Development of a framework for minimum and optimal safety and quality standards for hemodialysis and peritoneal dialysis

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Substantial heterogeneity in practice patterns around the world has resulted in wide variations in the quality and type of dialysis care delivered. This is particularly so in countries without universal standards of care and governmental (or other organizational) oversight. Most high-income countries have developed such oversight based on documentation of adherence to standardized, evidence-based guidelines. Many low- and lower-middle-income countries have no or only limited organized oversight systems to ensure that care is safe and effective. The implementation and oversight of basic standards of care requires sufficient infrastructure and appropriate workforce and financial resources to support the basic levels of care and safety practices. It is important to understand how these standards then can be reasonably adapted and applied in low- and lower-middle-income countries.

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The quality of dialysis delivered to patients varies from country to country and from facility to facility. This is particularly so in countries that do not have universal standards of care or routine audits of quality of care, which then can result in suboptimal or poor quality of dialysis care.[1]

Guidelines for hemodialysis (HD) and peritoneal dialysis (PD) have been established for more than 30 years in high-income countries (HICs). A wide range of guidelines have been developed in Europe, Australia, New Zealand, the

Table 1 | Domains to be addressed in assessing hemodialysis and peritoneal dialysis care

HD domains	PD domains
Organization of the dialysis facility, including staffing, water treatment, and policies concerning infection control and management (including patient isolation)	Organization of the dialysis facility, including staffing, policies concerning infection control, home training and monitoring
Routine assessment of health-related quality of life	Routine assessment of health-related quality of life
Symptom management individualized for each patient	Symptom management individualized for each patient
Shared decision making about standards of care	Shared decision making about standards of care
Targeting a basic amount of dialysis (dialysis dose) put in the context of the individual patient: financial, quality of life, available resources, and so forth	Targeting a basic amount of dialysis (dialysis dose) put in the context of the individual patient: financial, quality of life, available resources, and so forth
Management of anemia, bone and mineral metabolism, nutrition, and albumin levels	Management of anemia, bone and mineral metabolism, nutrition, and albumin levels
Vascular access; dialyzer reuse	Strategies to preserve residual kidney function
Volume control, salt restriction, BP control	Volume control, salt restriction, BP control
Routine monitoring of facility outcomes such as mortality, infection rates, and so forth	Routine monitoring of facility outcomes such as technique survival, mortality, transfer rates to HD, and so forth
Strict policies concerning infection control and management	Strict policies concerning infection control and management
Attention paid to physical activity, functional status, falls, exercise, social interactions, caregiver support	Attention paid to physical activity, functional status, falls, exercise, social interactions, caregiver support

BP, blood pressure; HD, hemodialysis; PD, peritoneal dialysis.

United States, and Canada. Comprehensive PD guidelines have been published by the International Society for Peritoneal Dialysis (ISPD) dating back to 1998[2] and have been revised regularly[3–7] to reduce practice variability and improve quality and safety standards. Despite this, there is still large heterogeneity in practices and outcomes between different centers in HICs.[8–11] The application of such standards and guidelines in lower-middle-income countries (LMICs) is variable because their implementation requires adequate infrastructure, workforce, and financial resources to support the appropriate levels of care and safety practices. It is important to understand what is necessary for these standards to be adapted and applied in LMICs. If standards from HICs are to be adapted to LMICs, then the nephrology community in the latter should participate with guideline developers to develop appropriate recommendations and standards of care that take into account the available resources and finances.

A major challenge facing LMICs is the expense of maintaining safety and good quality of care.[12] An important focus of the International Society of Nephrology (ISN) in supporting end-stage kidney disease (ESKD) care in LMICs should be through the application of evidence-based guidelines adapted to the resources and funding available in each country, using validated tools to ensure that safe and minimum standards of care are provided in the context of the practical and financial problems.[13] Innovative technology and procedures that reduce the cost of kidney replacement therapy and enhances access to and quality of care should be encouraged. For example, the use of telemedicine, the practical application of the affordable dialysis project (sponsored by the ISN and Asia Pacific Society of Nephrology), modern dialyzer reprocessing, incremental dialysis, longer but less frequent dialyses, and more credible assessment techniques for identifying dry weight should be enthusiastically welcomed and explored.

