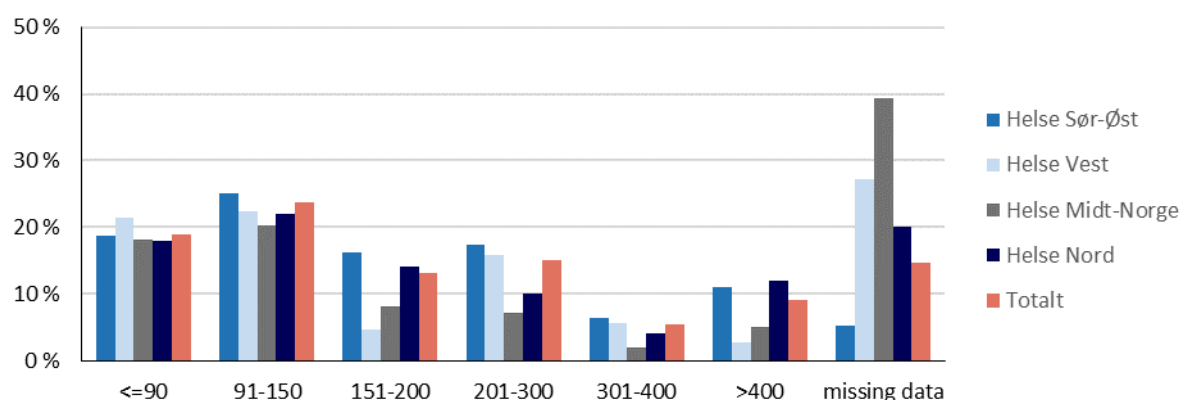


Figure 10. Mean serum creatinine at the time of kidney biopsy, per hospital in 2023

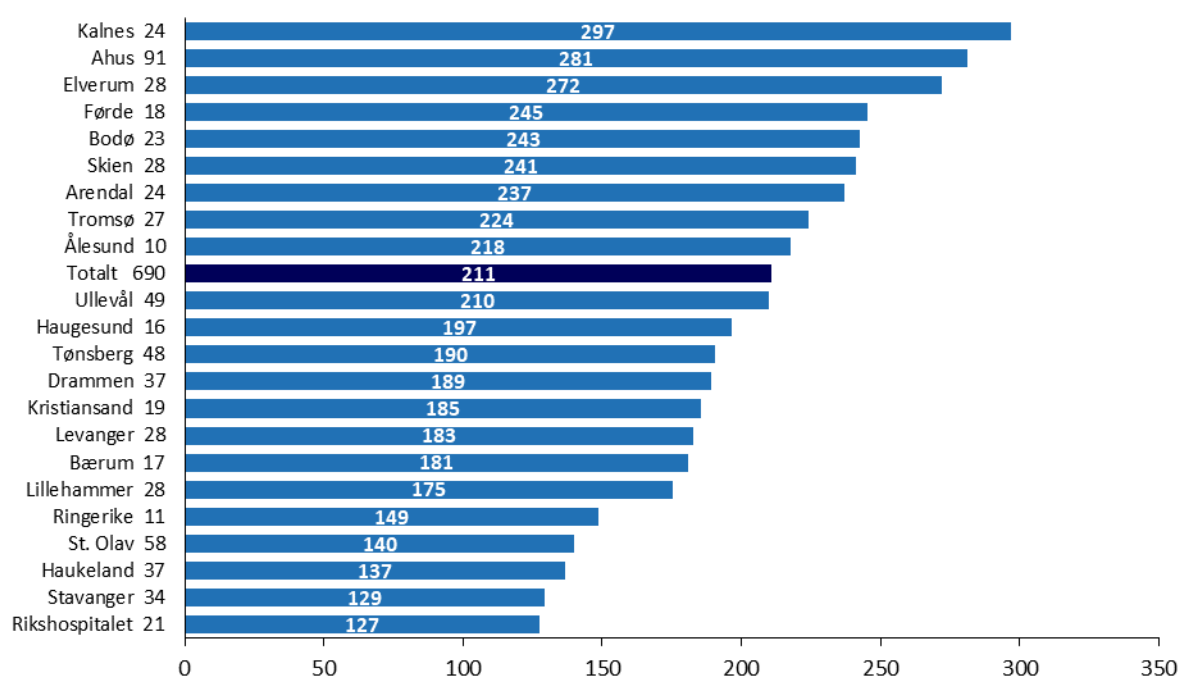
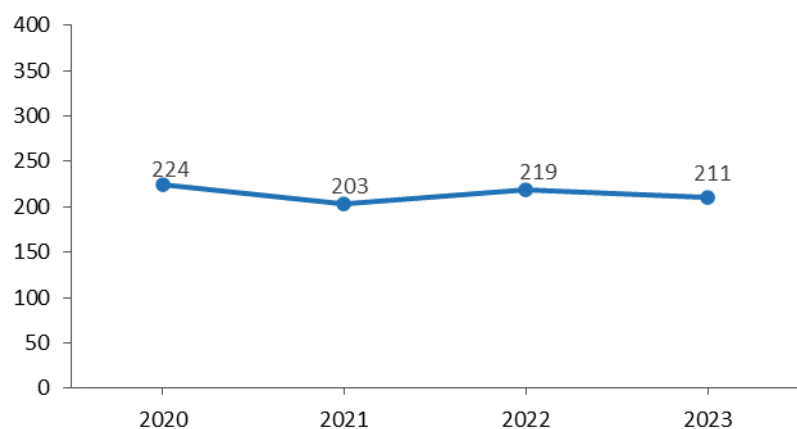


Figure 11. Total mean serum creatinine from 2020 – 2023



Quality indicators for kidney biopsies

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
Percentage of kidney biopsies with a final diagnosis within 1 month	80 %	Indicates how well routines and structure in the examination procedure by the pathology departments work
Number of primary kidney biopsies with moderate to severe chronic changes	<30 %	Indicates whether patients are being examined early by the specialist health service in the course of their kidney disease

Serious complications (quality indicator)

Most kidney biopsies are reported without procedure related complications. Of 590 kidney biopsies reported to the registry in 2023, 86 % were reported without complications (**Tables 5 and 6**).

A serious complication is defined as the need for blood transfusion, and/or the need for interventions. Minor, self-limiting bleeding is not considered a serious complication.

In 2023, serious complications were reported in 1.3 % of the 690 reported kidney biopsies (**Table 6**). This corresponds to nine serious complications (transfusion or intervention) in nine different patients. This is below the target of 2 %, and a decrease compared to the previous year. The biopsies where serious complications occurred, were taken at seven different hospitals, and there was a large variation in age in the patient group. Seven of the biopsies were performed with a biopsy needle 18G and four with biopsy needle 16G.

It is crucial to aim for more comprehensive reporting of serious procedure-related complications, as changes in the proportion of complications could impact 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 5. Percentage of procedure related complications

	2018	2019	2020	2021	2022	2023
Serious complications*	0.6 %	2.1 %	2.8 %	0.8 %	3.0 %	1.3 %
No complications	81.0 %	79.9 %	83.0 %	86.1 %	85.0 %	86.1 %
Not reported	9.8 %	11.8 %	7.7 %	6.2 %	7.4 %	7.1 %

* Transfusion and/or intervention

Table 6. Reported complications per regional health authority in 2023

	Total (N=690)		Helse Sør-Øst (N=434)		Helse Vest (N=107)		Helse Midt (N=99)		Helse Nord (N=50)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
No complications reported	594	(86.1 %)	363	(83.6 %)	97	(90.7 %)	90	(90.9 %)	44	(88.0 %)
Serious complications*	9	(1.3 %)	7	(1.6 %)	0	(0.0 %)	2	(2.0 %)	0	(0.0 %)
Transfusion	6	(0.9 %)	4	(0.9 %)	0	(0.0 %)	2	(2.0 %)	0	(0.0 %)
Intervention	3	(0.4 %)	3	(0.7 %)	0	(0.0 %)	0	(0.0 %)	0	(0.0 %)
Macroscopic Hematuria	19	(2.8 %)	12	(2.8 %)	3	(2.8 %)	4	(4.0 %)	0	(0.0 %)
Other**	29	(4.2 %)	27	(6.2 %)	1	(0.9 %)	1	(1.0 %)	0	(0.0 %)
Not reported	49	(7.1 %)	34	(7.8 %)	6	(5.6 %)	3	(3.0 %)	6	(12.0 %)

The total number of complications may exceed the total number of reported biopsies as it is possible to report more than one complication per biopsy.

* Transfusion and/or intervention

**Other complications, such as hematoma without the need for transfusion, are described as a comment in free text

Table 7. Procedure-related parameters in 2023 in total and per regional health authority

	Total (N=690)		Helse Sør-Øst (N=434)		Helse Vest (N=107)		Helse Midt (N=99)		Helse Nord (N=50)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Biopsy performed by										
Nephrologist	68	(9.9 %)	4	(0,9 %)	62	(57.9 %)	2	(2.0 %)	0	(0.0 %)
Radiologist	598	(86.7 %)	417	(96,1 %)	41	(38.3 %)	94	(94.9 %)	46	(92.0 %)
Other	0	(0.0 %)	0	(0,0 %)	0	(0.0 %)	0	(0.0 %)	0	(0.0 %)
Not reported	24	(3.5 %)	13	(3,0 %)	4	(3.7 %)	3	(3.0 %)	4	(8.0 %)
Biopsy needle										
14G	3	(0.4 %)	0	(0,0 %)	3	(2.8 %)	0	(0.0 %)	0	(0.0 %)
16G	217	(31.4 %)	15	(3,5 %)	78	(72.9 %)	94	(94.9 %)	30	(60.0 %)
18G	412	(59.7 %)	387	(89,2 %)	17	(15.9 %)	2	(2.0 %)	6	(12.0 %)
Unknown	34	(4.9 %)	15	(3,5 %)	7	(6.5 %)	2	(2.0 %)	10	(20.0 %)
Not reported	24	(3.5 %)	17	(3,9 %)	2	(1.9 %)	1	(1.0 %)	4	(8.0 %)
No. of passes										
1	56	(8.1 %)	34	(7,8 %)	22	(20.6 %)	0	(0.0 %)	0	(0.0 %)
2	362	(52.5 %)	212	(48,8 %)	62	(57.9 %)	62	(62.6 %)	26	(52.0 %)
3	145	(21.0 %)	98	(22,6 %)	13	(12.1 %)	23	(23.2 %)	11	(22.0 %)
4 or more	83	(12.0 %)	65	(15,0 %)	6	(5.6 %)	10	(10.1 %)	2	(4.0 %)
Not reported	44	(6.4 %)	25	(5,8 %)	4	(3.7 %)	4	(4.0 %)	11	(22.0 %)
Level of care										
Out-patient	79	(11.4 %)	65	(15,0 %)	2	(1.9 %)	11	(11.1 %)	1	(2.0 %)
In-patient	455	(65.9 %)	277	(63,8 %)	82	(76.6 %)	66	(66.7 %)	30	(60.0 %)
Not reported	156	(22.6 %)	92	(21,2 %)	23	(21.5 %)	22	(22.2 %)	19	(38.0 %)

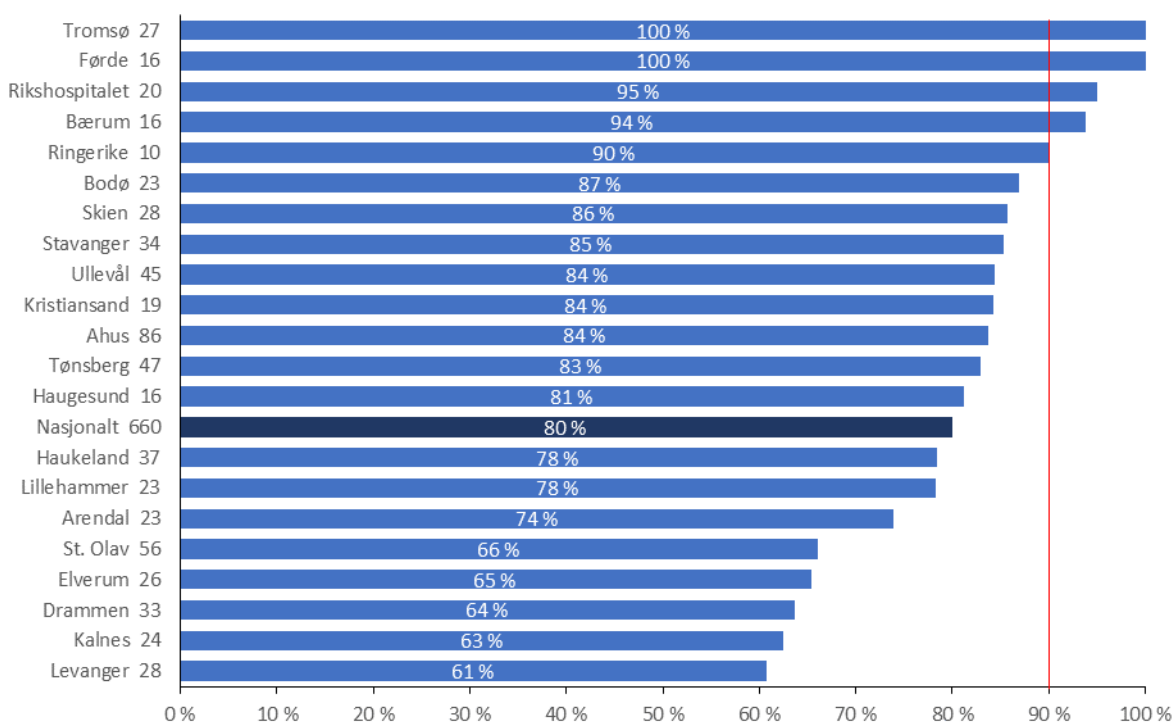
Kidney biopsies with 10 or more glomeruli (quality indicator)

The kidneys consist of three compartments, which may be attacked by disease: the glomeruli, the tubules/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, capillary convolutes, which continuously filter the blood, producing pre-urine. Numerous diseases can affect the glomeruli. It is important to realize, that a disease may not affect all glomeruli and that the affected glomeruli might only show changes in a part of the glomerulus. In addition, early and late stages of a disease may be observed in different glomeruli at the same time in one biopsy. Therefore, to detect changes and to be able to evaluate changes, the kidney biopsy must contain sufficient material. For a reliable diagnosis, at least 10 glomeruli should be present in the biopsy material prepared for light microscopy. This number is the basis for

the definition of the national quality indicator “Percentage of kidney biopsies with 10 or more glomeruli”. At least 90% of biopsies taken at one nephrology centre should contain 10 or more glomeruli.

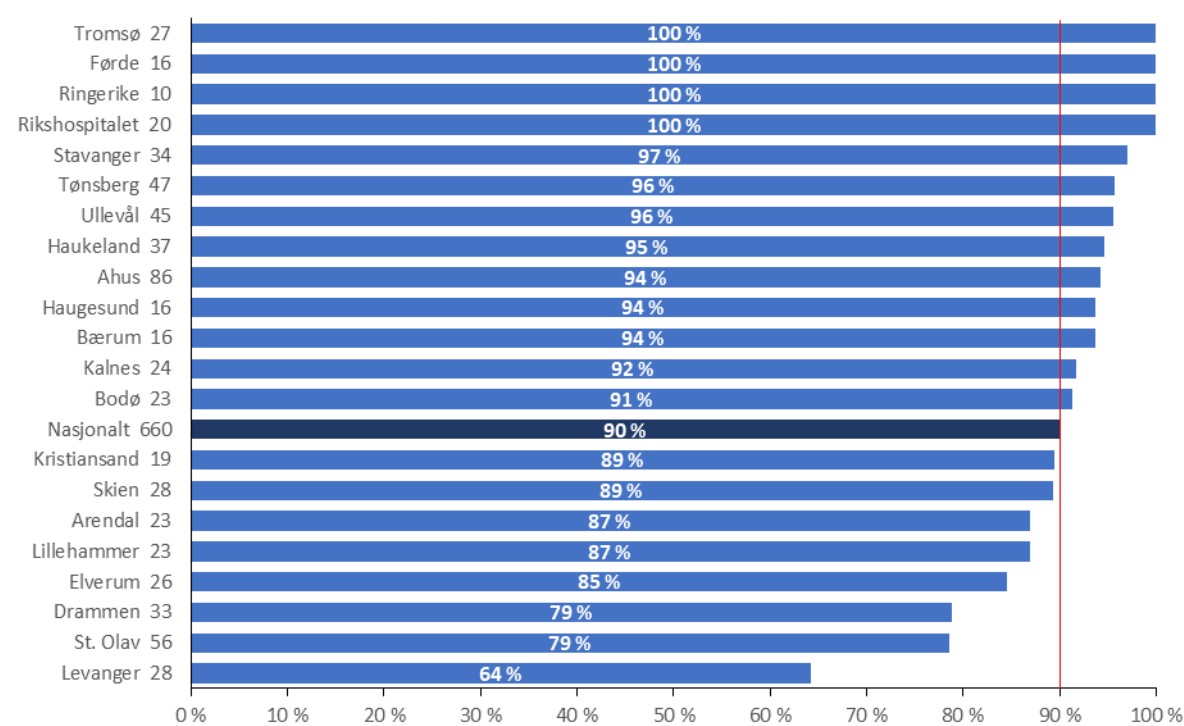
The number of glomeruli in a kidney biopsy may be obtained by different methods. The most common approach is to count the number of glomeruli in the paraffin embedded material prepared for light microscopy. Five of the hospitals reported 10 or more glomeruli in 90% or more of the kidney biopsies (**Figure 12**), thus fulfilling the national quality indicator.

Figure 12. Percentage of kidney biopsies with 10 or more glomeruli, in paraffin-embedded material, in total and per hospital in 2023.



The number behind the hospital name is the number of non-neoplastic kidney biopsies with complete pathology data in 2023. 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.

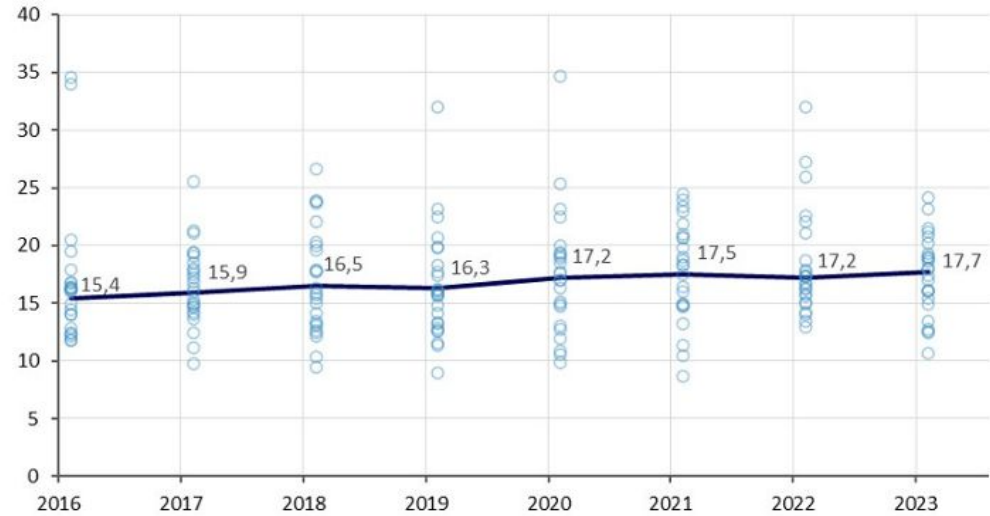
Figure 13. Percentage of kidney biopsies with 10 or more glomeruli, based on all material from a kidney biopsy, in total and per hospital in 2023.



The number behind the hospital name is the number of non-neoplastic kidney biopsies with complete pathology data in 2023. The calculation is based on the recorded number of glomeruli both in the paraffin embedded biopsy tissue, the frozen tissue for immunofluorescence (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.

The average number of glomeruli per kidney biopsy shows a slight increase on a national basis over the years (**Figure 14**).

Figure 14. Mean number of glomeruli from 2016 - 2023



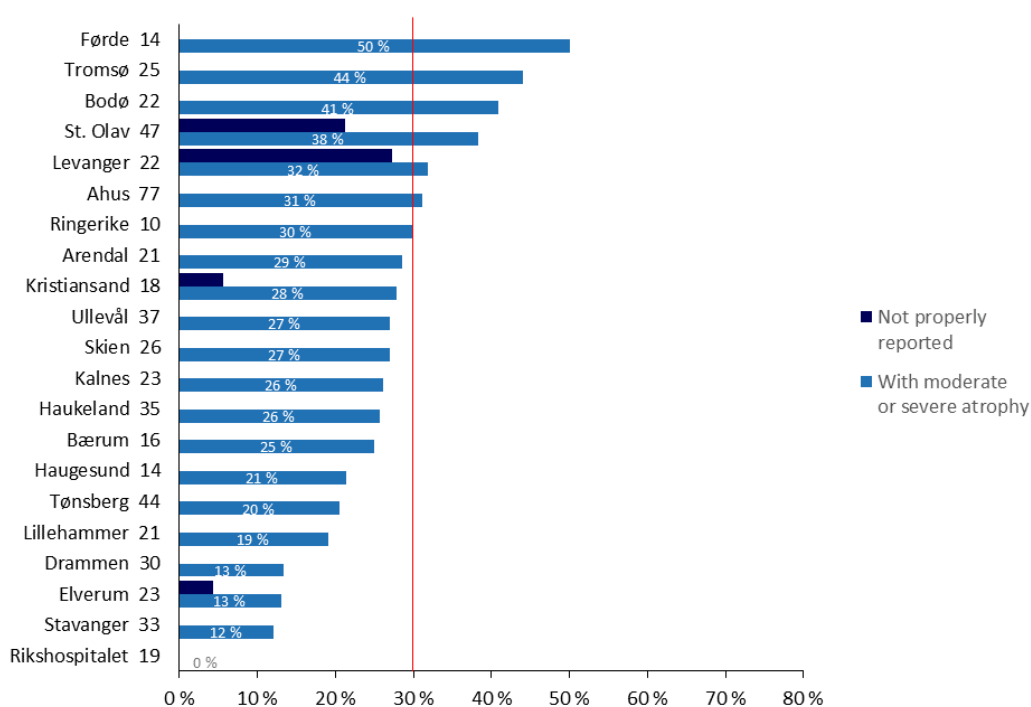
The light blue circles represent the hospitals and the dark blue line represent the mean number of glomeruli of all biopsies taken per year.

Number of primary kidney biopsies with moderate to severe chronic changes (quality indicator)

Chronic changes in the kidney are persistent and irreversible. A high proportion of chronic changes in the biopsy indicates a high risk of loss of kidney function. A high proportion of chronic changes may also indicate that treatment cannot achieve stabilization or improvement in kidney function. It is therefore important to diagnose kidney disease early in the disease process, before the disease manifestations result in chronic, irreversible changes. Tubular atrophy is a hallmark of chronic kidney disease. Moderate to severe tubular atrophy can indicate that the biopsy was taken late in the disease process implying that the patient was late in seeing a doctor or that the investigation process was not optimal. The proportion of biopsies with moderate or severe tubular atrophy is calculated by dividing the number of biopsies showing moderate or severe tubular atrophy by the total number of biopsies at the centre. Some patients have multiple kidney biopsies. For the calculation, only the first biopsy taken from a patient is used. The national quality indicator “Grade of chronic changes” expects that less than 30% of biopsies from one centre should show moderate or severe tubular atrophy.

Figure 15 highlights two issues: First, some nephrology units show a high number of cases with moderate to severe tubular atrophy. This could be due to either a high proportion of patients presenting late in the course of the disease or differing biopsy indications among these units. Second, the data for some nephrology units (e.g. Levanger and St. Olavs Hospital) should be interpreted with caution because reports from the associated pathology department showed many missing/incomplete data for this indicator.

Figure 15. Percent kidney biopsies with moderate to severe tubular atrophy and percent biopsies without proper registration of tubular atrophy per hospital in 2023.



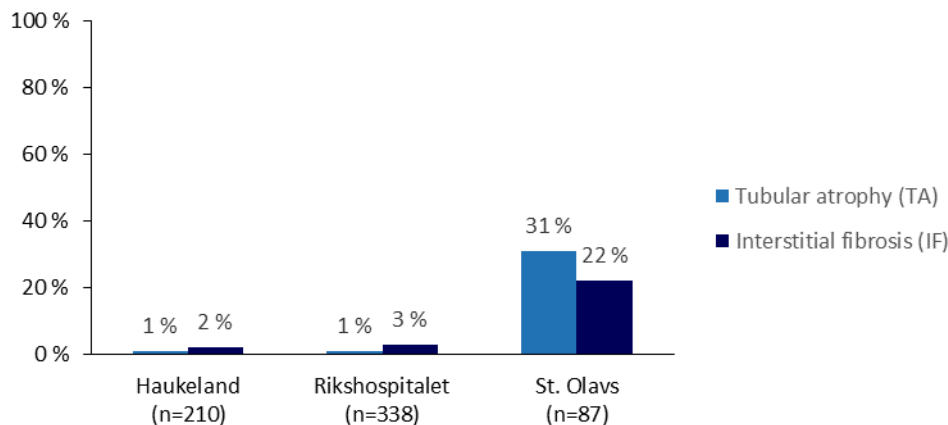
Light blue bars represent percent biopsies with moderate or severe tubular atrophy by hospital. Dark blue bars represent percent biopsies without proper registration of tubular atrophy by hospital. The number behind the hospital name is the number of primary non-neoplastic kidney biopsies with any records about tubular atrophy. Only hospitals with 10 or more non-neoplastic kidney biopsies are shown. Red line indicates quality indicator goal.

Missing/incomplete data

Based on the results for the quality indicator “Number of primary kidney biopsies with moderate to severe chronic changes” we looked at missing/incomplete data related to chronic tubulointerstitial changes and vascular changes. The registry records data based on the pathology report for the specific kidney biopsy. International guidelines are in place on what information should be included in a pathology report [1],[2]. “Datasett til Norsk nyrreregister – seksjon for nyrebiopsi” is available on the homepage of “Den norske patologforening” [3]. This data set shall also be the basis for a standardized pathology report. The data set has recently been expanded by the work of the national specialist group for non-neoplastic kidney biopsy. All guidelines and dataset recommend recording grade of tubular atrophy and interstitial fibrosis. Most guidelines recommend also to grade chronic vascular changes.

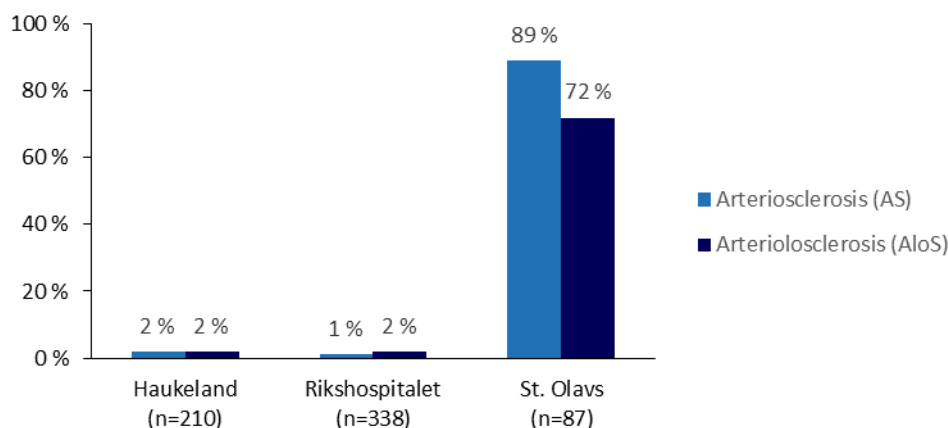
Figures 16 and 17 show an overview over missing/incomplete data per pathology department in 2023. Missing data is the absence of any information about the parameter in the pathology report. Incomplete data means, that there is some information, but not all information related to the parameter, for example “areas of tubular atrophy” is mentioned but not graded. One of the reasons that there are most missing/incomplete data in the reports from St. Olavs Hospital might be, that pathologists are using free text descriptions of findings, whereas the other pathology departments use either structured data or preformatted text building blocks for their reports.

Figure 16. Chronic tubulointerstitial changes: missing/incomplete information



The x-axis represents pathology departments and the annual number of non-neoplastic kidney biopsies performed. Light blue bars indicate the proportion of these biopsies with missing or incomplete data on tubular atrophy, while dark blue bars represent missing information on interstitial fibrosis.

Figure 17. Chronic vascular changes: missing/incomplete information



The x-axis represents pathology departments and the annual number of non-neoplastic kidney biopsies performed. Light blue bars indicate the proportion of these biopsies with missing or incomplete data on arteriosclerosis, while dark blue bars represent missing information on interstitial arteriolosclerosis.

[1] Chang A, Gibson IW, Cohen AH, Weening JW, Jennette JC, Fogo AB. A position paper on standardizing the nonneoplastic kidney biopsy report. *Hum Pathol.* 2012;43(8):1192-6.

[2] Sethi S, D'Agati VD, Nast CC, Fogo AB, De Vriese AS, Markowitz GS, et al. A proposal for standardized grading of chronic changes in native kidney biopsy specimens. *Kidney International.* 2017;91(4):787-9.

[3] www.legeforeningen.no/foreningsledd/fagmed/den-norske-patologforening/faggrupper/nyrepatologi-ikke-neoplastisk/

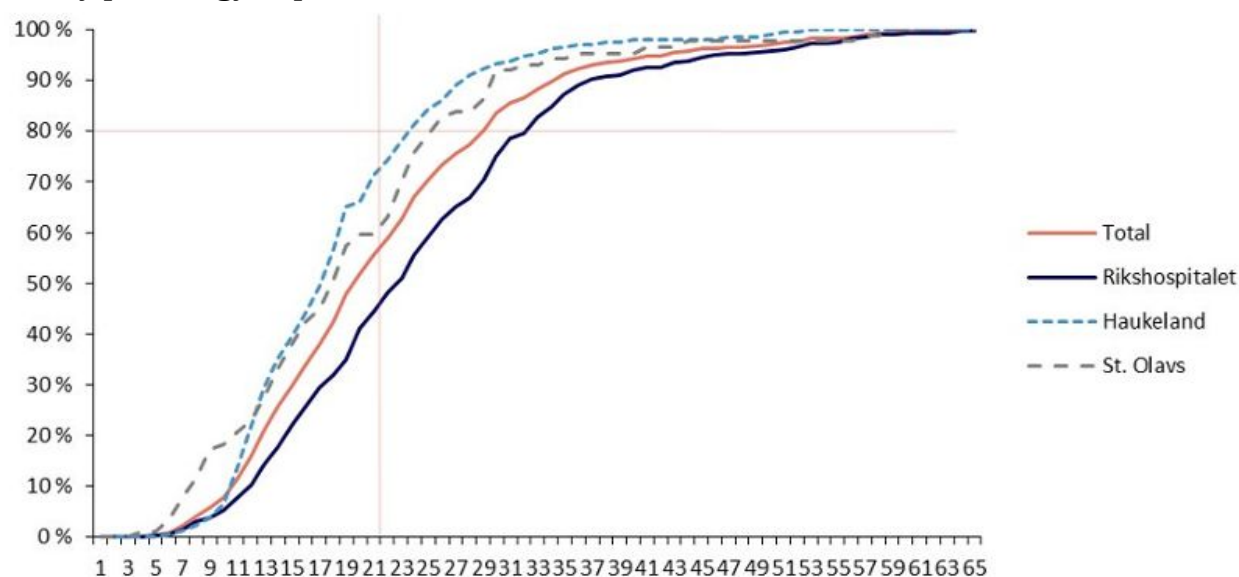
Turnaround time in pathology departments (quality indicator)

The turnaround 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 delays in treatment, and consequently impact patient outcomes negatively. The electron microscopy examination in particular is labour-intensive and 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 read for the first time by light microscopy. This oral report is followed by a preliminary written report, which may or may not include immunopathology findings. The final pathology report is usually signed after electron microscopy.

None of the pathology departments reached the quality goal of having send a final report within 21 working days (**Figure 18**). For kidney biopsy turnaround times, all pathology departments have shown a decrease in the percentage of biopsies reported within 21 working days compared to 2022. It is for the first time since recording this parameter, that none of the pathology departments met the quality standard of providing a final diagnostic report for at least 80 % of cases within 21 working days (one month) (**Figure 19**).

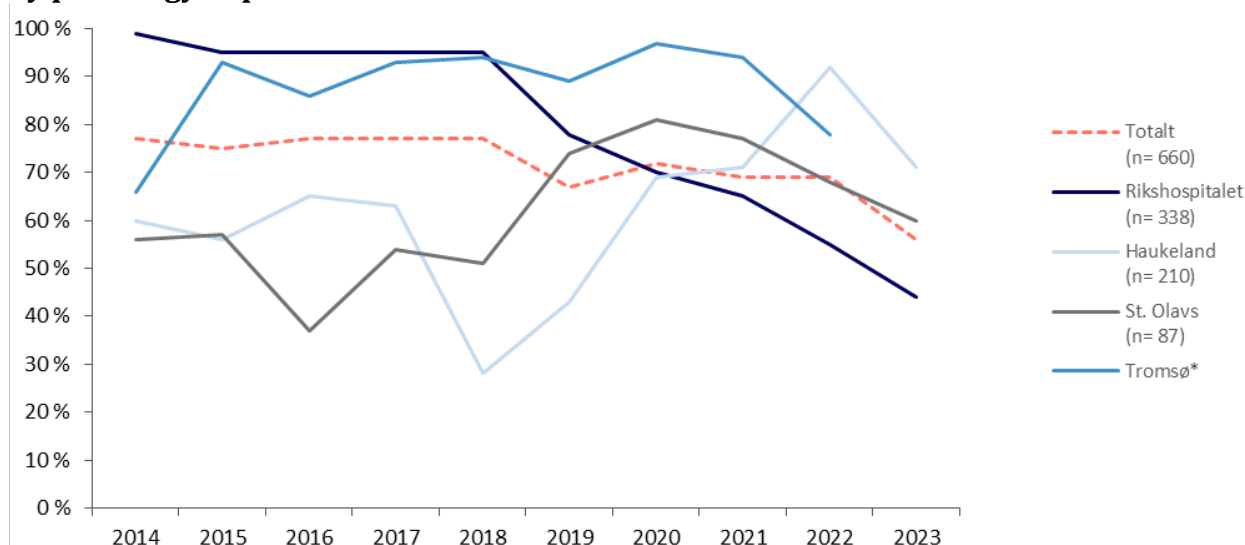
This development is concerning. One potential reason for the increased turnaround times is the significant increase in the number of biopsies in 2023 compared to previous years (see also table 8). It is possible that the pathology departments were unable to react quickly enough to the increased workload with appropriate organisational measures.

Figure 18. Percent kidney biopsies finally reported in relation to working days, total and by pathology department in 2023.



Lines placed in the upper left quadrant indicate that the pathology department has reached the quality criterion of having reported 80% of biopsies within 21 working days. The slope of the individual curves indicates how quickly biopsies are answered: the steeper the faster.

Figure 19. Percent kidney biopsies finally reported within 21 working days, total and by pathology department from 2014 – 2023



Red line indicates quality indicator goal.

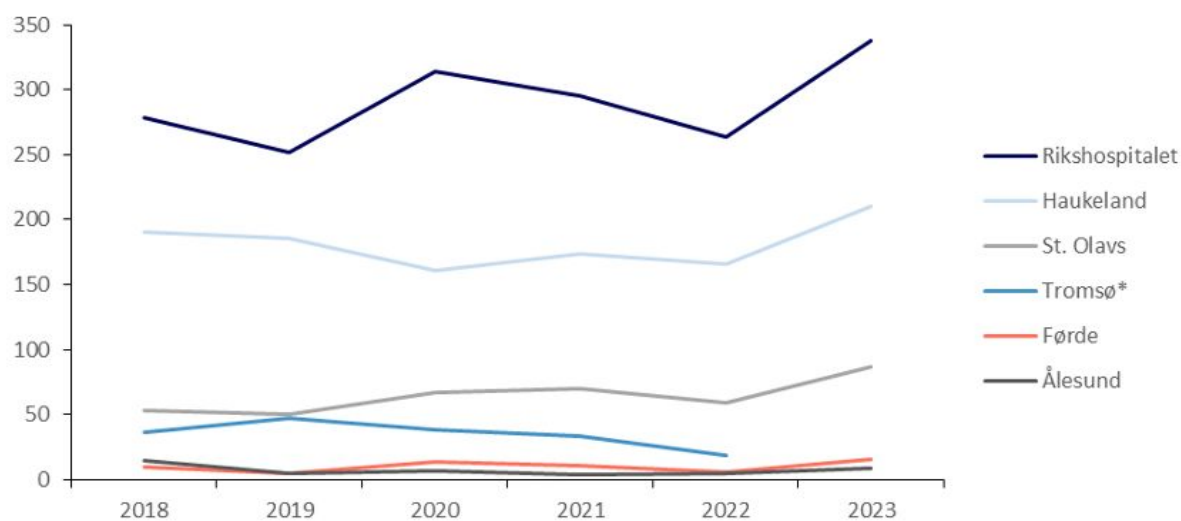
* The pathology department in Tromsø has not been recording kidney biopsies in 2023. Biopsies from Tromsø are currently reported by the pathology department of Haukeland University Hospital.

Electron microscopy investigation of kidney biopsies

In kidney biopsy diagnostics, an electron microscope is used in addition to the light microscope. Instead of light the electron microscope sends electron beams through a very thin section of tissue. These electron beams light up on a fluorescent screen which results in a black and white image of tissue structures. The examination is also called an ultrastructural examination. With the help of the electron microscope, we can achieve higher magnification than with the light microscope. In kidney biopsy diagnostics, we need these high magnifications to be able to see tissue changes in some kidney diseases. To be able to make sections thin enough, a part of the kidney biopsy is specially fixed and embedded in a hard plastic material (EPON).

Figure 20 and **Table 8** show an overview over the number of non-neoplastic kidney biopsies per pathology department and the percentage of biopsies, where an electron microscopic investigation has been carried out. Overall, a high proportion of kidney biopsies undergo electron microscopy. While two departments aim to perform electron microscopy on all cases, one department, despite examining a large number of cases by ultrastructure, opts not to use electron microscopy in certain instances (**Table 9**).

Figure 20. Number of kidney biopsies per pathology department 2016 – 2023



* The pathology department in Tromsø has not been recording kidney biopsies in 2023. Biopsies from Tromsø are currently reported by the pathology department of Haukeland University Hospital.

Table 8. Percentage of electron microscopic investigations per pathology department per year

	2018	2019	2020	2021	2022	2023
Rikshospitalet	96 %	91 %	95 %	96 %	96 %	93 %
Haukeland	83 %	94 %	88 %	90 %	90 %	91 %
St. Olavs	88 %	76 %	73 %	77 %	68 %	83 %
Tromsø*	97 %	94 %	89 %	97 %	100 %	-

* The pathology department in Tromsø has not been recording kidney biopsies in 2023. Biopsies from Tromsø are currently reported by the pathology department of Haukeland University Hospital.

Pathology diagnosis

Table 9 shows an overview over pathology diagnoses in Norway and per pathology department in 2023. Individual numbers are not shown for the departments in Førde and Ålesund because of low number of cases.

The registry is currently using 2 coding systems: The ERA Coding system for Primary Renal Diseases (PRD)^[1] and various versions of the proprietary coding system the registry is using since 1988. The table is based on the proprietary coding system of the registry. The current version still does not contain all pathology diagnoses as shown by 10 cases in the category “No code – free text”.

