

Delayed graft function and outcome-data readiness after pediatric kidney transplantation in Ecuador: a single-center retrospective cohort

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Abstract

Background

Recipient-level pediatric kidney transplant data from Ecuador are scarce, and the ability of routine records to support longitudinal outcomes is unknown. We described transplant characteristics, estimated delayed graft function (DGF), and audited outcome-data usability.

Methods

We conducted a single-center retrospective cohort and field-level audit of kidney transplants recorded from January 2022 through August 2025. Among 69 records, 62 met pediatric eligibility and date-validity criteria. DGF was dialysis within seven days after transplantation. We used available-case summaries, Wilson 95% confidence intervals, exploratory comparisons, and missing-case bounds.

Results

Median age at transplantation was 14.3 years. Hemodialysis preceded transplantation in 48/62 (77.4%); median dialysis exposure was 45.7 months among 54 records with valid dates. DGF occurred in 7/57 (12.3%; 95% confidence interval 6.1–23.2%), with full cohort bounds of 11.3–19.4%. Donor type was source-verified in 21/62 (33.9%). Among 57 records with evaluable last graft status, 54 (94.7%) were functioning; valid event or censoring dates were available in 41/62 (66.1%), biopsy-rejection ascertainment in 4/62 (6.5%), and validated donor-specific antibody and mortality endpoints in none.

Conclusions

The DGF estimate overlapped recent pediatric cohorts but could not be benchmarked by donor source or ischemia time. Prolonged dialysis and incomplete outcome ascertainment show why favorable last-recorded status cannot substitute for survival analysis. Source-audited minimum datasets are needed across settings with limited registry infrastructure.

Background

Kidney transplantation is the preferred kidney replacement therapy for many children with kidney failure because it offers better survival and quality of life than prolonged dialysis and can support growth and participation in school and family life [1-4]. Despite major improvements in short-term outcomes, pediatric recipients remain exposed to graft failure, retransplantation, alloimmune injury, medication toxicity, and adherence challenges across decades of follow-up [2-3].

Access to pediatric kidney transplantation and the capacity to measure its outcomes are unevenly distributed. Programs in resource-constrained settings must manage shortages in specialized personnel, histocompatibility testing, organ availability, longitudinal follow-up, and registry infrastructure [1, 4-5]. These constraints can prolong dialysis exposure. They can also make apparently favorable crude outcomes difficult to interpret when donor characteristics, follow-up dates, and outcome-ascertainment methods are incomplete.

Pediatric kidney data from Latin America and the Caribbean remain uneven, with sparse national pediatric registries and substantial reliance on aggregate reporting [6-7]. Ecuadorian governmental and peer-reviewed sources quantify the national kidney replacement therapy burden and describe transplant infrastructure and activity, but they do not provide a recipient-level pediatric transplant cohort with standardized longitudinal outcomes [8-10]. This leaves both a clinical evidence gap and a measurement gap.

A recent single-center Brazilian cohort of 101 pediatric kidney transplants demonstrated the value of recipient-level reporting by describing donor source, pre-emptive transplantation, DGF, complications, and graft survival [11]. Its comparatively complete event and censoring data also illustrate why last-recorded graft status must not be presented as survival. Evaluating outcome-data readiness addresses a broader question relevant to programs with emerging registry infrastructure: whether routine records can distinguish event absence from non-ascertainment and support valid longitudinal inference.

We aimed to characterize the recipient, donor, immunologic, and treatment profile of pediatric kidney transplant records at Hospital Pediátrico Baca Ortiz (HPBO) from 2022 to 2025; estimate the proportion with DGF; describe last-recorded graft status without treating it as survival; and quantify the completeness and analytic usability of fields required for longitudinal outcome analysis.

Methods

Study design and setting

This was an observational, descriptive, retrospective single-center cohort with an embedded field-level audit of routinely collected transplant data. HPBO is a public pediatric referral hospital in Quito, Ecuador, with a kidney transplantation program. The analytic period included eligible transplants recorded from January 2022 through August 2025; 2025 therefore represents a partial calendar year. The report follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations [12]. Because the analytic matrix was derived from routinely collected clinical information, relevant items from the Reporting of studies Conducted using Observational Routinely collected health Data (RECORD) extension were also applied [13]. RECORD guided reporting of data provenance, record selection, field definitions, cleaning and validation rules, missingness, and limits of outcome ascertainment; it was not used to imply that the underlying clinical record had been externally validated. The completed STROBE checklist and RECORD compliance map are provided in the Related Files Section (Related File #1).

Participants

The statistical repository of Hospital Pediátrico Baca Ortiz supplied an anonymized extract of the institutional master matrix containing 69 kidney transplant records. We included records for recipients younger than 18 years on the transplant date who underwent kidney transplantation at HPBO during the study period and had a valid transplant date and sufficient information to establish pediatric eligibility. Six records were excluded because age at transplantation was 18 years or older, and one because age or transplant-date validity could not be established. The resulting census cohort comprised 62 pediatric recipient-transplant observations. One matrix row was treated as one observation. Because the study-specified analytic layer did not contain a validated retransplantation indicator, repeated transplantation in the same person could not be independently identified.

