

# Models of care to address disparities in kidney health outcomes for First Nations people



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First Nations people of Australia, New Zealand, Canada, and the USA share a common history of European colonization with forced disconnection from land, community, and culture. Although reconciliation strategies differ between the 4 nations, lasting colonial effects of institutional racism, disproportionate social disadvantage, and disparities in health outcomes persist. Decades of consultation with First Nations communities evaluating the problem and government interventions aimed at addressing these disparities have yielded little improvement.

Chronic kidney disease represents a particular challenge when considering the burden of ill-health among First Nations people. First Nations people are more likely to develop kidney failure and are less likely to receive a kidney transplant than their non-Indigenous peers. Treatment of kidney failure requires a high level of engagement with mainstream health services, which can be hostile and discriminatory environments.

As part of the evidence synthesis to inform an inaugural guideline on clinically and culturally safe management of chronic kidney disease for First Nations Australians,<sup>1</sup> this review aimed to identify studies that delivered First Nations-specific health interventions that included, or could be embedded, as models of care to improve health outcomes for First Nations people with kidney failure in Australia, New Zealand, Canada, and the USA. This work was informed by an extensive process of First Nations community consultation<sup>2–4</sup> and prioritized First Nations governance and research methodologies (Supplementary Appendix S1). First Nations-specific quality appraisal tools<sup>5,6</sup> were used in addition to Cochrane methods to comprehensively critique the quality of evidence. To ensure adherence to the ethical principle of First Nations self-determination,<sup>7</sup> consistency of the evidence with well-established First Nations community voice<sup>2–4</sup> was considered when grading certainty. The full systematic review, including methods (Supplementary Appendix S2) and complete results (Supplementary Appendices S3–S5), is provided in the Supplementary Material.

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## RESULTS

From a comprehensive systematic review considering all health care interventions specific to this population, we identified only 8 models of care, evaluated by 14 studies (Supplementary Figure S1) specific to First Nations people living with kidney disease (Table 1<sup>S1-S14</sup>). Study quality through a First Nations lens was variable (Figure 1). The risk of bias in quantitative studies ranged from moderate to critically high. Quality of qualitative and economic studies was fair. Full details of study quality are provided in Supplementary Appendix S4.

### First Nations-specific models of care

#### *Community-controlled, nurse-supported, remote area dialysis.*

Clinical effectiveness and cost-effectiveness of community-controlled, nurse-supported, remote area dialysis models were assessed in 3 Australian studies<sup>S6,S7,S9</sup> (Table 2). Marley *et al.*<sup>S9</sup> found that this model of dialysis care was safe, with no mortality difference for 110 Aboriginal and/or Torres Strait Islander patients receiving remote area dialysis when compared with all Aboriginal and/or Torres Strait Islander patients (adjusted mortality ratio [AMR]: 1.05, 95% confidence interval [CI]: 0.91–1.21) and with non-Indigenous Australians (AMR: 0.8, 95% CI: 0.51–1.23). Gorham *et al.*<sup>S7</sup> established that higher median costs of treatment/patient/year of remote dialysis are offset by lower hospital costs resulting in lower per patient health expenditure. The greatest cost saving was \$15,118/patient/year for a very remote dialysis model compared with relocation to an urban dialysis facility.

**Urban community-based home hemodialysis.** Urban community-based home hemodialysis was assessed by 2 studies.<sup>S10,S14</sup> This model addressed barriers to home dialysis, including inadequate housing and/or utilities, by providing home dialysis facilities in a supported environment. Outcomes included mortality compared with other dialysis models and patient/staff acceptability (Table 2). Marshall *et al.*<sup>S10</sup> showed an AMR of the model similar to conventional home hemodialysis (AMR: 1.48, 95% CI: 0.64–3.40) and lower than facility hemodialysis (AMR: 2.18, 95% CI: 1.78–2.67). Walker *et al.*<sup>S14</sup> reported major themes of reducing burden on family, increased flexibility and freedom, control over one's own health, and increased community supports associated with the model.

**Primary care-supported tele-hemodialysis care.** A tele-hemodialysis model whereby consultation between a nephrologist and patient is conducted via videoconference, supported by an on-site dialysis nurse or a general practitioner, was evaluated in a single Canadian-interrupted time-series study across 2 remote First Nations communities.<sup>S11</sup> There was no significant reduction in quality of care with implementation of the model, no deaths, and no difference in dialysis attendance or hospital transfer. There was a reduction in medication changes (8.1 changes/month before intervention to 3.1 changes/month after intervention;  $P = 0.01$ ) at the site where the model was supported by a general practitioner.

