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Cohort profile: Alliance for Quality Assessment in Healthcare-Dialysis (AQuAH-D) prospective cohort study of patients on haemodialysis in Japan

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ABSTRACT

Purpose The global burden of kidney failure is increasing, but the treatment of kidney failure varies widely between patients, between dialysis facilities and over time. The Alliance for Quality Assessment in Healthcare-Dialysis (AQuAH-D) aims to conduct efficient and timely cohort studies on associations between those variations and clinical and patient-reported outcomes.

Participants Included are outpatients aged 20 years old or older who are undergoing haemodialysis and have consented to participate. A total of 2895 patients were enrolled from 25 facilities in Japan between August 2018 and July 2020 and are to be followed until 31 December 2026. Chart review and annual questionnaires are used to collect data on patient characteristics and on outcomes including quality of life. Data on medications, haemodialysis prescriptions and blood tests are obtained from existing electronic records. Data are collected prospectively from 1 January 2017 to patient enrolment, and retrospectively from patient enrolment until the end of December 2026.

Findings to date To date, the mean age is 68.3 (SD 12.2) years and 35.2% are female. The most common cause of kidney failure is diabetic nephropathy (37.4%). In January 2020, the facilities’ median weekly doses of erythropoietin stimulating agent (ESA) and of intravenous vitamin D ranged from 1846 to 9692 IU (epoetin alfa equivalent) and 0.78 to 2.25 µg (calcitriol equivalent), respectively. The facilities’ percentages of patients to whom calcimimetics are prescribed varied from 19% to 79%. During the retrospective period (averaging 1.85 years per participant), the incidence rates of any hospitalisation and of cardiovascular hospitalisation were 67.2 and 12.0 per 100 person-years, respectively.

Future plans AQuAH-D data will be updated every 6 months and will provide valuable data that can be used for timely studies on changing haemodialysis practice.

Strengths and limitations of this study

► The Alliance for Quality Assessment in Healthcare-Dialysis, a multicentre prospective cohort of outpatients on haemodialysis in Japan. It will be updated every 6 months and will provide valuable data that can be used for timely studies on changing haemodialysis practice.

► With electronic records of highly granular, sequential practice-related data and data on outcomes including quality of life, a wide range of important research questions are expected to be addressed.

► Results from this cohort study are expected to inform approaches to the problems of ageing and multimorbidity of patients on haemodialysis, which are becoming more important worldwide.

► We are not attempting to construct a representative sample of dialysis facilities in Japan.

► We are unable to include data on prescriptions or examinations from facilities other than those participating in the study.

INTRODUCTION

Kidney failure is an important non-communicable disease. The number of people receiving kidney replacement therapy (KRT, either dialysis or kidney transplantation) worldwide was estimated to be 2.6 million in 2010 and is expected to reach 5.4 million by 2030.1 Kidney transplantation is preferred because of its favourable effects on prognosis and on quality of life (QOL).2 However, haemodialysis is currently the mainstay of KRT especially in eastern and southeastern Asia including Japan, where deceased-donor organ transplantation is relatively rare, probably due to cultural context.3,4 In Japan, approximately 300 000 people were on maintenance haemodialysis in 2018 and the number is increasing.5

Variations in haemodialysis practice have been described in observational studies, and possible associations of patient outcomes with patient-level, institutional and temporal variations have been evaluated.5–8 Management of kidney failure with haemodialysis requires
attention to anaemia, mineral–bone disorder (MBD), dialysis prescriptions, vascular access, comorbidities (diabetes mellitus, cardiovascular disease, etc) and changes over time. A database allowing questions about management of kidney failure to be answered quickly and efficiently would be useful. Researchers lack information that is granular enough to facilitate investigation of those questions.

Because Japan’s population is ageing faster than those in many other parts of the world, it is already dealing with the problems of ageing and multimorbidity of patients on haemodialysis that are starting to emerge in some other countries. In addition to survival, patient-reported outcomes (PROs), including QOL and symptoms, are important outcomes in this chronically ill and ageing population. In that context, we see an unmet need for a haemodialysis cohort database that includes both PROs and highly granular data, and for that database to be updated frequently and to be quickly available to researchers.