Data source, provenance, and curation rules

This report is a secondary analysis of a fixed anonymized extract supplied by the statistical repository of Hospital Pediátrico Baca Ortiz and derived from routine clinical documentation. The corresponding author confirmed that the workbook containing names served solely as institutional backup; the research team received a separate extract anonymized at source, without names or internal patient codes. The anonymized extract, rather than the underlying paper or electronic clinical records, was the sole participant-level source available to the analytic team for this manuscript. No new chart re-abstraction, external database linkage, automated clinical-code case finding, or natural-language extraction was performed. Accordingly, the field-level audit assesses whether supplied values were analytically usable under explicit rules; it does not establish the completeness or accuracy of the underlying clinical record.

Analyses were restricted to a study-specified analytic layer, and values were assessed using explicit field-specific analytic-usability rules. A value was retained only when it met the applicable plausibility, chronology, source-documentation, or standardization rule summarized in the operational-rules table at the end of the manuscript. Values flagged for source review, unverified inference, doubtful standardization, impossible chronology, or non-documentation were treated as missing for the corresponding analysis. The analysis and all reported outputs excluded direct identifiers and internal patient codes. The identified master workbook remained an access-restricted institutional backup, separate from the anonymized research extract. The exact source-database lock date was not validated; August 2025 was therefore treated as the operational end of the transplant-inclusion window, not as a recipient-specific censoring date. Follow-up dates extending beyond this window were not independently validated against the source records; recipient-specific time-to-event estimates were therefore not reported.

Age at transplantation was recalculated from birth and transplant dates. Dialysis and wait-list durations were calculated only when the documented start date preceded transplantation; negative or otherwise invalid intervals were excluded. Causes of kidney failure were grouped as glomerular disease; congenital

anomalies of the kidney and urinary tract (CAKUT) or urological causes; hereditary or cystic disease; secondary or immunologic disease; other; or unknown or unclassified. Sparse etiologic categories were combined for public reporting.

Immunologic descriptors included ABO compatibility, standardized crossmatch result, qualitative panel-reactive antibody (PRA) class I and II status, and the conventional HLA-A/B/DR mismatch score (0–6). Quantitative PRA thresholds, HLA-DQ mismatch, and donor-specific antibody (DSA) fields were not analyzed because they did not pass the matrix-level validation rules. Donor type inferred from narrative text was not considered source-verified and was excluded from donor-type comparisons. Induction therapy was grouped as basiliximab-based, antithymocyte globulin (ATG)-based, or other or unclassifiable. Maintenance therapy at discharge was classified as tacrolimus, mycophenolate, and corticosteroid triple therapy only when all three components were documented. Tacrolimus initiation was analyzed only when expressed as a plausible interval of 0–30 days after transplantation.

Outcomes

The primary clinical outcome was DGF, defined as dialysis within seven days after kidney transplantation [14-15]. The denominator was restricted to records with a standardized yes or no DGF value. The data-usability outcome was the proportion of eligible records that met each explicit field-specific analytic-usability rule. This required more than a non-empty cell. Secondary descriptions included last-recorded graft status and the proportion of records with a valid graft event or censoring date.

A record was considered evaluable for time-to-graft-outcome analysis only when a valid graft-loss date accompanied graft loss or a valid last-follow-up date accompanied a functioning graft, and the date was not earlier than transplantation. Because the matrix did not provide sufficiently validated longitudinal endpoints, Kaplan-Meier graft survival, patient survival, rejection incidence, DSA incidence, and mortality were not estimated. Last-recorded graft status is reported only as a cross-sectional service description.

Bias and missing-data management

Selection bias at cohort entry was limited by including all records that met the explicit eligibility and date-validity criteria during the analytic period. Misclassification was addressed by retaining only values that met field-specific source-documentation, chronology, plausibility, and standardization rules; undocumented events were not coded as absent. Missing values were not imputed, variable-specific denominators were displayed, and missing-case bounds were calculated for DGF. Potential selection related to follow-up evaluability was explored using age and sex standardized mean differences. Residual bias from the matrix-only source and non-random outcome missingness could not be eliminated.

Statistical analysis

Categorical variables are summarized as number and percentage using the available case denominator shown for each result. Continuous variables are reported as median and interquartile range (IQR). The DGF proportion is accompanied by a two-sided 95% Wilson confidence interval (CI). Missing values were not imputed. To show the maximum influence of the five records without evaluable DGF status, we calculated full-cohort missing-case bounds by assuming first that none and then that all had DGF.

Exploratory comparisons between DGF and no-DGF observations used Fisher's exact test for categorical variables and the two-sided Mann–Whitney U test for continuous variables. For non-suppressed 2 x 2 comparisons, conditional maximum-likelihood odds ratios (ORs) and exact 95% CIs were calculated; descriptive differences between group medians were also reported. Analyses were unadjusted, non-causal, and hypothesis-generating, with no multiplicity correction. Multivariable modeling was not performed because only seven DGF events were observed and several candidate variables had substantial missingness. Because this was a census of all eligible records during the study period, no a priori sample-size calculation was performed. Potential selection related to follow-up evaluability was described using standardized mean differences (SMDs) for recipient age and sex; joint distributions required to compare other covariates were unavailable in the fixed analytic output supplied for analysis. Analyses used Python 3.12.13, pandas 2.2.3, NumPy 2.3.5, and SciPy 1.17.0.

Use of generative artificial intelligence

OpenAI ChatGPT/Codex was used for document formatting. It was not used to generate the source data or to replace author review of the clinical and statistical content. All authors reviewed the final text; responsibility for the accuracy and integrity of the work remains with the authors.