**Mobile dialysis units.** Patient and staff acceptability of a mobile dialysis unit was evaluated in one Australian study.<sup>S4</sup> This model facilitated return to traditional homelands for

patients dislocated for treatment. Patients reported improved happiness and quality of life and enhanced relationships with staff. Factors affecting successful, equitable implementation of the model include provision of accommodation, transport, and sufficient workforce support.

**First Nations involvement in multidisciplinary teams.** The benefits of a multidisciplinary dialysis access team approach (now considered in many centers as a standard of care), for First Nations people commencing dialysis in an urban center, were considered in 2 Australian studies by Treacy *et al.*<sup>S13</sup> and Cho *et al.*<sup>S3</sup> One study, Cho *et al.*,<sup>S3</sup> involved First Nations health care workers within the team. Both studies reported an improvement in clinical outcomes, specifically arteriovenous fistula patency and 12-month peritoneal catheter survival consistent with the benefits seen in the general population. The benefits seen by Cho *et al.*<sup>S3</sup> extended beyond standard clinical outcomes, to the provision of culturally appropriate dialysis education, established rapport and communication channels with remote primary health care facilities, and a notable proportion of patients (60%) returning to their home communities after an average time of 33.9 ( $\pm 5.9$ ) days.

**Culturally adapted, First Nations-specific, psychological support systems.** Dingwell *et al.*<sup>S5</sup> assessed the effectiveness of a culturally adapted, First Nations specific digital well-being application, modified for use in First Nations people on dialysis in northern Australia. The application used an evidence-based form of “low-intensity” psychological therapy developed specifically for use in remote Australian First Nations communities. The holistic, strengths-based approach promotes First Nations cultural and family values and empowers patient self-management. It was adapted to the kidney failure population and made available in 11 different local First Nations languages. The application had a significant impact for those with pre-existing symptoms of psychological distress at baseline, with a clinically significant improvement in scores relating to both depression at 3 months (mean score difference:  $-4.1$ , 95% CI:  $-6.4$ ;  $-1.8$ ) and 6 months (mean score difference:  $-4.7$ , 95% CI:  $-7.0$ ;  $-2.4$ ) and psychological distress at 6 months (mean score difference:  $-6.8$ , 95% CI:  $-10.2$ ;  $-3.5$ ).

**First Nations consumer voices in health service policy and planning.** A single qualitative study addressed cultural responsiveness of health systems in Northern Australia.<sup>S8</sup> In this model, a First Nations reference group had direct access to health service leadership through a continuous feedback loop, whereby First Nations opinions and priorities were presented, by reference group members, to the health service integration steering committee. It showed that direct involvement of First Nations consumers in policy and planning decisions allowed for meaningful, First Nations consumer-driven change and improved health system responsiveness and professional capacity building.

**Increasing community awareness around First Nations transplantation.** There were 3 studies<sup>S1,S2,S12</sup> of community health promotion campaigns aimed at increasing the rates of transplantation for First Nations people in the USA. Each model differed (video and booklet, social media campaign,