Definition of safe and minimum standards for sustainable dialysis treatment

To define safe and minimum standards for sustainable dialysis treatment, existing established guidelines, such as those proposed by the Kidney Disease Outcomes Quality Initiative, Kidney Disease: Improving Global Outcomes, European Renal Best Practices, Kidney Health Australia Caring for Australasians with Renal Impairment, Canadian Society of Nephrology, The Latin American Society of Nephrology and Hypertension, National Institute for Health and Care Excellence, and so forth, should be adapted to focus on their practical use in countries with limited financial and workforce resources. Organizations in some countries, such as the Indian Society of Nephrology,[14] the Kenya Renal Association, the South African Renal Society, as well as various hospital, academic, and commercial providers (some of which are identified in the ISN Collection Survey[15] and library), provide additional guidance adapted to local realities. The nephrology community in individual countries and regions must be involved in critical vetting and eventual acceptance of these approaches or provide acceptable alternatives. In addition, individuals affected by kidney disease, industry, government, and global health care organizations should be involved in these discussions. Lay patient organizations are useful for educational purposes. Broad dissemination of guidelines is essential, followed by subsequent assessment of their value by measured effects on outcomes.

In developing a monitoring framework for minimum and optimal safety and quality standards for both HD and PD, a variety of domains are considered. These domains are outlined in Table 1 and summarized later.

Hemodialysis

Globally, the vast majority of patients with ESKD receiving dialysis are treated with HD.[16] A challenge in LMICs is the availability of economic and physical resources to build and maintain HD facilities. This requires trained physicians, nurses, technicians (including those trained to repair HD machines), appropriate physical space, HD machines, accurate scales, the necessary disposable supplies, water processing equipment, dialyzer reprocessing equipment, a reliable electricity supply, and so forth. It also is essential that basic

standards of patient care are adhered to in a variety of domains to provide safe and adequate care.

HD facility. A dialysis unit is more than a treatment facility, it is also a place to socialize, discuss common problems, and seek comprehensive understandable answers from the staff. An appropriate design of the HD facility is critically important. If possible, each patient station should have at least 110 square feet (10 m^2), with access to cardiac resuscitation equipment. A stable electrical supply and oxygen and vacuum outlets should be available at each patient station. Patients with hepatitis B should be dialyzed in a separate area. Universal precautions should be adhered to, which makes the isolation of patients infected with hepatitis C or HIV unnecessary.[17] Nurses and all assistants should be gowned and masked when dealing with patients, particularly when initiating or discontinuing treatment, or when drawing blood. This applies equally to patients with all types of vascular access, including jugular venous catheters, arteriovenous fistula, and shunts. Dialysis machines should be disinfected internally and externally after each use with special attention to the removal of all blood stains. All staff should wear gloves when in contact with the dialysis machine and gloves must be changed between patients. Facilities for hand washing and disinfecting must be available at several sites. An area should be set aside for the preparation of drugs and sterile trays for dialysis initiation. A designated area for dirty utilities should be available. Storage facilities for patients' belongings are necessary. A procedure room is required for dealing with accesses, preferably containing imaging and ultrasound systems (usually not necessary if the dialysis facility is situated close to a general hospital). The HD unit preferably should be staffed by doctors with nephrology training, nurses, technicians, social workers, and dietitians. However, because LMICs often lack the trained personnel to provide care, an acceptable compromise is the recruitment of all-purpose assistants, often repurposed technicians, trained in the locally relevant aspects of HD care. Staff should be trained in dealing with dialysis emergencies, including acute hypotension, blood loss, hemolysis, air embolism, dialyzer membrane reactions, severe pyrexia, sepsis, and cardiovascular emergencies. Patient immunization for hepatitis B and endemic topical diseases is required.