[1] <https://www.era-online.org/research-education/era-registry/prd-search-tool/>

Table 9. Overview pathology diagnosis in Norway 2023

	All	RH	HUS	St. Olavs
Minimal change nephropathy	43	25	13	4
FSGS[1] primary	14	8	3	2
FSGS secondary	15	5	9	1
Membranous GN[2]	18	11	7	0
IgA nephropathy	119	49	50	17
Mesangioprol. GN without IgA	2	2	0	0
Endokapillary prol. GN	7	2	5	0
Membranoproliferativd GN	14	6	4	3
ANCA associated GN	55	22	22	6
Anti-GBM nephritis	5	5	0	0
GN with crescents not ANCA	11	8	2	0
HSP[3]	4	2	2	0
Lupus nephritis - I	0	0	0	0
Lupus nephritis - II	3	2	1	0
Lupus nephritis - III	2	0	2	0
Lupus nephritis - IV	9	1	3	4
Lupus nephritis - V	4	3	0	1
Lupus nephritis - VI	0	0	0	0
Lupus nephritis - not classified	0	0	0	0

Diffuse proliferative GN	0	0	0	0
Dense deposit disease	1	1	0	0
Fibrillary glomerulopathy	1	1	0	0
Immunotactoid GP[4]	1	1	0	0
Cryoglobulinemia	0	0	0	0
Pre-eclampsia-ass. GN	0	0	0	0
Sclerosing GN	0	0	0	0
GN unclassified	17	7	7	2
Alport syndrome	2	1	1	0
Thin basement membrane GP	8	5	1	2
Fabry's disease	1	0	0	1
Other hereditary diseases	0	0	0	0
Diabetic nephropathy	52	24	16	11
Benign nephrosclerosis	45	30	6	9
Malign nephrosclerosis	6	5	1	0
Cholesterol emboli	1	1	0	0
Vasculitis other	0	0	0	0
TMA[5]	3	3	0	0
TMA - atypical HUS[6]	0	0	0	0
Scleroderma	0	0	0	0
Amyloidosis not classified	6	4	1	1
Amyloidosis - AA	7	6	1	0
Amyloidosis - AL	16	7	4	2
Amyloidosis other	0	0	0	0
Myeloma kidney	6	3	2	0
Ig[7] deposition disease	2	1	0	0
ATN[8]	32	23	5	3
Acute interstitial nephritis	0	0	0	0
Tubulointerstitial nephritis	43	16	21	4
IgG4 related TIN [9]	1	0	0	1
Granulomatous TIN/ Sarc.	1	0	1	0
TIN - drug associated	10	7	2	1
Lithium nephropathy	3	2	1	0
Phosphate nephropathy	1	0	1	0
Oxalate nephropathy	2	2	0	0
TIN with uveitis	0	0	0	0
TIN hantavirus infection	0	0	0	0
Calcineurin inhibitor toxicity	2	2	0	0
Normal	12	6	2	4
Uncharacteristic atrophy	21	11	5	4
End stage kidney	0	0	0	0
No code - free text	10	5	3	1
Not representative	22	13	6	3
All	660	338	210	87

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

Incidence CKD5 not in KRT

New patients with CKD5 not treated with RRT that is reported to the registry have remained relatively stable at about 320 patients per year over the last years. Most patients are male (70%), with median (range) age of entering the CKD5 stage being 71 (11-92) years old and a mean BMI of 27.0 kg/m². Patients were known at the nephrology unit in 90% of the cases, and 85% were candidates for KRT. The percentage of patients who are not candidates for KRT at entry in the registry is declining, from 11% in 2020, 9% in 2021, 8% in 2022 and down to 5% in 2023. The main reason for not being a transplant candidate was comorbidity. Type II diabetes has become less prevalent in the CKD5 population, decreasing from 34% in 2020, 32% in 2021, 27% in 2022, increasing slightly to 29% in 2023.

Selected clinical chemistry values and demographic variables are available below (**Table 10**)

Table 10. Status at first time reported as CKD5 (without KRT) in 2023

	Total (n = 317)
eGFR (CKD-EPI 2021, mean) [mL/min/1.73m ²])	12
eGFR (CKD-EPI 2021 - % < 15 mL/min/1.73m ²)	90%
Creatinine (mean) [μmol/L]	410
Albumin (mean) [g/dL]	38
Haemoglobin (mean) [g/dL]	11.1
Haemoglobin - % with < 10 g/dL)	22%
Proteinuria (ACR>3 and/or PCR>15)	98%
ESA use	32%
Active vitamin D use	53%
Statin use	64%
Not on antihypertensive drugs	8%
Using ACEi or ARB	45%
Using ≥3 antihypertensive drug	50%
Using bicarbonate	61%

As of 2023, we will report the reasons for CKD5 over time using the grouping provided by the ERA (which is slightly different from what we have reported in previous years). The main cause of kidney failure remains vascular or hypertensive disease, at a rate of 39%, a number that has remained stable the last five years. Diabetes (18%), and glomerular disease (18%) show similar stable patterns. The yearly proportion of main cause of renal failure over the last three years is shown in **Table 11**.

Table 11. Reason for CKD5 over time

Reason for CKD5	2019	2020	2021	2022	2023
Hypertension / Renal vascular disease	43 %	38 %	46 %	40 %	39 %
Diabetes Mellitus	13 %	17 %	18 %	15 %	18 %
Glomerular disease	16 %	19 %	15 %	14 %	18 %
Familial / hereditary nephropathies	13 %	10 %	10 %	13 %	10 %
Tubulointerstitial disease	9 %	7 %	7 %	10 %	8 %
Miscellaneous renal disorders	3 %	4 %	2 %	4 %	5 %
Other systemic diseases affecting the kidney	3 %	4 %	3 %	4 %	2 %

While the percentage of patients entering CKD5 using three or more hypertensive drugs has remained steady around 60% in previous years; 60% in 2021 and 57% in 2022, it decreased sharply to 50% in 2023. However, the percentage of patients using ACE-inhibitors or ARB

remains relatively similar to previous values (maybe a trend of reduction?); from 52% in 2021, 48% in 2022, and now 45% in 2023.

For patients starting KRT during 2023, the median (range) time in the CKD5 stage was 11.7 months (0-70.7). The median time in CKD5 prior to KRT has been relatively stable over the last five years 11.5 (2019), 12.6 (2020), 12.8 (2021), 13.1 (2022), and now 11.7 (2023) months, with a similar trend for the mean.

Incidence CKD5 in KRT (Dialysis or Transplantation)

The total number of new patients in KRT has been stable over the last three years, with 551 patients in 2020, 530 in 2021, 540 in 2022, and now 558 in 2023 (**Figure 22**). It seems that the breaking of the 600 level in 2019 was an exception.

Most patients are male (70%) and median age at start of KRT was 66 years (mean 62 years), ranging from 1 to 95 years. At start of dialysis 43% were assessed by the treating physician to be a transplant candidate (and additionally 18% possible candidates). Of the patients starting hemodialysis, and that had been known at the treating center for at least 4 months, 33% started dialysis using an AV-fistula as blood access. A selection of clinical chemistry values and drugs used in patients starting KRT in 2023 are shown in **Table 12**.

Table 12. Status at start of KRT in 2023

	Total	HD	PD	Preempt. Tx
Number of patients	558	304	196	55
Age (mean) [year]	64.4	65.2	66.7	50.2
Age (median) [year]	67.8	68.5	69.5	51.1
eGFR (CKD-EPI 2021, mean) [mL/min/1.73m ²]	8	7	8	12
eGFR (CKD-EPI 2021 - % < 15 mL/min/1.73m ²)	96%	96%	98%	87%
Creatinine (mean) [μmol/L]	684	721	666	547
Albumin (mean) [g/dL]	35	33	37	44
Haemoglobin (mean) [g/dL]	10.1	9.7	10.5	9.2
Haemoglobin - % with < 10 g/dL)	47%	62%	31%	24%
ESA use	58%	56%	64%	53%
Active vitamin D use	65%	57%	73%	76%
Statin use	59%	56%	64%	53%
Not on antihypertensive drugs	10%	10%	7%	24%
Using ACEi or ARB	43%	42%	44%	51%
Using ≥3 antihypertensive drug	53%	55%	56%	29%
Using bicarbonate	56%	49%	66%	64%

As expected, pre-emptively transplanted patients had a lower serum creatinine, i.e. better renal function, and a higher hemoglobin compared with those starting hemodialysis. The proportion of pre-emptively transplanted patients using 3 or more antihypertensive drugs decreased from 36% (2022) to 29% (2023). However, the use of ACEi or ARB in this group has increased from its previously stable level of 40% (2020 to 2022) to 51% in 2023. The relative number of patients starting KRT with PD has increased over the last years. Since 2015 it has increased from 28% to 35% in 2023.

In **Figures 21 to 23** 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 21:

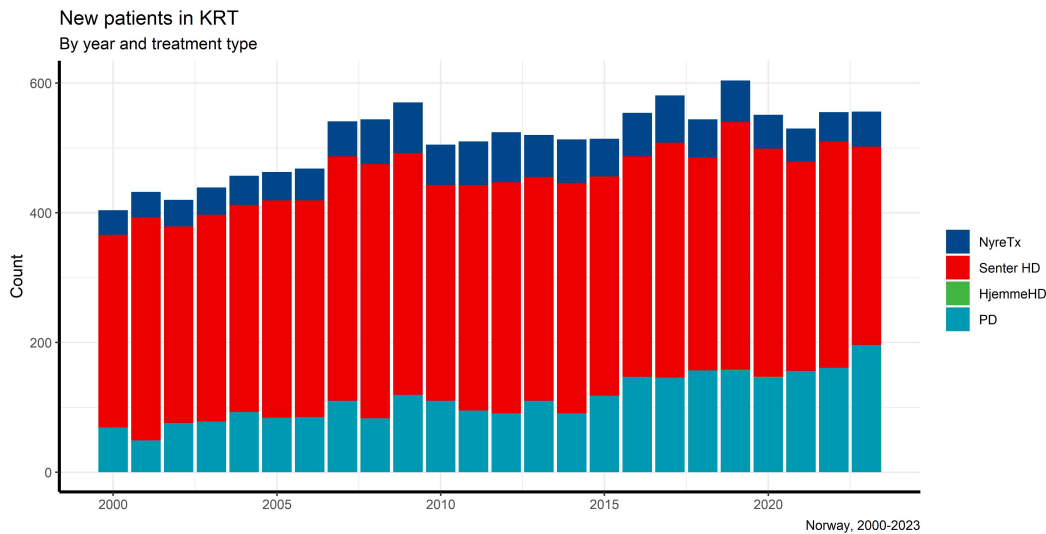


Figure 22:

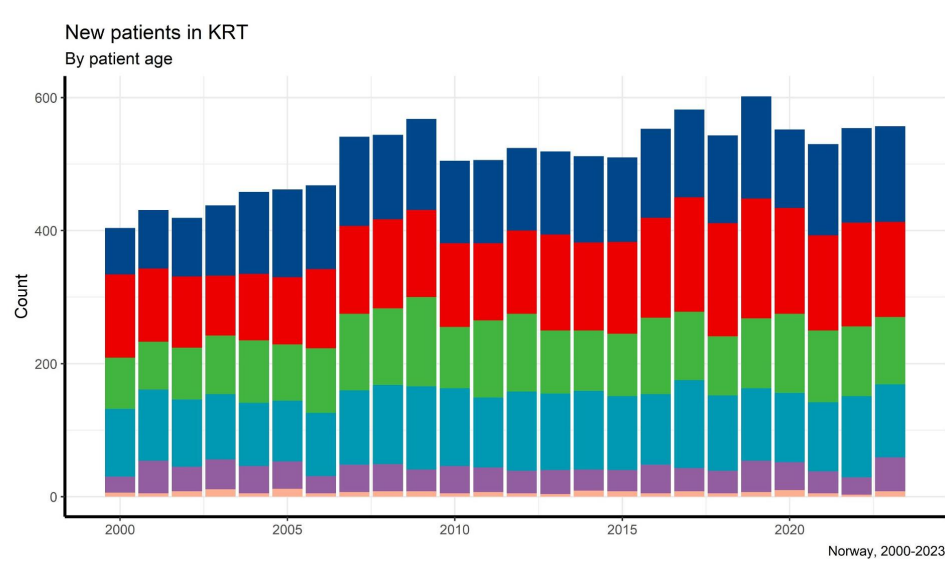
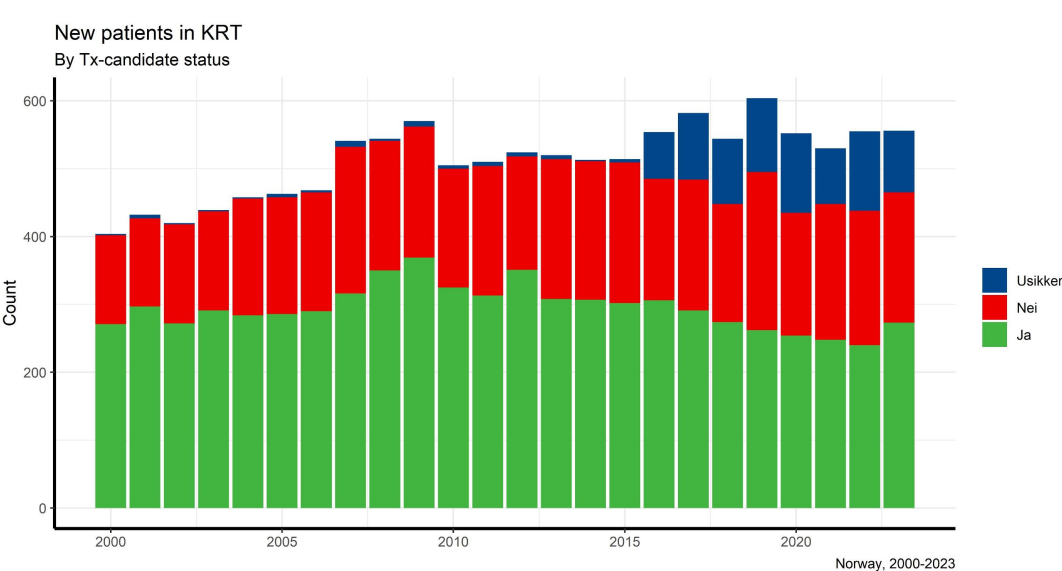
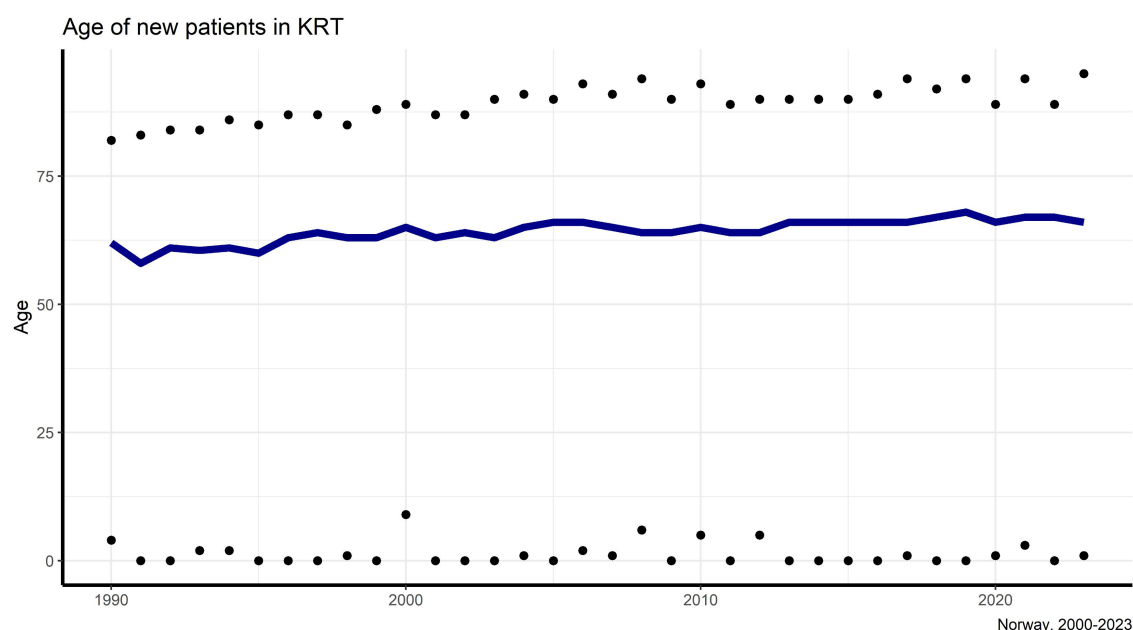


Figure 23



Since registration started in 1980 it has been a continuous shift in patient age. **(Figure 24)** Both the maximum and the median age at start of KRT have increased. Also, the 5-percentile and 95-percentile values (i.e. including the majority of patients) have increased during this period. But also, younger children have been accepted; the youngest ever started PD in 2011 at age two days. Twelve children below 18 years started KRT in 2023; transplantation (n=8), HD (n=4) and PD (n=0), as compared to 13 in 2020, 9 in 2021 and 5 in 2022.

Figure 24



In line with the reason for CKD5 over time, we now present the primary kidney disease at the start of KRT also according to the ERA grouping of kidney disease **(Table 13)**. The main change over time has been an increase in kidney disease due to hypertension or other kidney vascular disease, and a relative reduction in glomerular disease. Whether this only reflects changed coding practice or a true shift is not known. Worth noticing in Table 16 is that the number of “unknowns” have been almost none since 2015 which is a data quality improvement by those reporting the data.

Table 13. Primary renal disease at start of KRT

	80-89	90-99	00-04	05-09	10-14	15-19	20-23
Hypertension / Renal vascular disease	6 %	21 %	28 %	30 %	34 %	31 %	32 %
Glomerular disease	39 %	32 %	22 %	22 %	20 %	20 %	21 %
Diabetes Mellitus	13 %	11 %	15 %	16 %	16 %	17 %	16 %
Familial / hereditary nephropathies	11 %	10 %	10 %	9 %	9 %	10 %	12 %
Tubulointerstitial disease	16 %	13 %	11 %	10 %	10 %	9 %	9 %
Miscellaneous renal disorders	3 %	3 %	3 %	4 %	4 %	6 %	6 %
Other systemic diseases affecting the kidney	9 %	7 %	6 %	5 %	4 %	6 %	5 %
Unknown	3 %	4 %	4 %	4 %	2 %	0 %	0 %
N:	2038	3247	2153	2586	2571	2798	2191

Diabetic nephropathy has stabilized on a higher levels as primary diagnosis cause for kidney disease the last decade. In 2023, 25% of these were registered as having Type I diabetes mellitus in relation to 26% in 2020, 17% in 2021 and 30% in 2022. However, this fluctuation is likely due to the relatively low (< 30) number of patients starting KRT with Type I diabetes.

Also including patients with other primary diagnoses of kidney disease a total of 185 patients were recorded as having diabetes mellitus at start of KRT (13% Type I), thus 33% of new patients in KRT were diabetics in 2023. The time from onset of diabetes to start of KRT differed considerably. For the patients with Type I diabetes the median time was 25 years (as opposed to 32 in 2022), while for the patients with Type II diabetic nephropathy the median time was 17 years, just as the year before.

Cardiovascular disease is often present at the start of KRT. Coronary heart disease was reported in 23% and 19% had heart failure. Echo-verified left ventricular hypertrophy was reported in 23%. Cerebrovascular disease was reported in 12% and peripheral atherosclerotic disease in 12% while 9% had chronic obstructive lung disease.

Prevalence data CKD5 without KRT by December 31st 2023.

The national coverage of CKD5 patients not in KRT is in the range of 60% to 85%. The reported data on CKD5 patients not in KRT should hence be interpreted with caution. The registry has recently (September 2024) started a coverage analysis for the period 2019-2023 in cooperation with the Norwegian Patient Registry (NPR).

In 2023, there were 552 CKD5 patients in the registry who did not receive kidney replacement therapy by the end of the year. This is in line with previous years; 545 (2019), 558 (2020), 560 (2021), and 594 (2022). In total 276 of the 558 (49%) starting KRT during 2023 had not been included in the registry before KRT start; 43% of those starting in HD, 58% of those starting in PD and 50% of those being preemptively transplanted. This underlines that there is a significant underreporting of patients to the registry when they enter CKD5.

Prevalence data KRT by December 31st 2023.

By the end of 2023, 5,606 patients in Norway received kidney replacement therapy, i.e. 1010.1 per million inhabitants. In comparison, there were 5427 prevalent patients in 2022. Age distribution is shown in **Table 14**.

Table 14. Age distribution in prevalent patients by December 31st 2023

	Total	HD	PD	Tx
	(n:5606)	(n:1487)	(n:463)	(n:3653)
Age (mean) [years]	60.5	66.4	65.4	57.7
Age (median) [years]	62.5	68.8	69.1	59.4
Age (minimum) [years]	2.0	14.3	5.4	2.0
Age (maximum) [years]	96.4	92.8	96.4	94.8
Male (%)	65%	68%	70%	63%

Figures 25 and 26 show prevalence per treatment modality, development over time and by center in the report year

Figure 25:

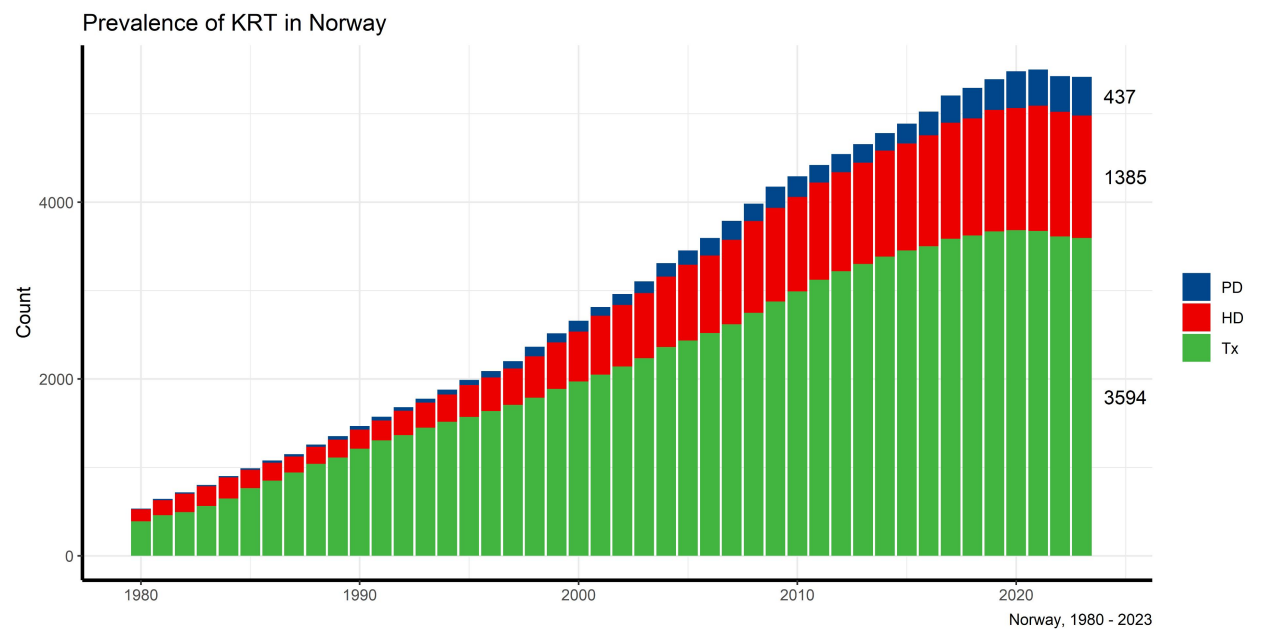
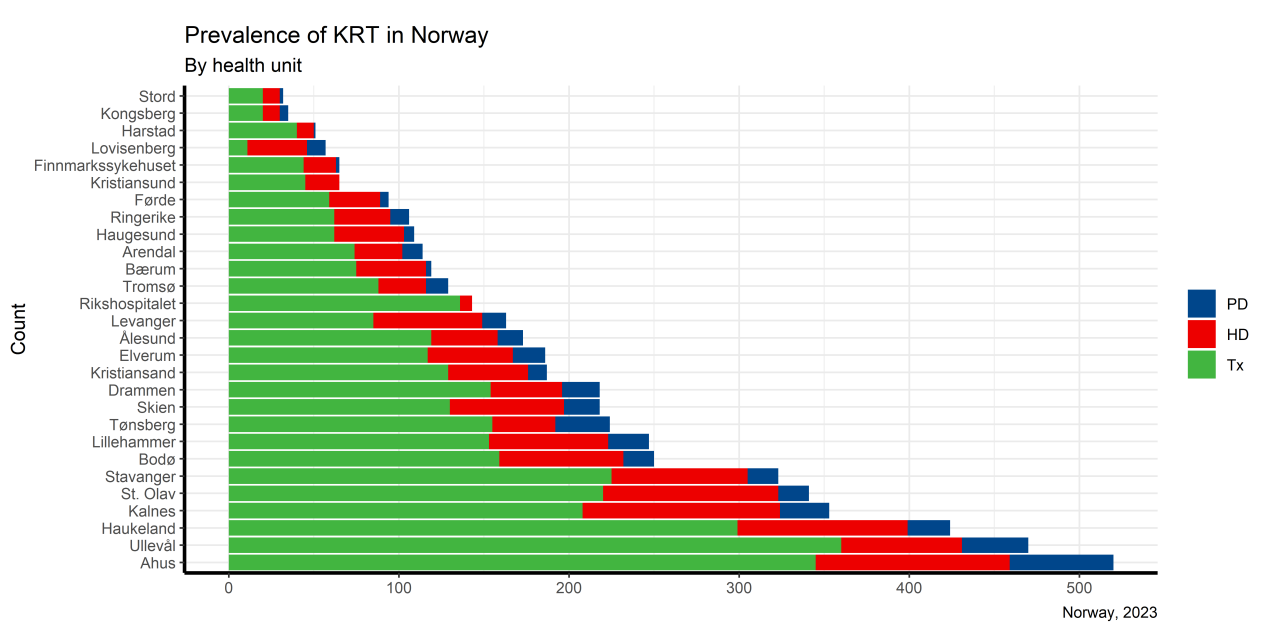


Figure 26:



Transplantations:

A total of 239 renal transplantations were performed in Norway in 2023, i.e. 43.1 per million inhabitants, 31 (13%) were re-transplantations (19% in 2022) and 45 (19%) were living donor transplants (20% in 2022) (**Figures 27-29**). Preemptive transplantation was performed in 25% of all first transplantations in 2023 (**Figure 30**). The 178 non-preemptive, first transplant recipients had been in dialysis for a median of 2.1 years (mean 2.6 years), ranging from 31 days to 10.7 years before transplantation.

In principle is transplantation offered to all patients considered to benefit from it, with no strict upper or lower age limit. The age of the 146 first DD-graft recipients in 2023 ranged from 1 to 82 years, with a median age of 57 years. Out of these, 26% were above the age of 65 and 5% were 75 or older. The 38 recipients of a first LD-graft were from 1 to 76 years, with a median age of 50 years. The re-transplant LD recipients ranged from 11 to 33 (median 22) years, and re-transplant DD recipients ranged from 5 to 80 (median = 48) years.

Figure 27:

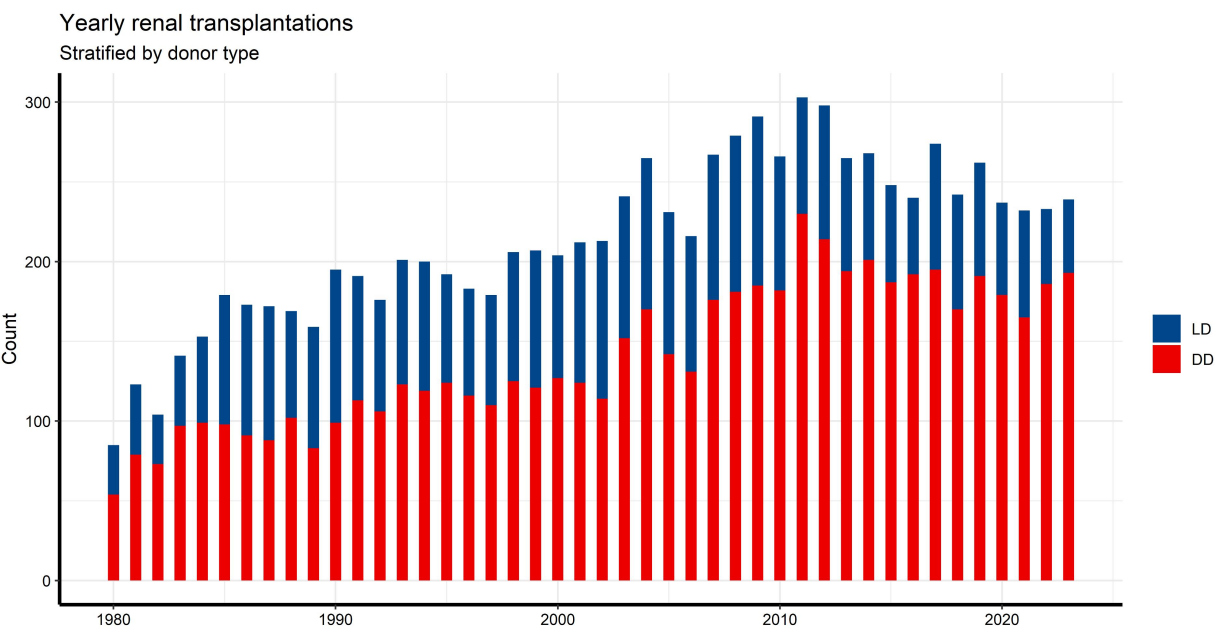


Figure 28:

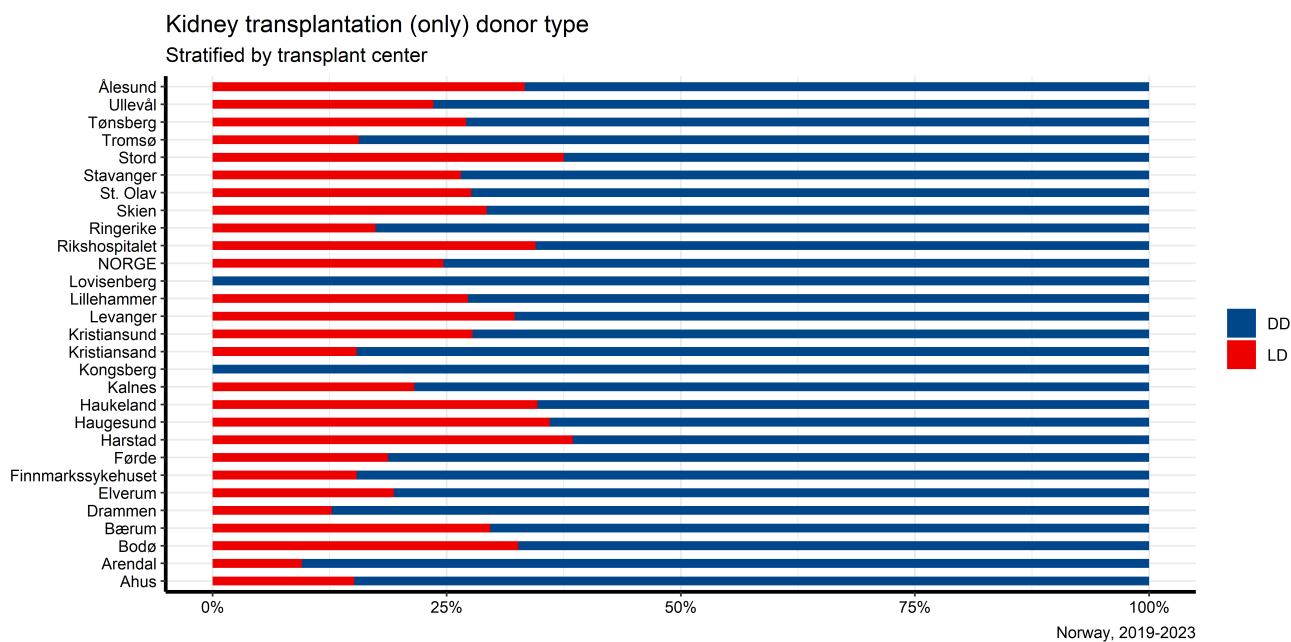


Figure 29:

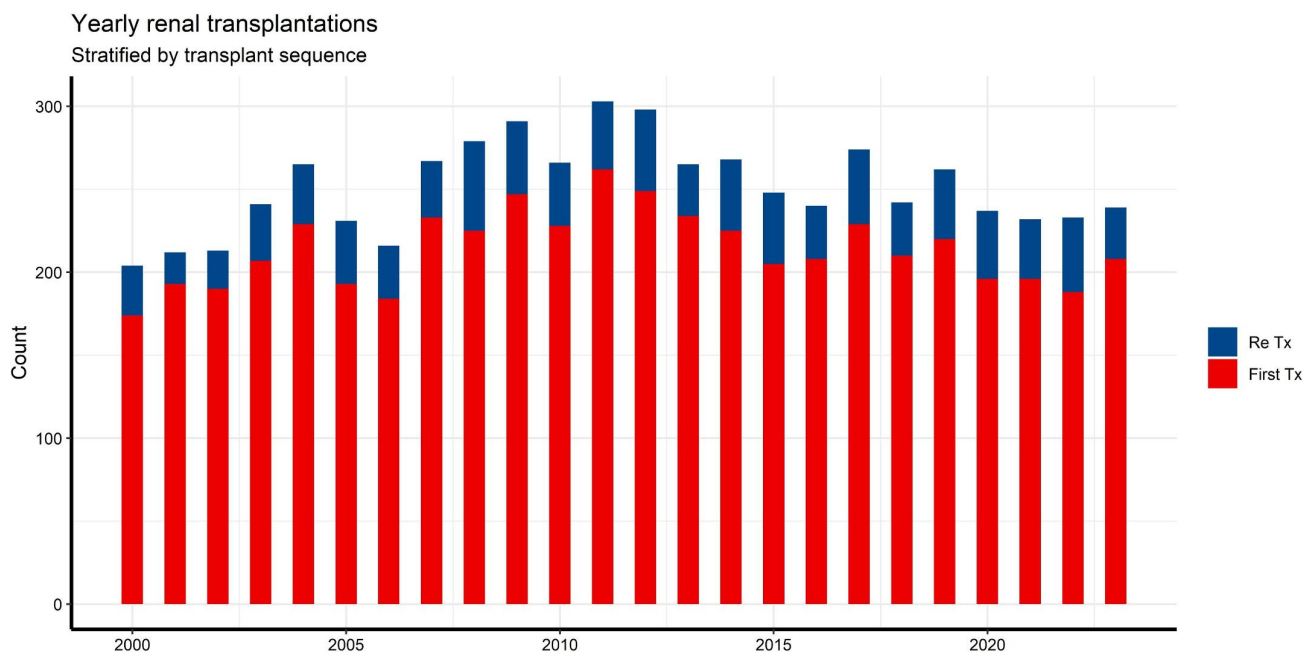
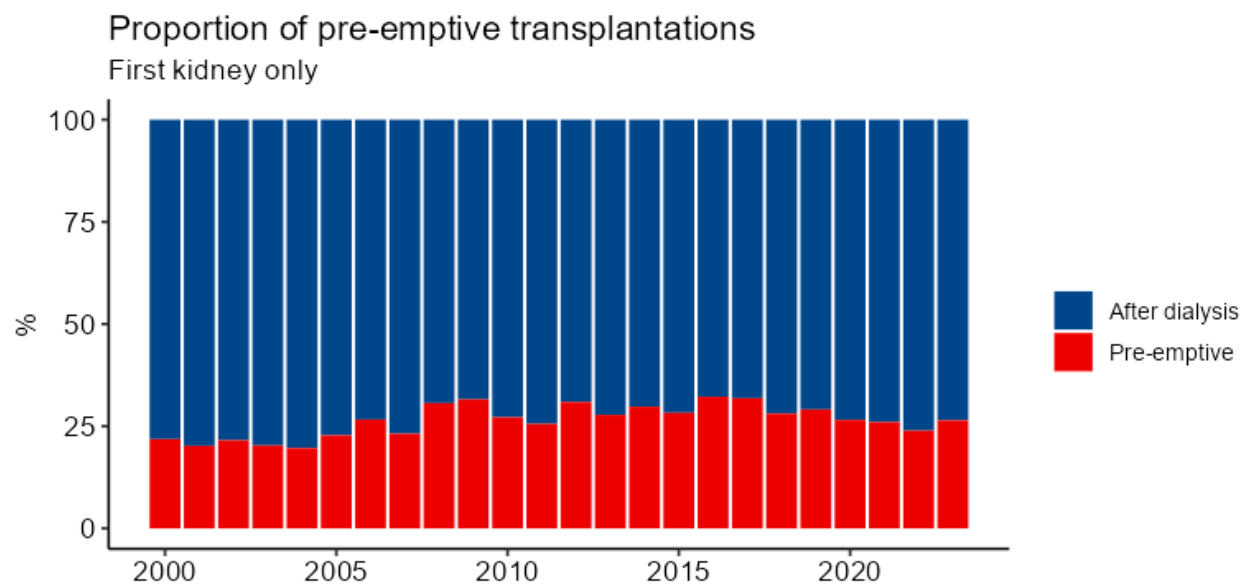


Figure 30



Distribution of relation between recipient and donor in living donor transplantation is presented in **Figures 31 and 32**. Simultaneous pancreas and kidney (SPK) transplantation was performed in 3 patients. One of each simultaneous liver-kidney and heart-kidney transplantation was performed in 2023.

Figure 31:

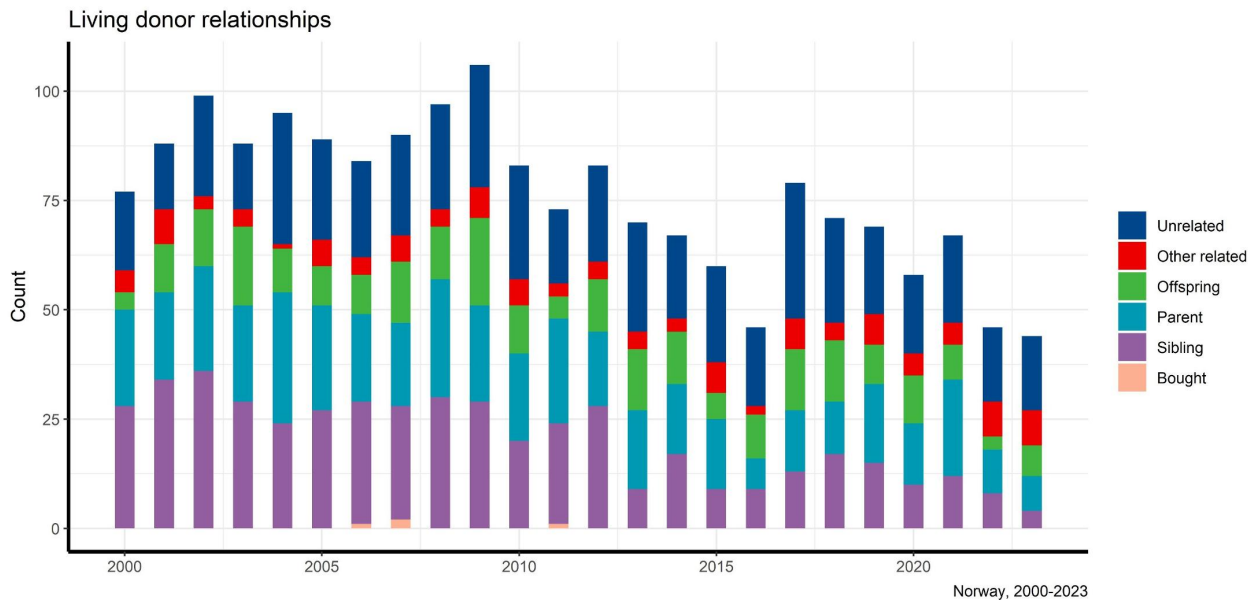
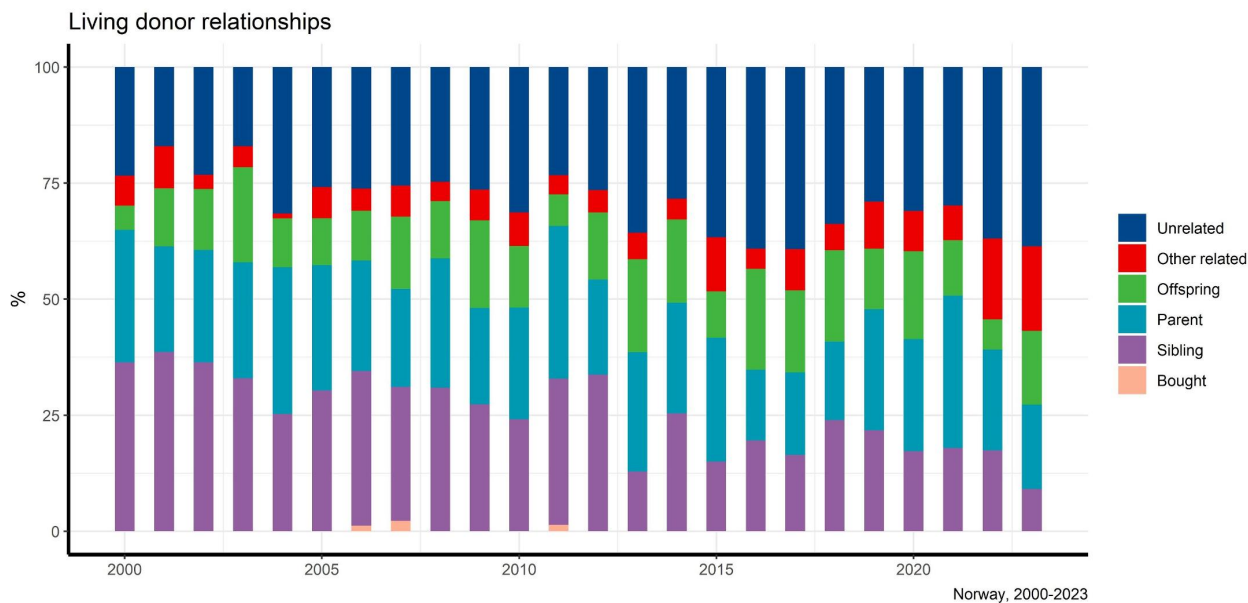


Figure 32:



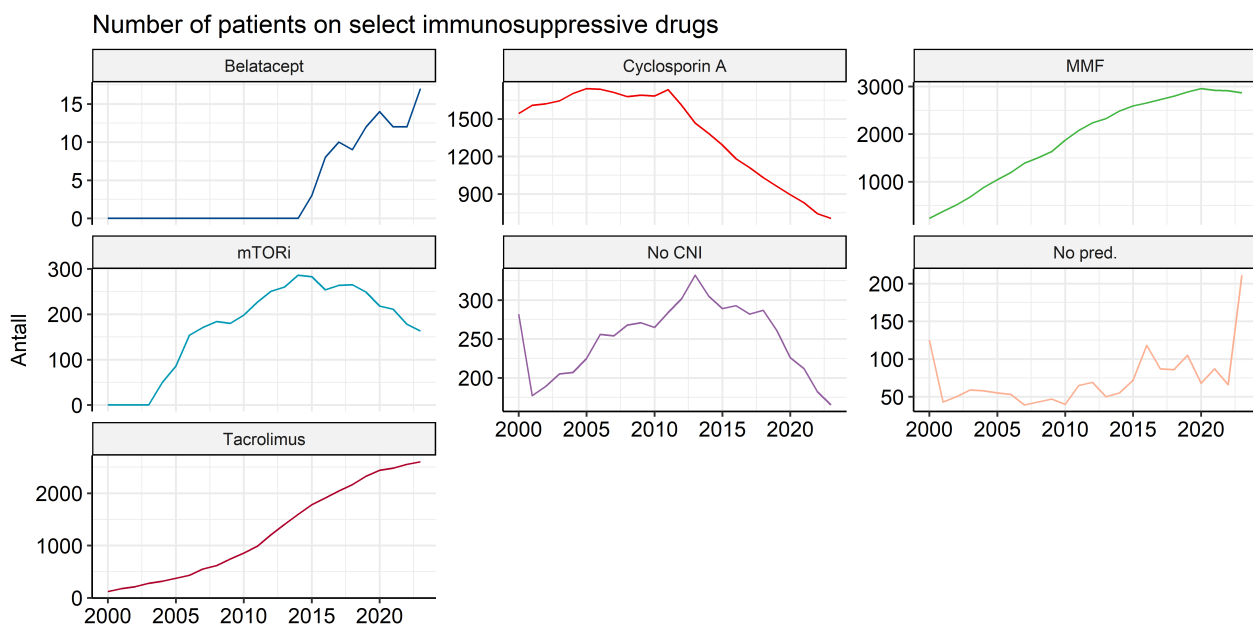
Fun-facts Transplantation (by 31.12.2023):

The oldest kidney transplant recipient ever was 84.1 year at time of transplantation (youngest 9.5 months). In total 1,083 recipients have been transplanted at an age older than 70 years, 49 older than 80 years. The oldest kidney transplant recipient ever is 94.8 years and she is still living. In total 21 patients have become older than 90 years (6 now living) and 731 reached an age over 80 years (188 now living).