**Table 1 | Study characteristics**

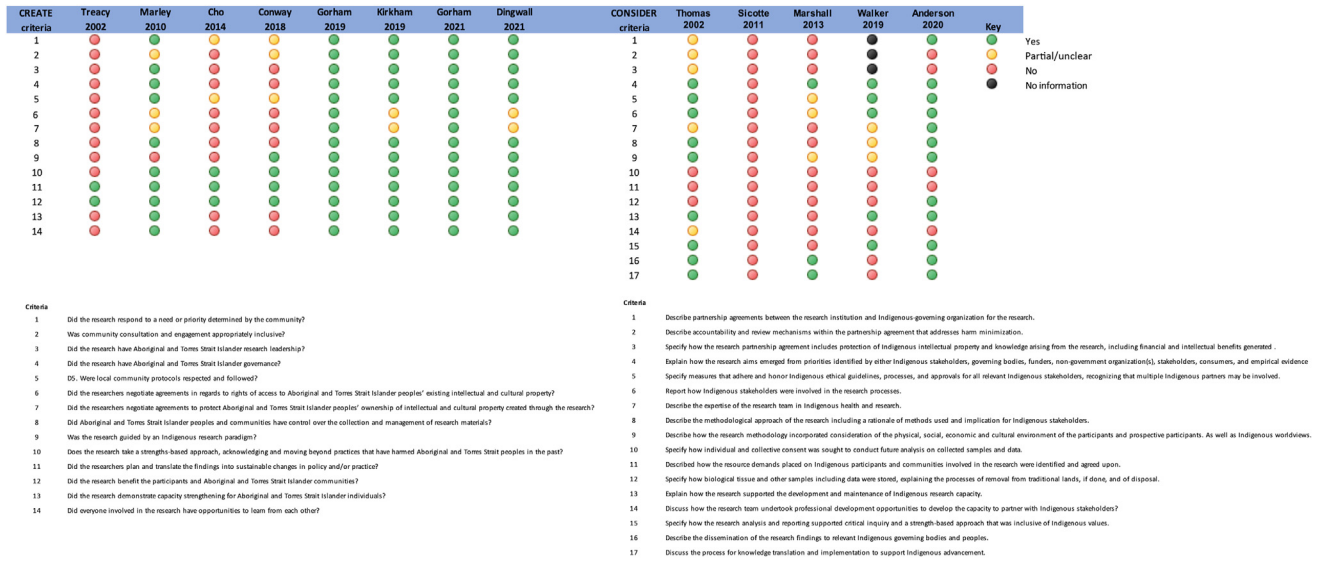
Study	Study design and setting	Participants	Studied model of care	Outcomes measured
Anderson <i>et al.</i> <sup>51</sup>	Qualitative study Native American living in tribal communities across a Northern Plains state in the USA	55 Native Americans currently undergoing dialysis treatment at 1 of 3 dialysis centers either on or near reservations who had been exposed to the “Hope and Healing” campaign	“Hope and Healing” co-created, culturally sensitive health education and promotion campaign (video and booklet) around living kidney donor transplantation	Frequency, content, and consequences of patients’ discussions regarding living kidney donation
Britt <i>et al.</i> <sup>52</sup>	Community-based participatory action research Online community	199 social media posts targeted at Native Americans with kidney failure, their families, and communities	“Sharing Hope and Healing,” a co-created, culturally sensitive health education and promotion, social media campaign around living kidney donor transplantation	Degree of engagement with campaign; enablers of engagement
Cho <i>et al.</i> <sup>53</sup>	Retrospective cohort study Regional renal unit, Cairns, Queensland	75 Aboriginal and/or Torres Strait Islander patients who received a PD catheter inserted using the Y-Tec peritoneoscopic technique	Multidisciplinary team approach including an Aboriginal Liaison Officer; Nephrologist inserted Tenckhoff catheters	Peritoneal dialysis catheter and technique survival rates Early dialysis complication rates Return to Homelands rates
Conway <i>et al.</i> <sup>54</sup>	Qualitative interview study Regional and remote South Australia	15 Aboriginal and/or Torres Strait Islander patients who have had to relocate off country for dialysis 10 nursing staff who have worked on the mobile dialysis unit	Mobile dialysis unit (dialysis bus/truck)	Patient and staff thoughts and opinions regarding the mobile dialysis service; enablers and disablers of successful service
Dingwall <i>et al.</i> <sup>55</sup>	Randomized controlled trial (3 arm) Urban dialysis unit, NT, Australia	156 adult Aboriginal and/or Torres Strait Islander patients receiving maintenance HD for more than 6 months	Stay Strong Wellbeing App: a First Nations–specific, culturally adapted, digital application (App) of strength-based, patient-centered, low-intensity psychological therapy, empowering First Nations cultural values and self-management adapted for the kidney failure setting and presented in local First Nations languages	Changes in degree of psychological distress (Kessler Psychological Distress Scale) and depression (Patient Health Questionnaire-9)
Gorham <i>et al.</i> <sup>56</sup>	Micro costing analysis Whole of renal service, NT, Australia	All patients receiving dialysis in the NT, Australia	Community-controlled, nurse-supported, remote area dialysis service	Cost-effectiveness
Gorham <i>et al.</i> <sup>57</sup>	Cost analysis Whole of renal service, NT, Australia	All patients in the NT who received dialysis for more than 3 months continuously 8 patients excluded due to the absence of cost data	Community-controlled, nurse-supported, remote area dialysis service	Cost-effectiveness
Kirkham <i>et al.</i> <sup>58</sup>	Participatory Action Research Urban dialysis services, NT, Australia	6 Aboriginal and/or Torres Strait Islander patients requiring maintenance HD who resided in Darwin	First Nations reference group integrated into kidney health services through direct feedback loops to health service leadership and policy steering committee	Degree of stakeholder participation and health service responsiveness