Water used for dialysate should meet the ultrapure water standards of the Association for the Advancement of Medical Instrumentation, European Best Practice Guidelines,[18] or the International Organization for Standardization Guidelines.[19] Microbiological and endotoxin monitoring of water and dialysate should be performed at least monthly. The chemicals used for making dialysis solutions (sodium, potassium, chloride, calcium, glucose, and bicarbonate) should be manufactured specially for HD.

The availability of affordable drugs needed for supporting the dialysis patients is another potentially difficult problem in LMICs. These drugs ideally should be covered by the health care system to avoid out-of-pocket patient expenses. Appropriate laboratory support is essential to monitor the effectiveness of dialysis treatments including the presence of anemia, abnormalities of mineral metabolism, nutrition, and the presence of infection.

Dialyzer reuse (manual or automated). Dialyzer reuse to reduce the costs of disposables is acceptable as long as proper protocols are followed.[20,21] Water used for reuse should be of ultrapure quality. Although chemical disinfectant reprocessing is the usual method, polysulfone dialyzers may be processed by heat. Separate reprocessing areas are necessary for reusing dialyzers from patients with hepatitis C. Dialyzers for patients with hepatitis B generally should not be reprocessed unless strict protocols are followed, including separating personnel and the site of reprocessing. Individuals performing reprocessing should wear appropriate protective clothing. Monitoring performance measurements of the reprocessed dialyzers is essential to sustain dialysis dose targets.

Vascular access. Ideally, every patient should have a permanent vascular access, preferably a native arteriovenous fistula. Arteriovenous grafts can be used as an alternative if placing an arteriovenous fistula is difficult. The use of jugular venous catheters should be kept to a minimum. Adequate care of the vascular access is essential. Complications in maturation and patency and infections are common in arteriovenous fistulas and grafts and should be monitored to asses center rates. Infection rates of temporary and tunneled catheters (frequent and life-threatening complications) should be recorded, and proper protocols followed up to reduce infections.[22]

Targeting a basic amount of dialysis (dialysis dose). The concept of dialysis adequacy originated from the National Cooperative Dialysis Study and was based on urea kinetic modeling.[23–26] With time, the concept of dialysis adequacy came to be considered in a more holistic manner as health care in general began to focus more on patient-centered care, shared decision making, and the individual patient experience.[27] Nevertheless, it generally is agreed that a certain amount or dose of dialysis (best measured by Kt/V urea) is necessary to provide a basic level of care to ensure that there is adequate removal of uremic toxins. Discussions regarding the notion of dialysis adequacy generally have focused on dialysis regimens of 3 times per week, the standard of care in most HICs. Recently, it was suggested that twice-weekly HD could be an acceptable option for dialysis initiation and continuation in ESKD patients with moderate residual kidney function.[28–30] Importantly, HD 3 times per week is practiced routinely in many LMICs because the costs of HD treatment become of prime importance in determining the number of patients who can be treated. However, a current question to be explored is whether the duration of each treatment should be extended if twice-weekly HD is used in patients with little residual renal function to improve solute removal and excess fluid while reducing the rate of ultrafiltration. In addition, a once-weekly HD option combined with a low-sodium and low-protein diet has been suggested in Japan for those patients with significant residual renal function.[31] How the outcomes of twice-weekly HD compare with outcomes of HD

3 times per week in terms of morbidity, mortality, and impact of quality of life requires careful investigation. These studies could have a major impact on policy decisions concerning HD in LMICs. Focusing attention on preserving residual renal function is important, emphasizing strategies to reduce the degree and frequency of intradialytic hypotensive episodes, applying slower ultrafiltration rates, encouraging a low-sodium diet, avoiding the unnecessary use of nephrotoxic drugs (such as aminoglycosides and radiocontrast), and preventing and containing infections.