The Alliance for Quality Assessment in Healthcare-Dialysis (AQuAH-D), was established (1) to describe patient-level and facility-level variations in dialysis practice, (2) to investigate the factors explaining and predicting variations in dialysis practice and (3) to investigate associations between variations in dialysis practice and clinical outcomes including PROs among ageing patients on maintenance haemodialysis in Japan. To achieve those objectives, we have established a system to frequently collect highly granular data, and to share them with researchers without delay.

COHORT DESCRIPTION
Study design and Setting
This is a multicentre prospective cohort study of clinics and hospitals with outpatient haemodialysis centres in Japan. Facility recruitment started in September 2018 and participants are recruited from the time of facility participation until 30 June 2026. Follow-up is intended to continue until the end of December 2026.

Participants
Outpatients aged 20 years old or older, the age at which people in Japan are legally considered to be adults, who are undergoing maintenance haemodialysis and have consented to participate are being included. Patients who receive peritoneal dialysis are being excluded, because we have not established a sustainable method to collect sufficient data on peritoneal dialysis, due to the lack of facility-by-facility electronic data on variables relevant to research, such as daily dialysis prescriptions over time. This cohort is open: Patients who were attending a facility at the time of the start of that facility’s participation and those who begin coming to the facility thereafter until 30 June 2026 are candidates for enrolment.

Data sources and data collection
In principle, the data come from three types of sources: existing electronic records of practice-related data, chart review and patient-completed questionnaires (figure 1). A unique application software called AQuAH-D app, installed on each facility’s computer, is used to integrate the data by patient ID, to create the facility database and to transfer the participants’ anonymised data to the central database every 6 months.

Data source 1: existing electronic records of practice-related data
To minimise the burden of data collection, we use each facility’s existing electronic records of practice-related data: health insurance claims data, haemodialysis management system data and laboratory data. Health insurance claims data are generated for reimbursement at each facility every month. Haemodialysis management systems are used by healthcare providers to manage haemodialysis prescriptions, to record the results of haemodialysis sessions, to hold data on patient characteristics and to hold data from each dialysis session. AQuAH-D, Alliance for Quality Assessment in Healthcare-Dialysis; DB, database, VPN, virtual private network.

Data source 2: chart review
Event data and data on patient characteristics that are not in the existing electronic records are obtained by reviewing medical charts. The AQuAH-D app displays a data-entry form to the user, based on the data imported automatically into the facility database. The form is manually filled in by trained facility staff or clinical research coordinators.
Variables

The measured variables, data sources and timing of measurements are summarised in table 1. Data on the patients’ characteristics are collected primarily from existing electronic records, and are supplemented by chart review or patient questionnaires. Practice-related data and data on haemodialysis results from existing electronic records are recorded at the time of each dialysis visit, that is, about 13 days per month. Laboratory data measured as part of usual practice are recorded approximately one to four times a month.

Outcome data consist of PROs and events. PROs are measured at the time of patient enrolment and annually thereafter, and event data are collected when a predefined event occurs. Data on 7 kinds of events are collected: death, hospitalisation, kidney transplantation, vascular-access intervention, transfer to another facility, discontinuation of dialysis and transfer to peritoneal dialysis or to home dialysis. The plan is to measure QOL repeatedly by using the Quality of Life General-10, the QOL Disease Impact Scale, and the Kidney Disease Quality of Life instrument. Details of other PROs to be measured will be revised. Table 1 shows the content of the first questionnaire, which is used at the time of facility enrolment.

Data availability

Data collected in the central database are converted into patient-level data with a format suitable for analysis. Participating facilities receive datasets generated from their own facility data, and are free to use them. All data from the AQuAH-D cohort are also available for use by participating institutions or third-party organisations under the following conditions: Each research question must be submitted to the publication steering committee, the committee must judge it to be relevant, and the committee must approve the validity of the study design.

Patient and public involvement

Patients and the public were not engaged in the design, conduct, or reporting of this study.