The longest graft survival is 54.1 years and is still functioning. In total 55 (28 still working) grafts have functioned in a new body for over 40 years. The oldest transplanted kidney ever is 112.2 years and the oldest still working is 106.8 years. In total 13 (5 still working) transplanted kidneys have reached a total age of over 100 years and 105 (41 still working) over 90 years.

An overview of different immunosuppressive drugs used by the end of 2023 is presented in **Figure 33** below.

Figure 33.



Patients listed for transplantation:

In total 315 patients actively waiting for a kidney transplant at entry into 2023 and by the end of 2023 it had increased to 337 patients (**Figure 34**). Including those temporarily withdrawn from the transplant list (“inactive”), the total number waiting for a kidney at the end of 2023 was 498 patients (89.7 per mill.). For the first time in some years below 500 patients!

Among those actively waiting by December 31st 2023, the median time on the wait list for a first transplant was 18 months, a slight increase from the 17 months in 2022. Of these, 28% (2022: 43%) had waited less than one year, and 60% (2022: 69%) had waited less than two years.

Recipients transplanted with a DD-graft in 2023 had a median (range) waiting time of 22.8 (0 to 104) months for a first transplant and 30 (0 to 100) months for a retransplant. Median and inter-quartile waiting time for first kidney since 1995 is shown in **Figure 35**.

Figure 34:

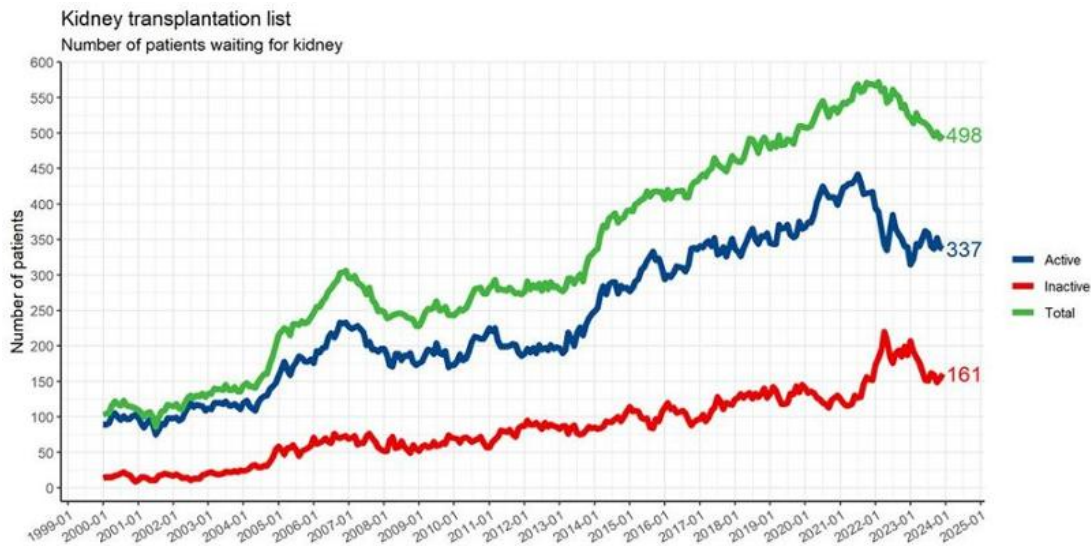
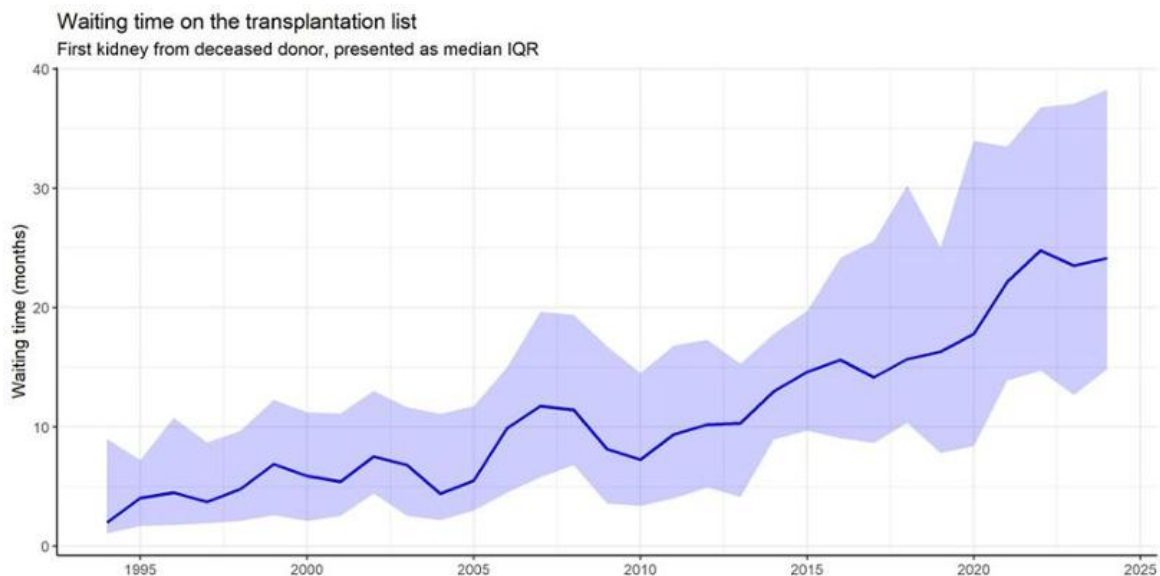


Figure 35:



Patient and graft survival:

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

Patient survival in RRT:

Figure 36:

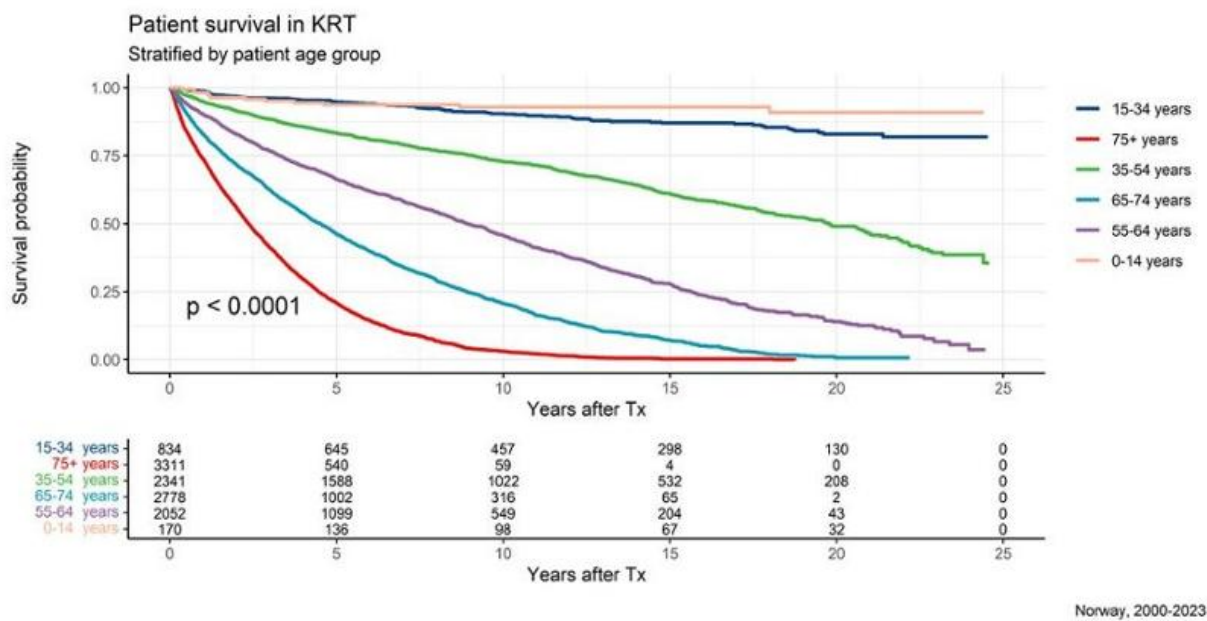
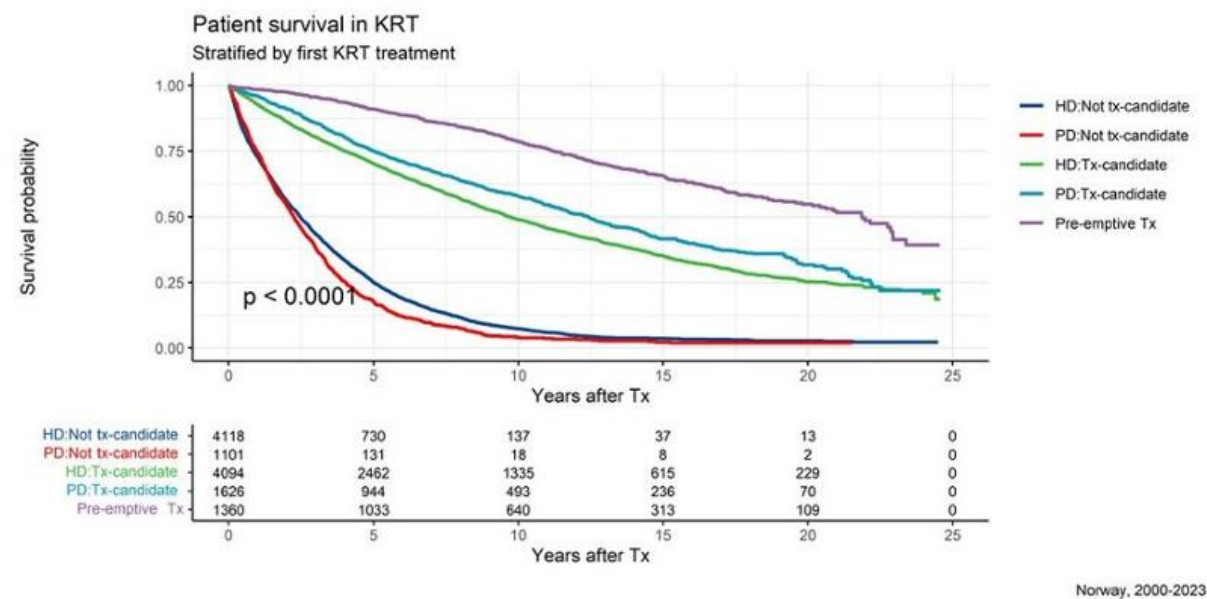


Figure 37:



Graft survival after transplantation:

Figure 38:

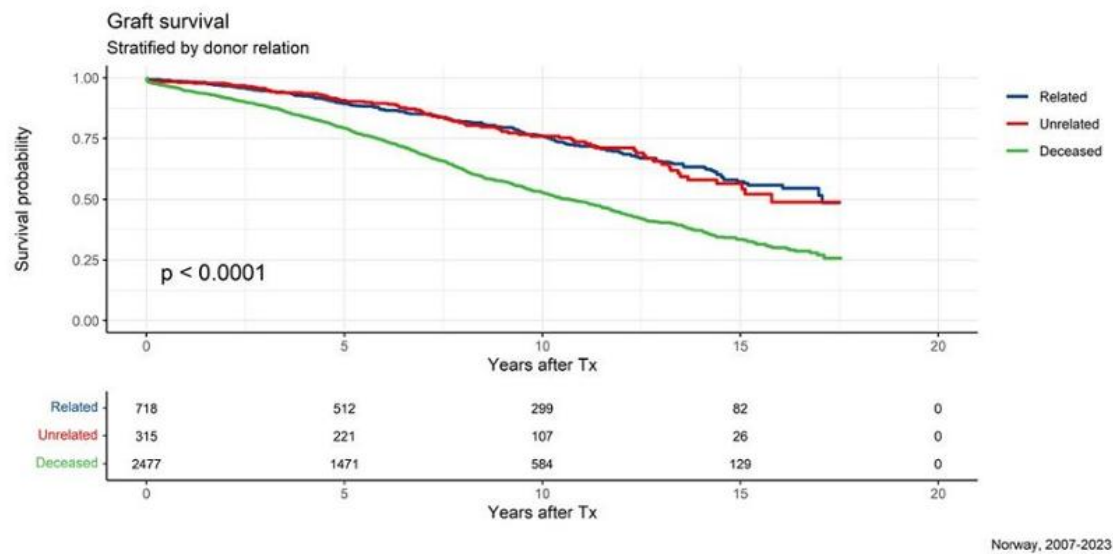


Figure 39:

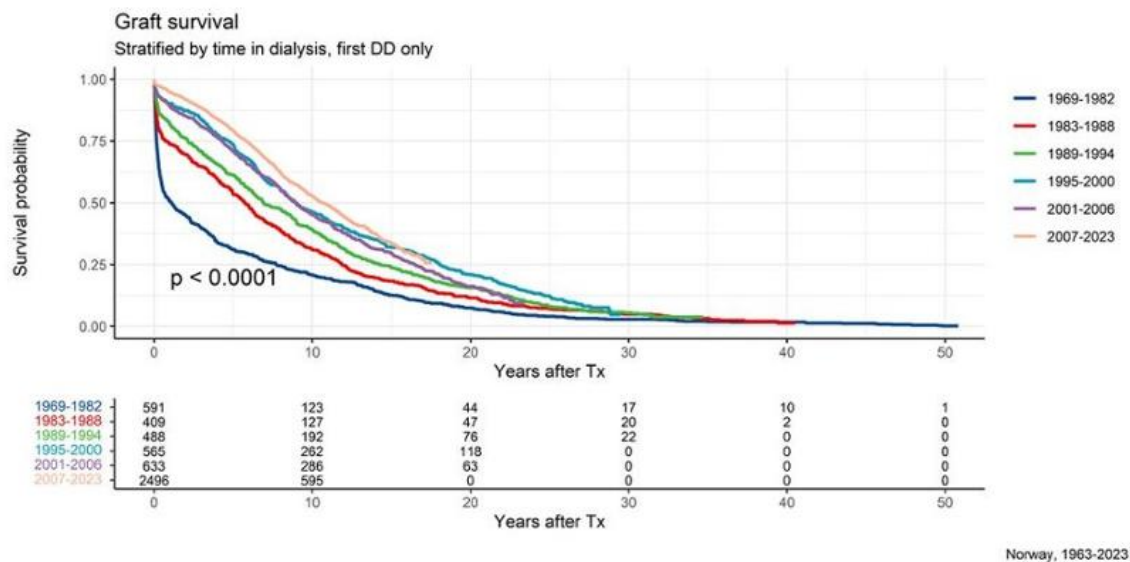


Figure 40:

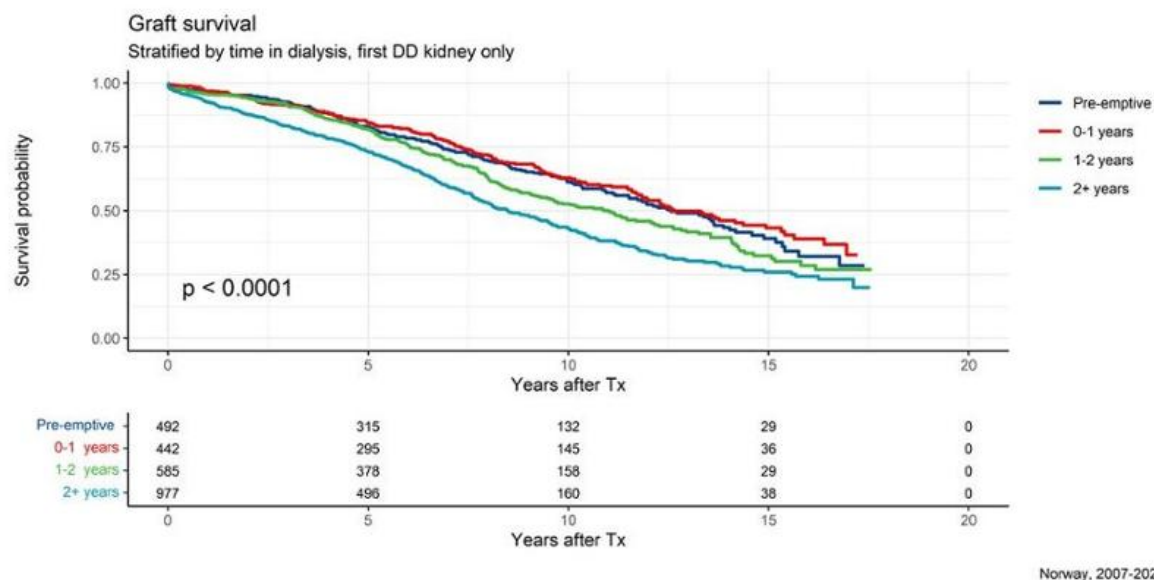


Figure 41:

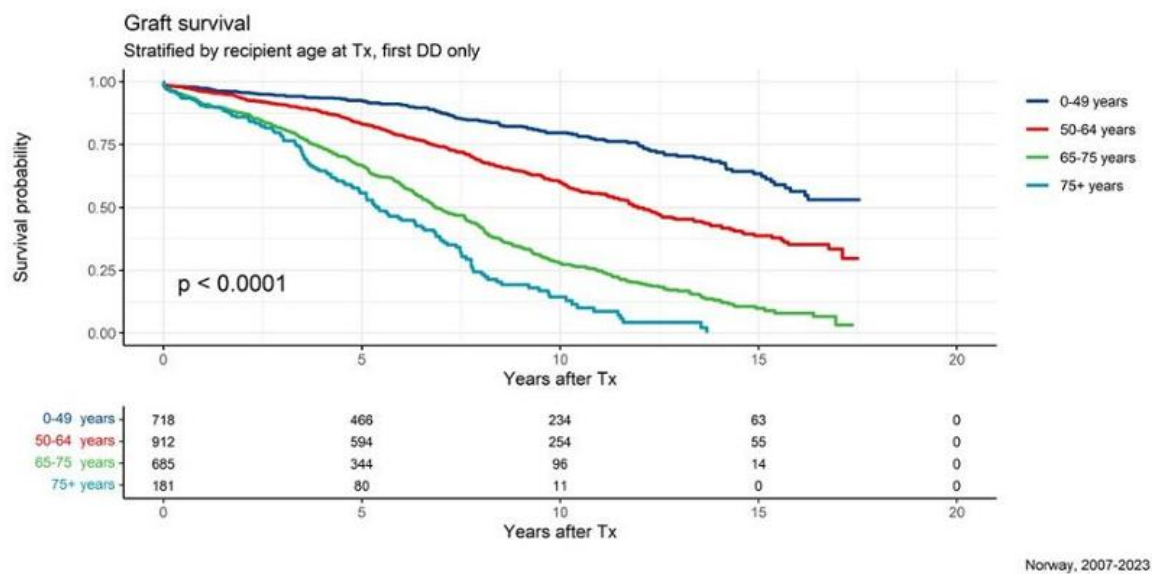


Figure 42:

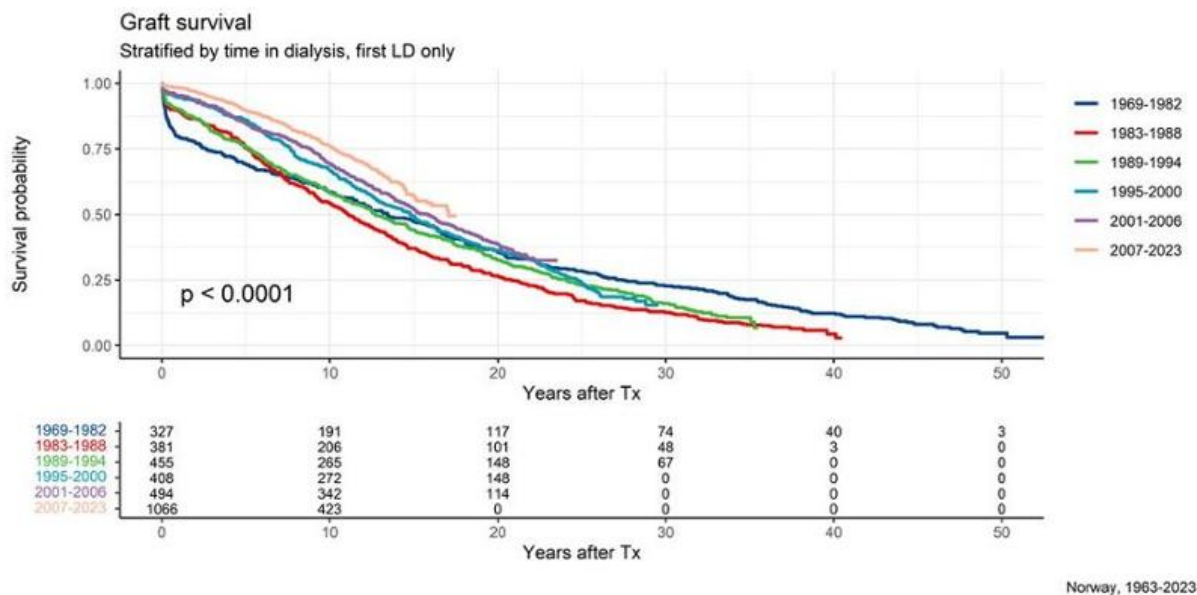


Figure 43:

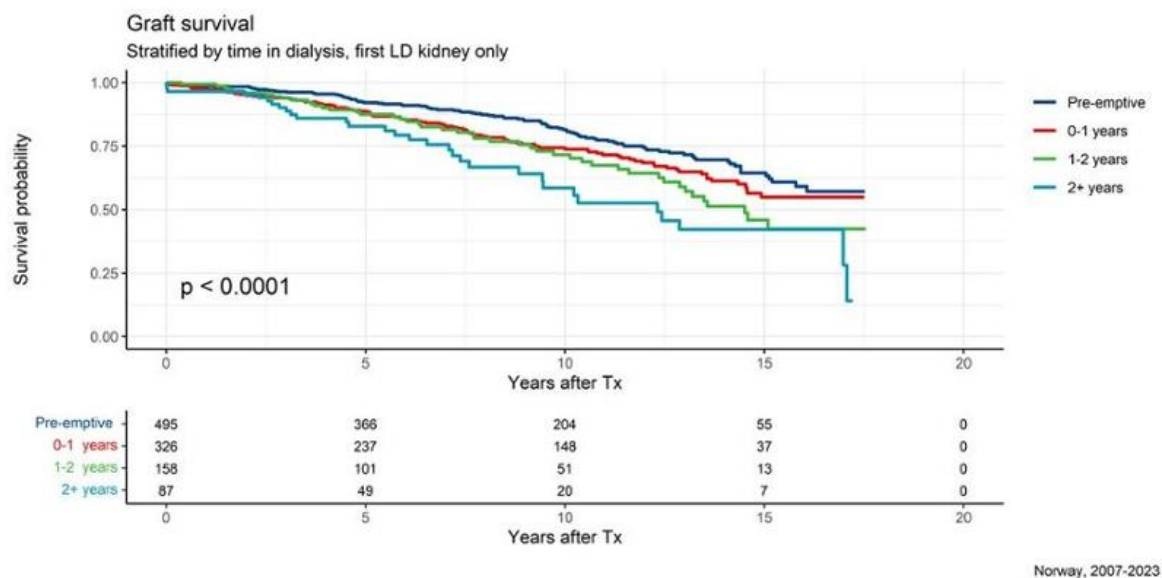
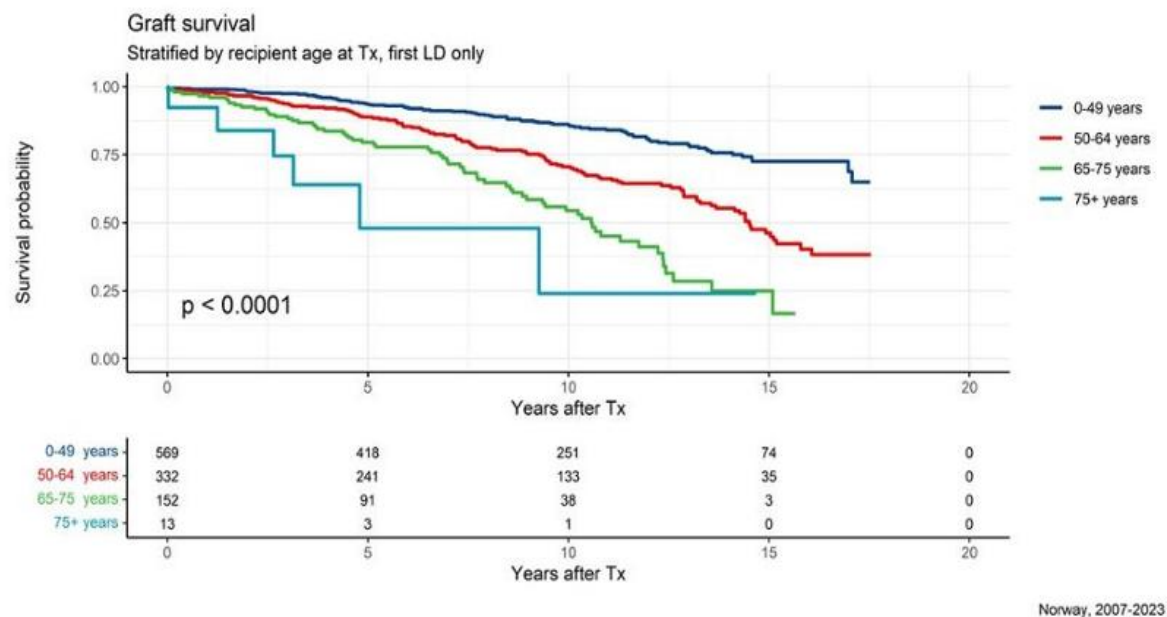


Figure 44:



Death in CKD5 patients:

A total of 529 CKD5 patients (including kidney transplants with good renal function) died during 2023. The majority of these were patients in hemodialysis ($n = 241$), followed by transplanted patients ($n = 139$), and patients in PD ($n = 81$). Median age at death was 76 years (mean 74 years), ranging from 36 to 96 years.

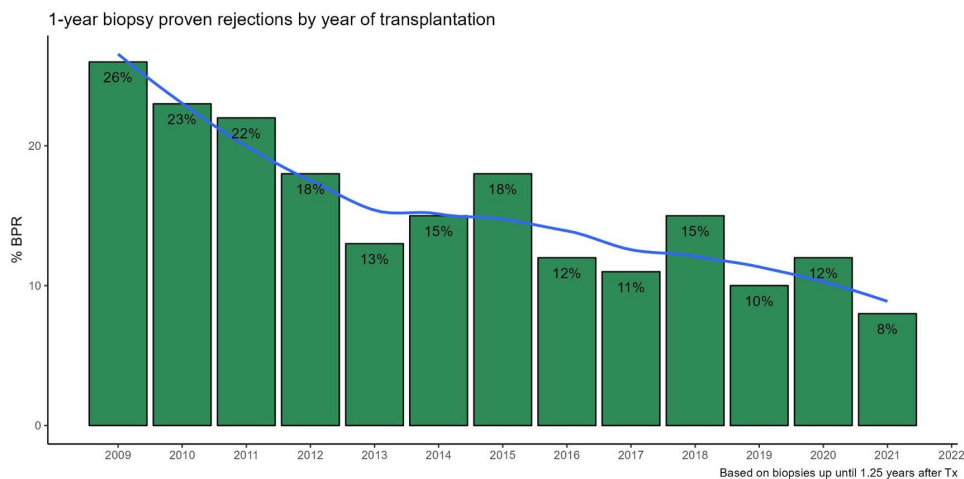
Median time from start of KRT until death was 4.7 years (mean 8.4 years), ranging from 4 days to 50.2 years. Cardiac complications and infections were the most frequent causes of death, followed by malignant tumors.

The incidence of death by suicide has remained at 1-2 each year, and since 2000, a total of 20 suicides have been reported to the registry (Hemodialysis = 9, Tx = 8, CKD5 = 2, PD = 1). As such, additional focus on mental health during regular follow-up should be considered.

Biopsy-proven rejections:

Recently the registry was able to obtain historic kidney biopsy results from the Department of Pathology. Additionally, we now receive biopsy records from Rikshospitalet every third month. This allows us to perform more granular analysis on the incidence of biopsy-proven rejections. **Figure 45** shows the rate of 1-year biopsy proven rejections by year of transplantation. The last three years the approximate acute rejection rate the first year after transplantation was in the range of 8% to 12%, a figure that has seen a steady decline over the last 10-year period, with intermittent spikes up to 14-18%.

Figure 45:



The prevalence of infections (bacterial, fungal, or viral) requiring hospital treatment the first two years after transplantation, in the same period as the decrease in acute rejection is seen, has remained steady around 25-30% (**Figure 46**). This indicates that the decrease in acute rejection episodes presented above is not primarily due to higher degree of immunosuppression in the period. The distribution of infection type is presented in **Figure 47**.

Figure 46:

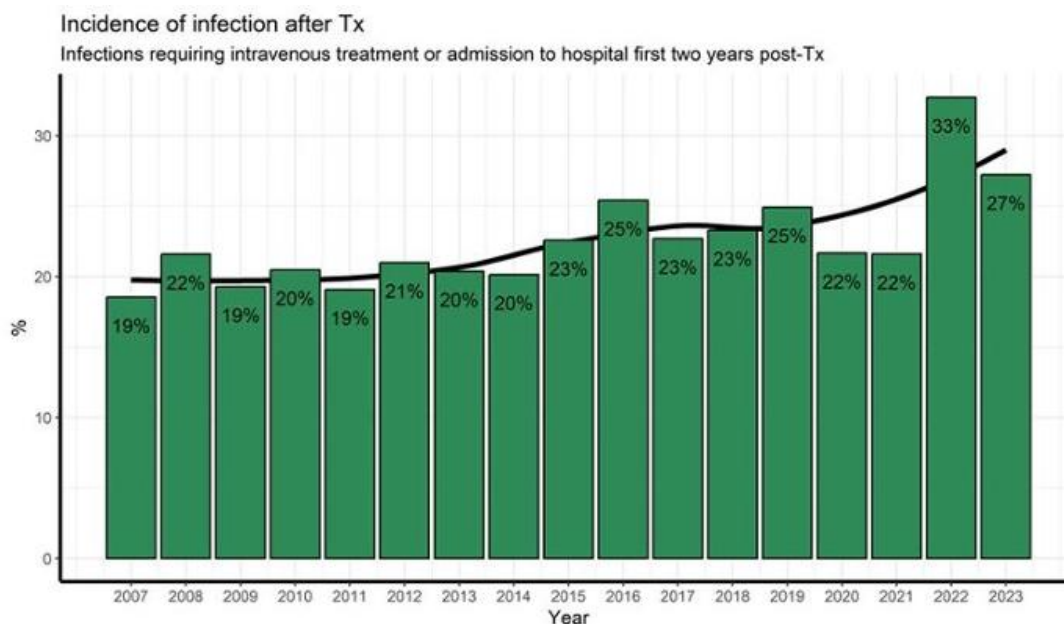
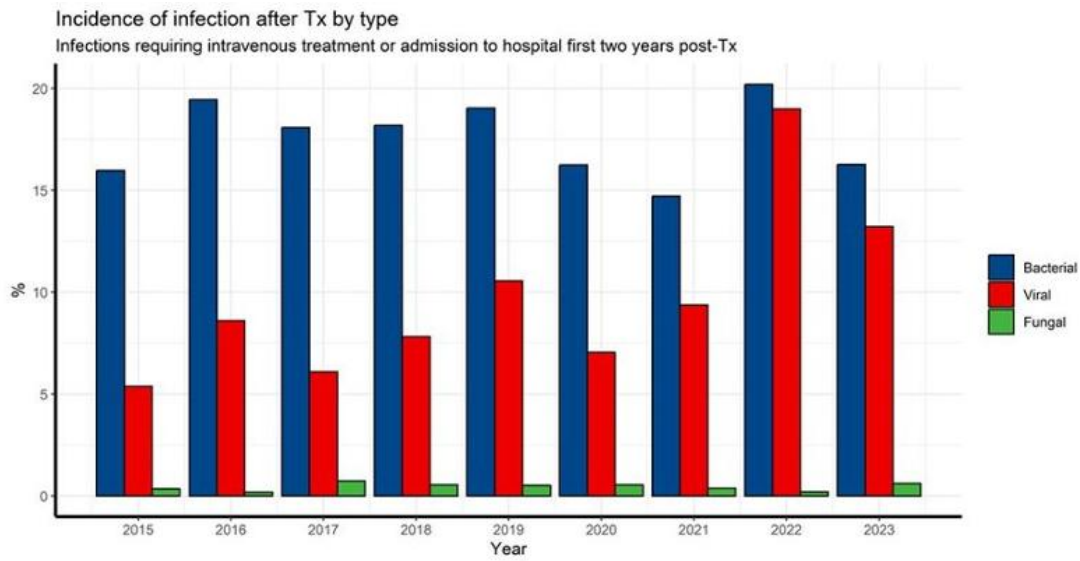


Figure 47: Incidence of infection after transplantation by pathogen

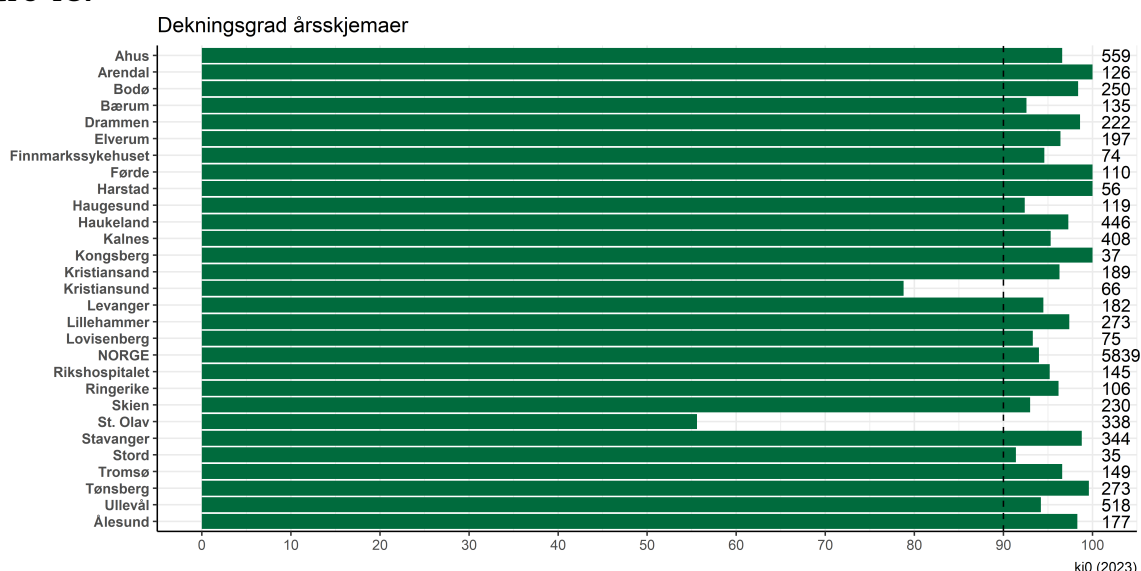


Quality indicators:

The registry has 22 quality indicators that will be followed year by year to assure the quality of the treatment. These data are presented interactively at this site (<https://www.kvalitetsregistre.no/registeroversikt/norsk-nyreregister/>) 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>).

During 2023 (and 2024) the quality indicators have been revised (**see Appendix**). New variables have been included in the reporting form to make it possible to differentiate if the primary aim of the treatment is life-prolonging or symptom-relieving. The current quality indicators are best suited for patients for whom the aim is to prolong life. To assess quality in patients receiving symptom-relieving care, PROMs will be included in the 2025 version of the MRS platform. A short summary of the quality indicators is presented in this report (**see Appendix**) and is based on a reporting coverage as shown in **Figure 48** below. We have also included 2023-results of the revised indicators, when possible, to outline the differences and prepare for next year's annual report.

Figure 48:



Quality projects

Standardization of non-neoplastic kidney biopsy reporting:

The scientific group for non-neoplastic kidney pathology has since year 2020 worked with the standardization on how to report non-neoplastic kidney biopsies. The specialist group has drawn up a specification for a standardized and structured response report for non-neoplastic kidney biopsies. The specification contains a structured data set that defines mandatory and optional content in each pathology report. The register pathologist and data from the registry have been instrumental in this work. The specified structured data has then been used to create the data set for the new MRS database for the register.

COVID-19 status:

Information about SARS-CoV-2 IgG status and vaccine response has been a focus for the registry during the pandemic. The data has been vital for relevant information to patients as

well as the health-authorities how to best deal with this virus in our high-risk population. For many reasons has the reporting of COVID-19 not been complete in 2023. Deaths attributed to COVID-19, reported by the treating physician, is however still of high quality and shown in **Table 15** below.

Table 15: Number of deaths attributed to COVID-19 by treatment modality

	2020	2021	2022	2023	Total
Tx	5	20	57	13	95
Dialysis	3	2	11	4	20
CKD5	0	1	4	3	8
Total	8	23	72	20	123

Method for blood pressure measurement:

The register collects information on blood pressure from all patients each year. As a follow-up on the quality project of blood pressure treatment in kidney transplanted patients, we now also collect the method used for the reported blood pressure. In **Table 16** the methods for blood pressure measurement are reported by treatment modality, CKD5, dialysis and kidney transplants. Home measurement and 24-hour ambulatory are the preferred methods, and the aim is to increase the use of these methods as they better describe the relevant blood pressure for long-term outcomes compared to attended office blood pressure.