Ethical considerations

This study was conducted in accordance with the Declaration of Helsinki. This retrospective cohort study was approved by the Comité de Ética de Investigación en Seres Humanos del Hospital Pediátrico Baca Ortiz (CEISH-HPBO; Of. No. 039-CEISH-HPBO-2026; study code 052-CEISH-HPBO-2026; 18 June 2026). The approved final protocol was submitted on 9 June 2026. The corresponding author confirms that this approved version already contemplated the matrix as the sole participant-level data source and the omission of Kaplan-Meier survival estimation. Research-specific access to data supplied by HPBO's internal biostatistics department and construction of the study matrix began on 19 June 2026, after ethics approval. Statistical analysis began on 28 July 2026. In a complementary determination dated 18 June 2026, the CEISH-HPBO stated that informed consent from participants or their legal representatives and assent from pediatric participants were not required for the approved retrospective study, because the information provided for analysis was anonymized at source. No kidneys used in the transplantations reported in this study were obtained from prisoners. The transplanted kidneys were obtained through the Nephrology/Pediatric Kidney Transplant Program of Hospital Pediátrico Baca Ortiz and Ecuador's Sistema Nacional Integrado de Donación y Trasplante, under the allocation, distribution,

and traceability procedures of the Instituto Nacional de Donación y Trasplante de Órganos, Tejidos y Células (INDOT), from donors identified at Hospital Pediátrico Baca Ortiz, accredited donation/transplant establishments, and establishments participating as 'establecimientos amigos de la donación'.

Results

Cohort assembly and recipient profile

Among 69 source records, 62 pediatric recipient-transplant observations met the eligibility criteria. Six records were excluded because the recipient was at least 18 years old at transplantation and one because age or transplant-date validity could not be established. The cohort included 13 transplants in 2022, 14 in 2023, 23 in 2024, and 12 through August 2025.

Median age at transplantation was 14.3 years (IQR 11.7–15.8), and 33/62 (53.2%) observations involved female recipients. Glomerular disease was the most frequently recorded cause of kidney failure (20/62, 32.3%), followed by CAKUT or urological causes (16/62, 25.8%); another 16/62 (25.8%) were unknown or unclassified. Hemodialysis was the recorded pretransplant modality in 48/62 (77.4%) observations and peritoneal dialysis in 14/62 (22.6%); no pre-emptive transplantation was documented in the validated analytic layer. Among 54 observations with chronologically valid dates, median dialysis exposure was 45.7 months (IQR 23.0-70.8). Median wait-list time was 5.9 months (IQR 4.0-15.6; n = 60) (Table 1).

Table 1
Recipient and transplant characteristics

Characteristic	Result	Available N
Age at transplantation, years	14.3 (11.7–15.8)	62
Female sex	33 (53.2)	62
Transplant year		
2022	13 (21.0)	62
2023	14 (22.6)	62
2024	23 (37.1)	62
2025 through August	12 (19.4)	62
Cause of kidney failure		
Glomerular disease	20 (32.3)	62
CAKUT/urological	16 (25.8)	62
Unknown/unclassified	16 (25.8)	62
Hereditary, secondary/immunologic, or other	10 (16.1)	62
Pretransplant dialysis modality		
Hemodialysis	48 (77.4)	62
Peritoneal dialysis	14 (22.6)	62
Dialysis duration, months	45.7 (23.0–70.8)	54
Wait-list duration, months	5.9 (4.0–15.6)	60
Note: Values are n (%) or median (IQR). Percentages use the full cohort unless an available-case denominator is shown. CAKUT, congenital anomalies of the kidney and urinary tract; IQR, interquartile range. The 2025 period ends in August and is not comparable as a full calendar year.		

Donor, immunology, and treatment characteristics

Donor age was available for 57/62 observations and had a median of 22.0 years (IQR 19.0–26.0). Donor type was directly source-documented for only 21/62 (33.9%); 34 matrix values had been inferred from narrative information but were not source-verified, and seven were undocumented. Donor type was therefore not used in outcome comparisons, and the overall DGF proportion cannot be stratified by living versus deceased donation.

All 62 recorded transplants were ABO-compatible. The standardized crossmatch was negative in all 50 observations with a definitive negative or positive result; 12 results were uncertain or undocumented.

Qualitative PRA class I and class II were available for 52 observations each. The conventional HLA-A/B/DR mismatch score was available for 44 observations and had a median of 4 (IQR 4–5).

Basiliximab-based induction was recorded in 33/62 (53.2%) observations and ATG-based induction in 13/62 (21.0%). At discharge, 53/62 (85.5%) had tacrolimus, mycophenolate, and a corticosteroid documented. Tacrolimus was initiated with a median of 2 days after transplantation (IQR 2–3; n = 57) (Table 2).