FINDINGS TO DATE

Facility and participant characteristics

From 1 September 2018 to 31 July 2020, 2895 participants from 25 facilities in Japan were enrolled in the study. Of those 25 facilities, 19 were clinics and 6 were hospitals (clinics are defined as having 19 or fewer inpatient beds, and hospitals are defined as having 20 or more inpatient beds). The patient volume, that is, number of visiting patients’ characteristics are collected primarily from existing electronic records, and are supplemented by chart review or patient questionnaires. Practice-related data and data on haemodialysis results from existing electronic records are recorded at the time of each dialysis visit, that is, about 13 days per month. Laboratory data measured as part of usual practice are recorded approximately one to four times a month.

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Participants’ characteristics at the time of enrolment (figure 2) are shown in table 2 together with demographic information from the Japanese Society of Dialysis Therapy (JSDT) Registry in 2018. That registry includes survey results from 94.7% of all dialysis facilities, and thus, it covers nearly all patients on dialysis in Japan. In the AQuAH-D cohort, the mean age was 68.3 (SD 12.2) years and 35.2% were female. The most frequent cause of kidney failure was diabetic nephropathy (37.4%), followed by glomerulonephritis (28.4%). These results were similar to those in the JSDT Registry.

**Data from existing electronic records**

As examples of existing electronic records of practice-related data, figure 3 shows the administration status of ESA for renal anaemia, intravenous vitamin D and calcimimetics for MBD management at each facility in January 2020, where data for the month is currently available.

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**Table 1  Measured variables, data sources, and the timing of measurements**

| Variable                        | Data sources | Timing of measurement                      |
|---------------------------------|--------------|---------------------------------------------|
| Characteristics of patients     | Electronic data | Start of observation*                      |
| Year and month of birth         | ✓            |                                             |
| Sex                             | ✓            |                                             |
| Cause of kidney failure         | ✓            | ❚                                             |
| Date of haemodialysis initiation| ✓            | ❚                                             |
| Height                          | ✓            | ❚                                             |
| Type of vascular access         | ✓            | Start of observation and when status changes |
| Comorbidities                   | ✓            | ❚                                             |
| Living status                   | ✓            | ❚                                             |
| Smoking status                  | ✓            | ❚                                             |
| Employment status               | ✓            | Study enrolment                             |
| Alcohol consumption             | ✓            | ❚                                             |
| Risk score for falls            | ✓            | ❚                                             |
| Practice-related data           | ✓            | ❚                                             |
| Procedures (examinations, interventions, prescriptions) | ✓ | Every visit from start of observation |
| Haemodialysis prescription      | ✓            | ❚                                             |
| Vital signs during haemodialysis| ✓            | Every session from start of observation     |
| Body weight before and after haemodialysis | ✓ | ❚                                             |
| Laboratory data                 | ✓            | ❚                                             |
| Items measured in daily practice| ✓            | ❚                                             |
| Outcomes                        |              | Study enrolment and annual. Every measurement |
| General QOL: QGEN-10            | ✓            | ❚                                             |
| Disease-specific QOL: QDIS      | ✓            | ❚                                             |
| Symptom scale in KDQOL          | ✓            | ❚                                             |
| Events                          |              | When the outcome occurs from start of observation |
| Death                           | ✓            | ❚                                             |
| Hospitalisation                 | ✓            | ❚                                             |
| Vascular-access intervention    | ✓            | ❚                                             |
| Kidney transplantation          | ✓            | ❚                                             |
| Transfer to peritoneal dialysis or home haemodialysis | ✓ | ❚                                             |
| Transfer to another facility    | ✓            | ❚                                             |
| Discontinuation of haemodialysis| ✓            | ❚                                             |

Risk score for falls. Start of observation is defined for each participant as 1 January 2017 or the participant’s first day of haemodialysis, whichever is later (figure 2). KDQOL, Kidney Disease Quality of Life instrument; QDIS, QOL Disease Impact Scale; QGEN-10, Quality of Life General-10; QOL, quality of life.
The median doses of ESA and of intravenous vitamin D ranged from 1846 to 9692 IU per week and from 0.78 to 2.25 µg per week, respectively. The percentage of patients to whom calcimimetics were prescribed varied by facility, from 19% to 79%.