Table 16. percentage of different blood pressure methods used for the reported blood pressure in 2023 annual forms.

	Total (n:5533)	CKD5 (n:442)	DIAL (n:1652)	Tx (n:3439)
Office present	85%	84%	95%	79%
Office alone	7%	8%	2%	9%
24-hour ambulatory	1%	1%	0%	1%
Home measurements	7%	5%	2%	10%

Blood access when starting hemodialysis:

In the 2022 annual report this was presented: *The register collected information on reasons for not starting hemodialysis with AV-fistula as blood access. The data clearly indicate that the target figure is set too high, as AV fistula is not possible for medical reasons in many patients. In consultation with the renal community, work has continued to adjust the quality indicator to better describe the quality of the health care provided. The Faculty Council will continue this work in 2023.*

A result of the work is that we now collect on the annual form both which blood access is considered best for the individual patient and if this is the blood access used. In 2023, for patients treated with dialysis to prolong life, and not just relieve symptoms, AV-fistula was considered the best choice for 60%, catheter for 39%, and graft for 1%, and 83% of patients were treated with their supposedly best blood access. **Figure A-58** in the "Appendix; quality indicator results" below also show these results.

CMV preventive strategies in kidney transplantation:

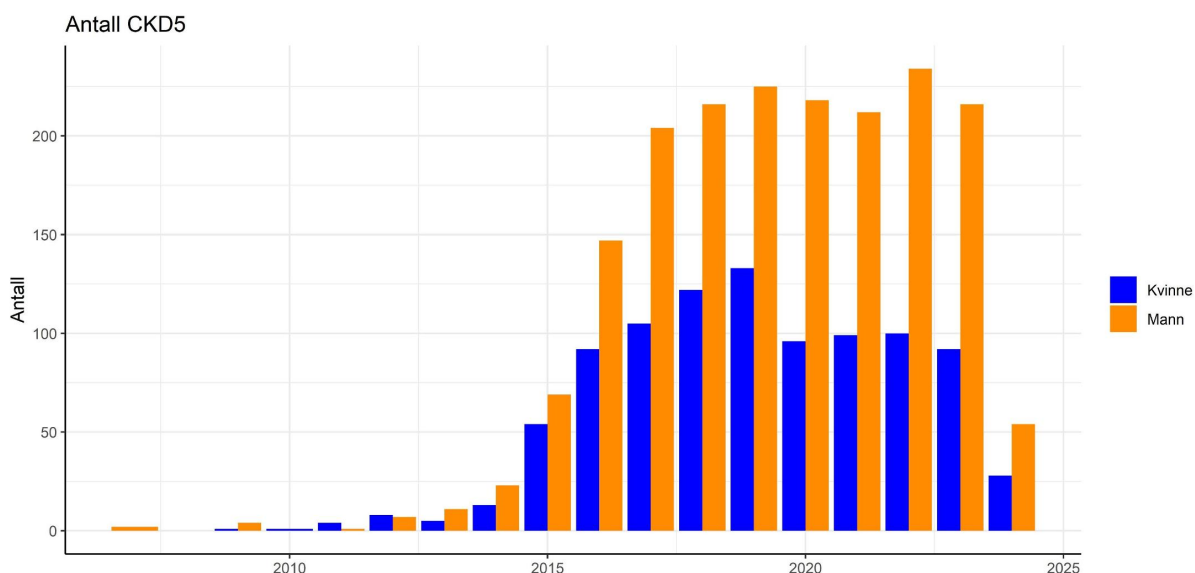
The register presented last year comprehensive data on CMV infections after transplantation differentiated on type of preventive strategy (prophylaxis versus preemptive treatment) in high-risk patients (D+/R-) [Blom KB et al. *Transplantation* 2023; 107(8): 1846-1853]. As a further follow-up on this finding, it has now been investigated if a new method to determine cellular immunity against CMV (CMV-IGRA) may be better suited to define patients at risk for a subsequent CMV infection compared to standard CMV-IgG serology. The main finding was those of the D+/R- patients that were still CMV-IGRA negative one year after transplantation had a higher risk of later CMV infection [Blom KB et al. *Frontiers in Immunology* 2024; 15: 1414830]. These data have been central in the revision of “*The fourth international consensus guidelines on the management of cytomegalovirus in solid organ transplantation*” that will be published early 2025.

Quality project to investigate sex differences:

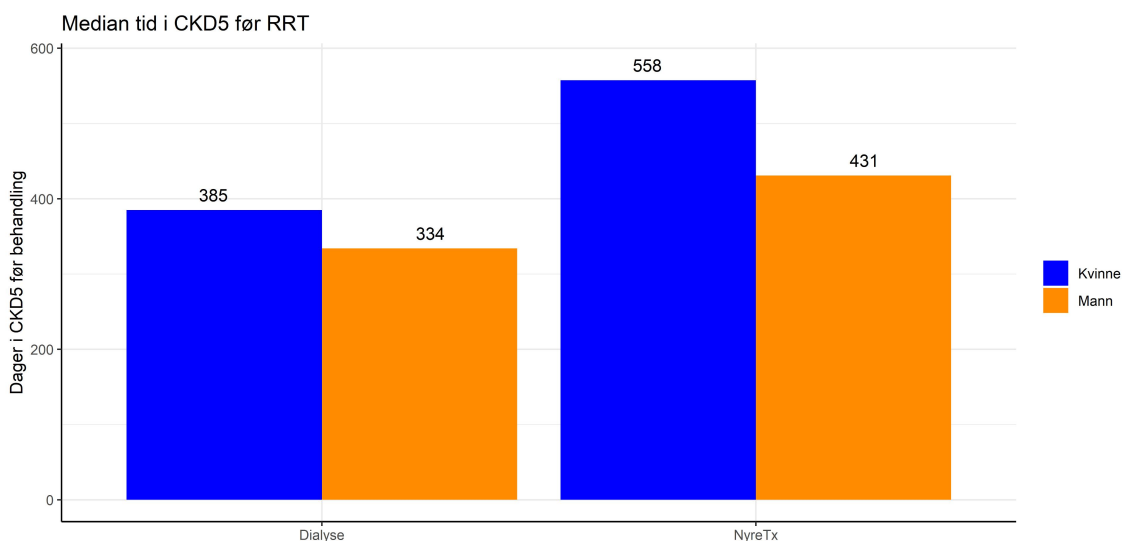
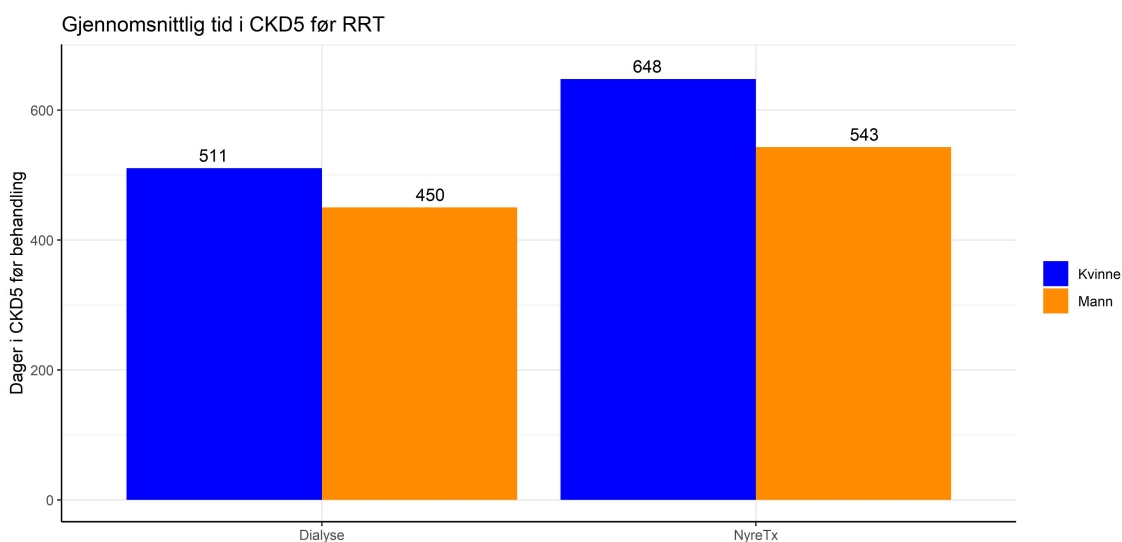
In 2023, an overview article on differences in the epidemiology and outcome of kidney disease between men and women was published in the journal Nature Reviews - Nephrology. In short, the evidence base for differences in risk and outcome is mixed, and largely related to differences in the etiology of kidney disease. The prevalence of chronic kidney disease (CKD) in stages 3-5 is higher in women, but the prevalence in stages 1-5 is higher in men. Men more often experience a more rapid decline in kidney function, which can result in a greater risk of kidney failure. The authors attribute this to a greater prevalence of unhealthy lifestyles and behaviors in men, which in turn is reflected by the higher prevalence of albuminuria. This is important, as the division for stage of chronic kidney disease is not sex-specific, and sex-specific differences in albuminuria can contribute to different treatment and diagnosis due to different classifications of kidney disease. The authors also postulate that women experience more barriers to kidney transplantation, but that after transplantation they have better outcomes than men, which contributes to an approximately equal prevalence of transplantation between the sexes.

To investigate whether this also applies in Norway, the register has carried out a quality project by investigating differences in incidence, treatment and outcome of kidney disease in Norway between men and women. We present here the results from our analysis, based on data from the Norwegian Renal Register, briefly summarized. The analyzes are limited from the introduction of modern immunosuppression in 2007 to recent times.

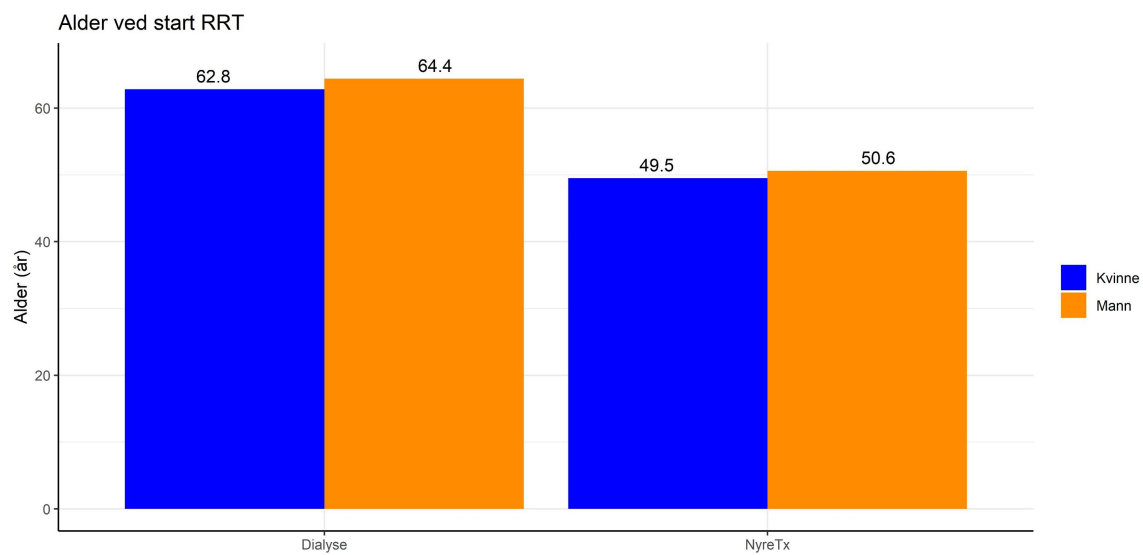
As is well known, the incidence of CKD5 chronic kidney disease is higher in men than women.



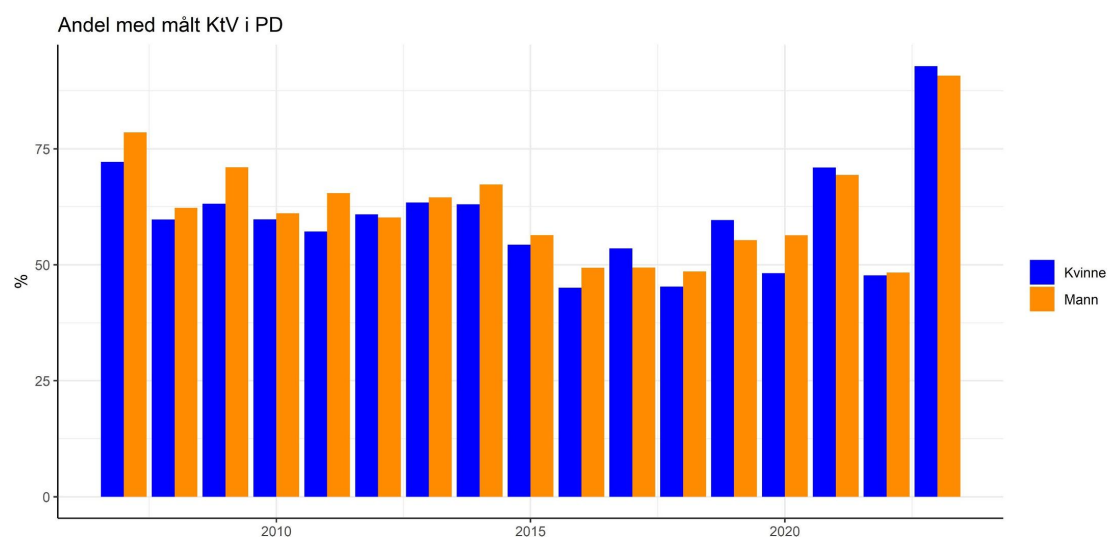
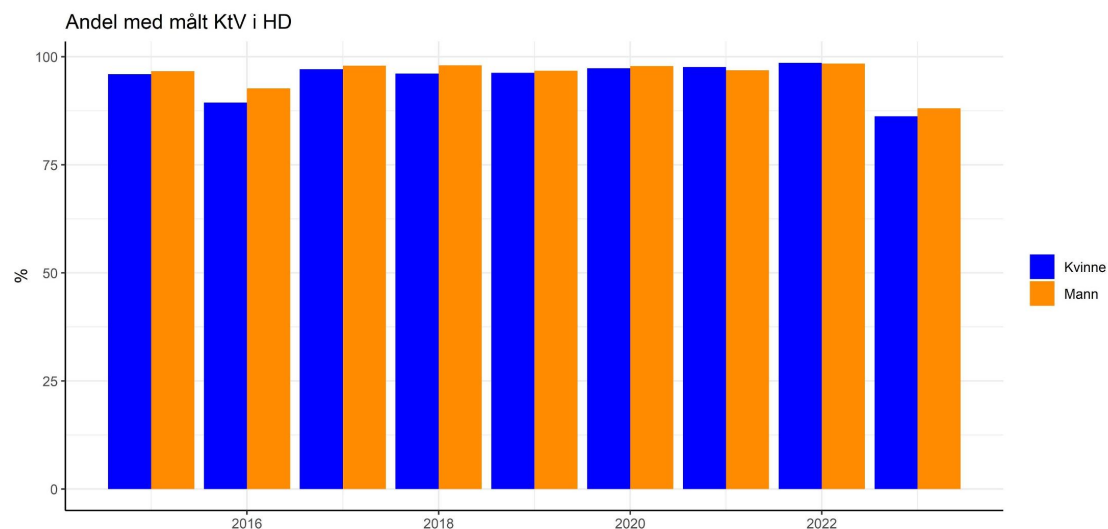
From the time the patient is reported as having CKD5 until they start kidney replacement therapy, the time is somewhat longer for women than for men, both as an average and median.



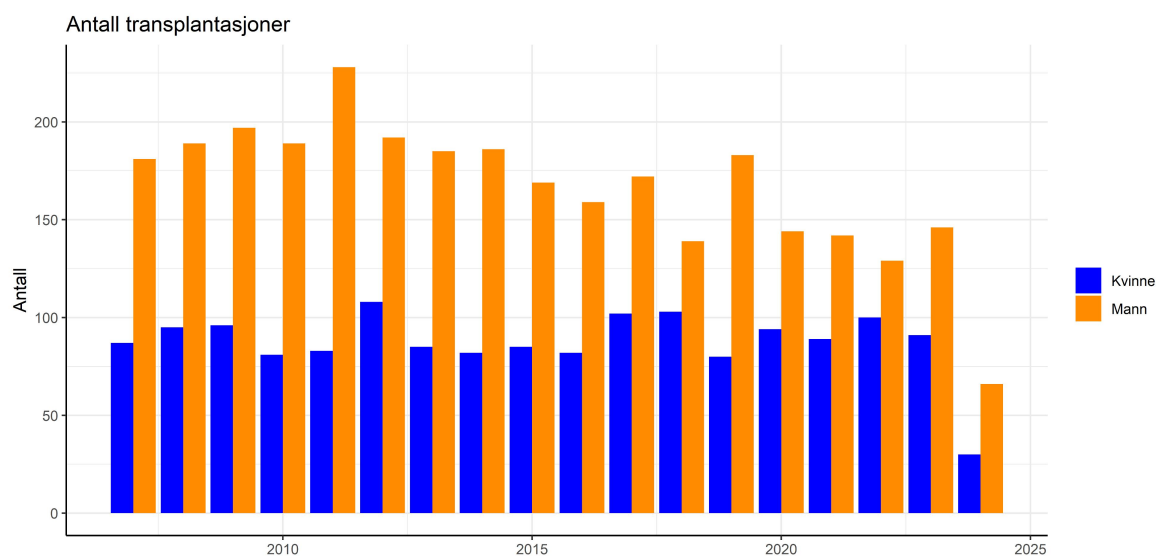
The patient's age at the start of kidney replacement treatment is similar for the sexes.



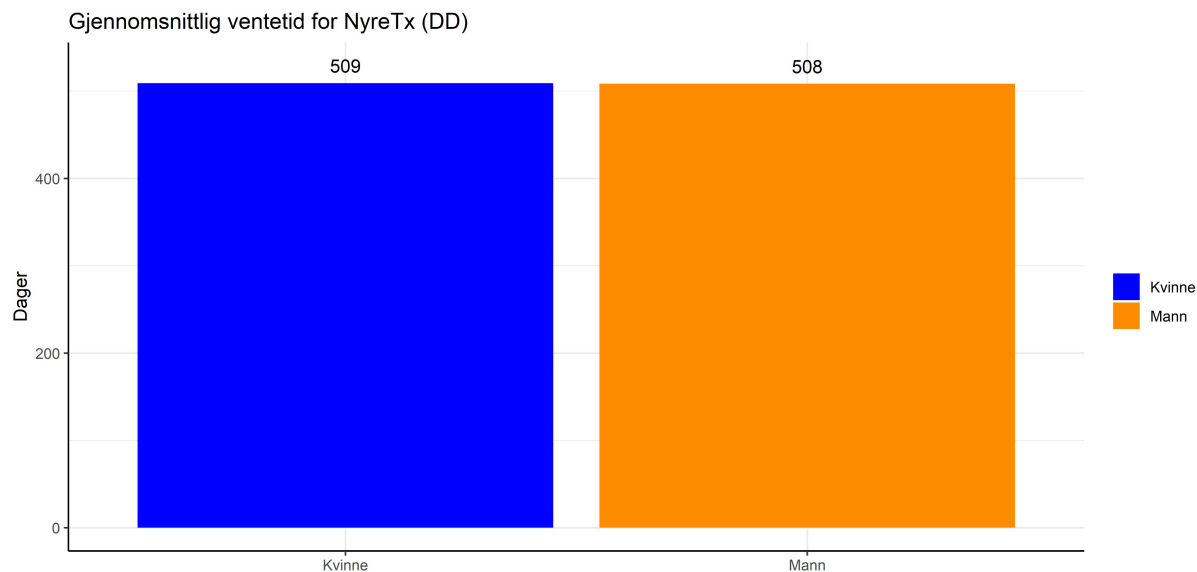
The quality and availability of dialysis is roughly the same between the sexes.



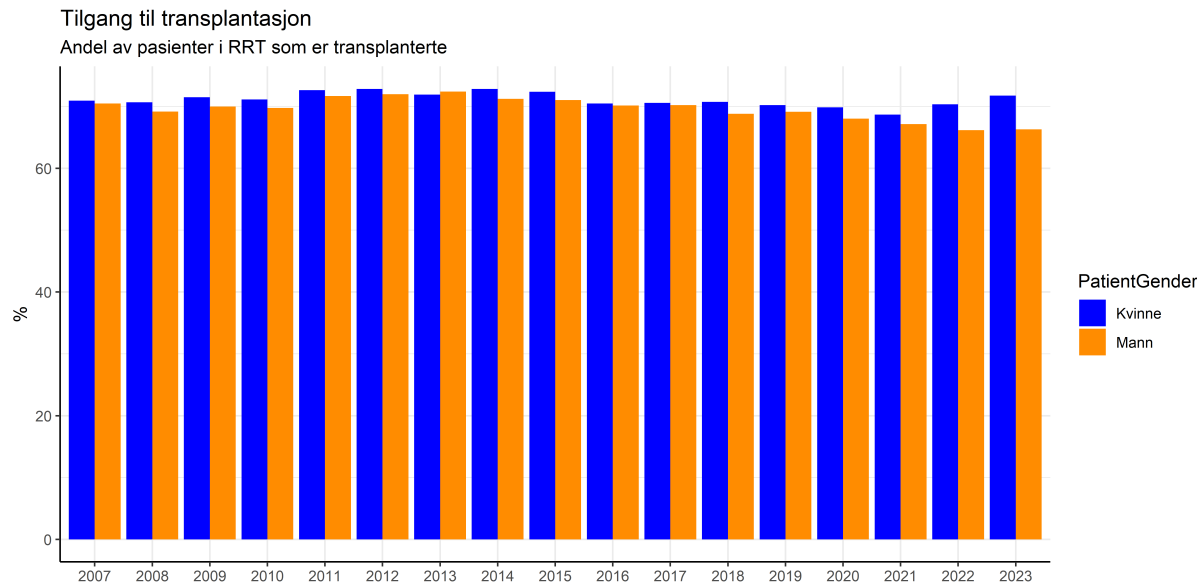
As there is a greater proportion of men who develop CKD5, the incidence of kidney transplantation is higher for men than for women.



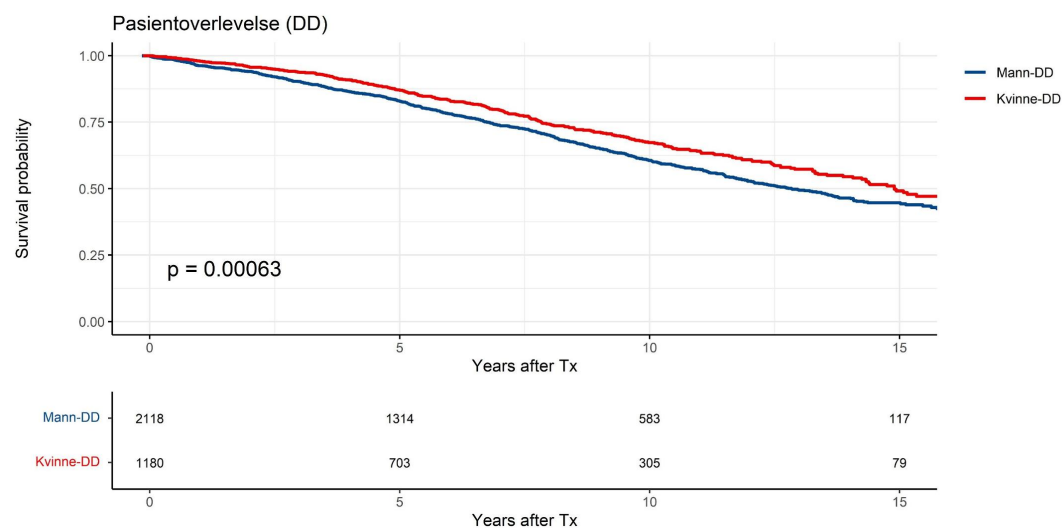
Nevertheless, time on the waiting list for transplantation with a deceased donor is the same for men and women. This is despite that women are more prone to be immunized against HLA during pregnancies.



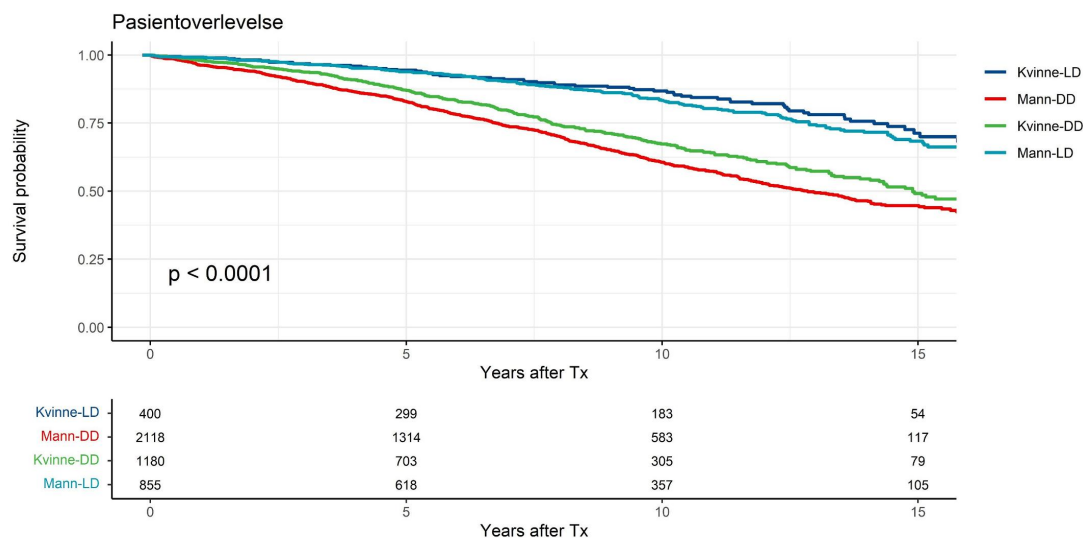
Access to transplantation as kidney replacement treatment is also similar for both sexes.



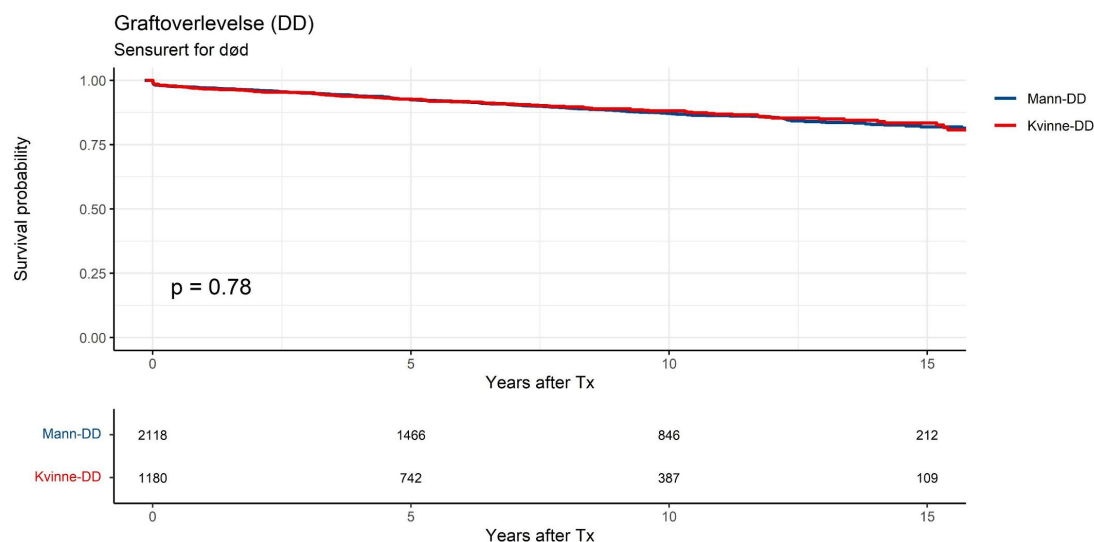
Patient Survival in the case of a deceased transplant is somewhat higher for women than for men.



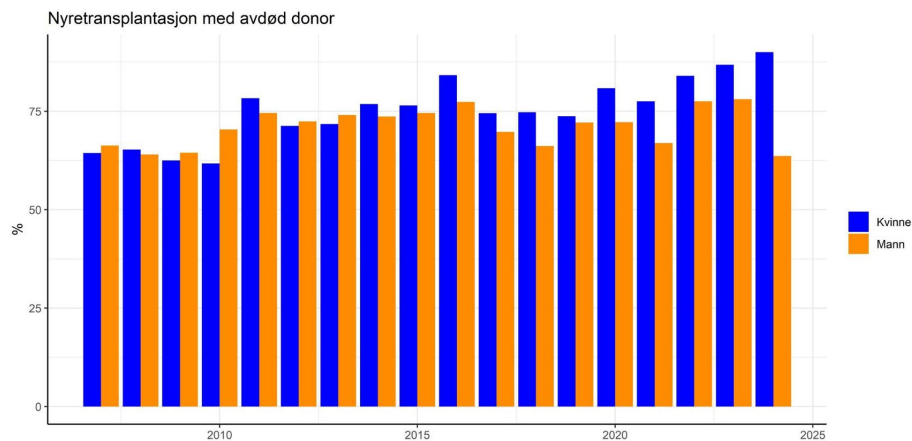
There are less differences between sexes for living donor transplantations.



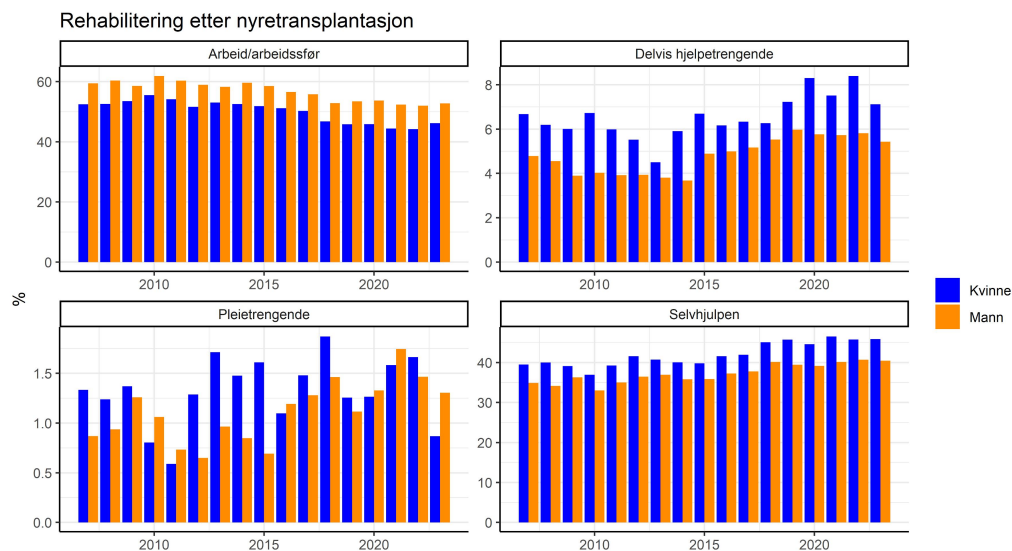
However, there are no differences in censored graft survival in the case of a deceased donor between the sexes.



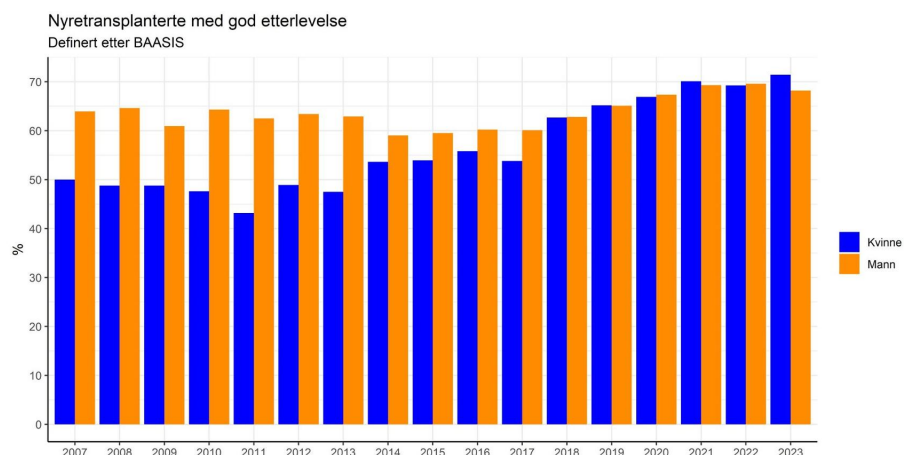
The proportion by gender transplanted with an organ from a deceased donor is roughly the same.



After a kidney transplant more men are in the category of “able to work” than women.



Immunosuppressive drug adherence was somewhat higher for men in the period 2007-2016, but there has been a change and recently there is no marked difference between the sexes.



In conclusion, these results show that there is not a predominantly greater burden of kidney disease and transplantation in one of the biological sexes. There is a known higher incidence of CKD5 in men, also in Norway. Nevertheless, this has not led to sex differences in survival, time as a chronic kidney disease patient before start of replacement therapy, or access to dialysis or transplantation.

[A quick look on new variables in the registry](#)

The registry contains a lot of data that is not presented in the annual report but available for quality and research projects. During the last years we have added a few new variables that is presented below.

Hypoxia-inducible factor inhibitors: From the erythropoietin stimulating agents (ESA) we have separated hypoxia-inducible factor (HIF) inhibitors into a new variable. For CKD5 patients the split between ESA and HIF is approximately 25:1. The same ratio for dialysis is 664:1, and no kidney transplant recipients are reported to use HIF over ESA.

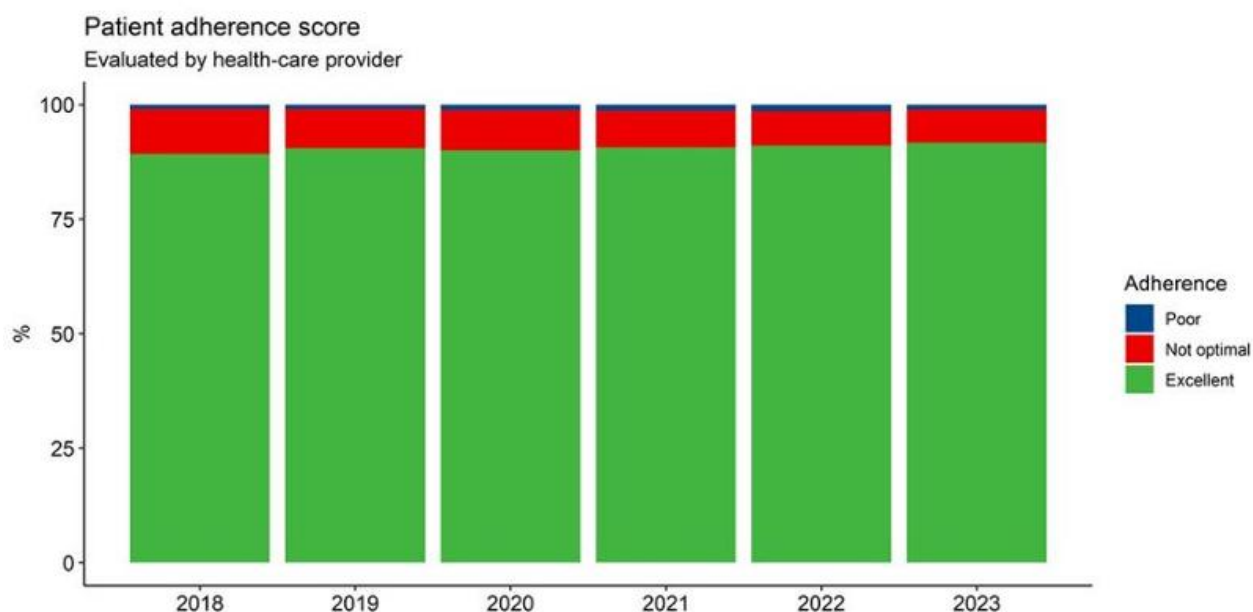
Calciphylaxis: We have now included calciphylaxis as one of the events that should be reported. So far, there have been no reported cases of calciphylaxis in 2023.

Planned dialysis modality / Referred to KTx: For patients in CKD5 without KRT we now also ask if the dialysis modality has been planned already, and if they are transplant candidate also if they have been referred for transplantation. Of the 442 CKD5 patients with an annual report form in 2023, 288 (65%) had a plan for dialysis modality. Of all CKD patients, 155 (35%) were considered a transplant candidate and 91 (59%) of these were referred for kidney transplantation.

Symptom relieving dialysis: To improve the analysis of dialysis quality indicators a variable on the treatment goal for the individual patient, either *life-prolonging* or *symptom-relieving*, was included. Of all patients, dialysis treatment was considered symptom-relieving in 8% (8% for center HD, 0% for home-HD and 10% for PD).

Adherence to immunosuppressive drugs: Over the last years the treating healthcare provider has been asked about their impression on patients' adherence to immunosuppressive drug treatment. This variable was included to be used as a risk factor when looking at graft- and patient survival. It is still too short follow-up time to make these analyses but the distribution between the three alternatives; *excellent*, *not optimal* and *poor* is presented in **Figure 49**.

Figure 49. Health care provider scoring patient adherence over time.



Concluding remarks:

The reporting of patients in CKD5 without KRT is very variable between centers and needs to come up to the coverage level of the rest of the registry. Coverage analysis for the period 2019-2023 together with NPR is ongoing and results are anticipated early 2025.

The registry has been quite busy working with the transition to a new database (MRS) during the year and annual data from 2023 is reported electronically in MRS for the first time. With the new system each center now has their own local registry where they can make center-specific analyses.

An area of improvement is the completeness of the pathology reports submitted to the registry. As shown in **Figures 16 and 17** there are areas where a definite diagnosis and stage is not possible to determine as a result.

During the years as a combined registry (since 2016) intensive work has been made to get relevant quality indicators. They have now gone through considerable revision and the new version is presented in the present report. It will be interesting to see how they develop in the years to come.

An analysis presented in the present report show that there is no relevant difference between male and females when it comes to availability of kidney replacement therapy or the outcomes of these treatment modalities.

Registry data are 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. The total number of international peer reviewed publications from the registry are 344, of which 23 were published in 2023. In total 48 PhD-theses, of which three were in 2023, have at least partly been based on data from the registry.

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 the hard work over the entire country is GREATLY acknowledged!

Report completed 26.11.2024

Appendix; misc survival curves.

More Kaplan Meier survival curves is available by contacting the registry or the local center contacts.