*(Continued on following page)*

**Table 1 | (Continued) Study characteristics**

Study	Study design and setting	Participants	Studied model of care	Outcomes measured
Marley <i>et al.</i> <sup>S9</sup>	Retrospective registry cohort study Regional/remote dialysis unit, Western Australia (WA)	110 Aboriginal and/or Torres Strait Islander patients; Kimberley origin 221 Aboriginal and/or Torres Strait Islander patients; rest of WA 502 Aboriginal and/or Torres Strait Islander patients; NT origin 733 Aboriginal and/or Torres Strait Islander patients; rest of Australia	Community controlled, nurse supported, remote area dialysis service	Mortality
Marshall <i>et al.</i> <sup>S10</sup>	Retrospective registry cohort study Urban dialysis services, NZ	13,273 Non-Indigenous Australians 4709 incident adult patients on dialysis in NZ 34.5% Māori	Community-based home HD: urban house, owned and maintained by patient support group, with home dialysis machines used by patients Accessible to patients and families	Mortality
Sicotte <i>et al.</i> <sup>S11</sup>	Interrupted time series cohort study Remote Cree communities, James Bay region, Canada	19 adult Cree residents of 2 remote communities receiving conventional HD for at least 9 months (pre) and tele-HD for at least another 9 months (post)	Primary care supported tele-HD service where consultation between a nephrologist and patient is conducted via videoconference, supported by an on-site dialysis nurse or a general practitioner	Dialysis attendance Medication changes Medical evacuation rates Mortality
Thomas <i>et al.</i> <sup>S12</sup>	Community-based participatory action research Salt River Council Region, USA	Not reported	Organ Donation and Kidney Transplant Education Committee of community members, clinicians, and government/council stakeholders who designed culturally sensitive educational materials and trained tribal members to disseminate the information	Health care provider reflections
Treacy <i>et al.</i> <sup>S13</sup>	Interrupted time series cohort study Urban hospital, NT, Australia	161 HD patients who underwent AVF surgery during the study period 74.5% Aboriginal and/or Torres Strait Islander	Multidisciplinary vascular access team. No Aboriginal and/or workforce role	AVF patency and revision rates
Walker <i>et al.</i> <sup>S14</sup>	Qualitative interview study Urban community HD units, NZ	25 patients with kidney failure who had received or were receiving community house HD 40% Māori	Community-based home HD: urban house, owned and maintained by patient support group, with home dialysis machines used by patients Accessible to patients and families	Thoughts and opinions of patients regarding the community-based home HD model

AVF, arteriovenous fistula; HD, hemodialysis, NT, Northern Territory; NZ, New Zealand; PD, peritoneal dialysis; SA, South Australia.



**Figure 1 | Quality assessment through a First Nations lens using the Centre of Research Excellence in Aboriginal Chronic Disease Knowledge Translation and Exchange (CREATE),<sup>1</sup> Aboriginal and Torres Strait Islander Quality Appraisal tool (Australian studies), or against the Consolidated Criteria for Strengthening Reporting of Health Research Involving Indigenous Peoples (CONSIDER) statement<sup>2</sup> (studies from New Zealand, USA, and Canada).**

and whole of community approach), but all had a consistent approach of co-creation and delivery with First Nations communities. Each study reported different outcomes with a common theme of increased awareness of transplantation resulting from each campaign.

**DISCUSSION**

For decades, the voices of First Nations people have described the devastating impacts of kidney failure on their communities. Across the globe, communities have identified priorities and proposed solutions that include addressing First Nations health workforce and providing holistic, culturally safe care close to home (Figure 2). Despite the established knowledge that current systems of kidney care fail to meet the needs of First Nations people, scientifically rigorous studies of models of care addressing First nations priorities remain extremely limited.