Volume control, salt restriction, blood pressure control. Management of extracellular fluid (volume control) is critically important for all dialysis patients and must be considered a key component of dialysis adequacy.[32–38] The goal of fluid removal during dialysis is to maintain the patient's optimal weight and volume status while achieving normal blood pressure (BP) levels. The Kidney Disease Outcomes Quality Initiative recommends a goal of a predialysis BP less than 140/90 mm Hg.[20] A challenge, however, is to optimize volume status while avoiding hypotensive episodes during HD treatment because these have been associated with adverse outcomes, including increased mortality, myocardial stunning, central nervous system dysfunction, endotoxemia, vascular access thrombosis, accelerated loss of residual kidney function, and prolonged recovery time after dialysis.[39] A *post hoc* analysis of the Hemodialysis (HEMO) Study found that ultrafiltration rates greater than 13 ml/h per kilogram (vs. 10 ml/h per kilogram) were associated with a 71% increased risk of cardiovascular mortality in patients receiving HD.[40] Additional measures to control fluid and volume status in dialysis patients include salt restriction and diuretic use (when there is significant renal function). Antihypertensive drugs need to be used to control BP if volume control does not result in acceptable BP levels, recognizing that the use of these drugs may be associated with an increase in intradialytic hypotensive episodes.

The accurate evaluation of volume status in ESKD patients is problematic. Assessment of dry weights is difficult and can involve, in addition to clinical evaluation, a chest X-ray, echocardiographic assessment of the inferior vena cava diameter, N-terminal pro–B-type natriuretic peptide levels, bioelectrical impedance analysis, lung ultrasound, and so forth.[41] These tools may not be available in LMICs so the focus must be on clinical assessment. Small and gradual reductions in postdialysis weights should be practiced to reduce total body sodium levels to normal, accompanied by normotension.

Management of anemia, bone and mineral metabolism, and nutritional status. Various metabolic abnormalities accompany ESKD. Anemia typically develops in ESKD patients related to ongoing blood loss and reduced red blood cell survival and production (in part related to erythropoietin deficiency and reduced iron stores).[42] Complex bone and mineral metabolism alterations develop as a result of reduced excretion of phosphorus, reduced 25 vitamin D activation, and increased production of fibroblast growth factor 23 and parathyroid hormone.[43] Anemia in HD patients can contribute to a variety of symptoms and can be corrected by adequate iron replacement and exogenous supplementation of erythropoietic-stimulating agents. The Kidney Disease: Improving Global Outcomes guidelines suggest that erythropoietic-stimulating agents should be initiated when the hemoglobin level is between 9 and 10 g/dl and that the hemoglobin goal should not exceed 11.5 g/dl.[42] A topic of debate has been the impact of anemia correction on patients' health-related quality of life (HRQOL) when hemoglobin levels are increased within the Kidney Disease: Improving Global Outcomes targeted range.[42,44]

The assessment and treatment of mineral and bone disorders are complicated by the high cost of treatment to reduce serum phosphorus and parathyroid hormone levels and replace active vitamin D. Mineral and bone disease guidelines were updated in 2017 by Kidney Disease: Improving Global Outcomes.[43] The guidelines suggest that phosphorus levels should be maintained as close to the normal range as possible. Proper dietary counseling for reducing the intake of phosphorus is important, but frequently it is necessary to administer drugs to reduce phosphorus absorption from the gastrointestinal tract. Calcium-based phosphate binders should be restricted because of the high risk of vascular calcification. Long-term use of aluminum-containing phosphate binders should be avoided. Sevelamer has been associated with lower mortality rates than calcium-based phosphate binders,[45,46] but its use is limited by its high costs in LMICs. It is suggested to maintain intact parathyroid hormone levels in the range of 2 to 9 times the normal value, for which parathyroid hormone-lowering therapy may be needed (calcimimetics, calcitriol, or vitamin D analogs); however, the high cost of these drugs may limit their use in many LMICs.

Many dialysis patients are malnourished and a careful evaluation of their protein and energy nutritional status should be made with appropriate nutritional counseling. Underlying causes of malnutrition need to be considered carefully, including the problem of inadequate dialysis, underlying inflammation, and undiagnosed infections.