**Incidence of hospitalisations and vascular-access interventions in the retrospective period**

During the retrospective periods, the total observation time was 5356 person-years (an average of 1.85 years). The incidence rate of any hospitalisation was 67.2 per 100 person-years, and the most common cause of hospitalisation was vascular-access complication, followed by cardiovascular disease (19.8 and 12.0 per 100 person-years, respectively). The incidence rate of vascular-access intervention, which can be done as an outpatient treatment, was 60.6 per 100 person-years. Details are shown in online supplemental table 1.

**STRENGTHS AND LIMITATIONS**

The AQuAH-D is a multicentre cohort of outpatients on haemodialysis in Japan. With electronic records of practice-related data and data on outcomes including

**Table 2  Baseline characteristics of participants in the AQuAH-D cohort and of Japan’s dialysis population**

|                                      | AQuAH-D cohort | JSDT Renal Data Registry (2018)* |
|--------------------------------------|----------------|----------------------------------|
| No of patients                       | 2895           | 339 841                          |
| Age (years)                          | 68.3 (12.2)    | 68.8 (12.5)                      |
| Sex, female                          | 1019           | 34.6%                            |
| Cause of kidney failure              |                |                                  |
| Diabetic nephropathy                 | 1083           | 37.4%                            |
| Glomerulonephritis                   | 823            | 28.4%                            |
| Nephrosclerosis                      | 347            | 12.0%                            |
| Other diseases                       | 642            | 22.2%                            |
| Duration of dialysis (years)         | 5.4 (2.0, 11.2)|                                  |
| Body mass index (kg/m²)              | 22.2 (4.1)     |                                  |
| Type of vascular access              |                |                                  |
| Arteriovenous fistula                | 2532           | 87.6%                            |
| Arteriovenous graft                  | 224            | 7.7%                             |
| Others                               | 135            | 4.7%                             |
| Comorbidity                          |                |                                  |
| Cardiovascular disease               | 1505           | 52.0%                            |
| Diabetes mellitus                    | 1297           | 44.8%                            |
| Lung disease                         | 178            | 6.1%                             |
| Liver disease                        | 219            | 7.6%                             |
| Malignancy                           | 499            | 17.2%                            |
| Haemodialysis prescription           |                |                                  |
| Type of dialysis treatment           |                |                                  |
| Haemodialysis                        | 1433           | 49.5%                            |
| Haemodiafiltration                   | 1285           | 44.3%                            |
| Missing                              | 177            | 6.1%                             |
| Single pool Kt/V†                    | 1.62 (0.36)    |                                  |
| Laboratory data                      |                |                                  |
| Haemoglobin (g/L)                    | 112 (12)       |                                  |
| Serum albumin (g/dL)                 | 3.6 (0.4)      |                                  |
| Serum phosphorus (mEq/L)             | 5.3 (1.4)      |                                  |
| Corrected serum calcium‡ (mg/dL)     | 9.1 (0.6)      |                                  |

Continuous variables are described by the mean (SD) or the median (IQR), and categorical variables are described by the number and percentage. *Results of a survey carried out by the Japanese Society for Dialysis Therapy, in December 2018. The JSDT registry includes about 9000 patients on peritoneal dialysis. Percentages were calculated among participants without missing data. †Single pool Kt/V values were calculated using the equation by Daugirdas. ‡Serum calcium values were corrected for albumin concentration using a modified version of Payne’s formula. AQuAH-D, Alliance for Quality Assessment in Healthcare-Dialysis; JSDT, Japanese Society for Dialysis Therapy.
QOL, a wide range of important research questions are expected to be addressed.

To clarify the strengths and limitations of this cohort, online supplemental table 2 shows a summary of some major characteristics of the AQuAH-D together with those of four other registries: the US Renal Data System database,20–22 the European Renal Association-European Dialysis and Transplant Association Registry,23–25 the JSDT Renal Data Registry5 26 and the Dialysis Outcomes and Practice Patterns Study.27–29