Patient survival in RRT:

Figure A-1:

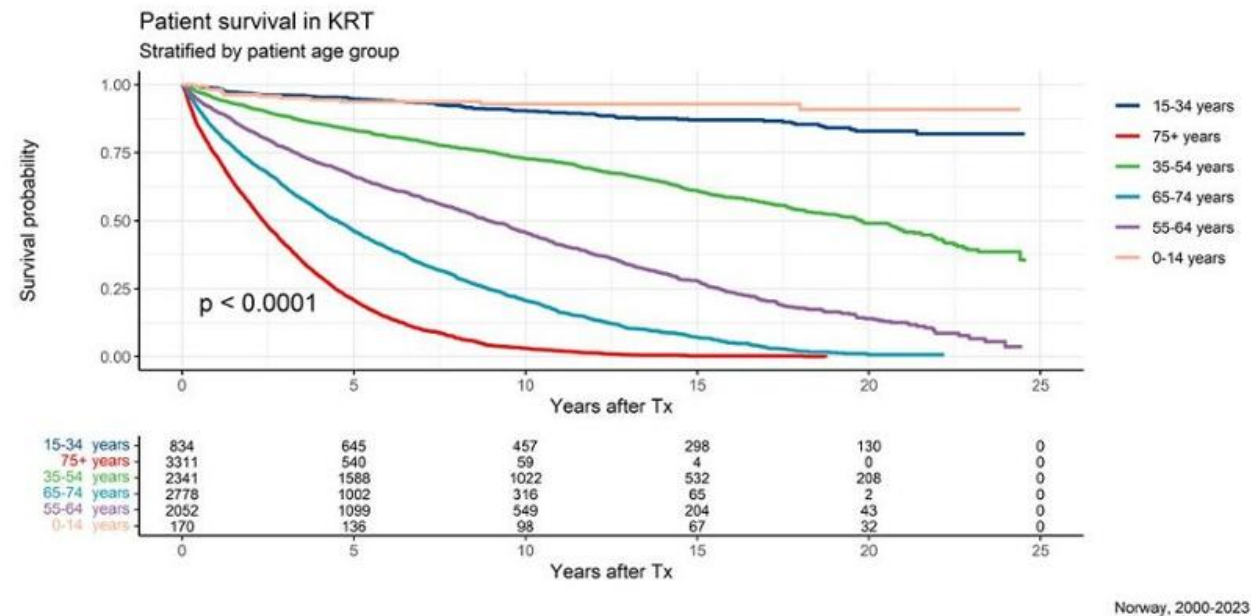
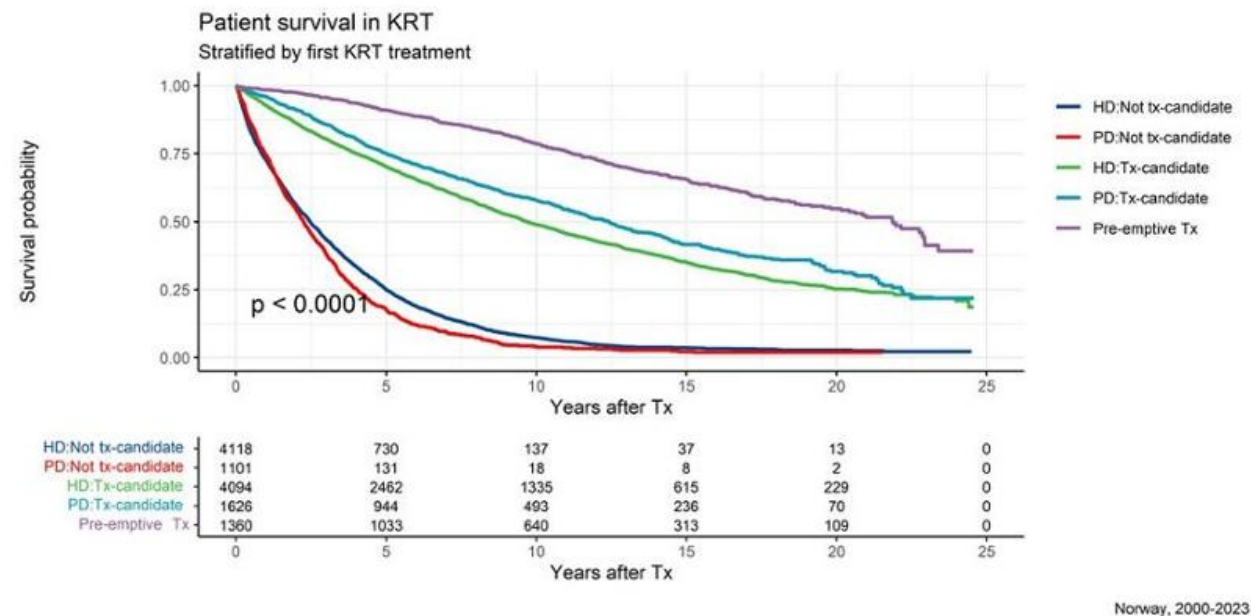


Figure A-2:



Patient survival after transplantation:

Figure A-3:



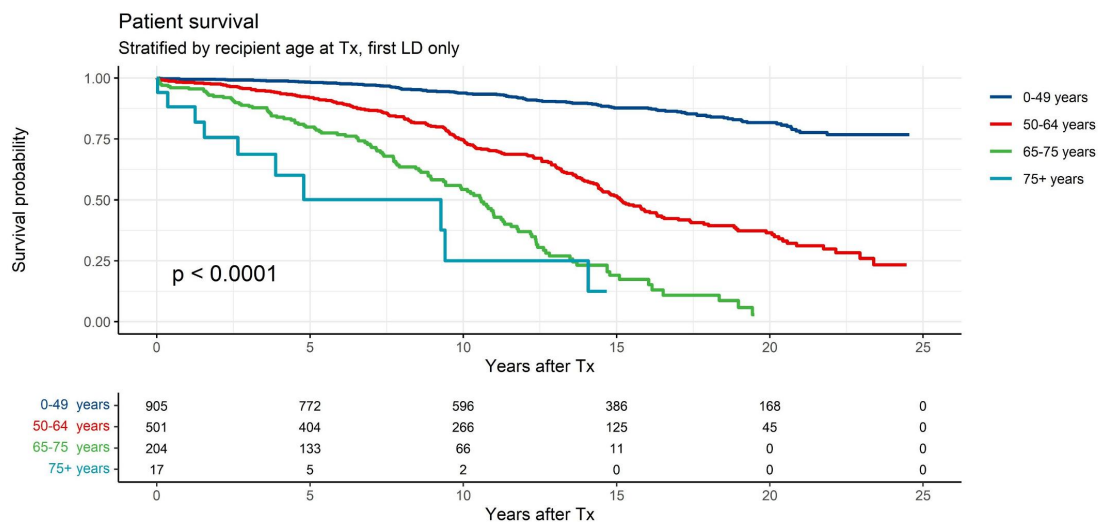
Norway, 2007-2023

Figure A-4:



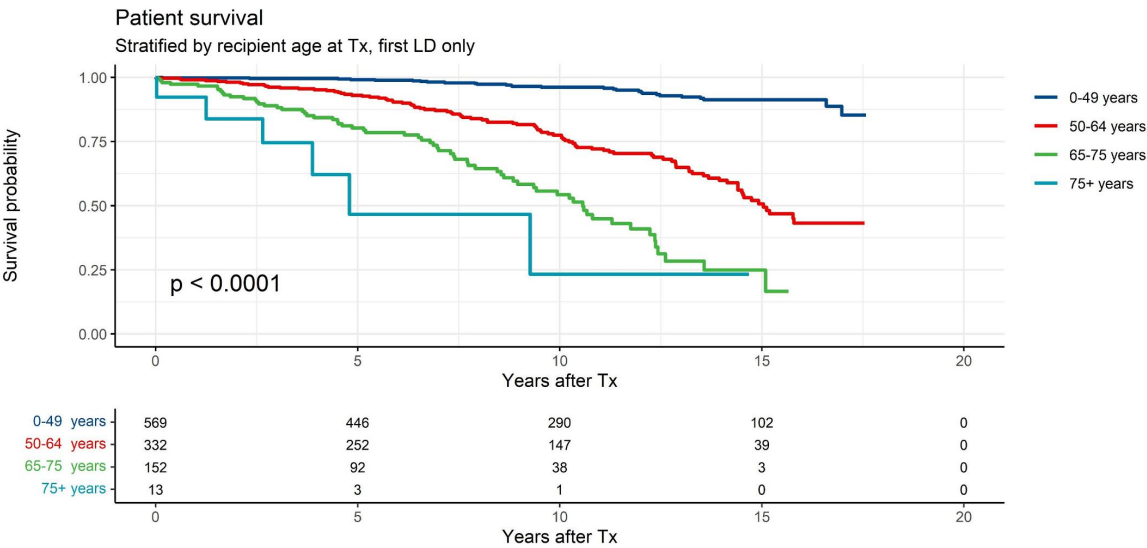
Norway, 2000-2023

Figure A-5:



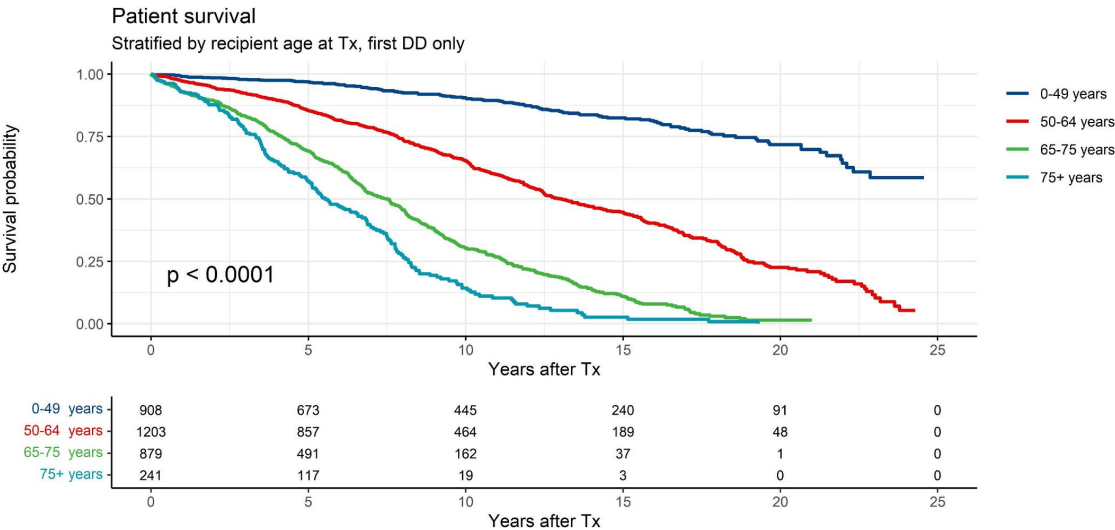
Norway, 2000-2023

Figure A-6:



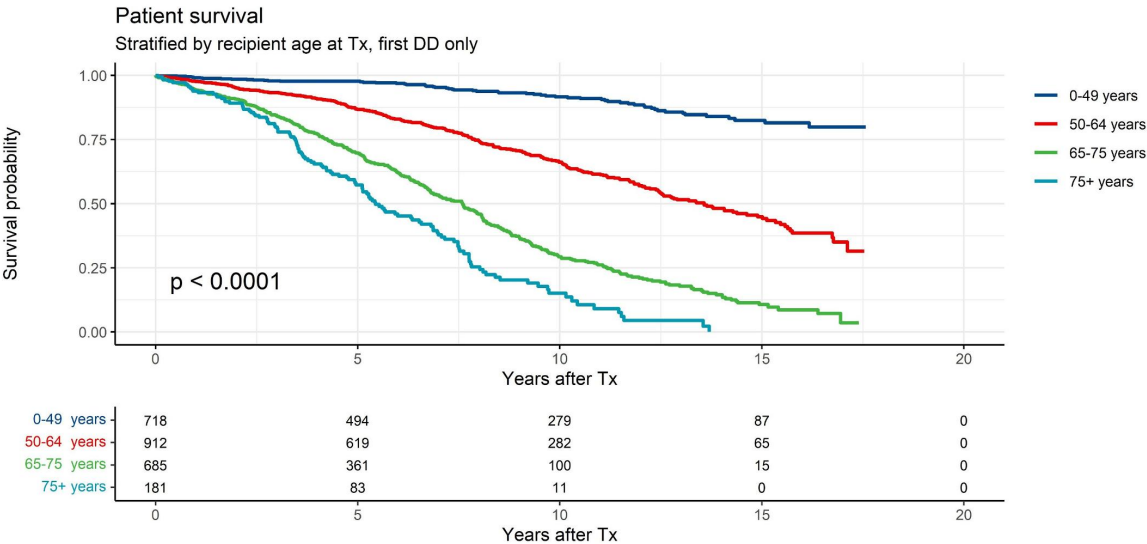
Norway, 2007-2023

Figure A-7:



Norway, 2000-2023

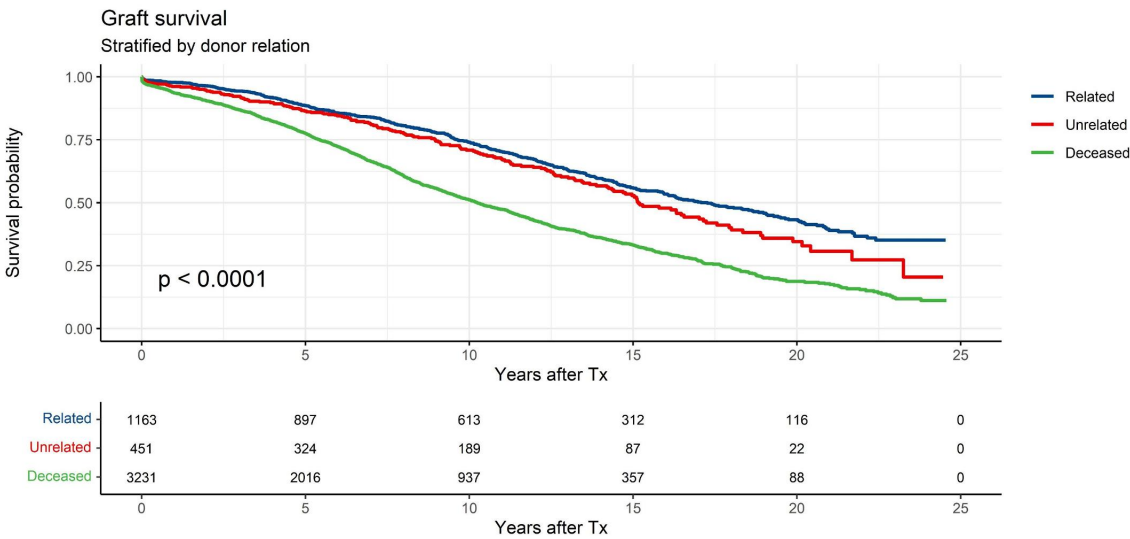
Figure A-8:



Norway, 2007-2023

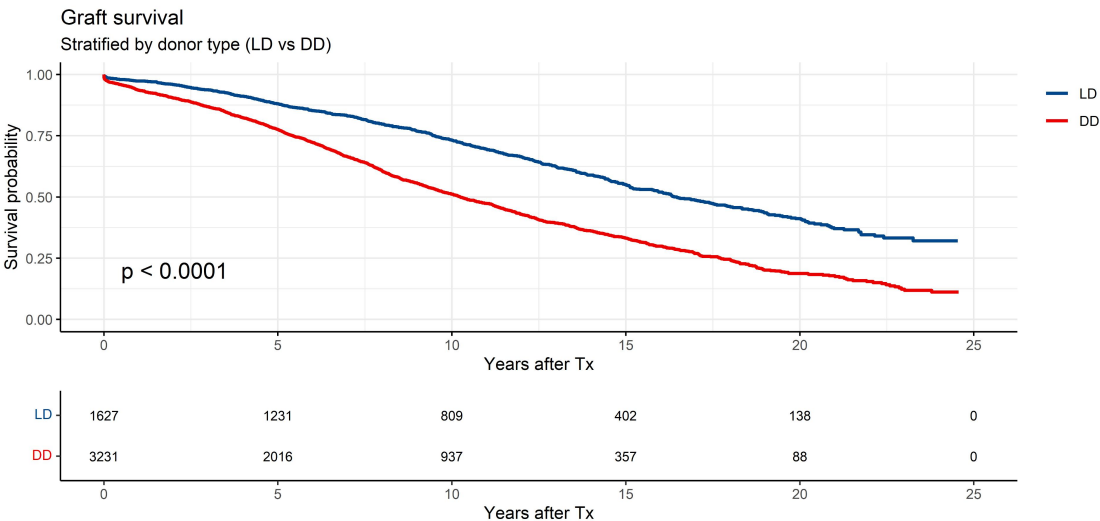
Graft survival after transplantation:

Figure A-9:



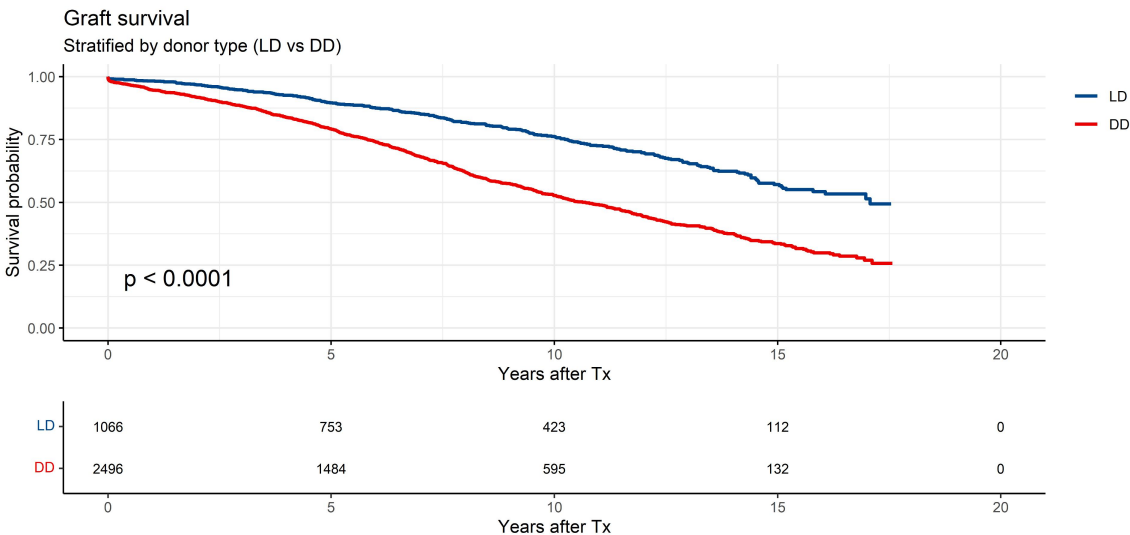
Norway, 2000-2023

Figure A-10:



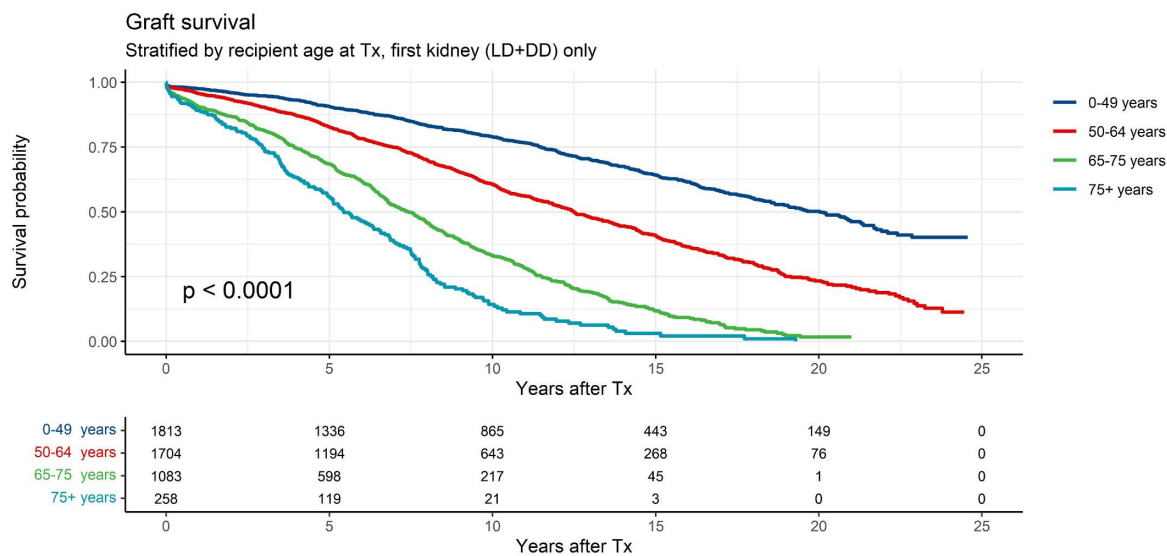
Norway, 2000-2023

Figure A-11:



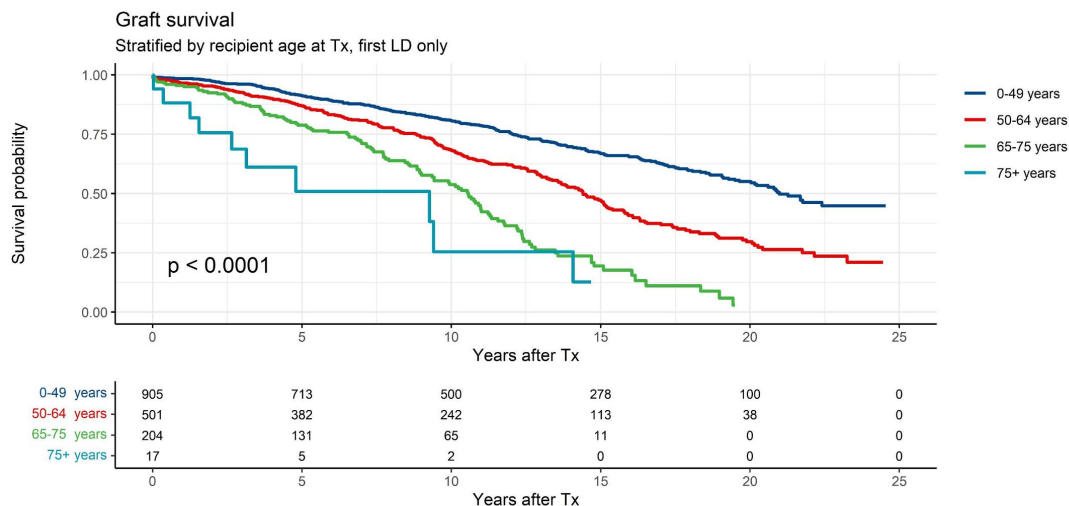
Norway, 2007-2023

Figure A-12:



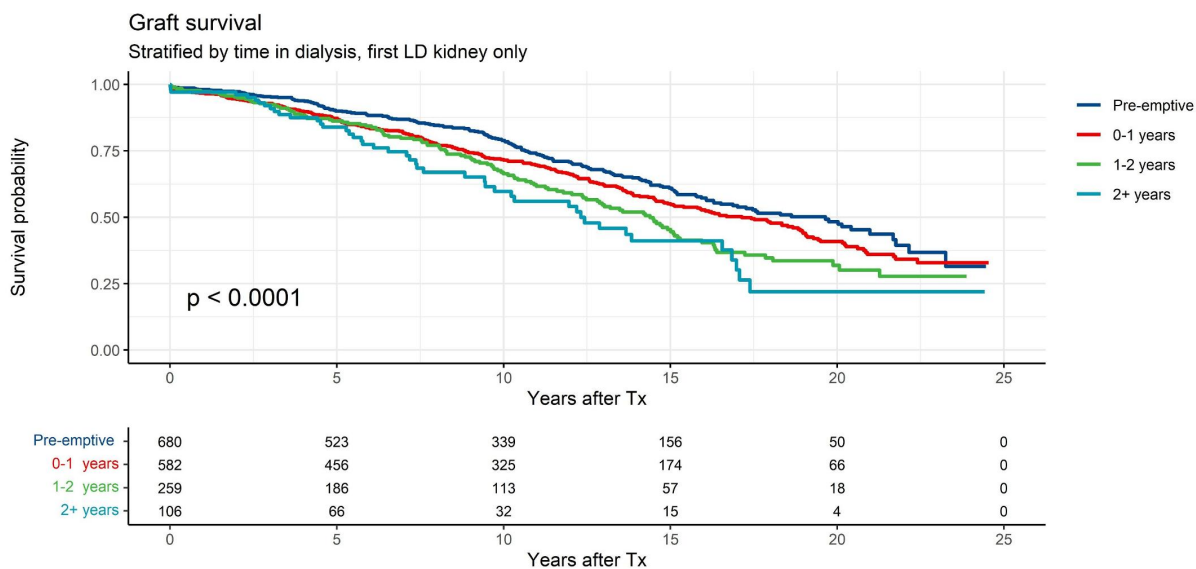
Norway, 2000-2023

Figure A-13:



Norway, 2000-2023

Figure A-14:



Norway, 2000-2023

Figure A-15:

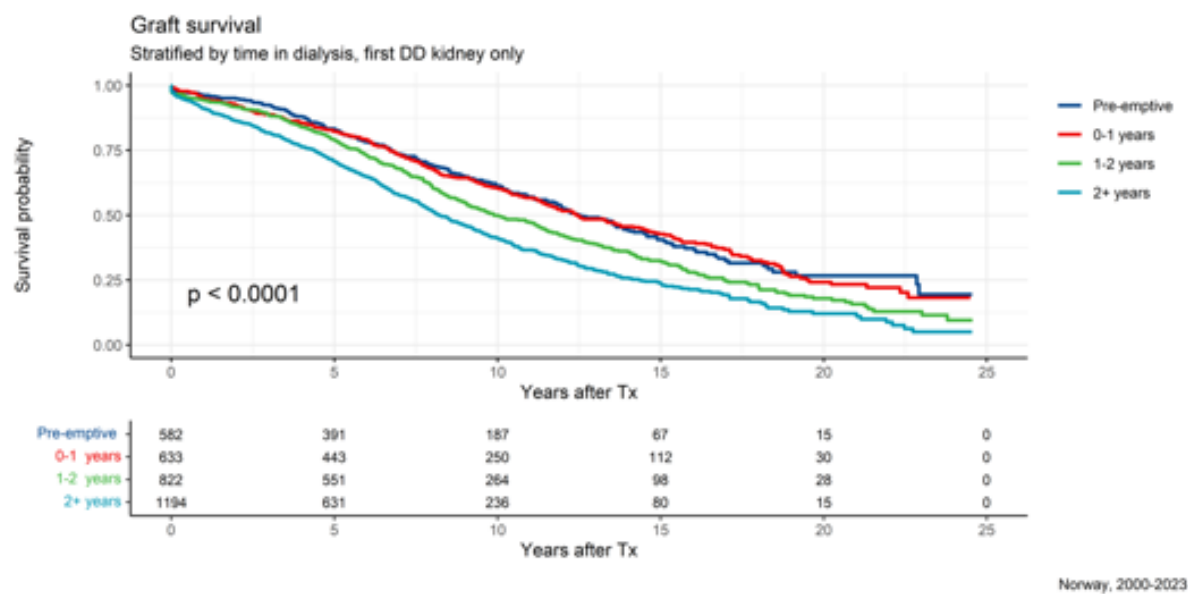


Figure A-16:

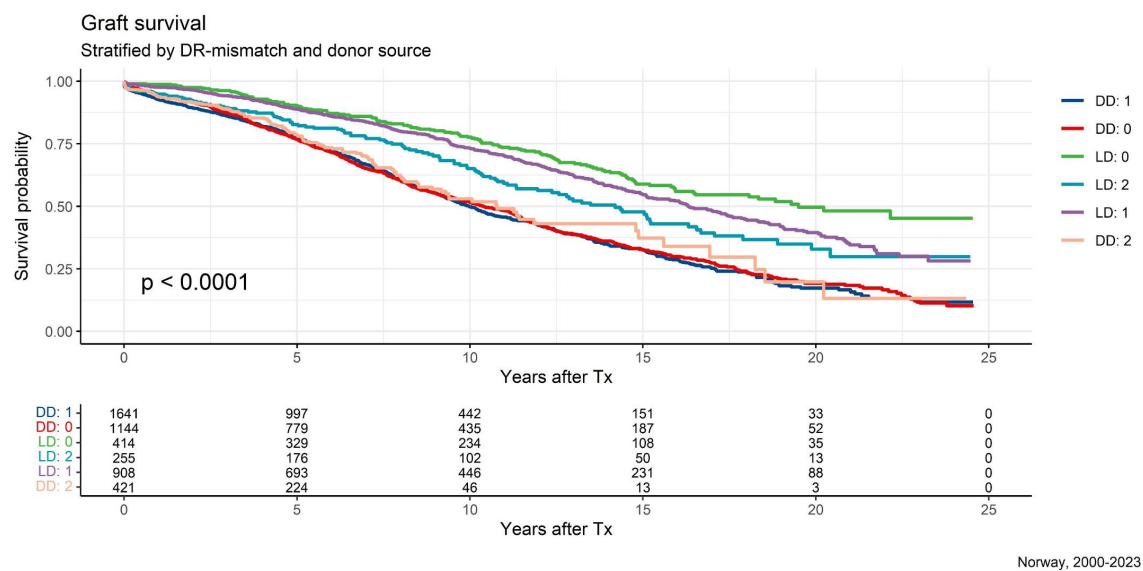


Figure A-17:

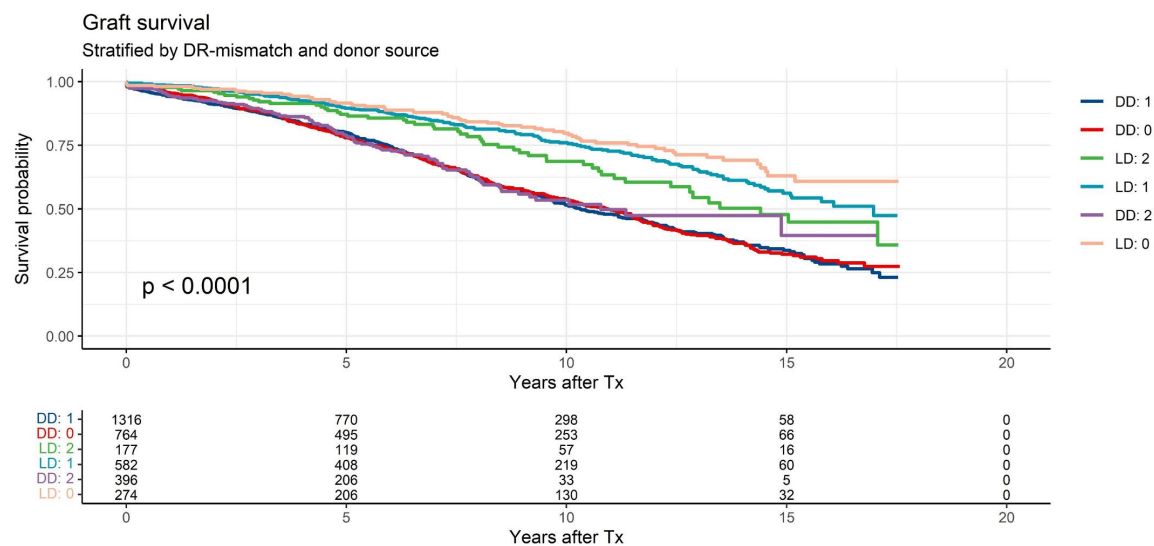
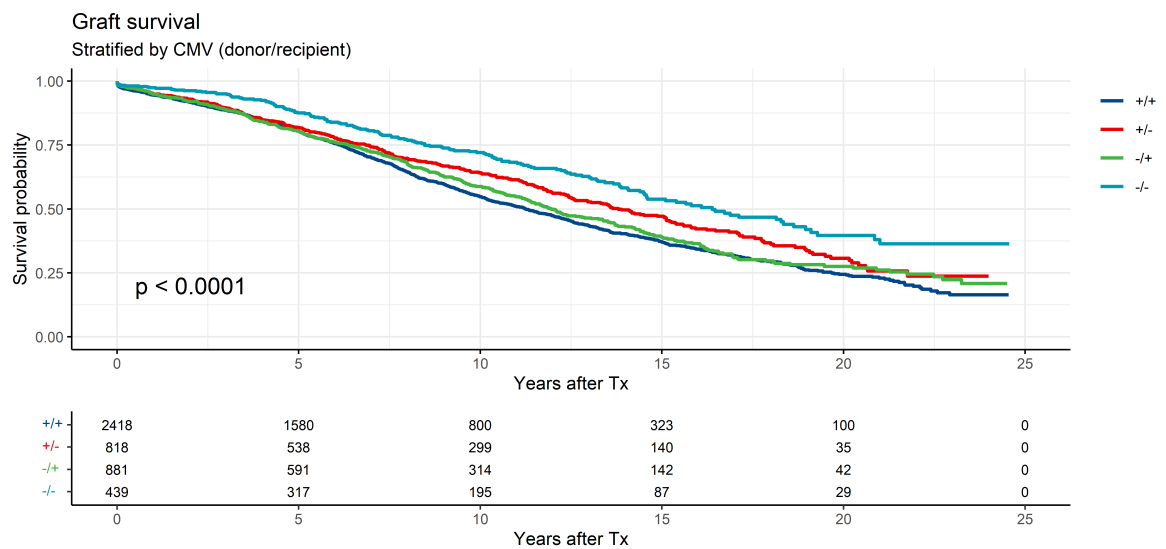
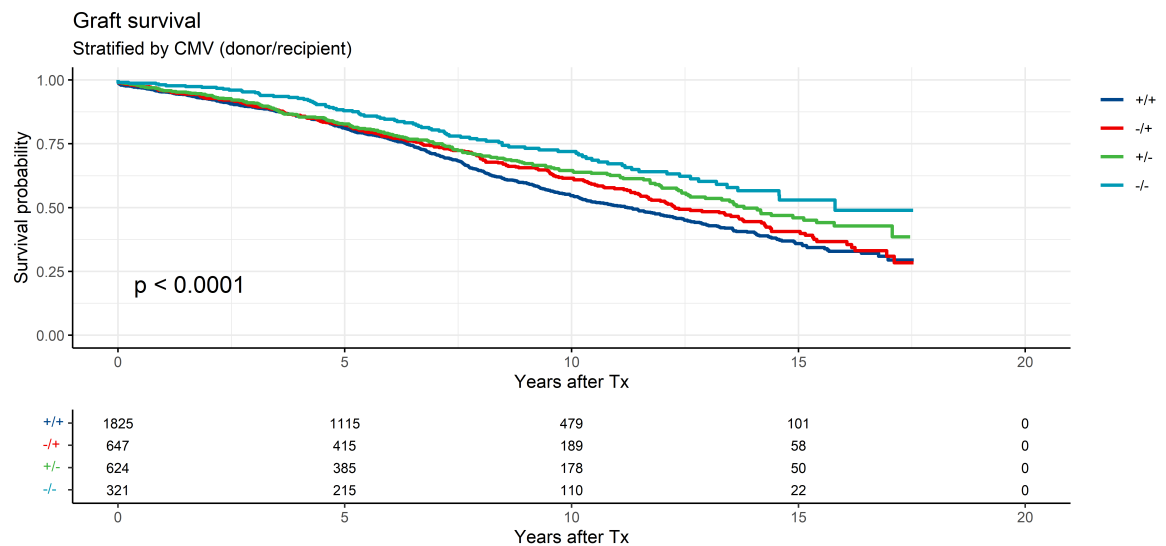


Figure A-18:



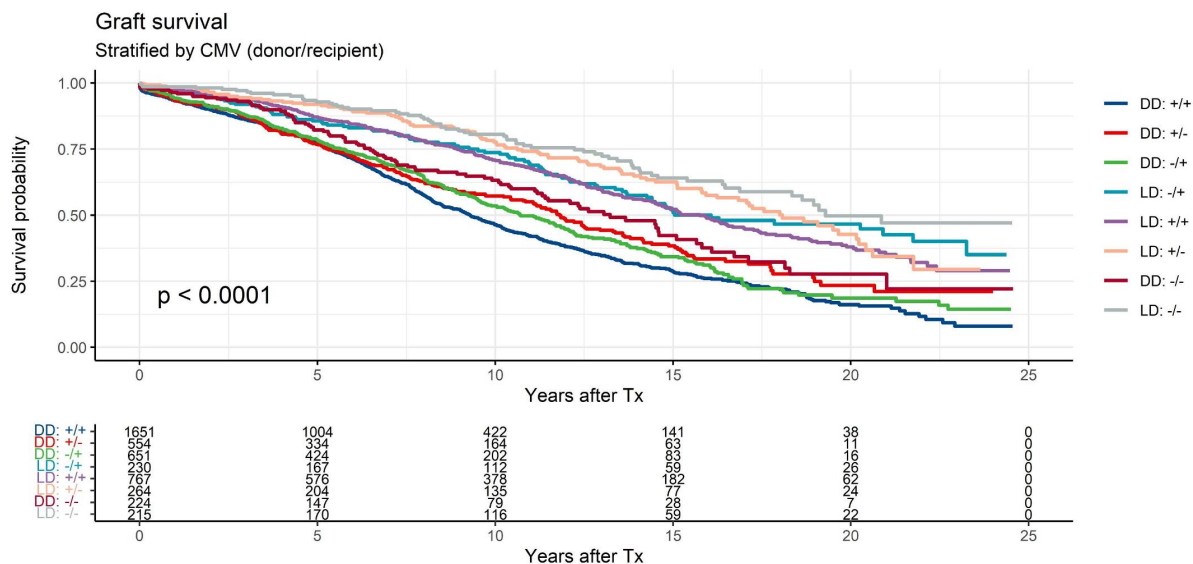
Norway, 2000-2023

Figure A-19:



Norway, 2007-2023

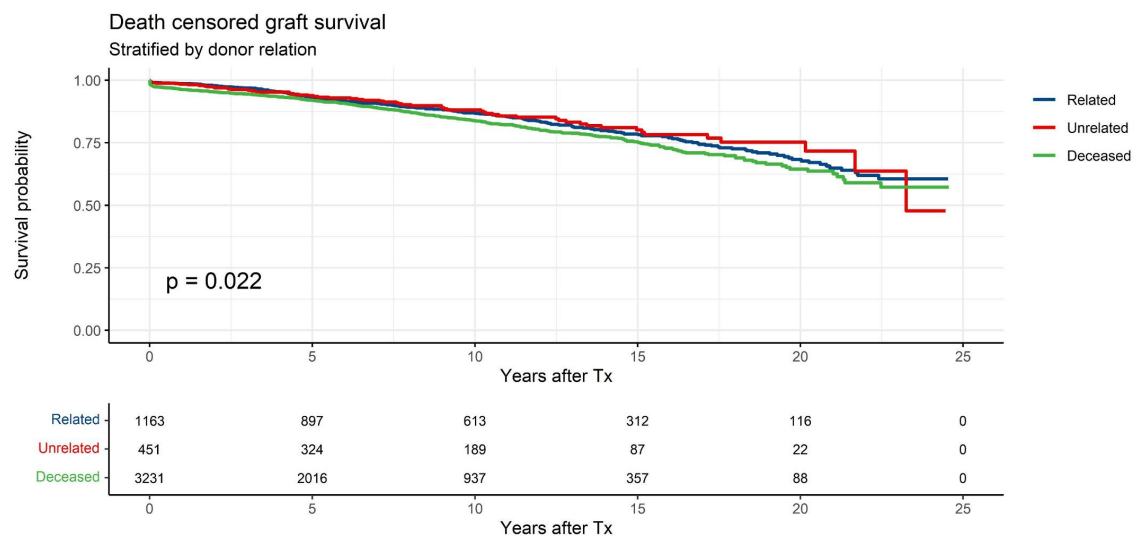
Figure A-20:



Norway, 2000-2023

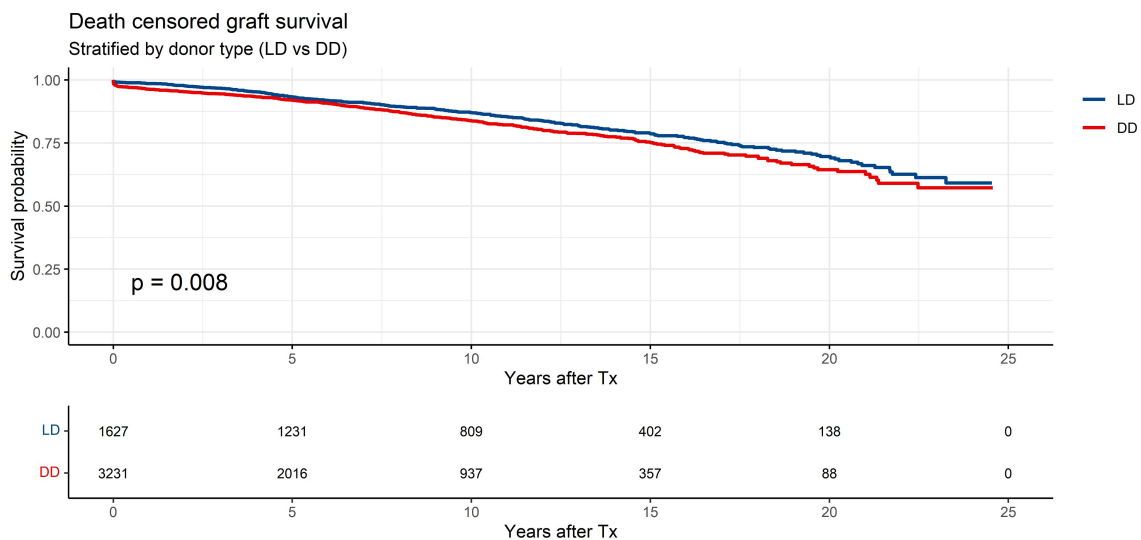
Death censored graft survival after transplantation:

Figure A-21:



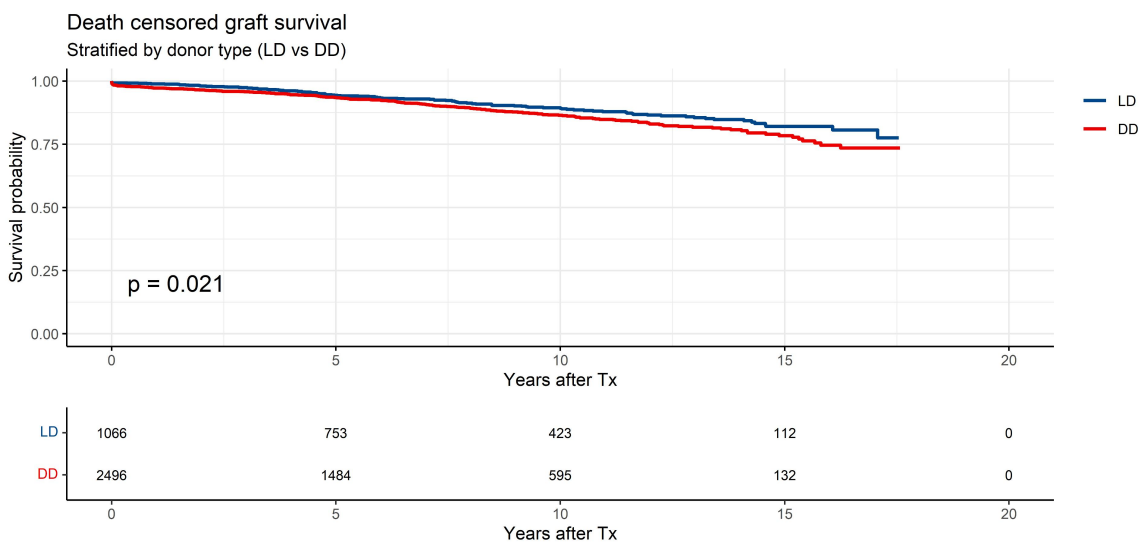
Norway, 2000-2023

Figure A-22:



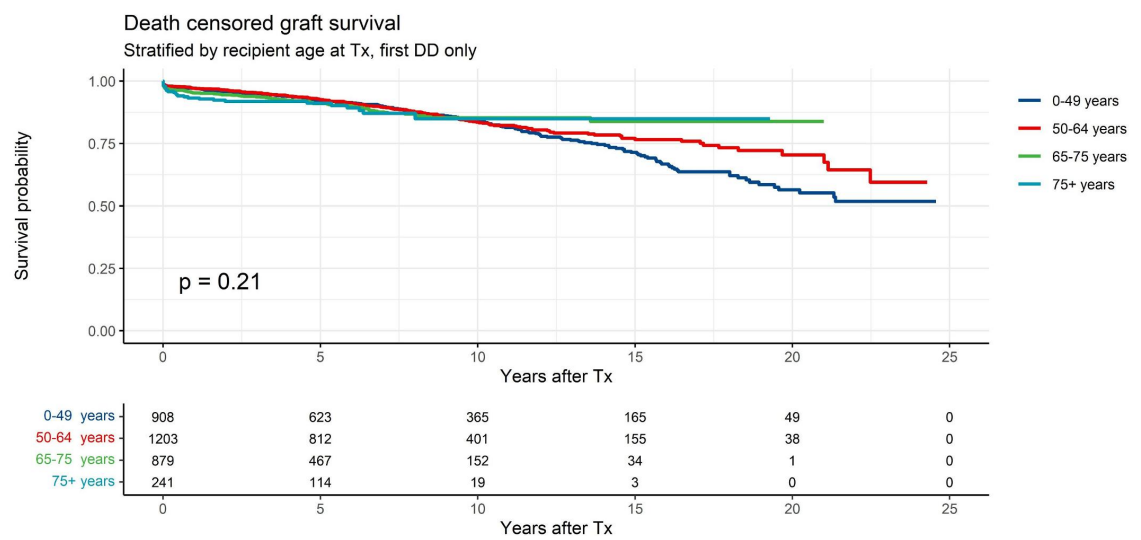
Norway, 2000-2023

Figure A-23:



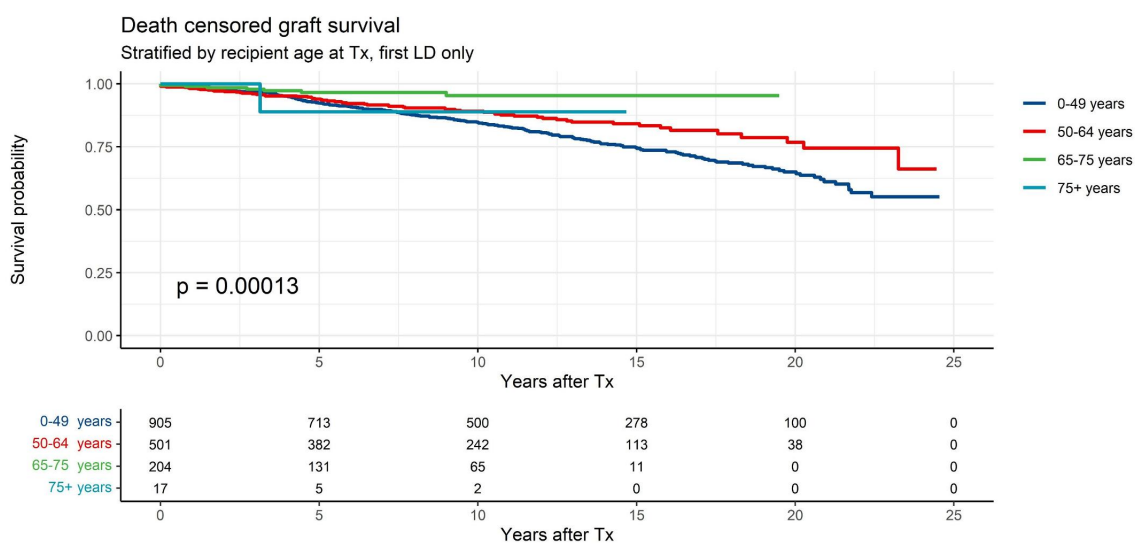
Norway, 2007-2023

Figure A-24:



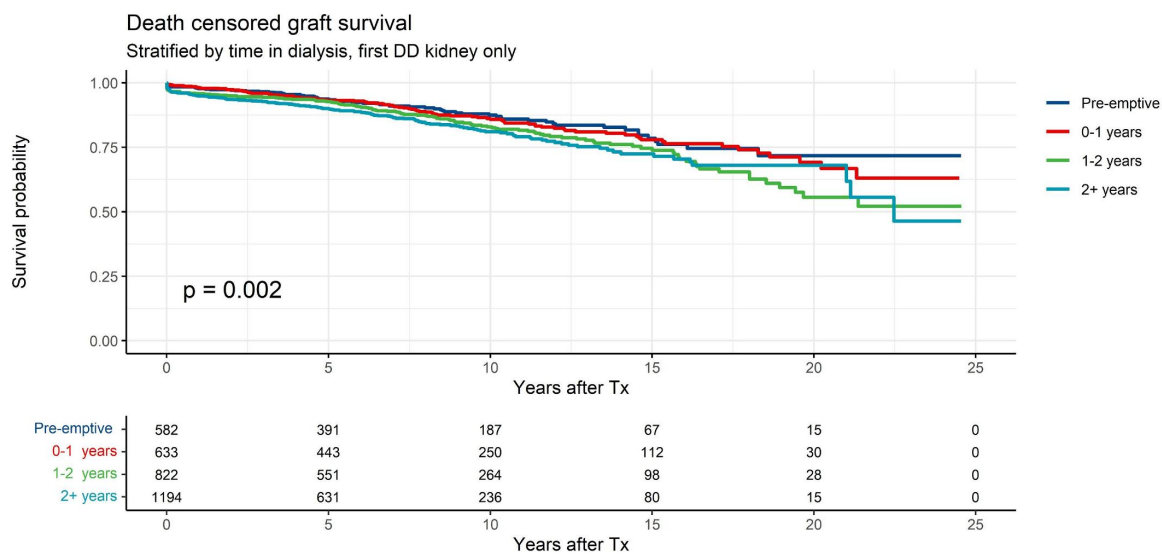
Norway, 2000-2023

Figure A-25:



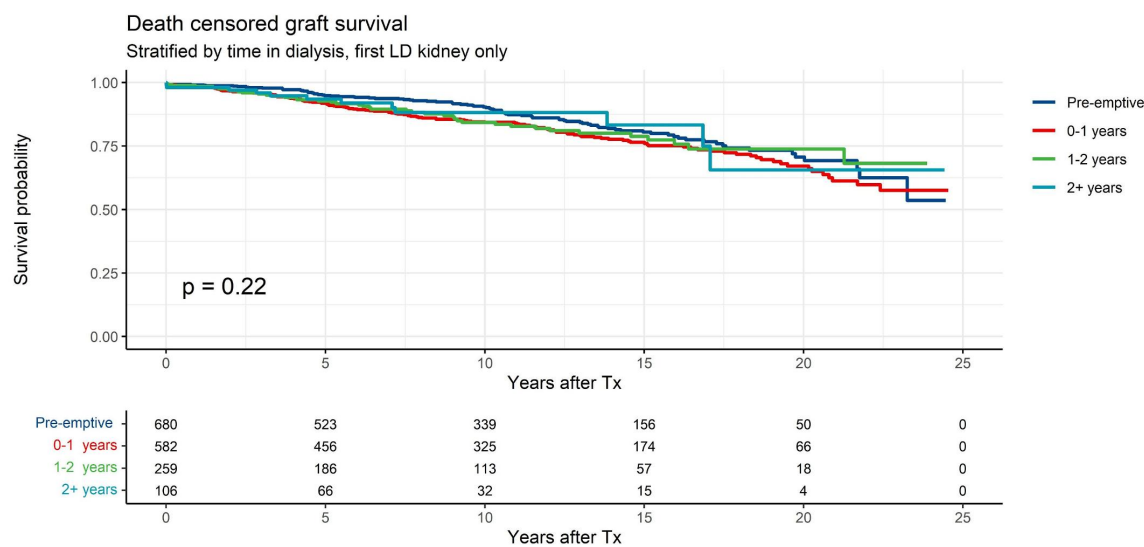
Norway, 2000-2023

Figure A-26:



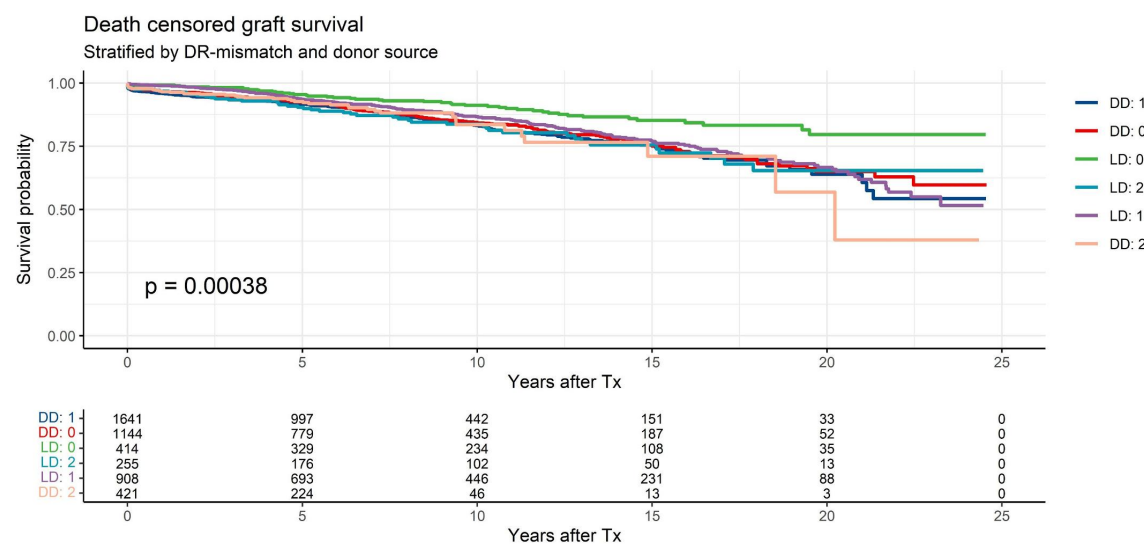
Norway, 2000-2023

Figure A-27:



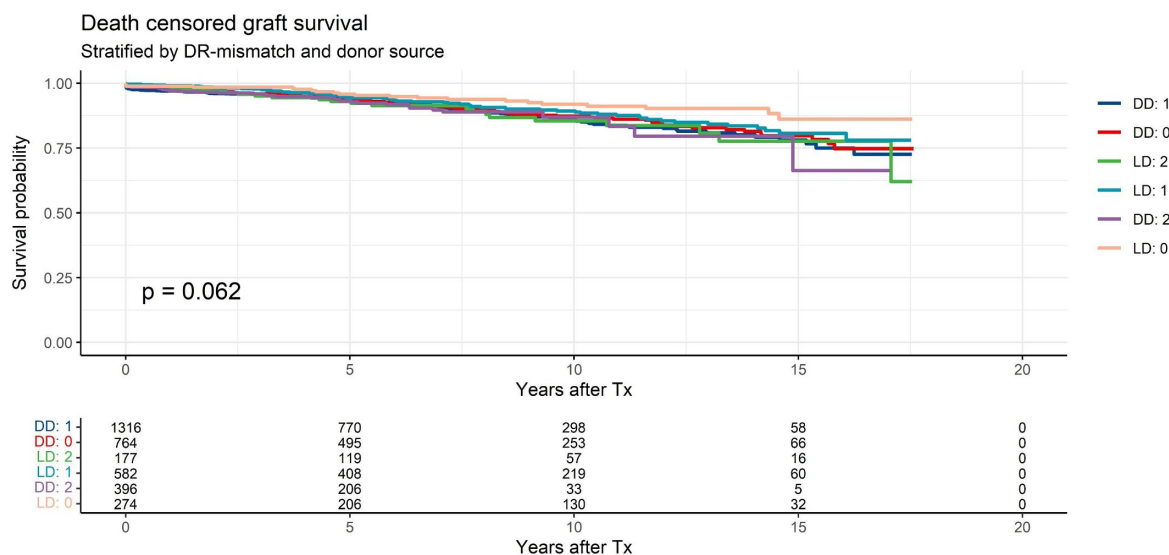
Norway, 2000-2023

Figure A-28:



Norway, 2000-2023

Figure A-29:



Norway, 2007-2023

Appendix: quality indicator results.

Please note that all data on biopsies are for native kidney biopsies, and not transplant biopsies!

Biopsy

Figure A-30:

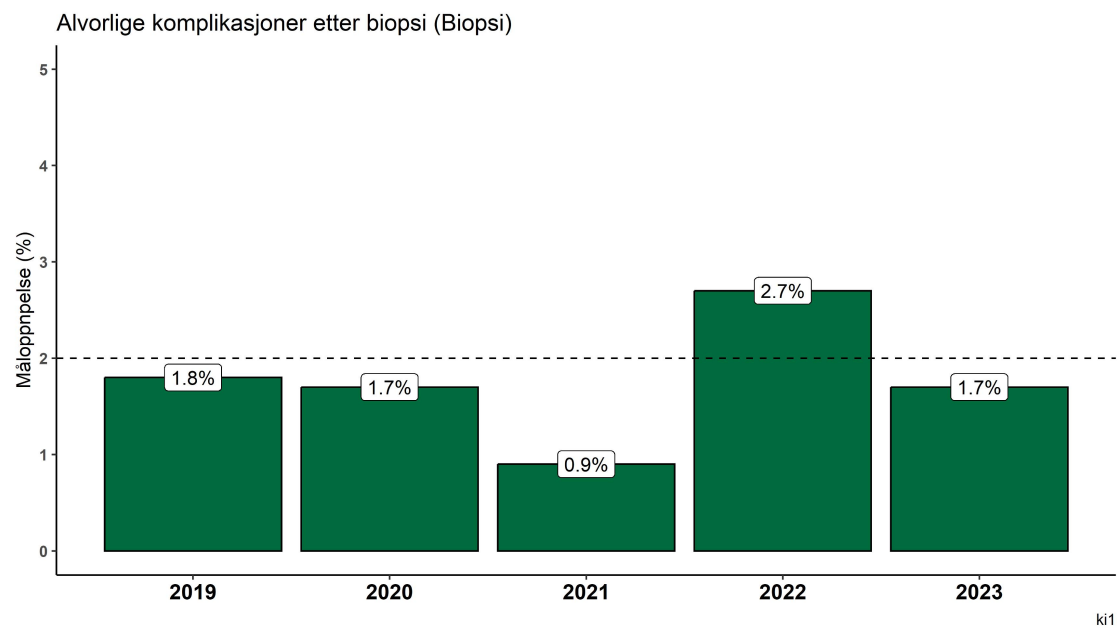


Figure A-31:

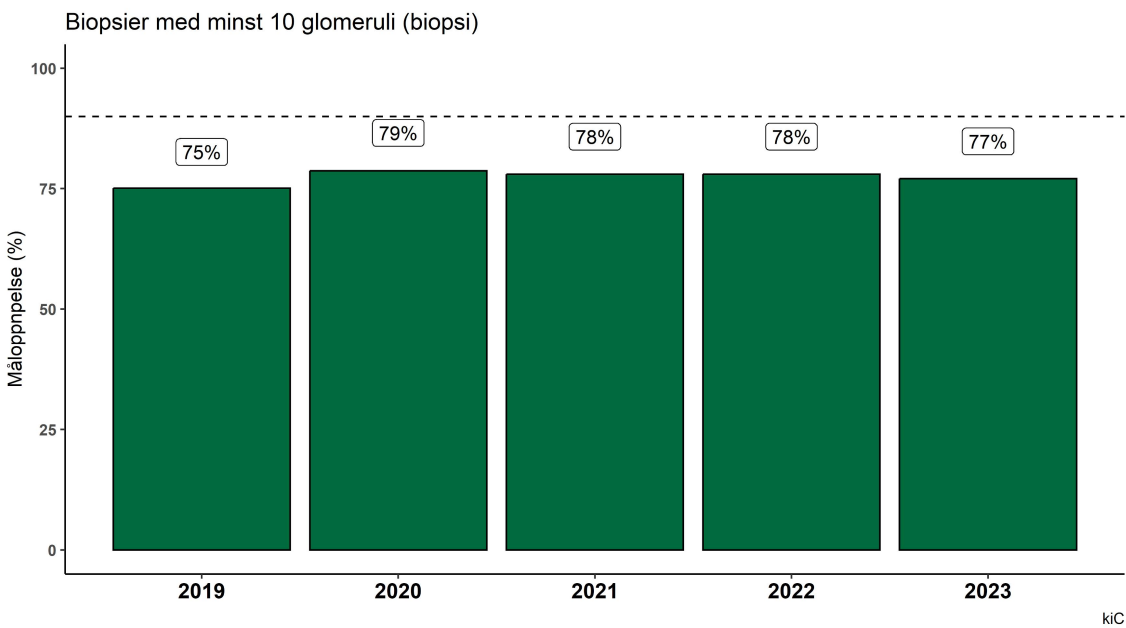


Figure A-32:

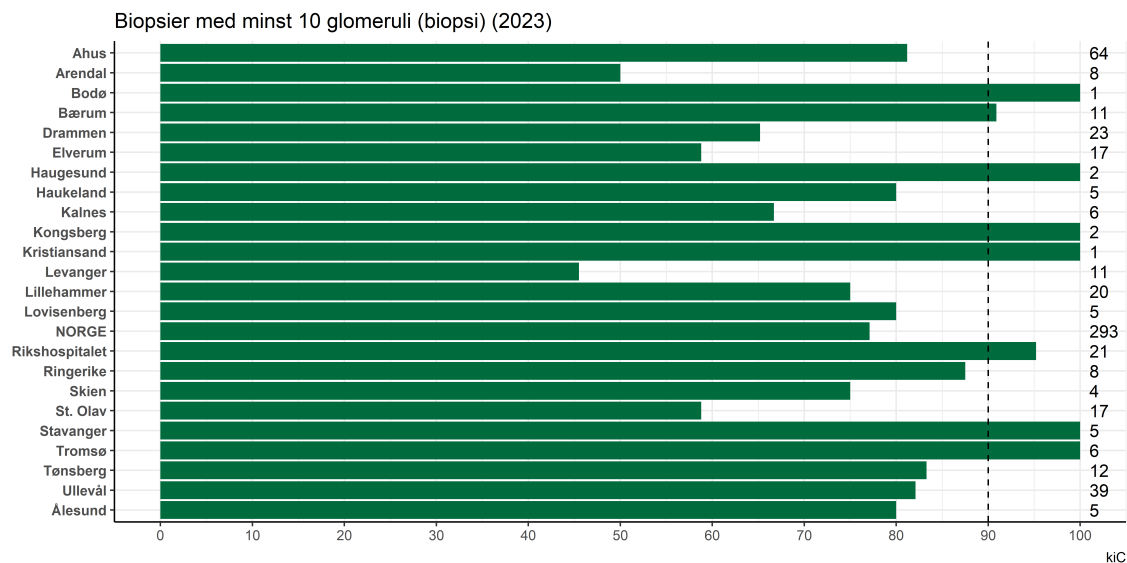


Figure A-33:

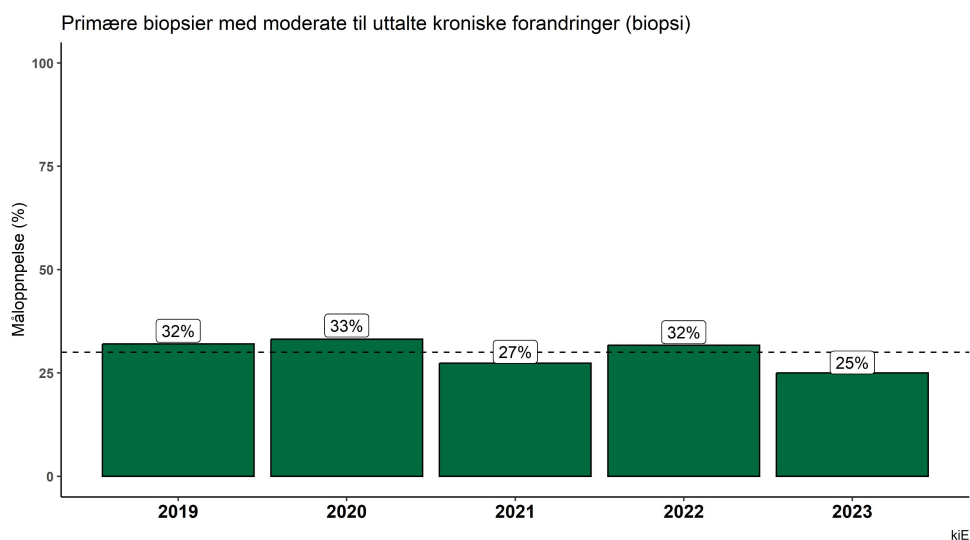


Figure A-34:

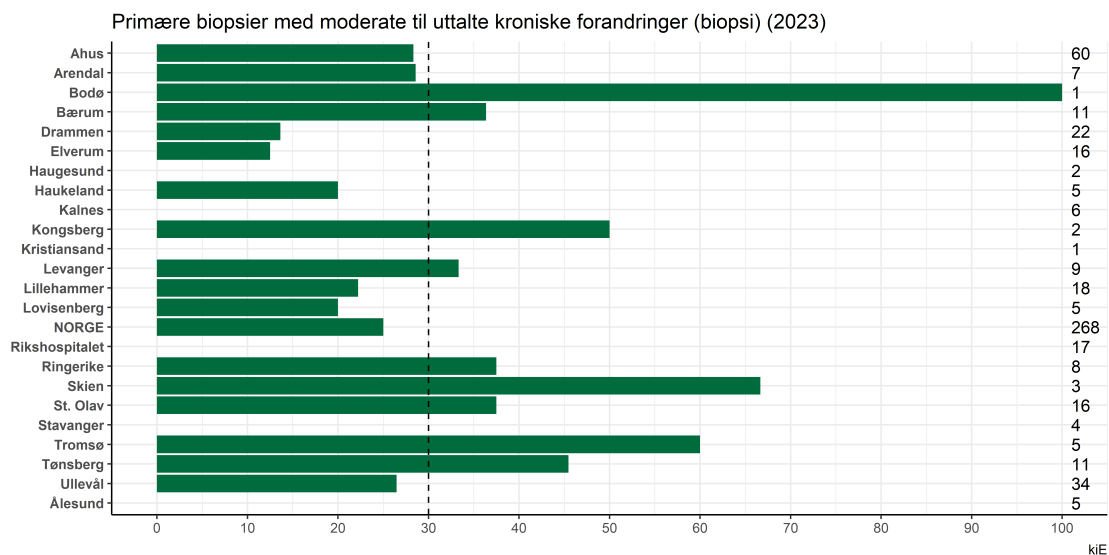


Figure A-35:

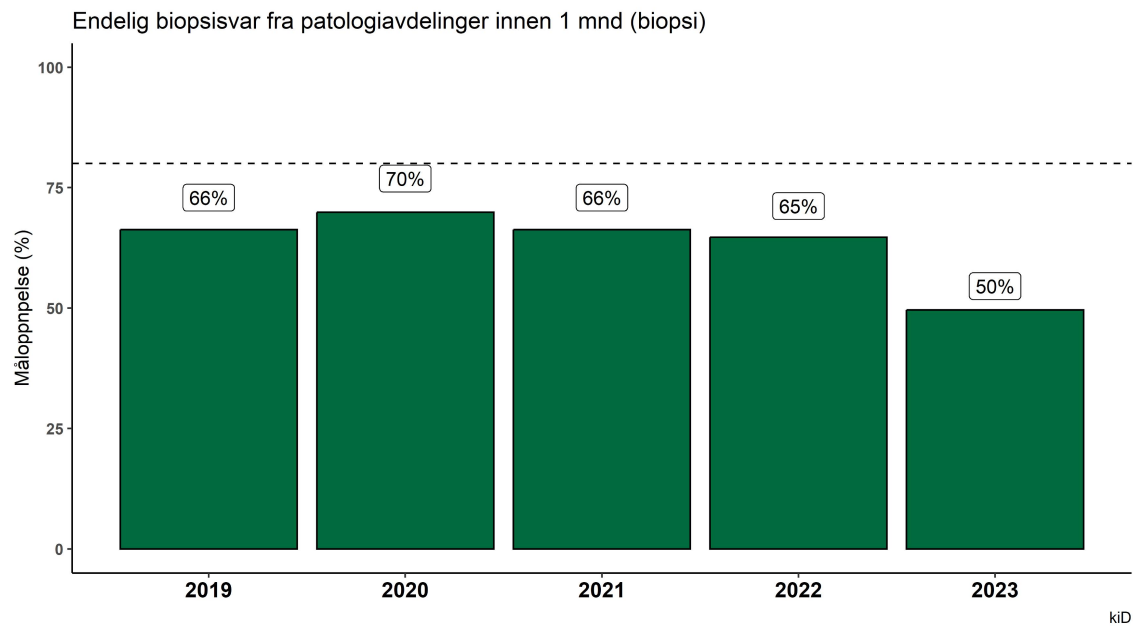
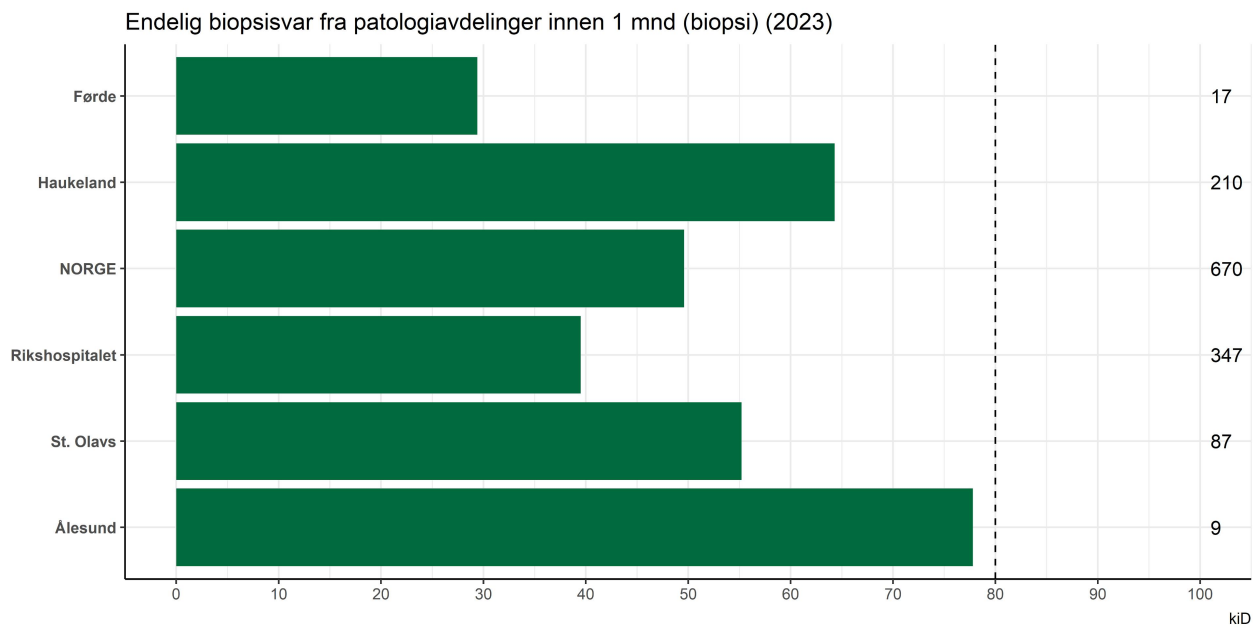


Figure A-36:



CKD5 (without KRT)

Figure A-37:

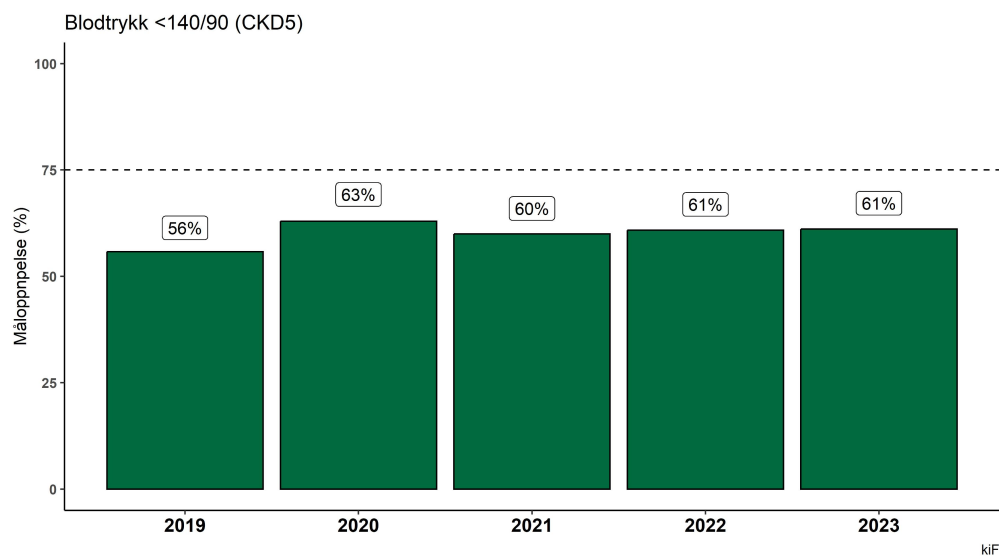


Figure A-38: NEW, only considering patients that are KRT candidates

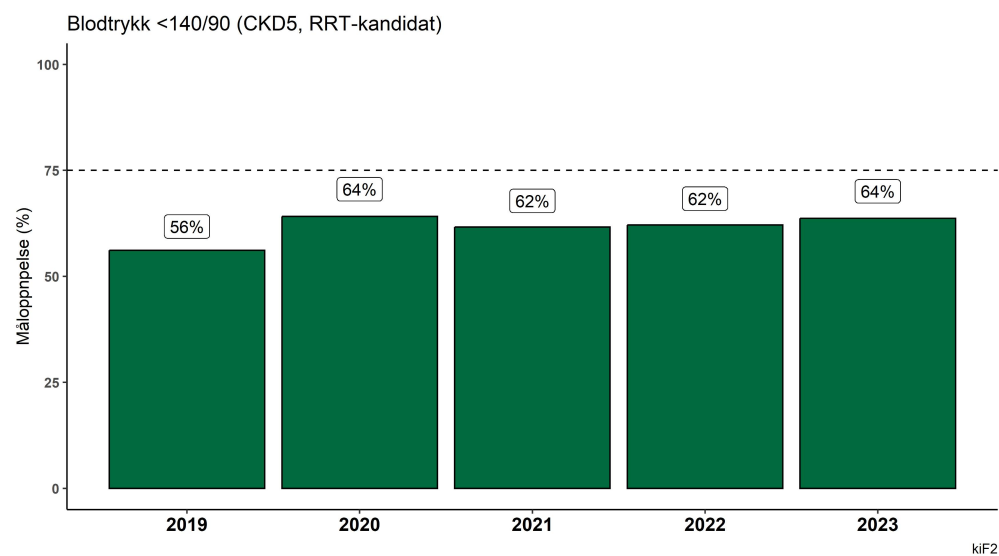


Figure A-39: NEW, not considering those with DBP <70 mmHg

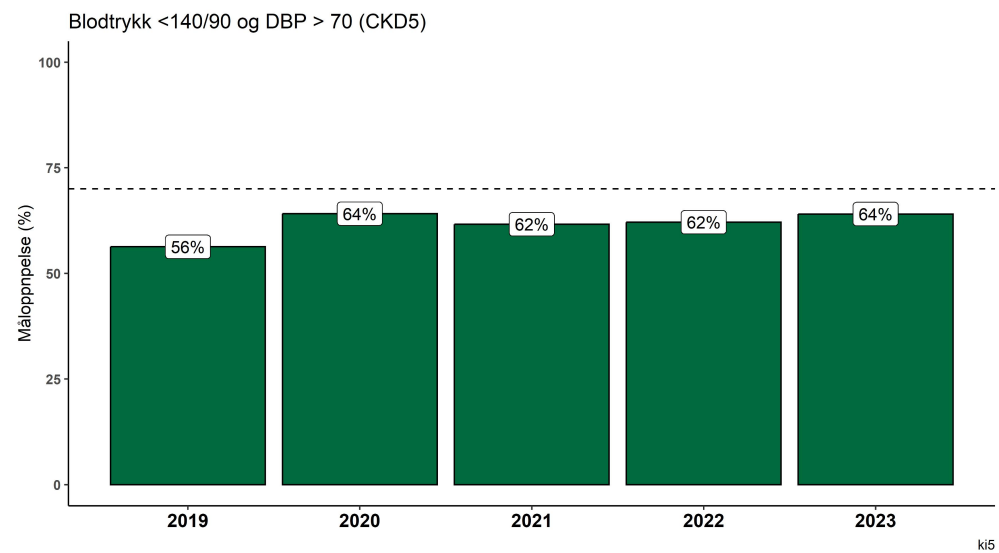


Figure A-40:

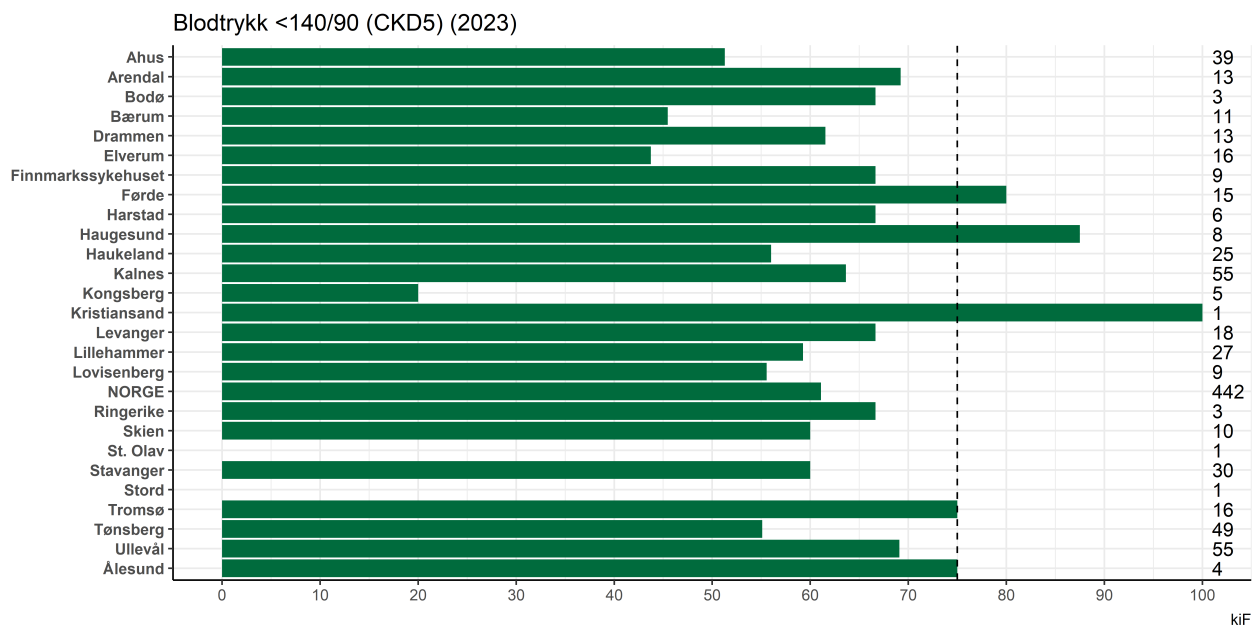


Figure A-41: NEW, only considering patients that are KRT candidates

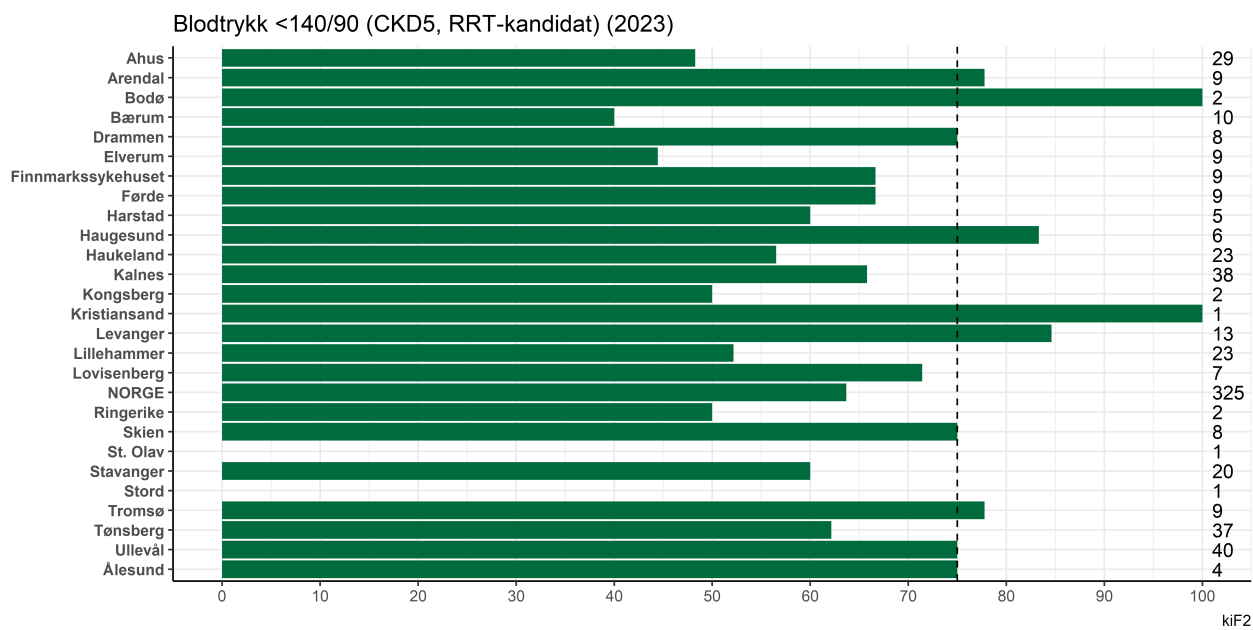


Figure A-42:

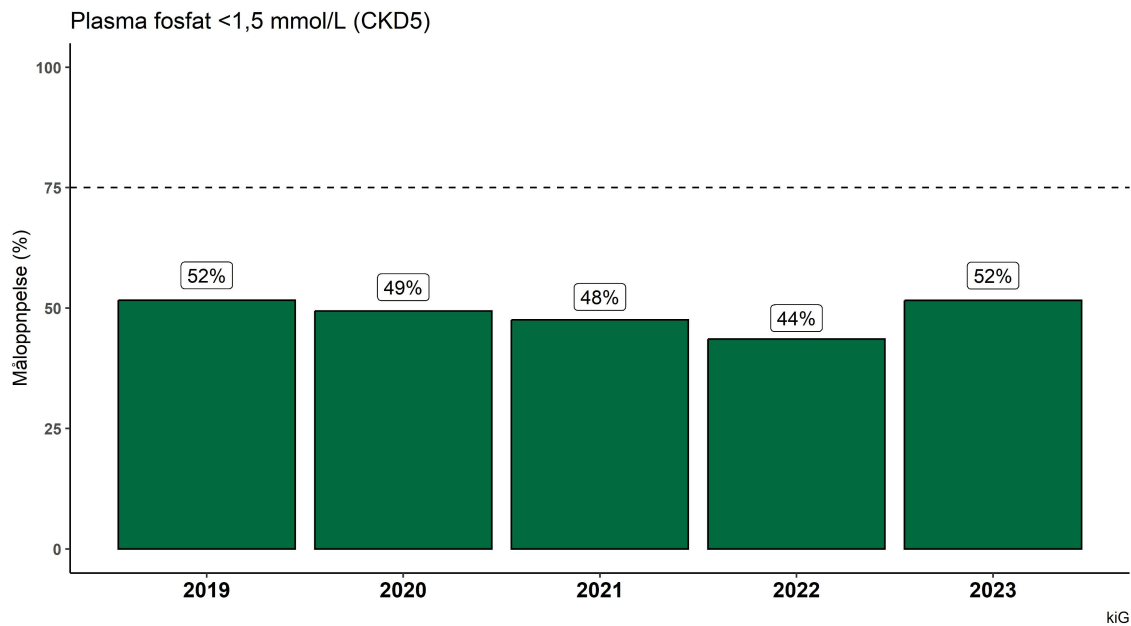


Figure A-43:

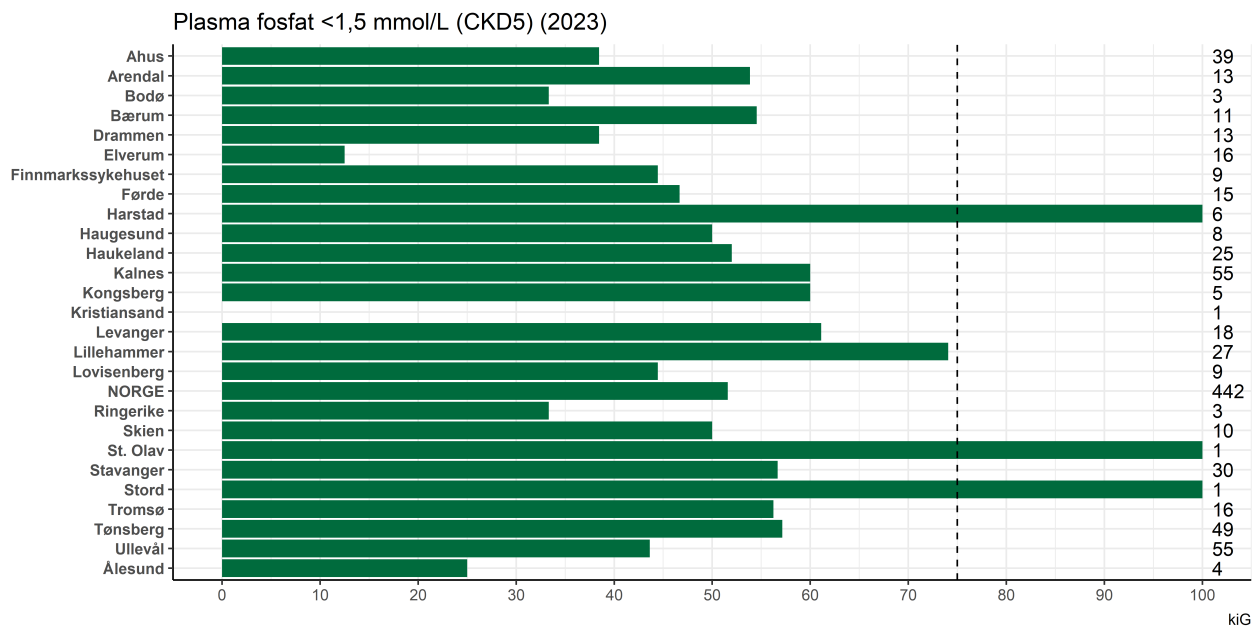


Figure A-44:

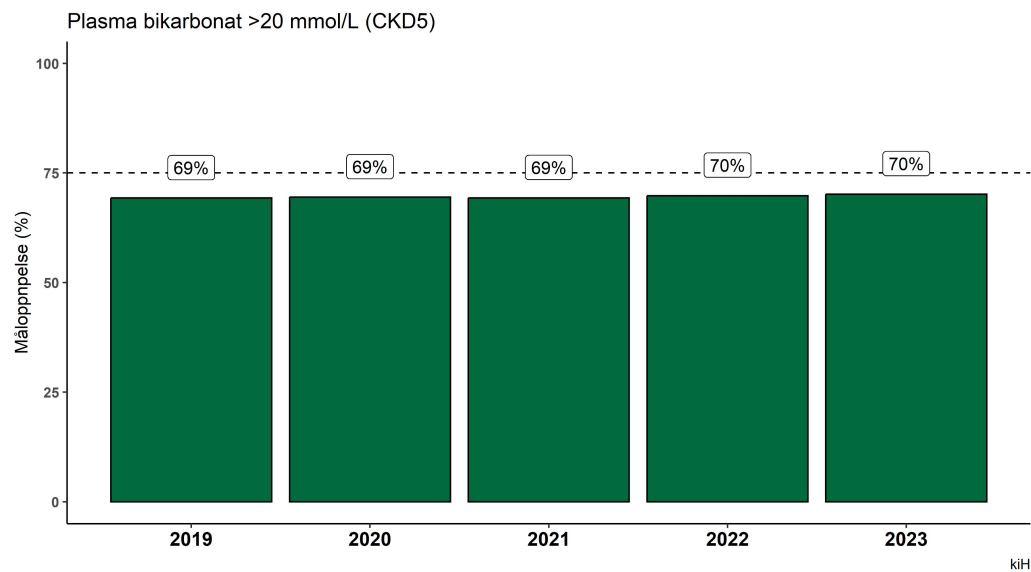


Figure A-45: NEW, only considering if these variables have been measured

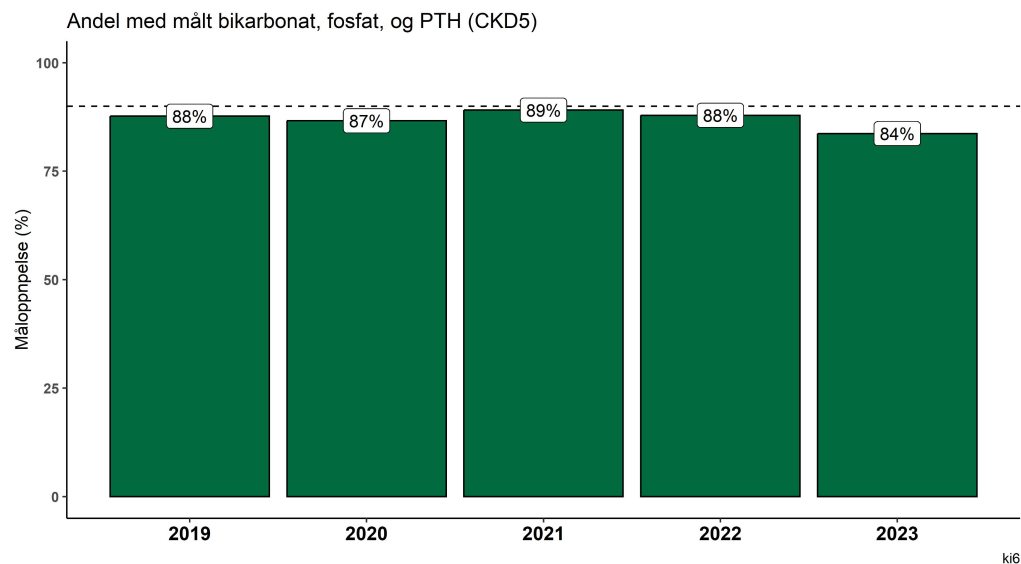


Figure A-46:

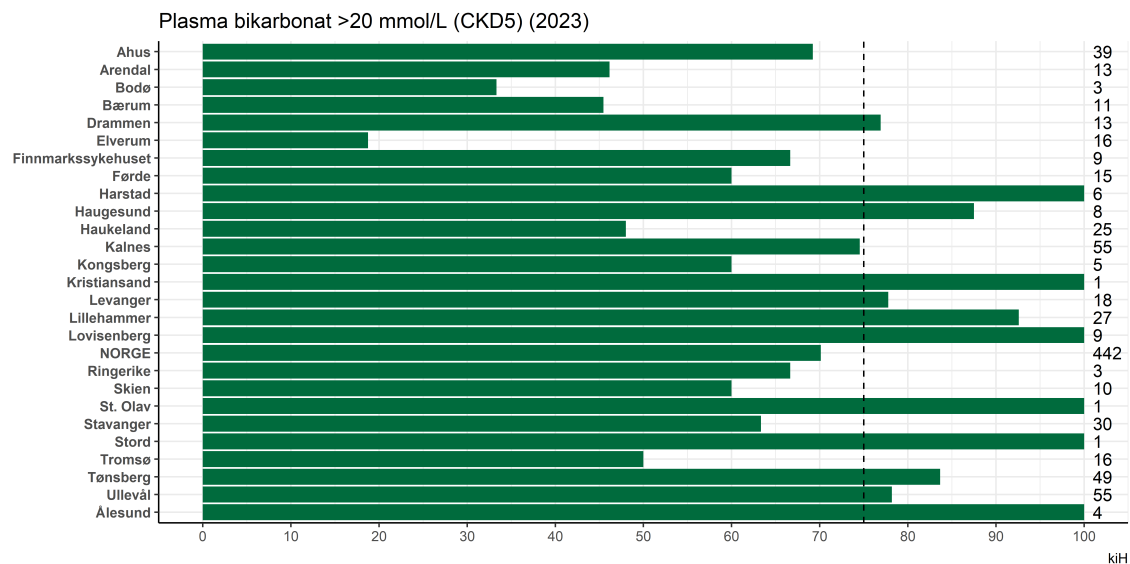


Figure A-47:

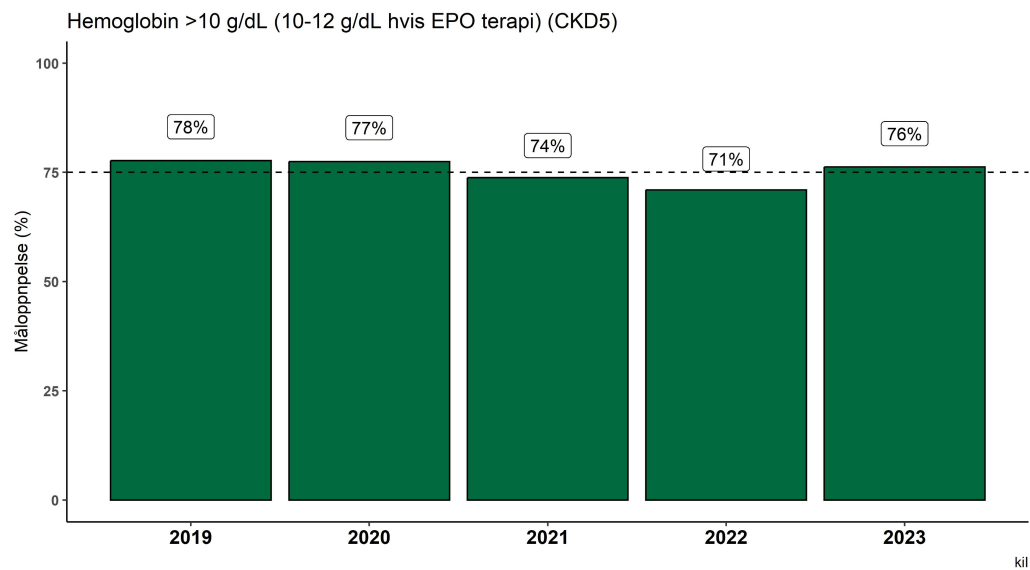


Figure A-48: NEW, only considering patients that are KRT candidates

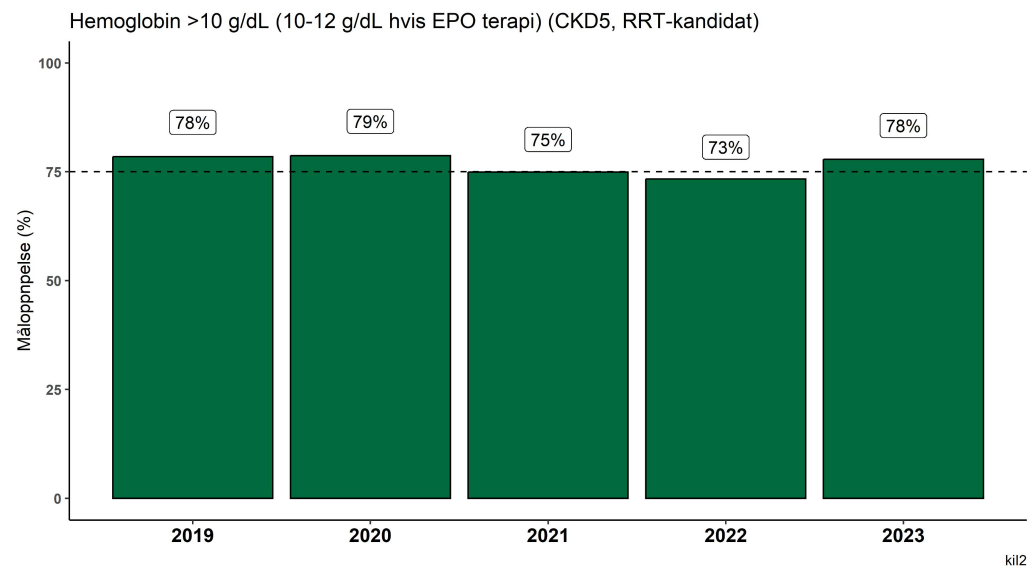


Figure A-49:

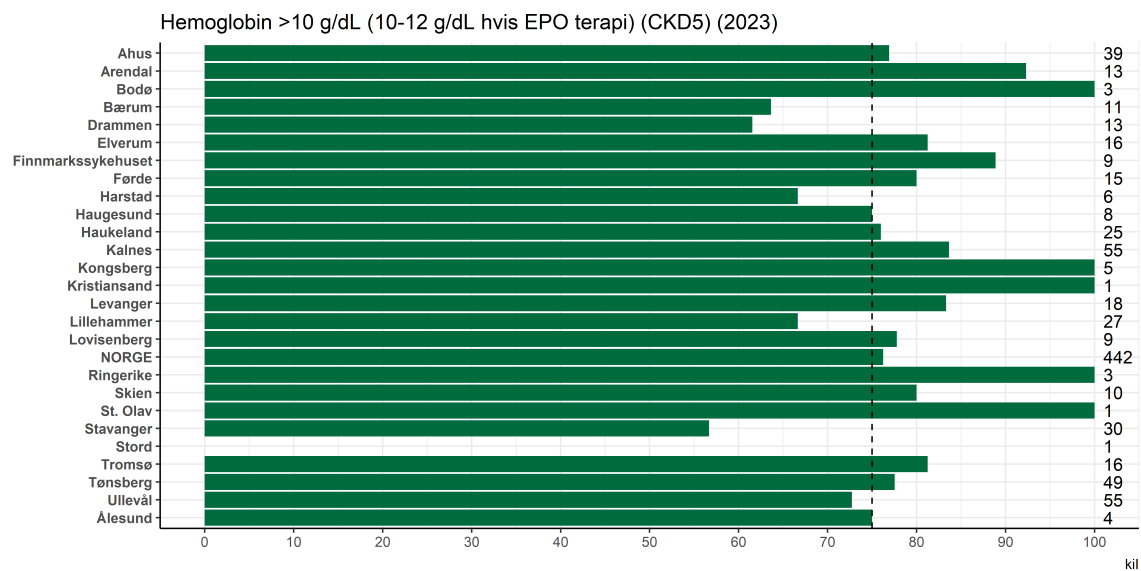


Figure A-50:

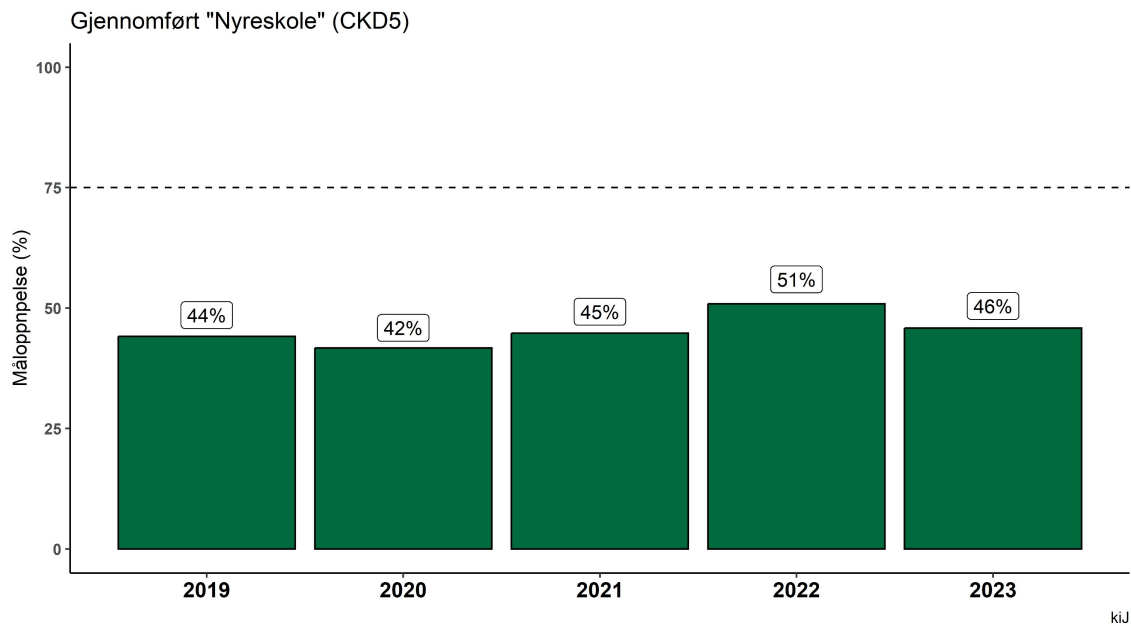
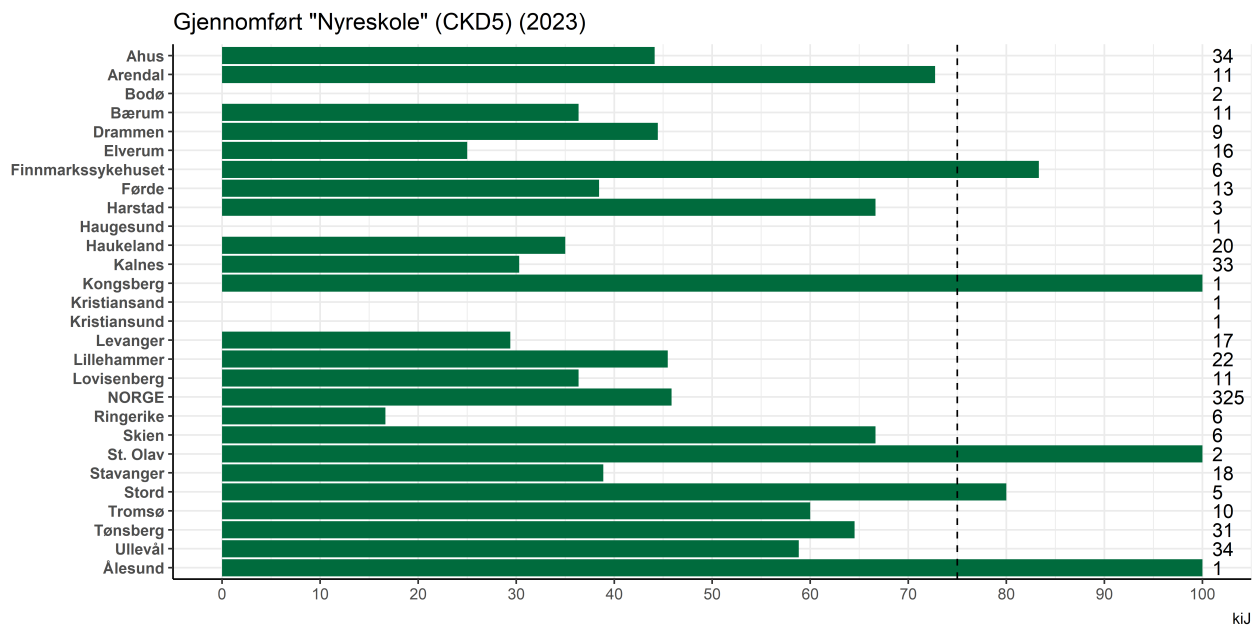


Figure A-51:



Dialysis

Figure A-52:

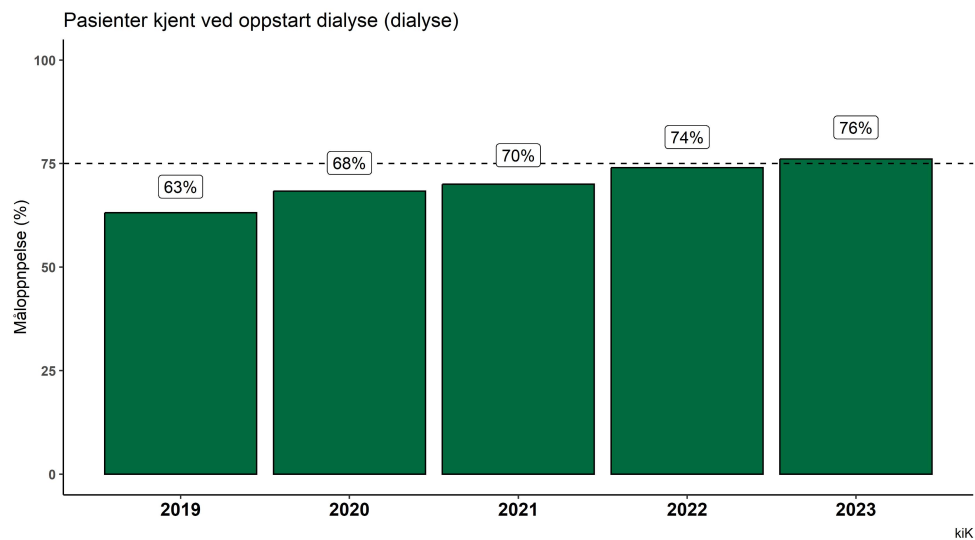


Figure A-53:

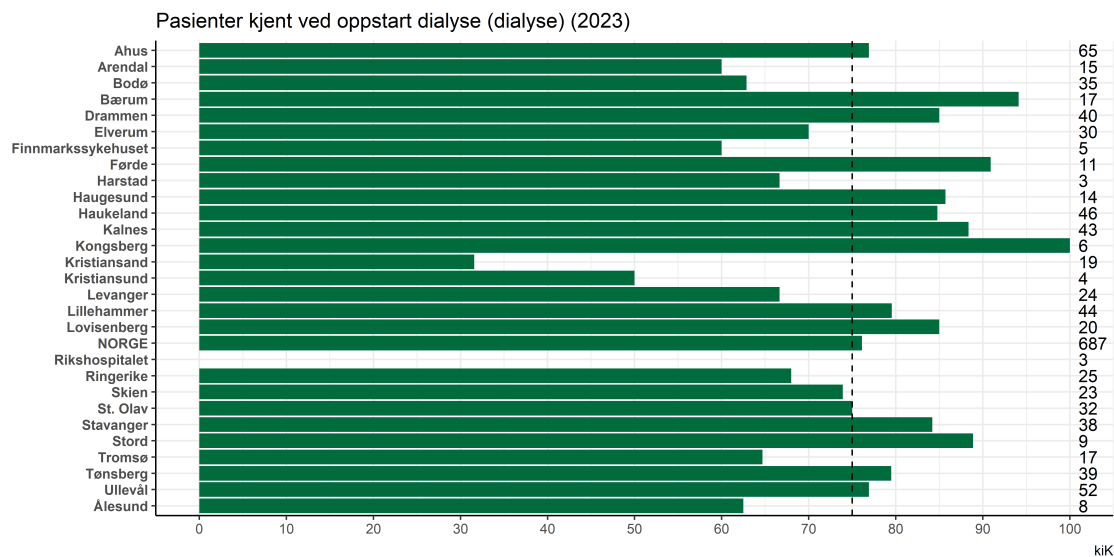


Figure A-54: NEW, assessing Hgb in dialysis patients

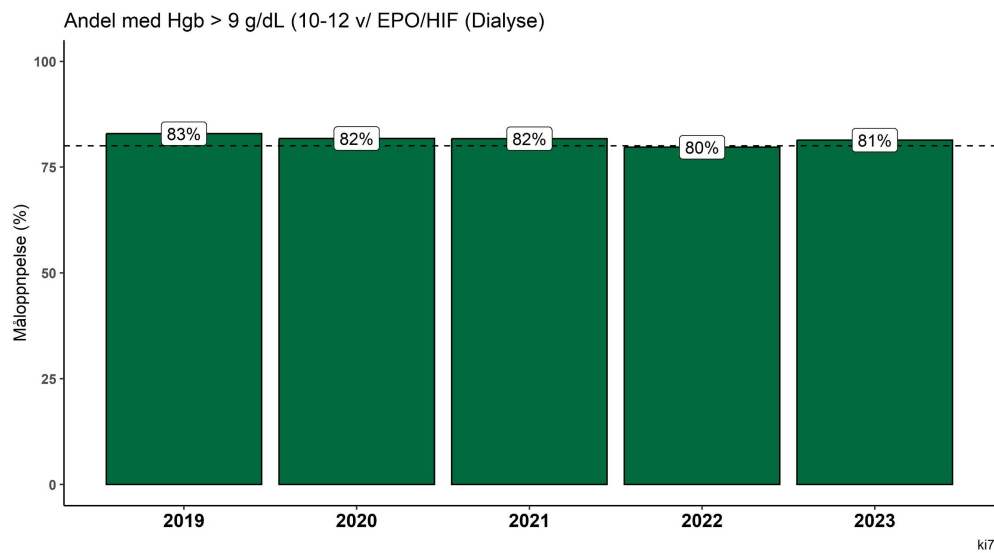


Figure A-55:

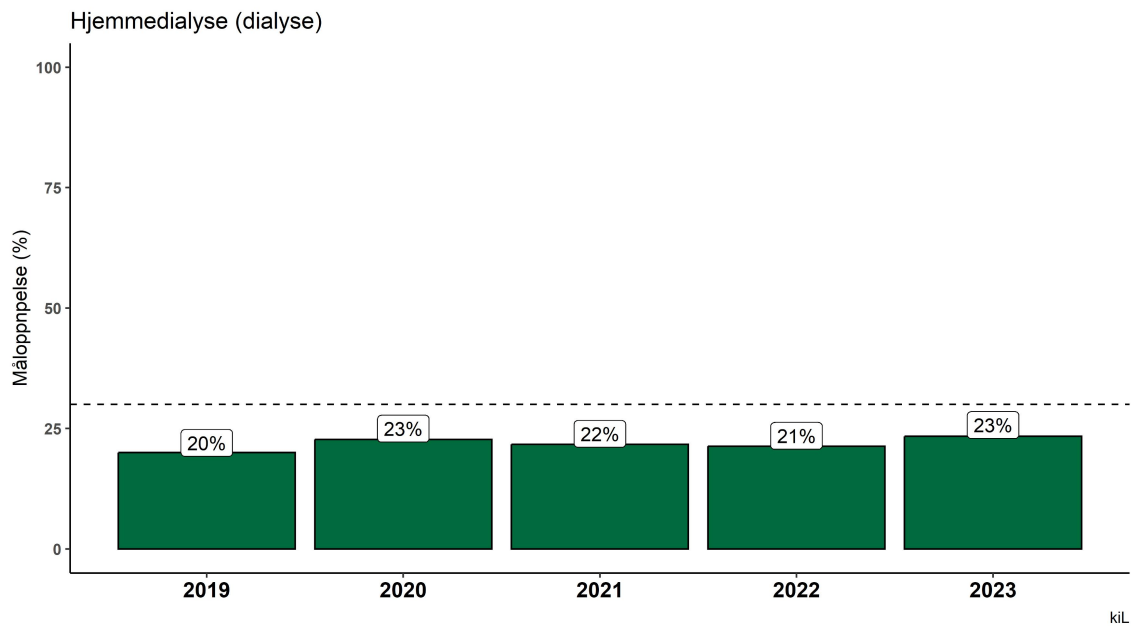


Figure A-56:

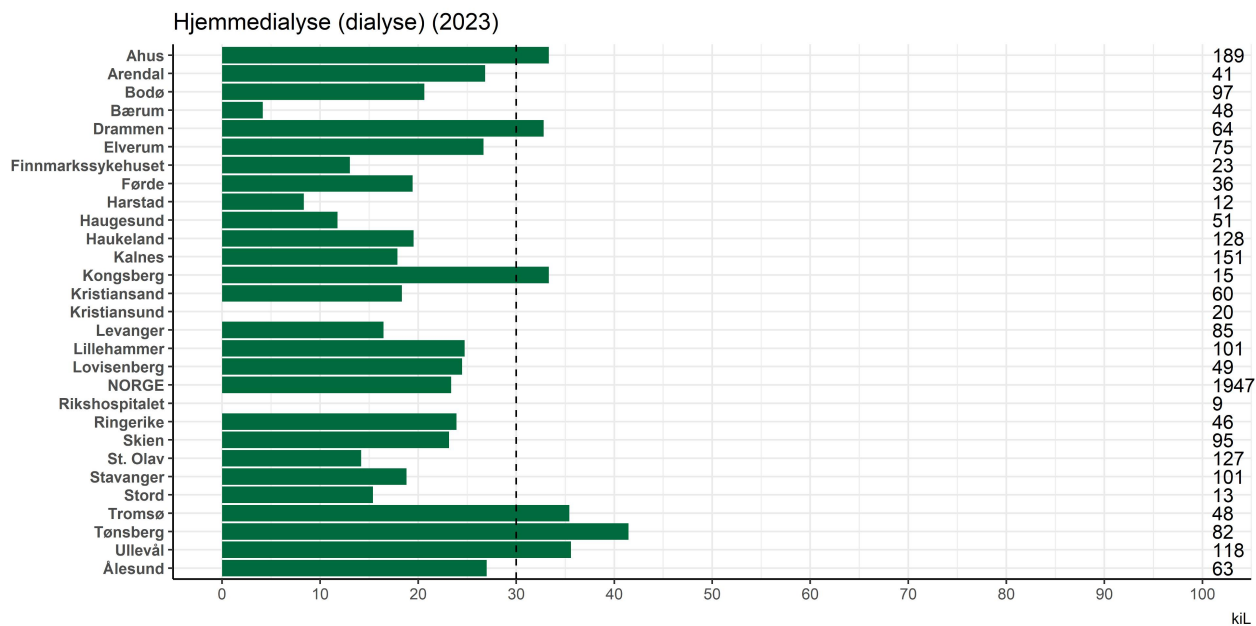


Figure A-57:

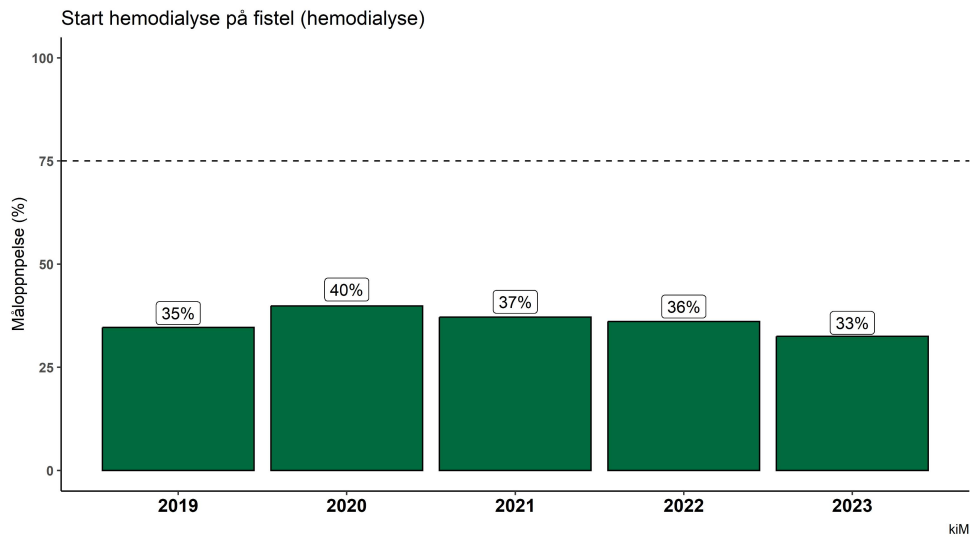


Figure A-58: NEW, NEW, assessing if patients get their individualized best treatment

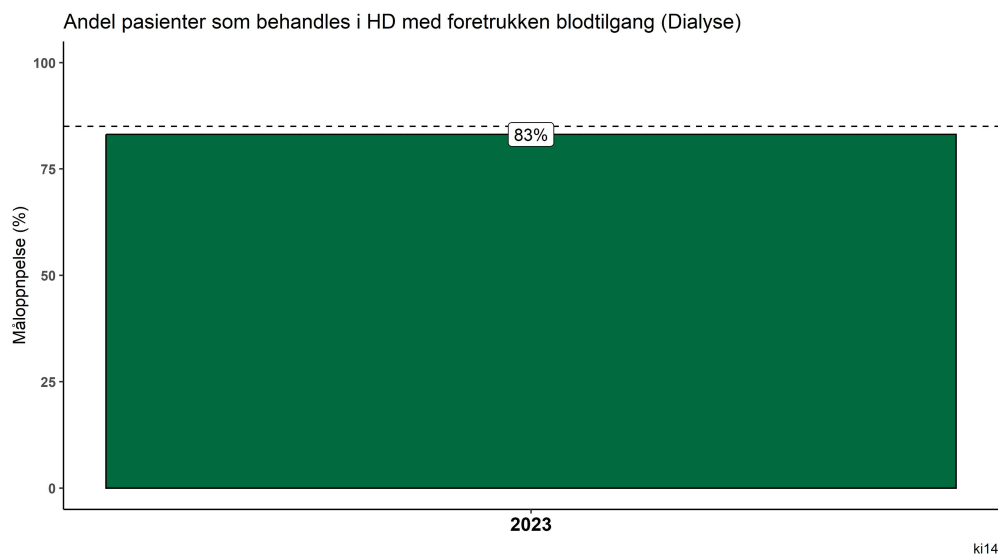


Figure A-59:

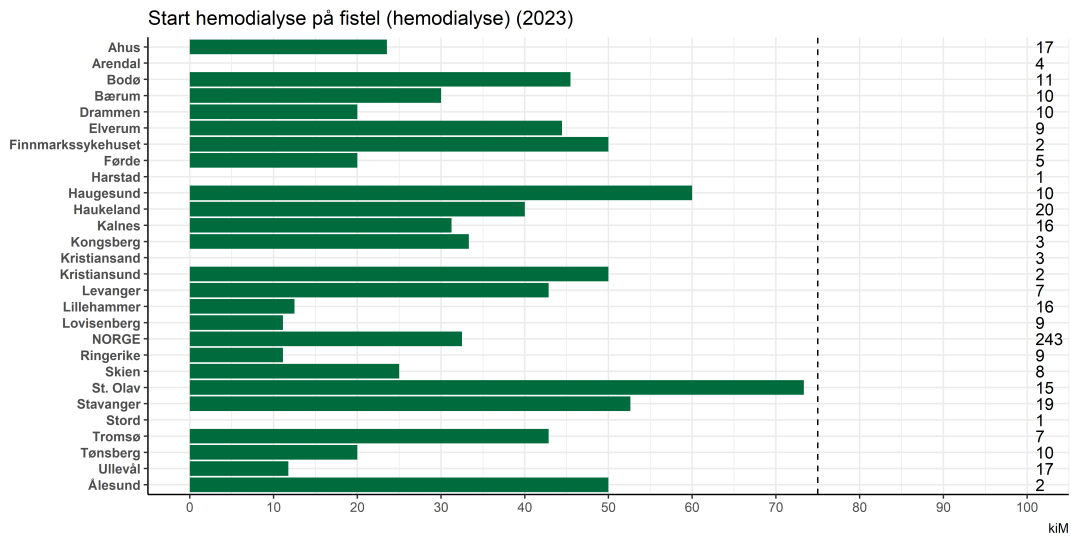


Figure A-60:

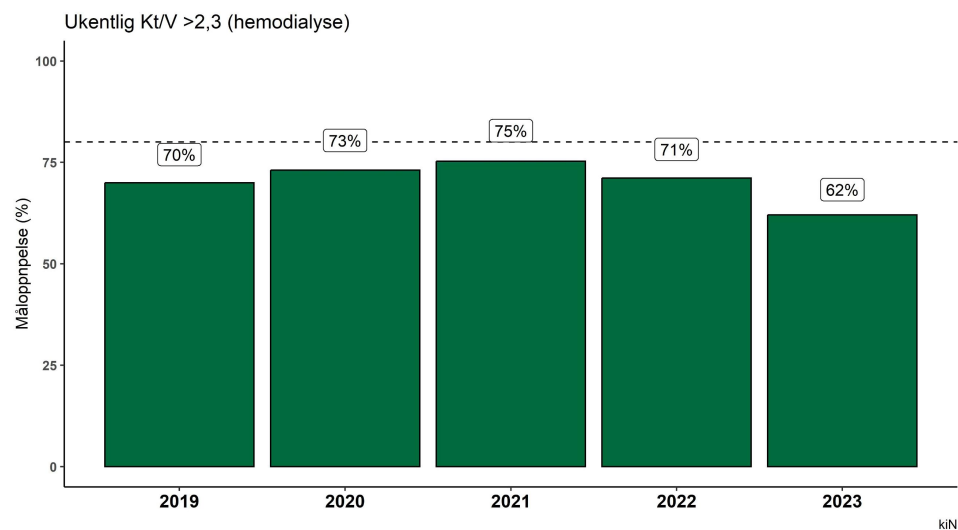


Figure A-61: NEW, only assessing if Kt/V has been measured

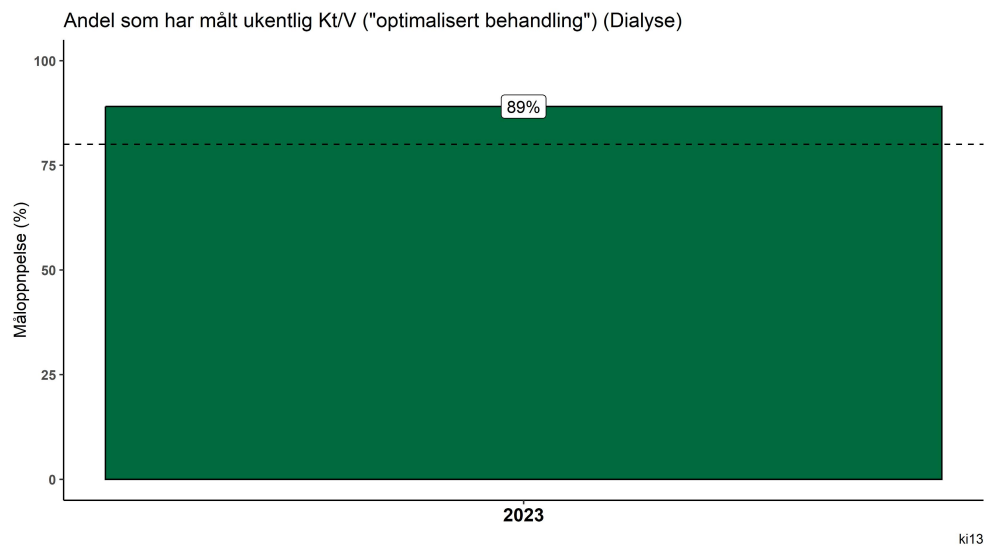


Figure A-62:

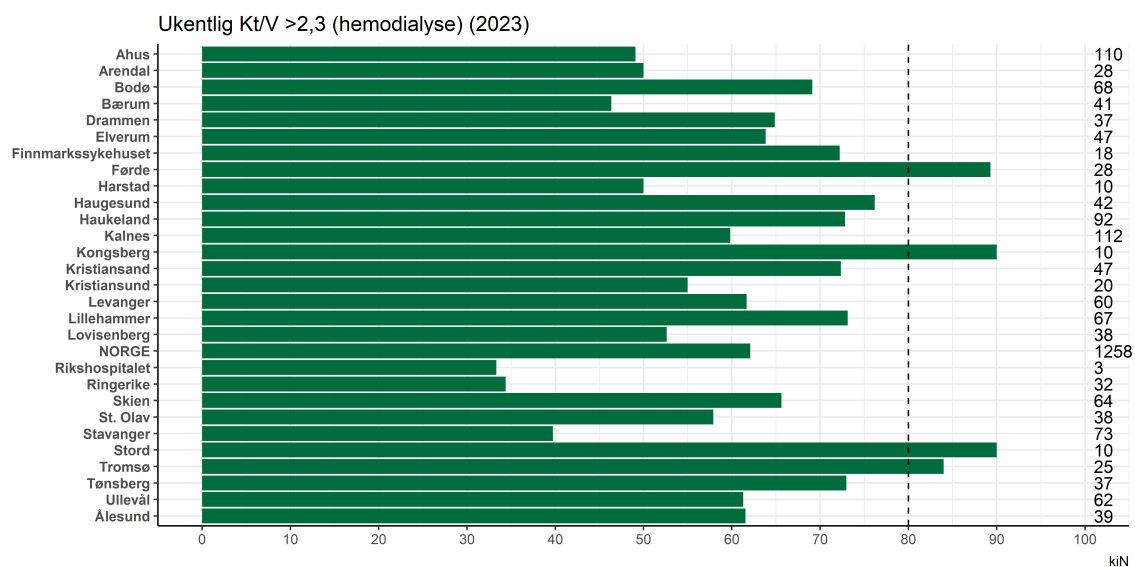


Figure A-63:

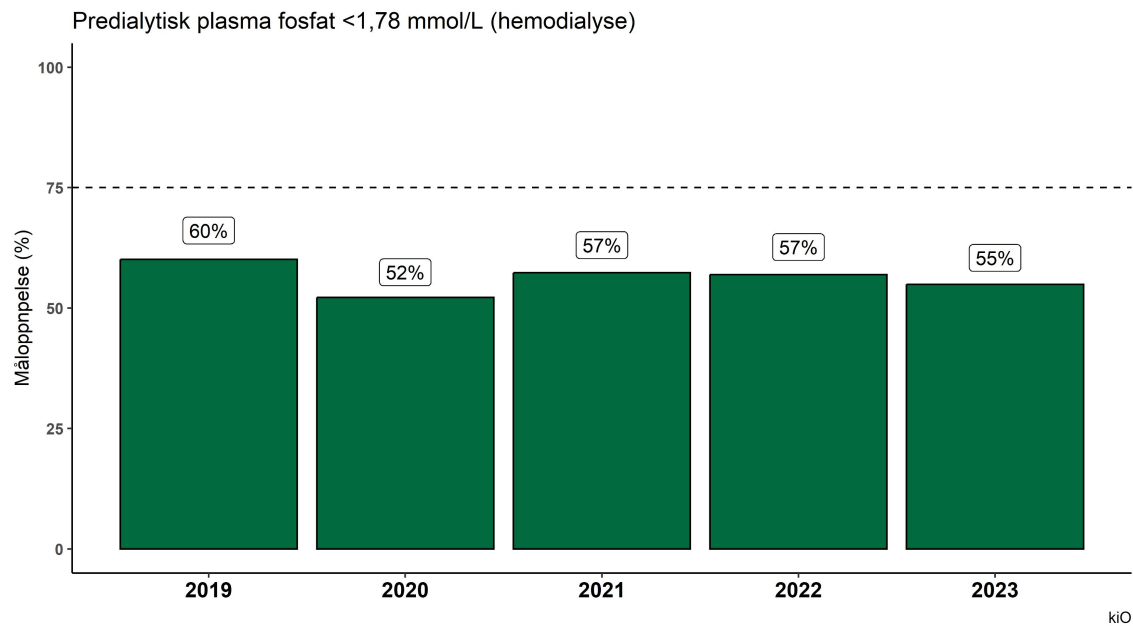


Figure A-64:

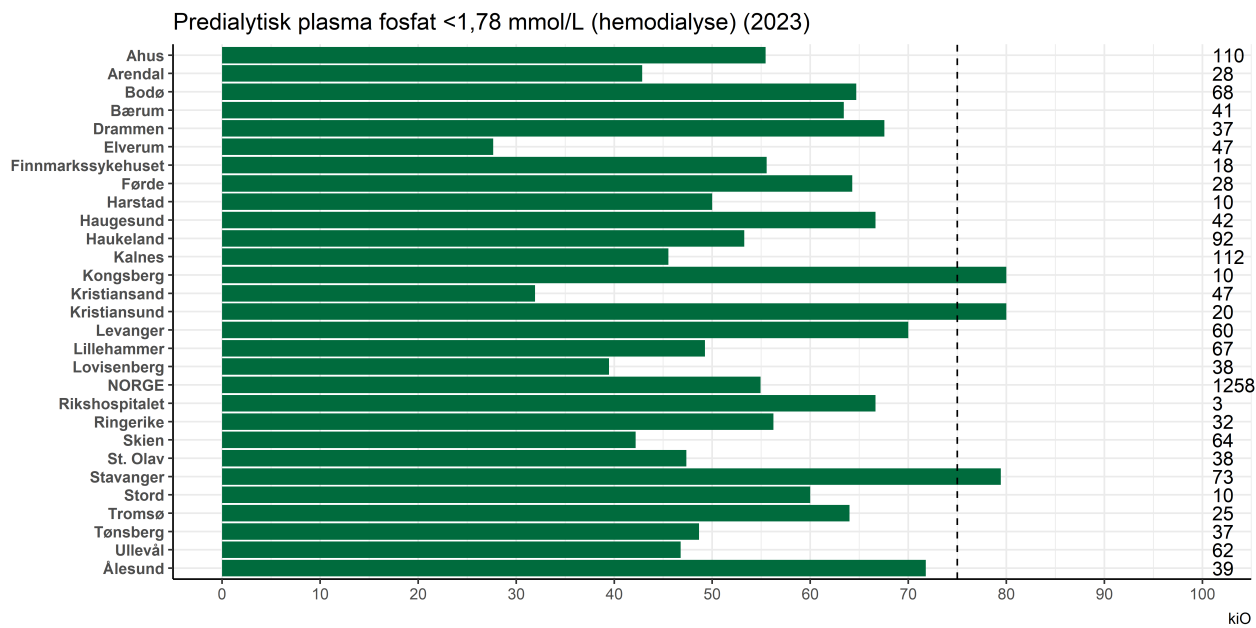


Figure A-65:

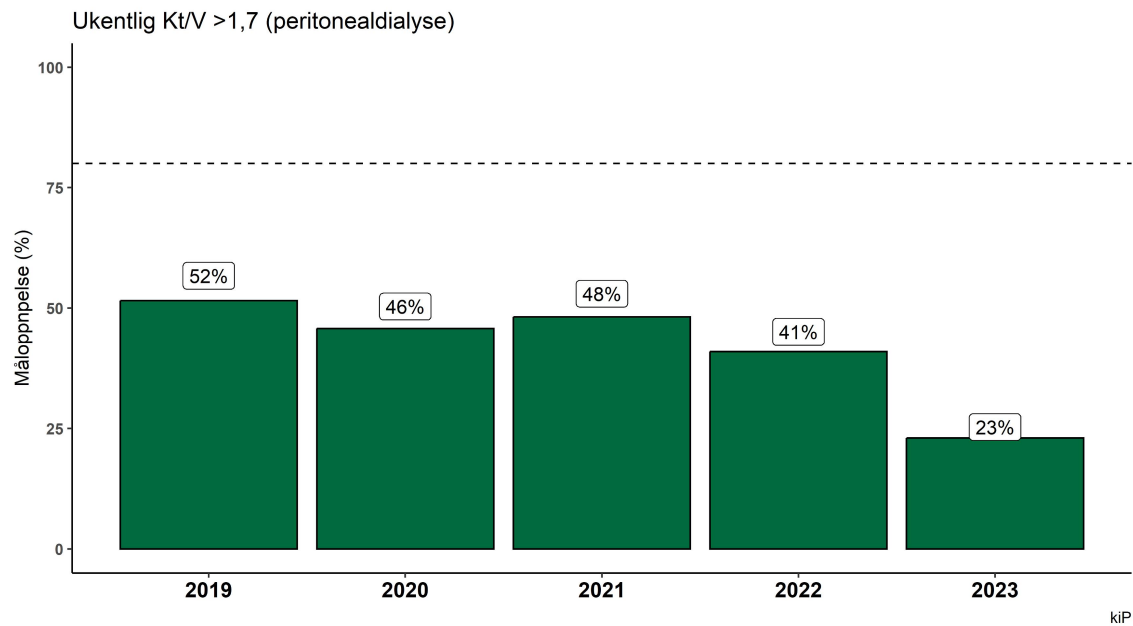


Figure A-66:

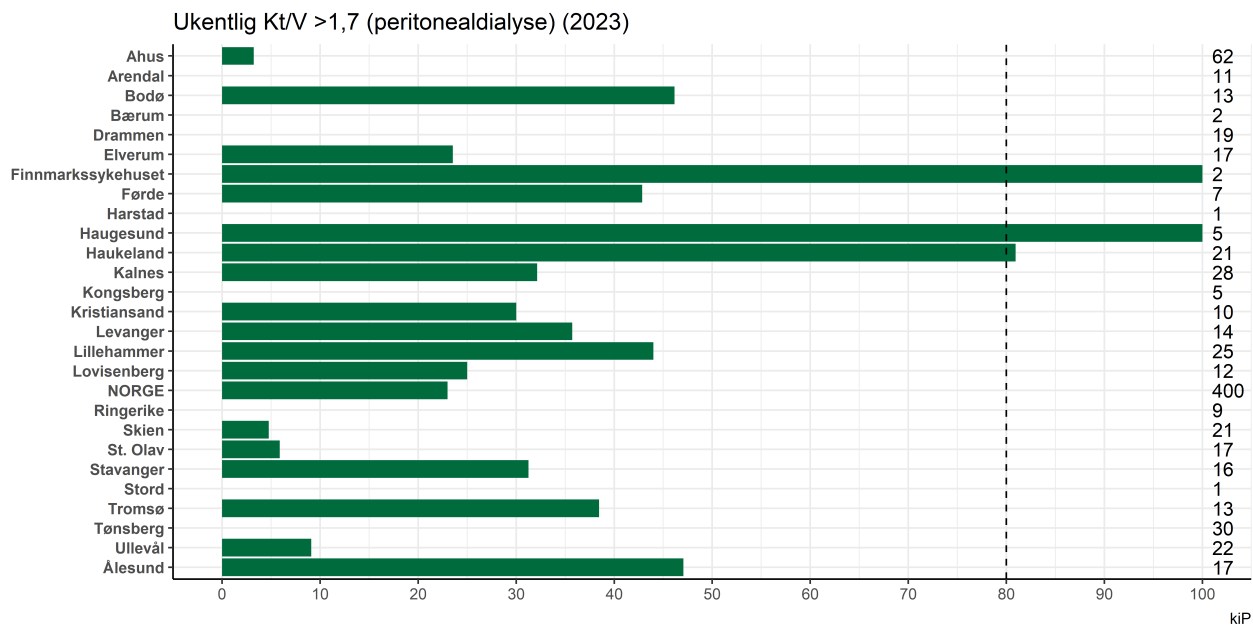


Figure A-67:

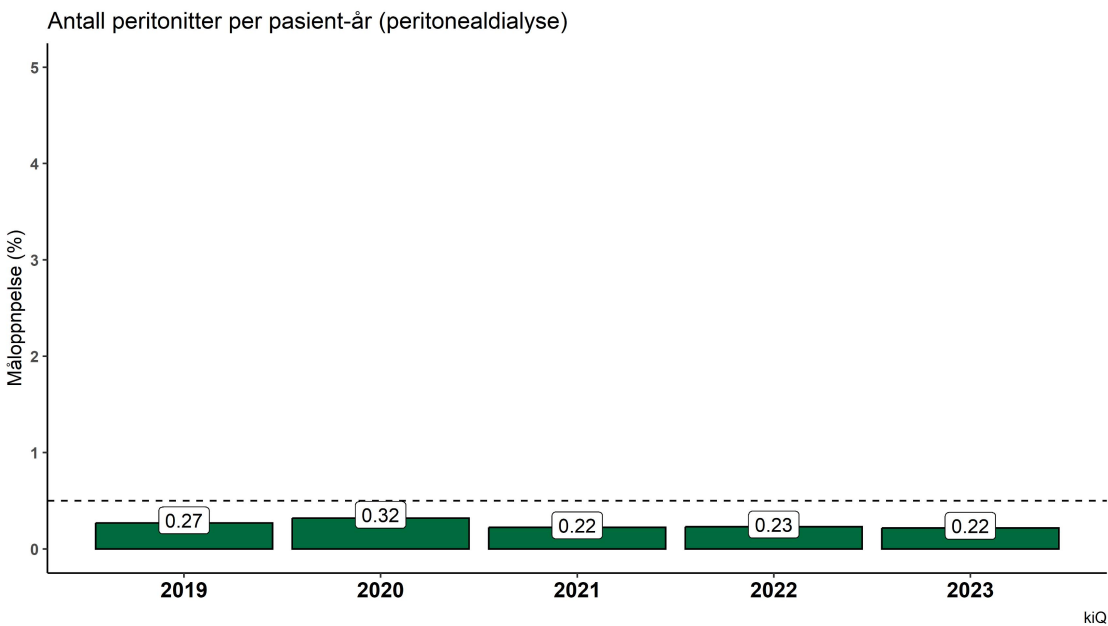
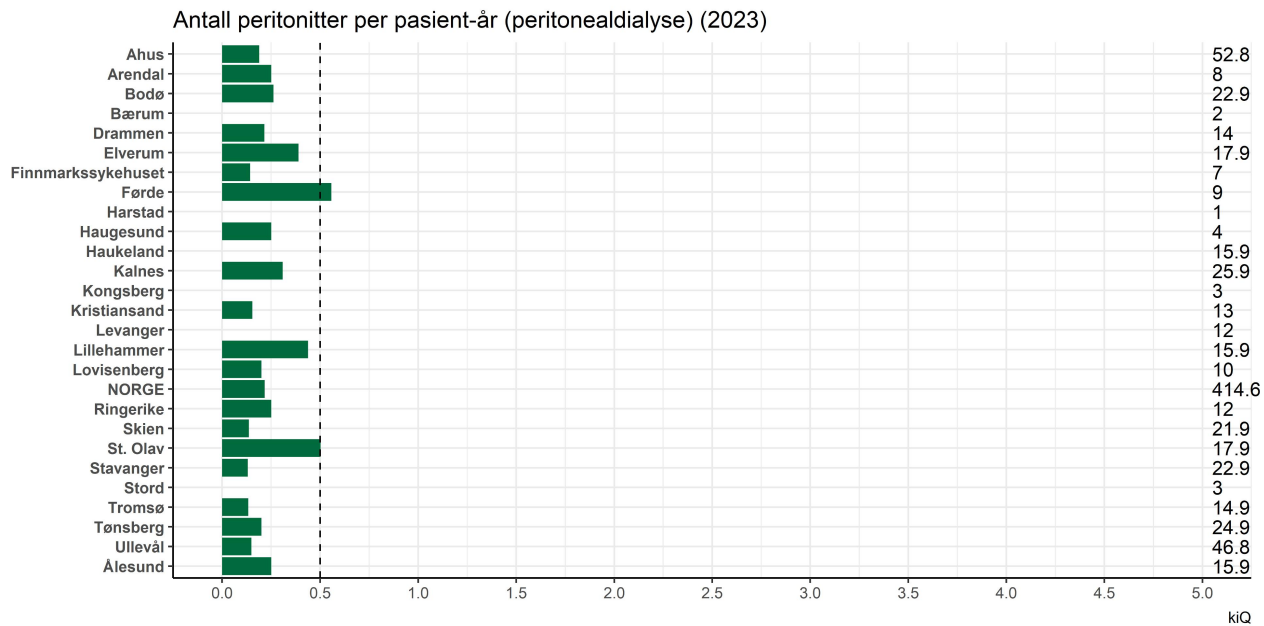


Figure A-68:



Kidney transplantation

Figure A-69:

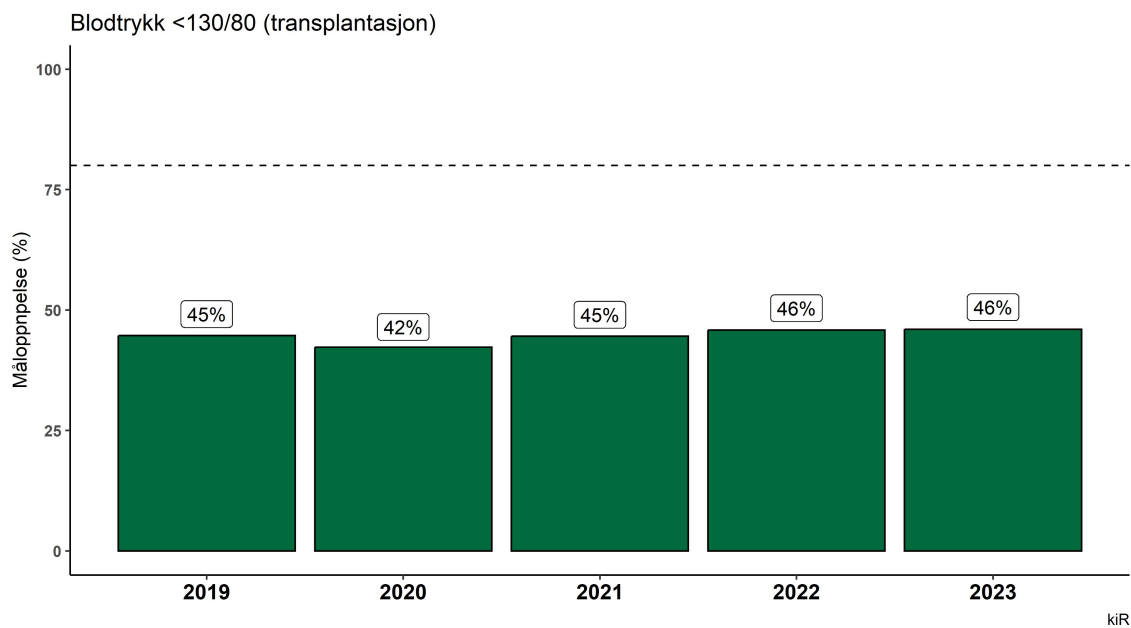


Figure A-70:

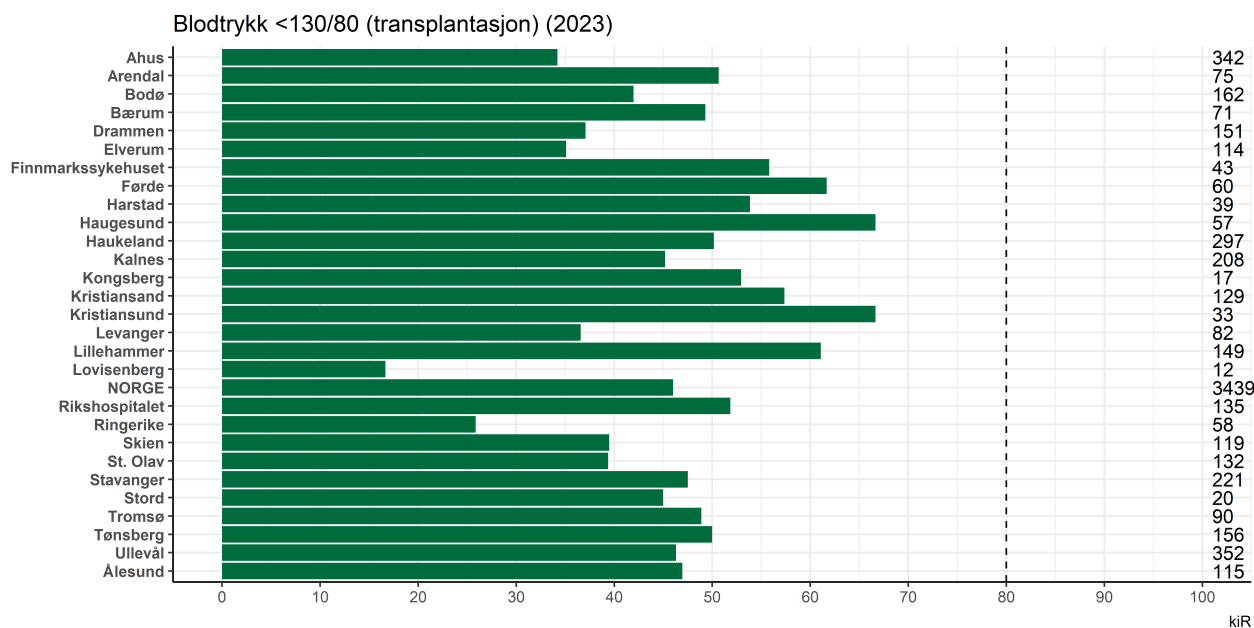


Figure A-71:

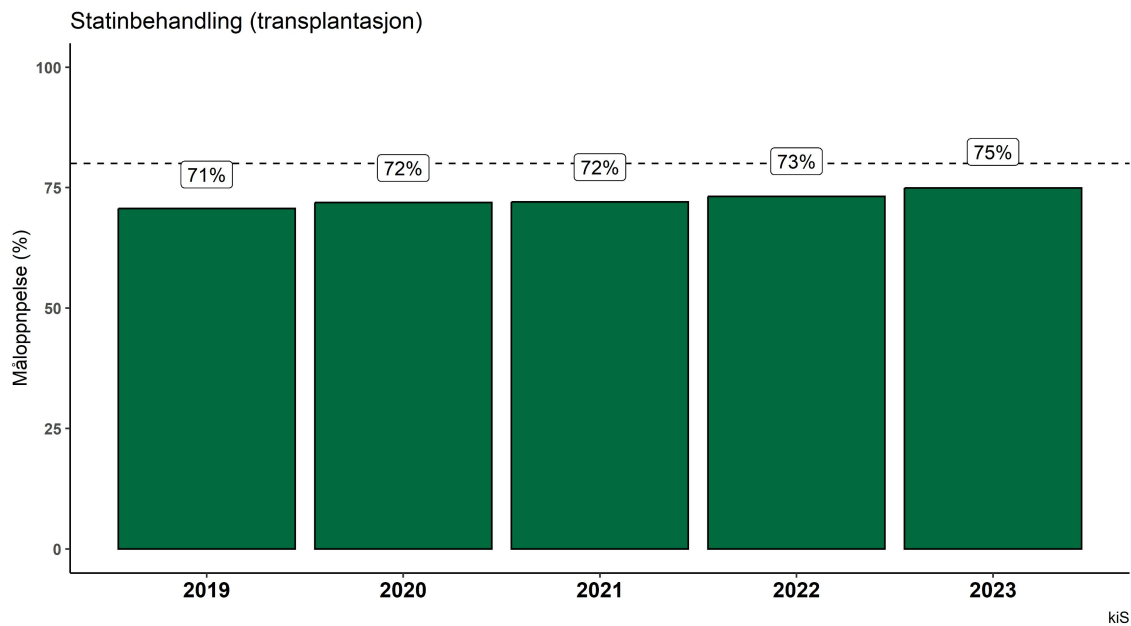


Figure A-72:

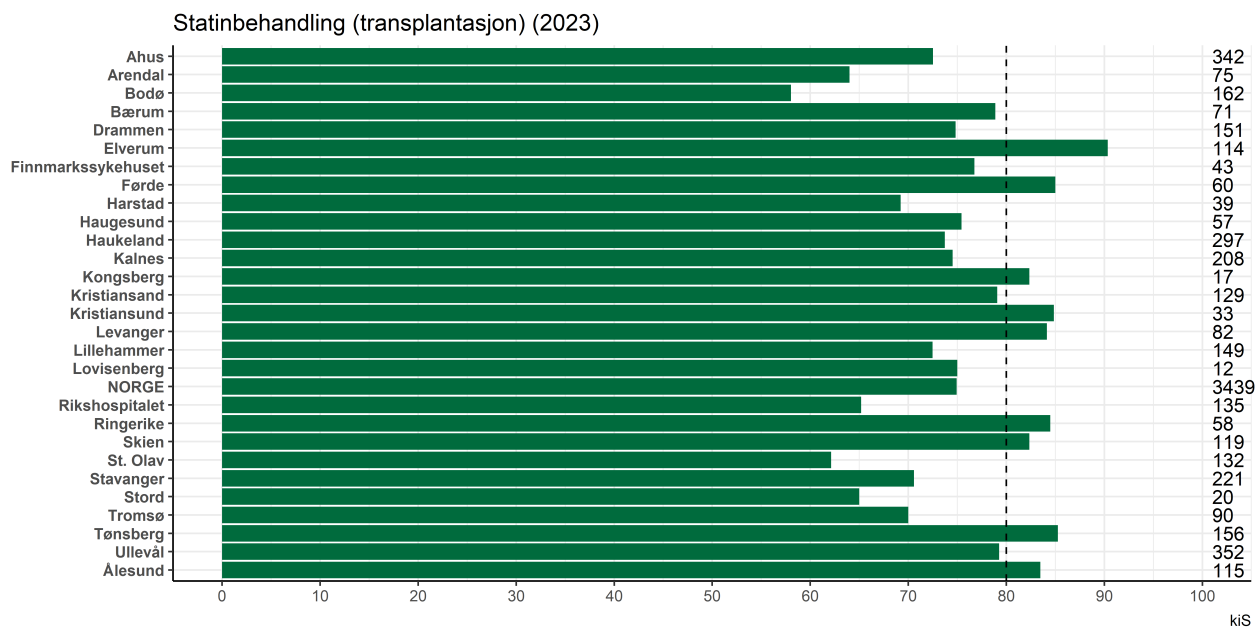


Figure A-73:

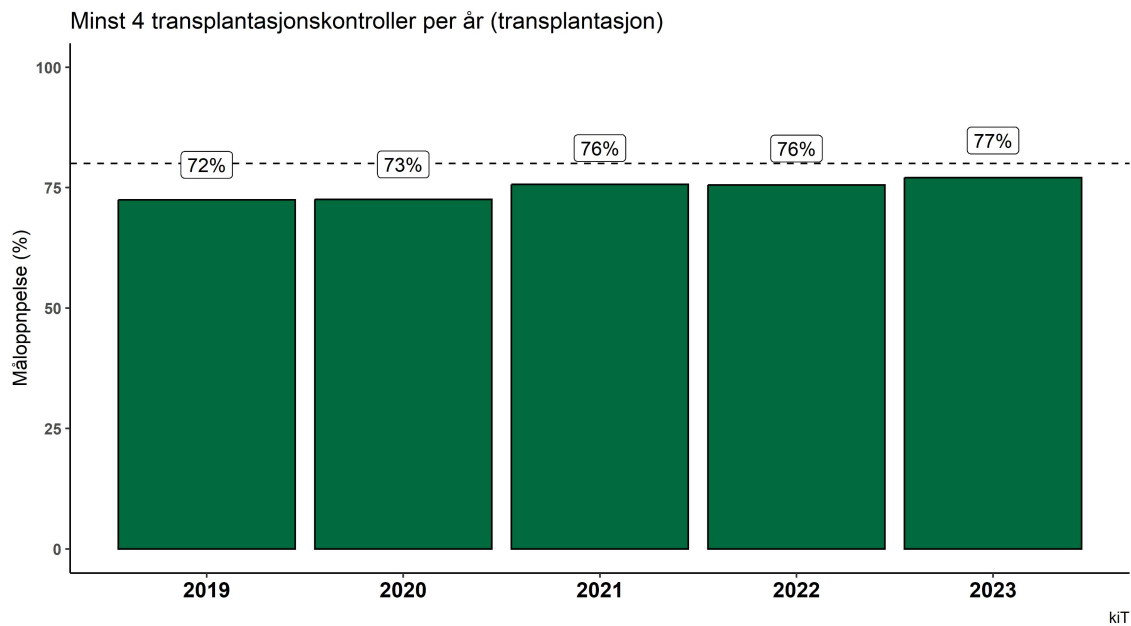


Figure A-74:

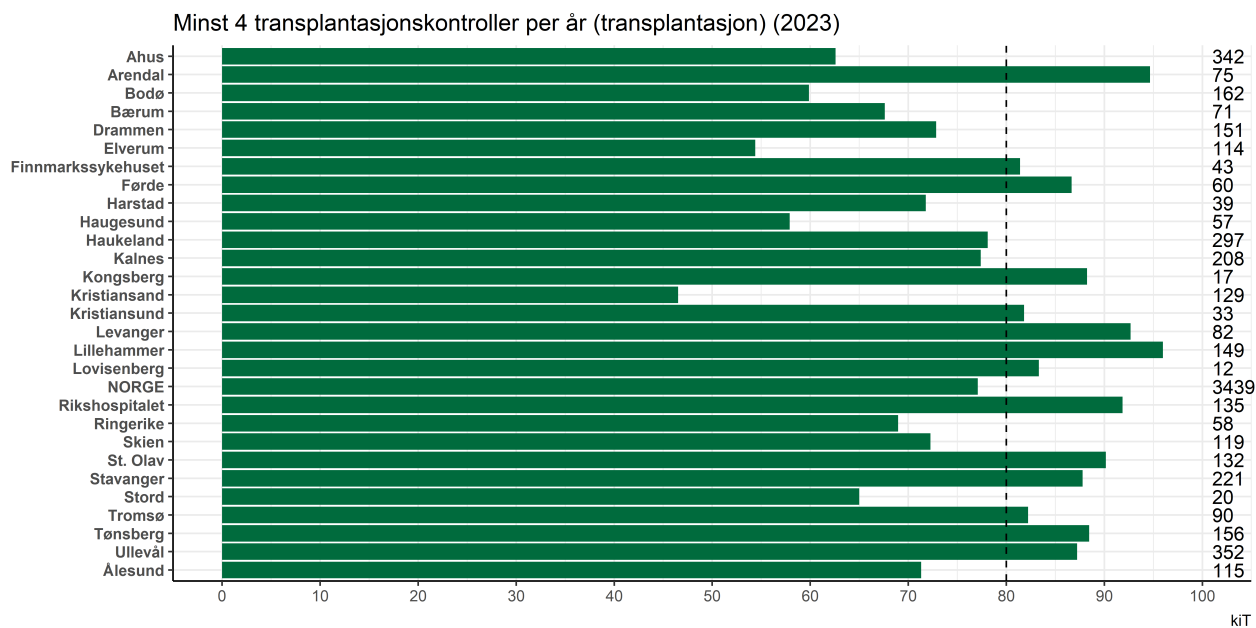


Figure A-75:

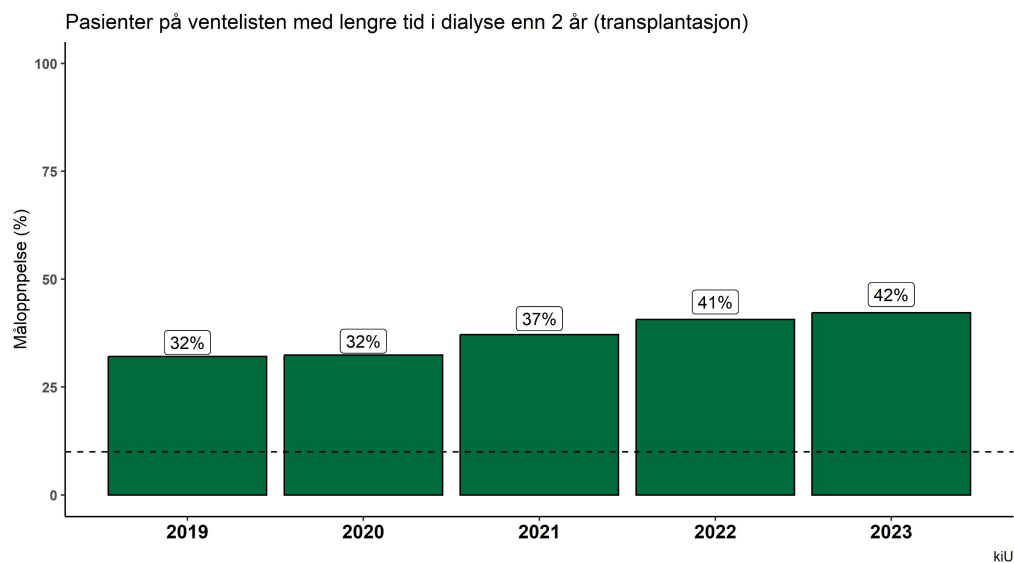


Figure A-76: NEW, only considering time on the list, irrespective of dialysis status

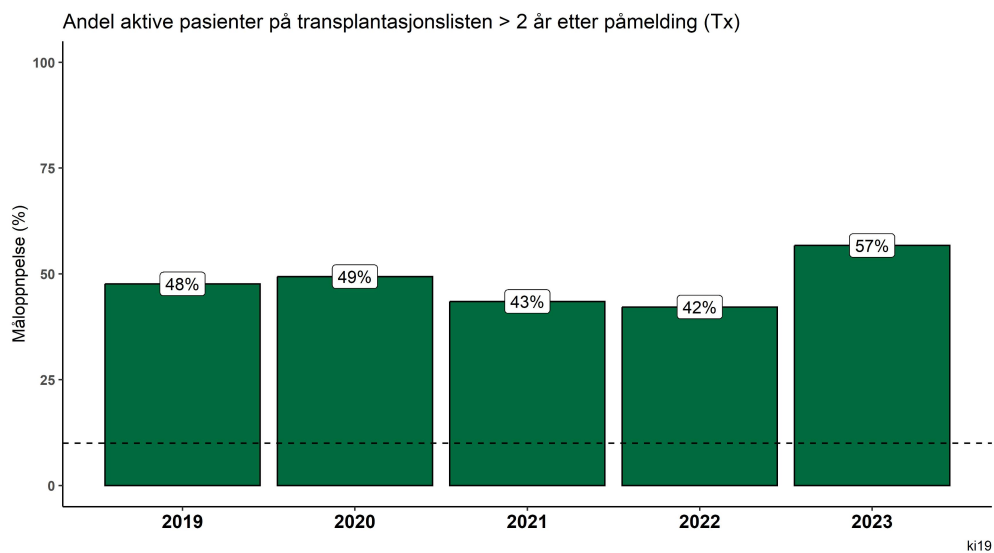
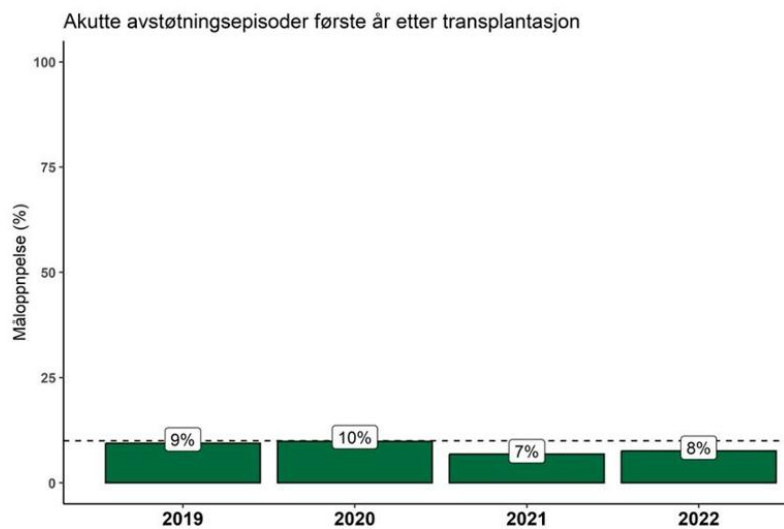


Figure A-77:



Appendix; center annual KRT numbers.

	Satellites	New patients in KRT 2023				Patients in KRT by 31.12.2023					Dialyses etc. 2023			Died 2023		Not tx-cand.
		HD/HDF	PD	Pre-emptive	Total	HD/HDF	HjemmeHD	PD	Graft	Total	HD sessions	Pl.exch.	Other	Dial.pat	Tx-pat	
AHUS	1	21	24	4	49	108	8	62	353	531	19,022	0	0	36	15	98
Arendal		6	8	2	16	29	0	13	77	119	3,960	0	43	5	1	30
Bergen	3	23	15	8	46	98	2	25	303	428	15,973	45	44	20	5	75
Bodø	9	17	9	0	26	72	0	19	162	253	11,166	17	0	21	4	45
Bærum		10	5	3	18	41	0	3	75	119	5,086	0	0	5	1	28
Drammen	1	16	19	3	38	45	5	27	172	249	9,674	49	0	15	13	31
Elverum		15	8	1	24	46	2	19	119	186	7,811	0	25	16	2	43
Finnmark	5	3	1	1	5	18	1	2	44	65	2,619	0	0	3	3	9
Førde	2	5	2	0	7	28	0	7	60	95	4,383	0	0	4	1	23
Harstad		2	1	0	3	10	0	1	41	52	1,956	0	0	1	2	8
Haugesund	2	11	1	0	12	42	0	6	64	112	6,263	80	25	6	3	26
Hønefoss	1	12	2	1	15	31	1	10	62	104	4,598	0	0	10	2	24
Kristiansand S	1	9	3	1	13	47	0	11	131	189	6,750	21	0	7	3	33
Kristiansund N	1	3		0	3	20	0	0	45	65	3,295	0	0	0	0	19
Levanger	6	11	7	2	20	61	2	14	86	163	10,051	0	155	9	4	51
Lillehammer	3	18	14	5	37	69	0	25	152	246	10,368	25	0	19	12	65
Lovisenberg		10	4	0	14	37	0	12	13	62	5,300	0	0	15	1	30
Rikshospitalet		3		1	4	7	1	0	141	149	3,271	215	52	2	2	3
Stavanger		23	6	5	34	79	1	18	229	327	12,675	34	29	21	6	54
Stord		1	4	0	5	9	1	2	20	32	1,686	0	0	3	1	5
Telemark	4	10	8	1	19	65	1	22	127	215	10,105	15	0	10	6	55
Tromsø	3	9	5	0	14	26	2	13	93	134	4,970	30	0	6	5	22
Trondheim	5	19	5	4	28	99	4	18	222	343	15,902	69	178	21	9	79
Tønsberg		14	15	2	31	34	1	34	156	225	6,454	112	80	18	10	32
Ullevål		21	17	7	45	65	3	43	368	479	12,428	120	0	23	16	58
Østfold	2	18	14	2	34	108	7	29	213	357	17,456	16	0	17	8	93
Ålesund	1	2	4	2	8	39	0	17	120	176	7,016	53	0	10	5	32
SUM	50	312	201	55	568	1,333	42	452	3,648	5,475	220,238	901	631	323	140	1,071
# Pr. mill innb.		55.9	36.0	9.8	101.7	238.7	7.5	80.9	653.2	980.3						191.8
% of total		54.9	35.4	9.7	100.0	24.3	0.8	8.3	66.6	100.0						19.6

Appendix: 2023- quality indicators for NNR.

20-11-2023

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
	Totalt, hvor fornøyd er pasienter i henholdsvis hjemmedialyse og senterdialyse med behandlingen?	90%	Totalt hvor fornøyde pasienter som behandles med hjemmedialyse er med denne behandlingen utfra PROM-skjema, skala 0-100%.
Hemodialyse	Andel som behandles «livsforlengende» med ukentlig Kt/V >2,3 (inkludert restfunksjon)	80 %	Mål på bevissthet og kvalitet av dialysebehandlingen
	Andel pasienter som behandles i HD med foretrukken blodtilgang	75 %	Gjennomførbarhet av behandling med optimal blodtilgang for pasienten.
Peritonealdialyse	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	75%	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≥90%, LAMP og STAMP)	<10%	Mål på om behandlingsforløpet er godt nok
	Biopsipåvist akutt rejeksjon første år etter transplantasjon	<10%	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)

20-11-2023

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
	Totalt, hvor fornøyd er pasienter i henholdsvis hjemmedialyse og senterdialyse med behandlingen?	90%	Totalt hvor fornøyde pasienter som behandles med hjemmedialyse er med denne behandlingen utfra PROM-skjema, skala 0-100%.
Hemodialyse	Andel som behandles «livsforlengende» med ukentlig Kt/V >2,3 (inkludert restfunksjon)	80 %	Mål på bevissthet og kvalitet av dialysebehandlingen
	Andel pasienter som behandles i HD med foretrukken blodtilgang	75 %	Gjennomførbarhet av behandling med optimal blodtilgang for pasienten.
Peritonealdialyse	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	75%	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≥90%, LAMP og STAMP)	<10%	Mål på om behandlingsforløpet er godt nok
	Biopsipåvist akutt rejeksjon første år etter transplantasjon	<10%	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)