Routine monitoring of facility outcomes. It is imperative that appropriate systems and quantitative and qualitative databases be used for record keeping for all dialysis programs, which ideally also would incorporate external review. Review by patients and relatives with request for comments can be valuable. Routine monitoring of facility outcomes (which need to be adjusted for patient mix) is important in assessing the overall quality of care delivered in an individual facility. These include tracking of mortality and hospitalization rates, which are essential. The dialysis dose delivered, anemia management, various metabolic parameters, and infections related directly to the dialysis procedure need to be tracked. A quality-improvement program should be established to address the standard of care delivered including hypertension, fluid overload, infections, and to report physical findings.[47,48]

HRQOL, symptom management, and patient-centered care. HRQOL is an important outcome measure for patients and assessments of HRQOL provide information about

patients' perception of their quality of life, sense of well-being, symptoms, and the impact of the treatment on their lives. Importantly, studies clearly have shown that various HRQOL measures are predictive of hospitalization and mortality in HD patients.[49] There recently has been an emphasis on patient-centered care and the incorporation of HRQOL measures and symptom assessment into the routine care of ESKD patients.[50,51] Recent work has emphasized the importance of evaluating patients' experiences in terms of their illness, symptoms, and health care delivery, suggesting that the focus of care change from an arbitrary adherence to rigid standards of care to include assessments that capture the individual patient's experience.[52,53]

The impact of various HD regimens on various HRQOL assessments now is being critically examined.[54] An increase in the dose of dialysis as in the HEMO study or the use of hemodiafiltration did not improve the HRQOL of patients compared with conventional HD.[55] On the other hand, changing treatments from conventional HD 3 times per week to more frequent home HD resulted in an improvement in various HRQOL measures. Studies have suggested that widely accepted clinical performance targets recommended by the Kidney Disease Outcomes Quality Initiative are not related to the HRQOL assessments in HD patients.[56,57]

The functional status of patients, exercise capacity, and risk of falls are areas of the utmost importance for HD patients.[58,59] Frailty, limited exercise capacity, and falls all have been associated with poor outcomes for patients. Careful assessments of functional capacity, institution of planned exercise programs, and strategies to reduce the risk of falls all are important aspects of patient care to be addressed. Patients should be taught heel-first walking.

Other aspects of patient-centered care that should be considered include the needs for dialysis patients to be transported back and forth to the dialysis facility, assistance with some activities of daily living, and economic support. Where relevant, patient organizations, even at the simplest, play a very positive role in improving both health and quality of life. Thus, the burden on the individual caregiver(s) for each patient needs to be evaluated in designing the optimal treatment regimen.[60] In addition, various networks of support (including relationships with the community, family, social groups, and medical teams) can be useful adjuncts to facilitate patient care and good health.

Peritoneal dialysis

PD has a number of features that are attractive in LMICs, including lower expense (depending on local manufacturing and/or low import duties and taxes), fewer technical demands, greater feasibility of use in remote regions, reduced need for trained staff, and fewer management challenges in the setting of natural disasters.[61–63] Practical problems in expanding PD programs include the training of individuals to insert catheters, the potential risk of infection, and the ability to obtain dialysate and catheters at an acceptable cost. Although the dialysate problem could be ameliorated by local manufacture of PD solutions, this has been difficult to realize. Furthermore, the costs of distribution of supplies has limited the availability of PD in many LMICs.[64,65] The development of PD programs involves not only the provision of dialysis solutions, but also the availability of satisfactory connection ports between PD solutions and the catheter, and the availability of appropriate facility, nursing, and physician support systems. In addition, because 10% to 15% of PD patients transfer to HD each year because of various complications, having a HD facility available to help receive and manage these patients is essential.[66] Some countries, such as Thailand, have achieved cost reductions for ESKD care by means of a PD-First policy.[67] This has been adopted as a governmental policy and has made universal ESKD coverage possible. Other countries are considering adopting similar policies.