Strengths
This study has several strengths. First, our unique software (the AQuAH-D app) enables us to automatically import patient data and thus minimise the administrative burden on facility staff. This advantage will contribute to cohort sustainability. In addition, the availability of highly granular, sequential, patient-level data is expected to allow researchers to address a wide range of research questions, including questions about the impact of various exposures on patient outcomes. The AQuAH-D app can import data in a variety of formats. If each facility enters more of its data into electronic health records, then we will be able to collect data on more variables. Second, data from medical chart reviews are incorporated to address two common limitations of existing databases: missing data and misclassification.22 25 30 For example, one major limitation of some existing large databases is a lack of accurate data on comorbidities, but in this cohort those data are collected (by chart review) (online supplemental table 2). Third, measuring QOL provides important information about patients with kidney failure,16 and the plan here is to measure QOL repeatedly. Fourth, this cohort will provide information about problems that are emerging worldwide as a result of ageing and multimorbidity of patients on haemodialysis. Fifth, we consider the participating facilities to constitute a research consortium, and we encourage healthcare professionals there to use these data. We believe that will motivate participating facilities, which will help to sustain the cohort and will facilitate research on clinically relevant questions.

Limitations
There are several limitations. First, we are not attempting to construct a representative sample of dialysis facilities in Japan. In addition, only those participants who give their informed consent are included, which might result in the participants being healthier or younger than Japan’s haemodialysis population as a whole. Especially in descriptive studies, researchers should recognise that generalisability of the results is limited. Second, we are unable to include data on prescriptions or examinations from facilities other than those participating in the study. Third, data pertaining to the retrospective period (1 January 2017 to the time of patient enrolment) come from participants who survive until the time of enrolment, so inferences from those data can be affected by selection bias.

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REFERENCES

1. Liyanage T, Ninomiya T, Jha V, et al. Worldwide access to treatment for end-stage kidney disease: a systematic review. *Lancet* 2015;385:1975–82.

2. Tonelli M, Wiebe N, Knoll G, et al. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. *Am J Transplant* 2011;11:2093–109.

3. Robinson BM, Akizawa T, Jager KJ, et al. Factors affecting outcomes in patients reaching end-stage kidney disease worldwide: differences in access to renal replacement therapy, modality use, and haemodialysis practices. *Lancet* 2016;388:294–306.

4. Akabayashi A, Nakazawa E, Ozeki-Hayashi R, et al. Twenty years after enactment of the organ transplant law in Japan: why are there still so few deceased donors? *Transplant Proc* 2018;50:1209–19.

5. Nitta K, Goto S, Masakane I, et al. Annual dialysis data report for 2018, JSDT renal data registry: survey methods, facility data, incidence, prevalence, and mortality. *Renal Replacement Therapy* 2020;6.

6. Robinson BM, Tong L, Zhang J, et al. Blood pressure levels and mortality risk among hemodialysis patients in the dialysis outcomes and practice patterns study. *Kidney Int* 2012;82:570–80.

7. Kawaguchi T, Karabayas A, Robinson BM, et al. Associations of frequency and duration of patient-doctor contact in hemodialysis facilities with mortality. *J Am Soc Nephrol* 2013;24:1493–502.

8. Sood MM, Larkina M, Thumma JR, et al. Major bleeding events and risk stratification of antithrombotic agents in hemodialysis: results from the DOPPS. *Kidney Int* 2013;84:600–8.

9. Yamamoto H, Nishi S, Tomo T, et al. 2015 Japanese Society for dialysis therapy guidelines for renal anemia in chronic kidney disease. *Renal Replacement Therapy* 2017;3.

10. Fukagawa M, Yokoyama K, Koika F, et al. Clinical practice guideline for the management of chronic kidney disease-mineral and bone disorder. *Ther Apher Dial* 2013;17:247–88.

11. Watanabe Y, Kawanishi H, Suzuki K, et al. Japanese society for dialysis therapy clinical guideline for “Maintenance hemodialysis: hemodialysis prescriptions”. *Ther Apher Dial* 2015;19:Suppl 1:67–92.

12. Kukita K, Ohira S, Amano I, et al. 2011 update Japanese Society for dialysis therapy guidelines of vascular access construction and repair for chronic hemodialysis. *Ther Apher Dial* 2015;19 Suppl 1:1–39.

13. Nakao T, Inaba M, Abe M, et al. Best practice for diabetic patients on hemodialysis 2012. *Ther Apher Dial* 2015;19 Suppl 1:40–66.

14. Hirakata H, Nitta K, Inaba M, et al. Japanese Society for dialysis therapy guidelines for management of cardiovascular diseases in patients on chronic hemodialysis. *Ther Apher Dial* 2012;16:387–435.