This review identified only 14 studies of 8 models of care, with variable study quality. Study quality through a First Nations lens improved over time, particularly in community consultation and governance. Weaknesses in study design and data sovereignty persist. The role of peer-reviewed publications in upholding standards of ethical First Nations research continues to evolve and is essential to ensuring research equity. Underpinning this work is an extensive process of consultation with First Nations Australians.<sup>2-4</sup> The results are diverse; yet several themes, consistent with the international literature, are common across all communities. Some were addressed, in part, by the models of care identified in this review.

Social, emotional, and cultural well-being of First Nations communities relies upon “profound bonding of people to one another [and] to their Country [homelands].”<sup>8</sup> Models

addressing the need for treatment to be available close to home include community-controlled, remote dialysis models, mobile dialysis services, and community-based home hemodialysis. All were found to be safe, cost-effective, and/or acceptable to staff and patients.

Institutional racism and rigid mainstream health services contribute to inequitable health outcomes for First Nations people. Health service redesign must be First Nations led and culturally responsive to address these and other impacts of colonization. Dialysis services incorporated within community-controlled health services adhere to the principle of self-determination, empower communities to take ownership over their health, and allow for service provision in a culturally safe way. Embedding First Nations reference groups into mainstream health services with direct access to health service leadership and influence on health care policy and planning improves health service responsiveness. This direct and integrated approach provides an opportunity for meaningful First Nations consumer-driven change.

Increasing the number and presence of First Nations health workers has been proposed as a mechanism for improving care for First Nations people since the 1990s. Inclusion of First Nations team members has been shown to improve the cultural safety of the broader health system, but the extent of their impact within multidisciplinary kidney care teams has not yet been established. Were First Nations health workers included as valued and essential members of multidisciplinary dialysis and transplant teams, the ability to positively engage with First Nations communities would likely to be increased and outcomes improved.

**Table 2 | Summary of findings**

Models of care for First Nations people living with kidney disease	Studies contributing	Risk of Bias (tool used)	First Nations quality assessment	Coherence/consistency	Imprecision/adequacy	Directness/relevance	Certainty of evidence
Community-controlled, nurse-supported, remote area dialysis models are clinically safe, with no mortality disadvantage, and allow people to have dialysis on their Homeland	Marley <i>et al.</i> <sup>59</sup>	Moderate (ROBINS-I)	No concerns	Finding consistent with community voice	1 safety study (Australia)	–	Very low
Community-controlled, nurse-supported, remote area dialysis models are cost-effective when total health expenditure is considered	Gorham <i>et al.</i> <sup>57</sup>	No concerns (CHEERS)	No concerns	Finding consistent with community voice	–	–	Low
	Gorham <i>et al.</i> <sup>56</sup>	No concerns (CHEERS)	No concerns				
Urban community-based home hemodialysis is a safe model, which does not increase mortality when compared with conventional home hemodialysis	Marshall <i>et al.</i> <sup>510</sup>	Moderate (ROBINS-I)	Some concerns <sup>a</sup>	–	–	Variable First Nations populations; no subgroup analysis	Very low
Urban community-based home hemodialysis is acceptable to First Nations communities and may reduce the treatment burden of in-center dialysis	Walker <i>et al.</i> <sup>514</sup>	No concerns (COREQ)	Some concerns	–	1 study (NZ)	Variable First Nations populations; no subgroup analysis	Very low
Adopting a primary care-supported telehealth model of dialysis care does not lead to health disadvantage in terms of clinical outcomes or mortality. Telehealth should be considered as an option to augment traditional face-to-face care	Sicotte <i>et al.</i> <sup>511</sup>	Moderate (ROBINS-I)	Concerns <sup>a</sup>	Finding consistent with community voice	1 study (Canada)	Study in remote Cree patients only	Very low
Mobile dialysis units may facilitate return to Homelands and have important psychosocial benefits for patients and community. However, successful uptake of mobile dialysis requires local accommodation, transport, and sufficient workforce support	Conway <i>et al.</i> <sup>54</sup>	Some concerns (COREQ)	Concerns <sup>a</sup>	Finding consistent with community voice	1 study (Australia)	–	Very low
Including First Nations health workers within dedicated multidisciplinary teams may improve outcomes for First Nations people commencing dialysis beyond standard care	Cho <i>et al.</i> <sup>53</sup>	Critical (ROBINS-I)	Significant concerns <sup>a</sup>	Finding consistent with community voice	1 study (Australia)	–	Low
The delivery of culturally adapted, First Nations-specific, social and emotional well-being programs to patients who are on dialysis may decrease distress and improve well-being	Dingwall <i>et al.</i> <sup>55</sup>	High (RoB2)	No concerns	Finding consistent with community voice	1 study (Australia)	–	Moderate

