# Tool Summary Sheet

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| Tool: | Protocol Violation Tracking Register |
| Purpose: | 1. To record issues with application of the NZ Kidney Allocation Scheme (NKAS) algorithm, corrective action taken and preventative advice to mitigate against a recurrence, and 2) to disseminate learnings among other NZ clinical practice sites. The register does not replace District Health Board (DHB) or other legally required disclosures. |
| Audience/User: | Members of the National Renal Transplant Leadership Team (NRTLT) and Clinical Teams in DHBs |
| Background: | NRTLT provides clinical governance over the NKAS. NKAS is designed to provide clinically appropriate, reproducible and transparent kidney allocation according to the overall aims of NZs deceased donor kidney transplant program, balancing utility and fairness to patients waiting for a deceased donor transplant. |
| Details: | This tracking register provides de-identified details of any violation or near violation due to process error. Patient identifying information is not kept. |
| Best Practice Recommendations: | * The Medical Director of the Kidney Allocation Scheme, or delegate, reports protocol deviations to the NRTS as they occur. * NRTS records details in register (patient de-identified) including date that the information is registered, assign a sequential number, write a brief description of the incident including protocol violated, and any corrective action taken. * NRTLT reviews register at each meeting, makes any additional recommendations and/or disseminates information as appropriate |
| Definitions: | * Protocol Violation: Any deviation from NKAS that could have or has affected a waitlisted persons opportunity to be transplanted or clinical outcome |
|  | * This register is a log only; not a location for recording the processes undertaken and the personnel involved. |

| **Date violation information was entered** | **Violation number** | **Brief description of incident (including protocol contravened)** | **Corrective action taken** | **NRTS Preventative advice** |
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| 20170927 | 1. | Start date had been altered and had implications for the patient’s eligibility for transplant. | Nil | Monthly report to units with coordinator checking has been developed. |
| 20201204 | 2 | Low level autoantibody ascribed clinical importance without discussion with on call physician in error, leading to non-allocation. | Internal process review at NZBS, for further reporting once complete | Report received. Changes in DMRS to eliminate. |
| 20210127 | 3. | Decision not to use both DCD kidneys in Auckland due to concerns about timely operation in late 2020. | Nil | Nil |
| 20210601 | 4. | HLA-B27 testing undertaken on a patient currently active on deceased donor waiting list leading to patient category in the lab database from ‘RENAL’ to ‘B27’ due to staff unawareness of effects of that change on DRMS. Only patients in the ‘RENAL’ category are included in the DRMS algorithm, therefore this patient could no longer be matched to any deceased donors. Error detected on monthly checking process with coordinators within 3 weeks. Cross checking with allocated kidneys in that period revealed no misallocation due to the error (patient would not have received an offer). | All staff have been reminded not to change the category of any transplant patient without firstly consulting a senior staff member.  An incident has been raised in Q Pulse. | Nil additional. |
| 20220505 | 5. | Violation of rank – rank 8 not offered kidney as had been already transported to a centre where rank 8 was not, and prior allocated recipient found to be medically unsuitable. Cold ischaemic time lengthening, so decision taken to allocate to next available local recipient. | Nil | Nil |
| 20221031 | 6. | * Summary of case: Donor O group pancreas was allocated to B group recipient (compatible but not identical), due to no active O patients on pancreas list at that point. Intended approach would be to discard pancreas and allocate kidney only. * Support for current settings confirmed. * Discussion with allocating physician completed within ARTG. | Discuss at Strategic Group meeting 2 December 2022 |  |
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| **Version control** | |
| December 2020 | Incidents 1 & 2 entered |
| January 2021 | Incident 3 entered |
| June 2021 | Incident 4 entered and incident 3 edited. |
| May 2022 | Incident 5 entered |
| October 2022 | Incident 6 entered |