Table 2
Donor, immunologic, and immunosuppression characteristics

Characteristic	Result	Denominator N
Donor age, years	22.0 (19.0–26.0)	57
Donor sex		
Male	43 (69.4)	62
Female	15 (24.2)	62
Other/not documented	4 (6.5)	62
Donor type directly source-documented	21 (33.9)	62
ABO-compatible transplant	62 (100.0)	62
Definitive standardized crossmatch negative	50 (100.0)	50
Qualitative PRA class I available	52 (83.9)	62
Qualitative PRA class II available	52 (83.9)	62
HLA-A/B/DR mismatch score, 0–6	4.0 (4.0–5.0)	44
Basiliximab-based induction	33 (53.2)	62
ATG-based induction	13 (21.0)	62
Other, unclassifiable, or undocumented induction	16 (25.8)	62
Tacrolimus + mycophenolate + corticosteroid at discharge	53 (85.5)	62
Tacrolimus initiation, days after transplantation	2.0 (2.0–3.0)	57
Note: Values are n (%) or median (IQR). Donor sex percentages use the full cohort, including missing or other values. Crossmatch percentage uses only definitive negative or positive results; 12 uncertain or undocumented values are excluded. Exact sparse positive PRA cells are not displayed. Inferred donor types were not considered source-verified. ATG, antithymocyte globulin; HLA, human leukocyte antigen; PRA, panel-reactive antibody.		

Delayed graft function and exploratory comparisons

DGF status was evaluable in 57/62 (91.9%) observations. Seven required dialysis within seven days, corresponding to 12.3% (95% CI 6.1–23.2%). Across all 62 observations, the DGF proportion would be 11.3% if none of the five unevaluable records had DGF and 19.4% if all five had DGF. Unadjusted exploratory comparisons did not yield precise evidence of differences between groups. Female sex had a conditional OR of 2.46 (95% CI 0.36–28.16), and hemodialysis before transplantation had an OR of 2.08 (95% CI 0.22-104.32), illustrating the extreme imprecision. Descriptive DGF-minus-no-DGF median differences were + 1.6 years for recipient age, + 16.3 months for dialysis duration, and + 2.5 years for donor age. The HLA-A/B/DR subgroup comparison was suppressed because fewer than five DGF observations had a usable score. These estimates are displays of uncertainty and must not be interpreted as evidence for or against predictor effects (Table 3).

Table 3
Delayed graft function and exploratory comparisons

Characteristic	DGF (N = 7)	No DGF (N = 50)	P value
Recipient age, years	15.1 (14.8–16.0); N = 7	13.5 (11.7–15.7); N = 50	0.285
Female sex	5/7 (71.4)	25/50 (50.0)	0.427
CAKUT/urological cause	< 5/7	13/50 (26.0)	0.669
Hemodialysis before transplantation	6/7 (85.7)	37/50 (74.0)	0.669
Dialysis duration, months	62.0 (23.9–68.7); N = 7	45.7 (23.1–70.9); N = 43	0.933
Donor age, years	24.0 (21.0–24.5); N = 7	21.5 (18.0–26.0); N = 46	0.598
HLA-A/B/DR mismatch score	< 5; suppressed	Suppressed	—
ATG-based induction	< 5/7	10/50 (20.0)	0.630

Note: Values are n/N (%) or median (IQR). Five records without evaluable DGF status are excluded. Sparse stratified categorical cells are suppressed as < 5; continuous subgroup summaries and their tests are not reported when either subgroup has fewer than five usable observations. Whole-cohort outcome and data-completeness totals are retained. P values are from Fisher's exact test for categorical variables and the two-sided Mann-Whitney U test for continuous variables. Conditional exact ORs for non-suppressed binary comparisons and descriptive median differences are reported in the Results. Analyses are unadjusted, complete-case, and hypothesis-generating; no multiplicity correction was applied. ATG, antithymocyte globulin; CAKUT, congenital anomalies of the kidney and urinary tract; DGF, delayed graft function; HLA, human leukocyte antigen; OR, odds ratio.

Last-recorded graft status and outcome completeness

A definitive last-recorded graft status was available for 57/62 (91.9%) observations. Among those 57 evaluable records, 54 (94.7%) were classified as functioning and three (5.3%) as graft loss; expressed over the full cohort, these correspond to 54/62 (87.1%), 3/62 (4.8%), and 5/62 (8.1%) with unevaluable status. Recorded graft-loss mechanisms included vascular and rejection-related events, but sparse cells

were not disaggregated to reduce re-identification risk. These are cross-sectional last-recorded statuses, not graft-survival estimates.

A valid graft event or censoring date was available for 41/62 (66.1%) observations. Compared with non-evaluable observations, those with evaluable follow-up had a median age of 14.0 versus 15.2 years; the age SMD, based on means and pooled standard deviations, was -0.19 . The corresponding female proportions were 48.8% versus 61.9% (SMD -0.26). Joint distributions stratified by follow-up evaluability were not retained for additional clinical variables. This limited comparison cannot exclude selection related to transplant year, etiology, treatment, donor source, or DGF and precludes defensible complete-case survival analysis.

Biopsy-rejection ascertainment met the validity rule in only 4/62 (6.5%) observations. No validated DSA or mortality endpoint was available. Baseline clinical fields were generally more usable than longitudinal outcome fields: recipient age and dialysis modality were complete, whereas directly documented donor type (33.9%), valid event or censoring dates (66.1%), rejection ascertainment (6.5%), DSA (0%), and mortality (0%) showed major gaps (Table 4). The operational validity rules used to assess the analytic usability of these fields are summarized in Table 5. [Table 5 Insertion here].