Table 2 | (Continued)

Models of care for First Nations people living with kidney disease	Studies contributing	Risk of Bias (tool used)	First Nations quality assessment	Coherence/ consistency	Imprecision/ adequacy	Directness/ relevance	Certainty of evidence
Incorporating First Nations feedback directly into mainstream renal service policy and planning allows for meaningful First Nations consumer-driven change and improves health service responsiveness and professional capacity building	Kirkham <i>et al.</i> <sup>S8</sup>	No concerns (COREQ)	No concerns	Finding consistent with community voice	1 study (Australia)	–	Moderate
Community-based education and awareness campaigns that are co-created with First Nations communities can increase community awareness and acceptance of transplantation, including living and deceased kidney donation	Thomas <i>et al.</i> <sup>S12</sup> Britt <i>et al.</i> <sup>S2</sup> Anderson <i>et al.</i> <sup>S1</sup>	Unable to be assessed Unable to be assessed Some concerns (COREQ)	Some concerns <sup>a</sup> Some concerns Some concerns	Finding consistent with community voice	–	–	Moderate

CHEERS, Consolidated Health Economic Evaluation Reporting Standards (economic evaluations); COREQ, Consolidated Criteria for Reporting Qualitative Research (qualitative studies); RoB 2, Risk-of-Bias 2 tool (randomized studies); ROBINS-I, Risk Of Bias In Nonrandomized Studies of Interventions (nonrandomized studies)  
<sup>a</sup>Studies published before availability of the quality appraisal tool.

First Nations people have resilience and tenacity in dealing with an overwhelming burden of illness within their communities and in accessing and navigating health systems that are racist and discriminatory. The psychological and emotional distress associated with kidney failure and dialysis is best addressed through programs developed by and for First Nations people. Incorporating First Nations-specific programs into routine, holistic care, beyond what is currently delivered, is essential to address the impact that chronic disease has on the community.

First Nations people living with kidney failure are disempowered in pursuing transplantation as a treatment option. Considering the extent of inequity, few studies considered models of care designed to improve access to or outcomes of transplantation for First Nations communities. Multimedia and social media health promotion campaigns had a positive impact in raising awareness of kidney transplantation, specifically living donor transplantation, among American Indian communities. Preliminary results of a yet-to-be-published multifaceted health service project in New

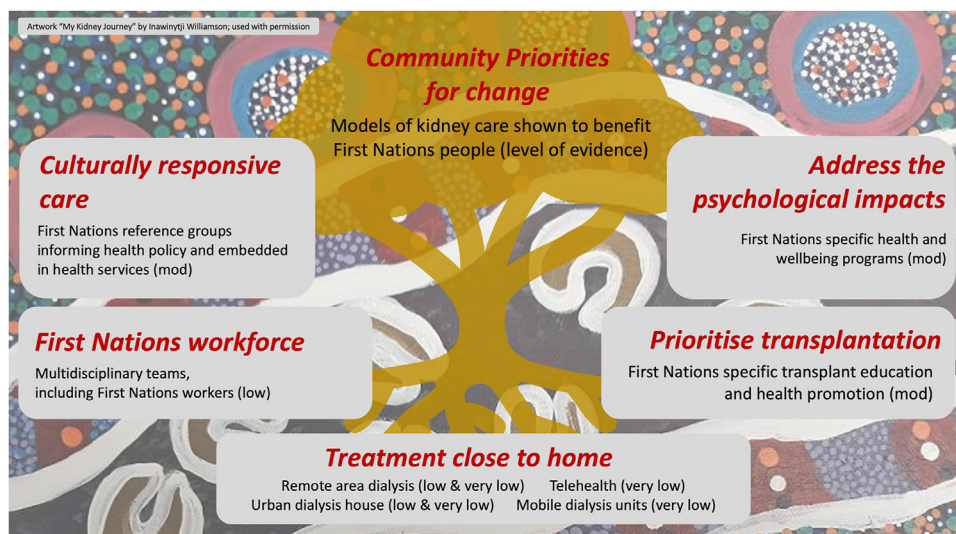


Figure 2 | Models of kidney care shown to benefit First Nations people (black) aligned to community-identified priorities for change (red). Artwork “My Kidney Journey” by Inawinytji Williamson reproduced with permission; Copyright © Inawinytji Williamson.