15. Kimata N, Tsuchiya K, Akiba T, et al. Differences in the characteristics of dialysis patients in Japan compared with those in other countries. *Blood Purif* 2015;40:275–9.

16. Ishiwatari A, Yamamoto S, Fukushima S, et al. Changes in quality of life in older hemodialysis patients: a cohort study on dialysis outcomes and practice patterns. *Am J Nephrol* 2020;51:650–8.

17. Ware JE, Gandek B. Measuring physical and emotional health with the SF-36 health survey: a one-dimensional concept? *Med Care* 1992;30:794–805.

18. Ware JE, Gandek B, Glick HA. Short-form SF-36 health survey: reliability and validity in a clinical sample. *Med Care* 1993;31:247–60.

19. Green J, Fukuhara S, Shintzato T, et al. Translation, cultural adaptation, and initial reliability and multi-trait testing of the kidney disease quality of life instrument for use in Japan. *Qual Life Res* 2001;10:93–100.

20. USDA. About USRDS. Available: https://usrds.org/about/ [Accessed February 17, 2021].

21. Nitta K, Goto S, Masakane I, et al. Annual dialysis data report for 2018, JSDT renal data registry: survey methods, facility data, incidence, prevalence, and mortality. *Renal Replacement Therapy* 2020;6.

22. Green J, Fukuhara S, Shintzato T, et al. Translation, cultural adaptation, and initial reliability and multi-trait testing of the kidney disease quality of life instrument for use in Japan. *Qual Life Res* 2001;10:93–100.

23. European Renal Association-European Dialysis and Transplant Association. ERA-EDTA registry. Available: https://www.era-edta.org/en/reg/ [Accessed February 17, 2021].

24. Kramer A, Boenink R, Noordzij M, et al. The ERA-EDTA registry annual report 2017: a summary. *Clin Kidney J* 2020;13:693–709.

25. Hamaratbat J, Bonthuis M, Groothoff JW, et al. Lessons learned from the ESPN/ERA-EDTA registry. *Pediatr Nephrol* 2016;31:2055–64.

26. The Japanese Society for Dialysis Therapy. About JSDT. Available: https://www.jsdt.or.jp/english/ [Accessed February 17, 2021].
Arbor Research Collaborative for Health. Dialysis outcomes and practice patterns study. Available: https://www.dopps.org/ [Accessed February 17, 2021].

Pisoni RL, Gillespie BW, Dickinson DM, et al. The dialysis outcomes and practice patterns study (DOPPS): design, data elements, and methodology. *Am J Kidney Dis* 2004;44:7–15.

UMIN. UMIN clinical trials registry. Available: https://upload.umin.ac.jp/cgi-open-bin/icdr_e/ctr_view.cgi?recptno=R000041884 [Accessed February 17, 2021].

Bikbov B, Purcell CA, Levey AS, et al. Global, regional, and national burden of chronic kidney disease, 1990-2017: a systematic analysis for the global burden of disease study 2017. *Lancet* 2020;395:709–33.

Okochi J, Toba K, Takahashi T, et al. Simple screening test for risk of falls in the elderly. *Geriatrics and Gerontology International* 2006;6:223–7.

Daugirdas JT. Second generation logarithmic estimates of single-pool variable volume Kt/V: an analysis of error. *J Am Soc Nephrol* 1993;4:1205–13.

Payne RB, Little AJ, Williams RB, et al. Interpretation of serum calcium in patients with abnormal serum proteins. *Br Med J* 1973;4:643–6.

Aljama P, Bommer J, Canaud B, et al. Practical guidelines for the use of NESP in treating renal anaemia. *Nephrol Dial Transplant* 2001;16:22–8.

Vega A, Abad S, Verdalles U, et al. Dose equivalence between continuous erythropoietin receptor activator (CERA), darbepoetin and epoetin in patients with advanced chronic kidney disease. *Hippokratia* 2014;18:315–8.

Ando R, Yoshikawa M, Yamashita Y, et al. Prospective comparison of the effects of maxacalcitol and of intravenous calcitriol on secondary hyperparathyroidism in chronic hemodialysis patients. *Nihon Toseki Igakkai Zasshi* 2003;36:317–25.