Table 4
Completeness of protocol-relevant fields meeting analytic-usability rules

Variable	Available N	Completeness, %
Recipient age at transplantation	62	100.0
Dialysis modality	62	100.0
Dialysis start date yielding non-negative duration	54	87.1
Donor type directly recorded, not inferred	21	33.9
Donor age	57	91.9
Standardized crossmatch, negative/positive	50	80.6
Qualitative PRA class I	52	83.9
Qualitative PRA class II	52	83.9
HLA-A/B/DR mismatch, 0–6	44	71.0
Classifiable induction regimen	48	77.4
Tacrolimus start, 0–30 days	57	91.9
DGF, yes/no	57	91.9
Definitive last recorded graft status	57	91.9
Valid graft event or censoring date	41	66.1
Biopsy-rejection ascertainment	4	6.5
Validated DSA endpoint	0	0.0
Validated mortality endpoint	0	0.0

Note: The cohort denominator is 62 for every row. Completeness denotes a value that met the field-specific analytic-usability rule, not merely a non-empty cell. DGF, delayed graft function; DSA, donor-specific antibody; HLA, human leukocyte antigen; PRA, panel-reactive antibody.

Table 5
Operational validity rules for protocol-relevant analytic fields

Field/domain	Operational analytic-usability requirement	Treatment in analysis
Eligibility and age	Valid birth and transplant dates; calculated age from 0 to < 18 years on the transplant date.	Exclude the record if pediatric eligibility or transplant-date validity cannot be established.
Unit of analysis	One eligible matrix row was treated as one recipient-transplant observation. A validated retransplantation indicator was unavailable in the study-specified analytic layer.	Interpret estimates as record based; repeated transplantation could not be independently assessed.
Dialysis and wait-list intervals	The documented start date had to precede transplantation and yield a non-negative chronological interval.	Treat an invalid interval as missing while retaining the record for other analyses.
Cause of kidney failure	Map source categories to glomerular; CAKUT/urological; hereditary/cystic; secondary/immunologic; other; or unknown/unclassified.	Retain unknown/unclassified as an explicit category; pool sparse etiologies for public reporting.
Donor type	Accept only a directly source-recorded donor type; do not accept a value inferred from narrative free text.	Describe completeness but exclude unverified donor type from outcome comparisons.
Crossmatch	Require a standardized definitive negative or positive result.	Treat uncertain or undocumented results as missing.
PRA and HLA	Require a qualitative PRA class I/II result or an HLA-A/B/DR mismatch score from 0 to 6.	Do not analyze unvalidated quantitative PRA, HLA-DQ mismatch, or DSA fields.
Induction and maintenance therapy	Classify induction only when the regimen was identifiable; classify triple therapy only when tacrolimus, mycophenolate, and corticosteroid were all documented.	Use an explicit unclassifiable/undocumented category; do not infer undocumented agents.
Tacrolimus initiation	Require a plausible interval of 0–30 days from transplantation.	Treat values outside the interval or without a valid date relation as missing.
DGF	Require a standardized yes/no value representing dialysis within seven days after transplantation.	Restrict the primary denominator to validated values and report missing-case bounds for unevaluable records.
Last recorded graft status	Require a classifiable functioning, graft-loss, or indeterminate status under the field rule.	Report only as a cross-sectional last-recorded status, not as a survival probability.
Note: These rules summarize the fixed study-specified analytic layer supplied for analysis. They do not establish that an event was absent from the underlying clinical record. Invalid, unverified, or non-standardized values were treated as missing for the corresponding analysis. CAKUT, congenital anomalies of the kidney and urinary tract; DGF, delayed graft function; DSA, donor-specific antibody; HLA, human leukocyte antigen; PRA, panel-reactive antibody.		

Field/domain	Operational analytic-usability requirement	Treatment in analysis
Event or censoring date	Require a valid graft-loss date for graft loss or a valid last-follow-up date for functioning status; the date could not precede transplantation.	Use only to determine time-to-event evaluability; do not estimate survival when ascertainment is incomplete.
Rejection, DSA, and mortality	Require a validated biopsy-based rejection field, a validated DSA assay endpoint, or a validated vital-status endpoint, respectively.	Do not interpret non-documentation as absence and do not estimate incidence or mortality without validated ascertainment.
Database lock and follow-up time	The analytic window ended in August 2025; an exact database-lock date and recipient-specific last-contact duration were not validated in the study-specified analytic layer.	Do not estimate the follow-up distribution or time-dependent outcomes from the available matrix.
Note: These rules summarize the fixed study-specified analytic layer supplied for analysis. They do not establish that an event was absent from the underlying clinical record. Invalid, unverified, or non-standardized values were treated as missing for the corresponding analysis. CAKUT, congenital anomalies of the kidney and urinary tract; DGF, delayed graft function; DSA, donor-specific antibody; HLA, human leukocyte antigen; PRA, panel-reactive antibody.		

Discussion

This study provides a recipient-transplant observation-level description of 62 pediatric kidney transplant observations from a public referral hospital in Ecuador and, equally importantly, identifies which routinely collected fields can support inference. Three findings are central. First, dialysis exposure was prolonged, with a median approaching four years among observations with valid dates. Second, DGF occurred in 12.3% of evaluable observations, but incomplete donor source and absent ischemia-time data prevent meaningful risk adjustment or center-to-center benchmarking. Third, the apparently favorable last-recorded graft status could not be translated into survival because event dates, rejection ascertainment, donor-specific antibody, and mortality were inadequately captured. Although the numerical estimates are center-specific, the measurement challenge is potentially relevant to other programs relying on incompletely standardized routine transplant data [13].