Zealand reported increased rates of living kidney donation,<sup>9</sup> and we await further peer review. In Australia, the National Indigenous Kidney Transplantation Taskforce is working to enhance data collection, evaluate cultural bias, and pilot initiatives to improve patient equity and access,<sup>10</sup> but is yet to report its final outcomes.

When reflecting on the limitations of this work, we acknowledge that although the need for this review arose from consultation with First Nations communities, many of the research teams are non-Indigenous and bring unconscious biases to the work. We ensured that First Nations researchers were involved in every part of the research design and process, and the research team worked proactively to build First Nations research capacity within the group. All data synthesis and interpretation were taken back to a First Nations community reference group for checking. The research team is based in Australia, and our First Nations team members are Aboriginal and/or Torres Strait Islander. We acknowledge the limitations in extrapolating our findings and interpretation to other First Nations communities; however, we are confident that the learnings can be adapted to local contexts and cultures to improve the care of First Nations people of colonized countries globally.

Finally, multiple abstract-only publications were excluded from data synthesis due to a lack of outcome data, increasing publication bias with this review. The barriers preventing these studies from progressing to peer review and publication must be explored and addressed to ensure equity in research impact for First Nations communities.

### Future directions and policy implications

The ongoing impacts of colonization for First Nations communities and the subsequent health inequities, including kidney failure, are well known. This review found few methodologically rigorous, First Nations-specific studies of models of care to improve outcomes, despite the persistent call from community for change. The existing evidence supports treatments close to home, culturally responsive care, First Nations workforce, managing the psychological impacts of disease, and inclusion of kidney transplantation as a treatment option as potential determinants of achieving equitable outcomes. Given the long-standing inequities faced by First Nations people of colonized countries, the paucity of research is not acceptable; as researchers, funders, and health care providers, we must do better. Health care services and research institutions must fund and support First Nations-led research of co-created First Nations-led studies to achieve the greatest benefit for First Nations people.

### DISCLOSURE

All the authors declared no competing interests.

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### SUPPLEMENTARY MATERIALS

[Supplementary File \(Word\)](#)

**Supplementary Appendix S1.** Research involving First Nations people; Centre of Research Excellence in Aboriginal Chronic Disease Knowledge Translation and Exchange (CREATE) criteria.

**Supplementary Appendix S2.** Systematic review methodology.

**Supplementary Table S2.1.** Four-phase search strategy.

**Supplementary Table S2.2.** Databases searched and search terms.

**Supplementary Table S2.3.** Template for Intervention Description and Replication (TIDieR)<sup>18</sup> data extraction template.

**Supplementary Appendix S3.** Search results.

**Supplementary Figure S3.1.** PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of search results and screening.

**Supplementary Appendix S4.** Results of methodological quality assessments.

**Supplementary Table S4.1.** Risk-of-bias assessment of quantitative studies using Risk of Bias 2 (RoB2)<sup>14</sup> for randomized studies and Risk Of Bias In Nonrandomized Studies of Interventions (ROBINS-I) for nonrandomized studies.

**Supplementary Table S4.2.** Results of methodological quality assessment using the Consolidated Criteria for Reporting Qualitative Research (COREQ)<sup>16</sup> checklist (qualitative studies).

**Supplementary Table S4.3.** Methodological assessment using the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist<sup>17</sup> (economic evaluations).

**Supplementary Appendix S5.** Systematic review results and synthesis.

**Supplementary Table S5.1.** Included studies: details and findings.

**Supplementary Table S5.2.** Summary of findings.

**Supplementary Appendix S6.** Unpublished data: details and analysis.

**Supplementary Table S6.1.** Unpublished data: details and findings.

**Supplementary Table S6.2.** Unpublished data: study characteristics.

**Supplementary Table S6.3.** Unpublished data: summary of findings.

**Supplementary Appendix S7.** Studies not included in this review.

**Supplementary Appendix S8.** Supporting evidence: background, discussion, and supplementary materials.

**Supplementary Appendix S9.** Supplementary references.

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