The etiological and access profile warrants attention. Glomerular disease was the largest recorded category, one quarter of observations had an unknown or unclassified cause, no pre-emptive transplant was documented, and 77.4% had hemodialysis before transplantation. The median 45.7-month pretransplant dialysis exposure was numerically similar to the approximately 3.9-year mean time on dialysis reported in Ecuador's national registry; however, the national estimate represents the broader dialysis population and is not directly comparable with pediatric pretransplant exposure [8-9]. By contrast, the recent Brazilian pediatric cohort identified CAKUT as the most common cause, included 20.8% pre-emptive transplants, and reported a median 16 months of dialysis among non-pre-emptive recipients [11]. Our matrix cannot determine whether the longer exposure reflects late diagnosis, referral delay, donor scarcity, listing practices, access barriers, or documentation. Future capture should

separate kidney-failure recognition, specialist referral, transplant evaluation, wait-listing, and transplantation so that potentially modifiable delay can be localized rather than inferred [6-7].

The observed DGF proportion of 12.3% overlaps the 8.5% overall estimate in the 694-recipient CERTAIN analysis and the 15.0% estimate in a 113-recipient Tunisian cohort [16-17]. This numerical overlap should not be mistaken for equivalence. In CERTAIN, DGF differed markedly between deceased and living donation (11.8% versus 1.77%) [16], whereas donor type was source-verified for only one third of our cohort and ischemia times were unavailable. The wide CI (6.1–23.2%), the 11.3–19.4% missing case bounds, and only seven events further limit interpretation. The exploratory ORs and P values should be read as demonstrations of low information, not as negative predictor findings.

The available immunologic profile documented ABO compatibility and negative definitive crossmatches but did not support a full assessment of alloimmune risk. Twelve crossmatch results were uncertain or undocumented, the HLA-A/B/DR mismatch score was available in 44 observations, and quantitative PRA and DSA endpoints were not validated. Molecular HLA mismatch and tacrolimus exposure variability have been associated with humoral alloimmunity and graft deterioration in pediatric recipients [18-19]. Those relationships cannot be studied retrospectively unless the registry stores assay date, platform, threshold, antigen specificity, mean fluorescence intensity where applicable, and linked treatment exposure in standardized, time-stamped fields.

The denominator correction for last-recorded graft status is clinically important. Among evaluable records, 54/57 (94.7%) were functioning, but 54/62 (87.1%) represents the proportion over the entire cohort and includes five records with unknown status in the denominator. Neither figure is a survival probability. Without a valid event or censoring date for every participant and an adequately described follow-up distribution, a Kaplan-Meier curve would introduce false precision and potentially informative censoring. Similarly, non-documentation of biopsy, DSA, or vital status cannot be interpreted as absence of rejection, antibody development, or death.

A staged minimum dataset is the most actionable response. At transplantation, mandatory fields should include source-verified donor type, cold and warm ischemia times, transplant and dialysis dates, pretransplant referral and listing milestones, HLA typing, crossmatch method and result, PRA and DSA assay details, and induction and maintenance therapy. Longitudinal capture should include time-stamped graft status, last known clinical contact, kidney function, tacrolimus trough values, biopsy date and standardized rejection category, return to permanent dialysis, graft-loss date and cause, and vital status. Required denominators, range and chronology checks, controlled vocabularies, audit trails, and periodic source verification should be built into data entry. Kidney-transplant minimum-dataset work and multicenter pediatric networks support this approach [20-21]. Such infrastructure is a clinical-quality intervention, not merely a research convenience.

This study has several strengths. It used a census of eligible records at a public pediatric referral center, recalculated pediatric eligibility and chronological intervals from dates, applied explicit field-specific rules, defined DGF consistently, displayed available-case denominators, and reported a Wilson

confidence interval and full-cohort missing-case bounds. Exact and nonparametric methods were used for sparse exploratory comparisons, unstable multivariable and time-to-event models were avoided, and missing outcomes were not silently coded as absent. Reporting was mapped to STROBE and the RECORD extension, including data provenance, record selection, cleaning rules, missingness, and limits of outcome ascertainment [12-13]. The embedded audit converts a limitation that is often hidden into a reproducible service-improvement target.

The limitations remain substantial. This is a small, retrospective, single-center study, and the 2025 calendar year is incomplete. The analysis relied on a previously curated matrix rather than duplicate re-abstraction of source records; chart-level extraction error, inter-rater agreement, and the accuracy of fields excluded from the analytic layer could not be assessed. A validated retransplantation indicator, exact database-lock date, recipient-specific follow-up duration, donor type for most observations, ischemia times, and longitudinal kidney-function measures were unavailable. Missing outcome data may be informative: preferential non-ascertainment of graft losses would make the observed functioning proportion overly favorable, whereas transfer of stable recipients could bias it in the opposite direction. The DGF missing case bounds address only the five unevaluable DGF records and do not correct other sources of error. Follow-up evaluability could be compared only by age and sex, and seven DGF events precluded stable multivariable modeling. The clinical estimates should not be interpreted as national Ecuadorian rates. The potentially transferable contribution is the field-level framework for determining whether routine data can support longitudinal pediatric transplant outcomes. No causal inference, rejection or donor-specific antibody incidence, patient survival, or graft survival can be drawn from these data.

Conclusions

Among 62 pediatric recipient-transplant observations at HPBO, glomerular disease was the most frequently recorded cause of kidney failure, dialysis exposure was prolonged, and DGF occurred in 12.3% of evaluable observations. Although 54/57 evaluable records had a functioning graft at last documentation, incomplete time-stamped outcomes prevented valid survival, rejection, donor-specific antibody, and mortality analyses. The cohort provides an Ecuadorian pediatric transplant baseline while demonstrating a general reporting principle: non-documentation cannot be interpreted as event absence. Programs with limited registry infrastructure should prioritize prospectively defined, source-audited datasets linking access milestones, donor and ischemia characteristics, immunology, treatment exposure, kidney function, and time-to-event outcomes.

Abbreviations

ATG

antithymocyte globulin

CAKUT

congenital anomalies of the kidney and urinary tract

CI
confidence interval
DGF
delayed graft function
DSA
donor-specific antibody
HLA
human leukocyte antigen
HPBO
Hospital Pediátrico Baca Ortiz
IQR
interquartile range
OR
odds ratio
PRA
panel-reactive antibody
RECORD
REporting of studies Conducted using Observational Routinely-collected health Data
SMD
standardized mean difference
STROBE
Strengthening the Reporting of Observational Studies in Epidemiology.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki. This retrospective cohort study was approved by the Comité de Ética de Investigación en Seres Humanos del Hospital Pediátrico Baca Ortiz (CEISH-HPBO; Of. No. 039-CEISH-HPBO-2026; study code 052-CEISH-HPBO-2026; 18 June 2026). The approved final protocol was submitted on 9 June 2026. The corresponding author confirms that this approved version already contemplated the matrix as the sole participant-level data source and the omission of Kaplan-Meier survival estimation. Research-specific access to data supplied by HPBO's internal biostatistics department and construction of the study matrix began on 19 June 2026, after ethics approval. Statistical analysis began on 28 July 2026. In a complementary determination dated 18 June 2026, the CEISH-HPBO stated that informed consent from participants or their legal representatives and assent from pediatric participants were not required for the approved retrospective study, because the information provided for analysis was anonymized at source. No kidneys used in the transplantations reported in this study were obtained from prisoners. The transplanted kidneys were obtained through the Nephrology/Pediatric Kidney Transplant Program of Hospital Pediátrico Baca Ortiz

and Ecuador's Sistema Nacional Integrado de Donación y Trasplante, under the allocation, distribution, and traceability procedures of the Instituto Nacional de Donación y Trasplante de Órganos, Tejidos y Células (INDOT), from donors identified at Hospital Pediátrico Baca Ortiz, accredited donation/transplant establishments, and establishments participating as 'establecimientos amigos de la donación'.

Consent for publication

Not applicable. No individual-level narrative, image, video, or identifiable participant information is reported.

Availability of data and materials

The data that support the findings of this study were obtained from the statistical repository of Hospital Pediátrico Baca Ortiz, Quito, Ecuador. The institutional master matrix is not publicly available because it contains direct identifiers and sensitive clinical information from a small pediatric transplant cohort. Access to a suitably de-identified extract may be considered by Hospital Pediátrico Baca Ortiz and the competent ethics body on reasonable request to the corresponding author, subject to a methodologically sound proposal, institutional permission, a data-use agreement, and applicable data-protection requirements. The privacy-safe data dictionary, analytic rules, aggregate verification targets, statistical code, environment versions, and analytic decision log supplied with the submission contain no participant-level values.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Conceptualization: FJFO, PCAV and MBOV. Data curation: JRGV, PCAV, SABL, DIMM and MBOV. Formal analysis: SACF, DXAA and DJCM. Investigation: FJFO, RAQR, DXAA, IECC, MJVR and EDHS. Methodology: IECC, DJCM, SABL and GMCdC. Project administration: FJFO and JRGV. Resources: JRGV, RAQR and DXAA. Software: SACF and MJVR. Supervision: JRGV and DXAA. Validation: RAQR, MJVR, EDHS, DJCM and GMCdC. Visualization: SACF, DIMM and GMCdC. Writing - original draft: FJFO, PCAV, IECC and DIMM.

Writing - review and editing: SACF, FJFO, JRGV, RAQR, DXAA, MBOV, PCAV, IECC, MJVR, EDHS, DIMM, SABL, DJCM and GMCdC. All authors read and approved the final manuscript.

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References

1. Iyengar A, McCulloch MI. Paediatric kidney transplantation in under-resourced regions-a panoramic view. *Pediatr Nephrol.* 2022;37(4):745–55. <https://doi.org/10.1007/s00467-021-05070-3>.
2. Van Arendonk KJ, Boyarsky BJ, Orandi BJ, James NT, Smith JM, Colombani PM, et al. National trends over 25 years in pediatric kidney transplant outcomes. *Pediatrics.* 2014;133(4):594–601. <https://doi.org/10.1542/peds.2013-2775>.
3. Coens F, Knops N, Tieken I, Vogelaar S, Bender A, Kim JJ, et al. Time-varying determinants of graft failure in pediatric kidney transplantation in Europe. *Clin J Am Soc Nephrol.* 2024;19(3):345–54. <https://doi.org/10.2215/CJN.0000000000000370>.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Kidney Transplant Candidate Work Group. KDIGO clinical practice guideline on the evaluation and management of candidates for kidney transplantation. *Transplantation.* 2020;104(4S1):S11–103. <https://doi.org/10.1097/TP.0000000000003136>.
5. Kamath N, Erickson RL, Hingorani S, Bresolin N, Duzova A, Lungu A, et al. Structures, organization, and delivery of kidney care to children living in low-resource settings. *Kidney Int Rep.* 2024;9(7):2084–95. <https://doi.org/10.1016/j.ekir.2024.04.060>.
6. Alvarez-Elías AC, Lou-Meda R, Exeni R, Exantus J, Bonilla-Félix M, González-Camac S, et al. Addressing health inequities and disparities in children with kidney disease in disadvantaged areas: the Latin American and Caribbean experience. *Curr Pediatr Rep.* 2023;11(2):40–9. <https://doi.org/10.1007/s40124-023-00287-2>.
7. Luxardo R, Ceretta L, González-Bedat M, Ferreiro A, Rosa-Diez G. The Latin American Dialysis and Renal Transplantation Registry: report 2019. *Clin Kidney J.* 2022;15(3):425–31. <https://doi.org/10.1093/ckj/sfab188>.

8. Ministerio de Salud Pública del Ecuador. Actualización, caracterización y análisis de supervivencia de los pacientes en terapia sustitutiva renal en el Ecuador, según el Registro Nacional de Diálisis y Trasplante. Quito: Ministerio de Salud Pública. 2022. https://www.salud.gob.ec/wp-content/uploads/2023/01/informe_de_caracterizaciOn_de_la_tsr_2022-1.pdf. Accessed 12 Aug 2026.
9. Gahona Villegas JR, Reyes Jurado P, Prado Cabrera AS, Meza Rodríguez KM, Benítez Kellendonk CH. MetroCiencia. 2023;31(2):35–40. <https://doi.org/10.47464/MetroCiencia/vol31/2/2023/35-40>. Descripción y análisis de la tasa de incidencia y prevalencia de pacientes en terapia de reemplazo renal en Ecuador.
10. Jiménez D, Jiménez F. Global perspective on kidney transplantation. Ecuador Kidney360. 2022;3(10):1772–4. <https://doi.org/10.34067/KID.0003452022>.
11. Lordelo MDR, Nunes CA, Araújo-Pereira M, Barreto-Duarte B, Andrade BB. Retrospective cohort of a decade of pediatric kidney transplant in a Brazilian state: clinical profile, main complications, and outcomes. PLoS ONE. 2025;20(5):e0323648. <https://doi.org/10.1371/journal.pone.0323648>.
12. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology statement: guidelines for reporting observational studies. Lancet. 2007;370(9596):1453–7. [https://doi.org/10.1016/S0140-6736\(07\)61602-X](https://doi.org/10.1016/S0140-6736(07)61602-X).
13. Benchimol EI, Smeeth L, Guttman A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM, RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) statement. PLoS Med. 2015;12(10):e1001885. <https://doi.org/10.1371/journal.pmed.1001885>.
14. Mallon DH, Summers DM, Bradley JA, Pettigrew GJ. Defining delayed graft function after renal transplantation: simplest is best. Transplantation. 2013;96(10):885–9. <https://doi.org/10.1097/TP.0b013e3182a19348>.
15. Grenda R. Delayed graft function and its management in children. Pediatr Nephrol. 2017;32(7):1157–67. <https://doi.org/10.1007/s00467-016-3528-9>.
16. Patry C, Boßung M, Feißt M, Krupka K, Höcker B, Pape L, et al. Risk assessment of delayed graft function in pediatric kidney transplantation-a CERTAIN Research Network analysis. Transpl Int. 2026;39:14640. <https://doi.org/10.3389/ti.2026.14640>.
17. Boussetta A, Abida N, Jellouli M, Ziadi J, Gargah T. Delayed graft function in pediatric kidney transplant: risk factors and outcomes. Exp Clin Transpl. 2024;22(Suppl 1):110–7. <https://doi.org/10.6002/ect.MESOT2023.020>.
18. Kim JJ, Fichtner A, Copley HC, Gragert L, Süsal C, Dello Strologo L, et al. Molecular HLA mismatching for prediction of primary humoral alloimmunity and graft function deterioration in paediatric kidney transplantation. Front Immunol. 2023;14:1092335. <https://doi.org/10.3389/fimmu.2023.1092335>.

19. Piburn KH, Sigurjonsdottir VK, Indridason OS, Maestretti L, Patton MV, McGrath A, et al. Patterns in tacrolimus variability and association with de novo donor-specific antibody formation in pediatric kidney transplant recipients. *Clin J Am Soc Nephrol*. 2022;17(8):1194–203. <https://doi.org/10.2215/CJN.16421221>.
20. Akhlaghi A, Langarizadeh M, Rahimzadeh N, Rostami Z. From designing minimum data set to developing kidney transplantation registry in Iran. *J Family Med Prim Care*. 2023;12(11):2590–5. https://doi.org/10.4103/jfmprc.jfmprc_2430_22.
21. Hooper DK, Misurac J, Blydt-Hansen T, Chua AN. Multicenter data to improve health for pediatric renal transplant recipients in North America: complementary approaches of NAPRTCS and IROC. *Pediatr Transpl*. 2021;25(1):e13891. <https://doi.org/10.1111/petr.13891>.