The percentage of ESKD patients maintained on PD varies from a high of 75% in Hong Kong (where a PD-First policy has been in place for years) to a low of less than 10%.[68] In countries with well-established pre-ESKD education programs and where patients freely can choose between HD and PD, between 20% and 25% of ESKD patients are maintained on PD.[68]

The success of PD programs depends very much on adhering to international standards of care. The ISPD has played a key role in setting these basic standards, which are freely available on its website (www.ispd.org). This organization is in the process of redefining the concept of *high-quality peritoneal dialysis care*. These guidelines defining goals and objectives and establishing acceptable levels of care of ESKD patients maintained on PD will be published in a series of articles in *Peritoneal Dialysis International* in 2020. Domains to focus on in establishing acceptable levels of care for ESKD patients maintained on PD include addressing the following areas.

PD facility. The cost of establishing a PD facility is much lower than the cost to establish a HD facility, reflecting the simplicity of the procedure. It is most important to have a thorough and careful training program organized in a comfortable supportive environment. Rigorous reviews of the training procedures are necessary, as carefully outlined in the ISPD guidelines.[69] Detailed monitoring of adherence to ISPD guidelines and outcomes, including mortality rates, infection rates, and reasons for transfer to HD need to be an integral part of the program. Similar to HD units, the role of nurses, dieticians, and individuals addressing psychosocial needs (such as social workers) need to be defined clearly.

PD access, exit site infections, and peritonitis. Cuffed PD catheters should be used for access to the peritoneal space. The techniques for placement of these catheters have been reviewed extensively.[70] They can be placed by nephrologists, internists, nurses, surgeons, or interventional radiologists. The care of the PD catheter and the techniques for exchanging fluid into and out of the peritoneal cavity is critically important. Peritonitis and existing site infections are the major cause of technique failure for PD patients, and peritonitis has been associated with increased mortality.

Detailed guidelines for management of exit site infections and peritonitis have been outlined by the ISPD.[3,5]

Targeting a basic amount of dialysis (dialysis dose). Recommendations for the amount of solute clearance that should be achieved have been outlined by the ISPD but now are being revisited.[71] This amount represents the sum of solute removal with PD and residual renal function. Careful monitoring of residual renal function over time therefore is necessary so that the amount of PD that is delivered provides acceptable levels of solute removal. Patients who start dialysis with higher levels of renal function will need less dialysis. This is important in terms of both limiting dextrose exposure, which can affect the peritoneal membrane adversely, and reducing the cost of doing PD because fewer supplies will be necessary at dialysis initiation. Similar to HD, efforts to preserve residual renal function are most important (avoiding nephrotoxins, hypotensive episodes, infections, blocking the renin-angiotensin system, and so forth) in terms of limited dextrose exposure and preserving the integrity of the peritoneal membrane.[71,72]

Volume control, salt restriction, BP control. Similar to HD (see earlier), volume and BP control need close monitoring. Ultrafiltration can be controlled by adjusting the dextrose content of PD solutions, altering the dwell time of the PD solution, and the use of icodextrin, a large molecular weight solute. Avoidance of hypotension is important because this can have a negative impact on residual renal function. A high-dose loop diuretic should be used to maximize urine output and facilitate volume control while minimizing the use of hypertonic dialysate to achieve adequate volume control.[71,72]

Management of anemia, bone and mineral metabolism, and nutritional status. Similar to HD, various metabolic parameters need to be tracked. Anemia management for PD patients requires lower erythropoietic-stimulating agents and iron doses because there is no ongoing blood loss with the dialysis procedure, as occurs during HD, resulting in significant cost savings.[73] Nutritional parameters (albumin levels) can be more difficult to maintain than with HD because of ongoing albumin losses in the peritoneal fluid.

Routine management of facility outcomes. Similar to a HD unit, the routine monitoring of facility outcomes is essential to assess the overall quality of care delivered in an individual facility. These outcomes include mortality and hospitalization rates, peritonitis and exit site infections rates, dialysis treatment regimens, anemia management, and various metabolic parameters. Infectious problems are the major cause of transfer to HD for PD patients and therefore each facility must have a detailed understanding of their rates and types of infections.[3,5] Adherence of individual facilities to international standards of care has a significant impact on infection rates. A quality-improvement program should be established to address the standard of care delivered.[6]

HRQOL, symptom management, and patient-centered care. A patient-centered care approach focusing on the patient's assessment of their HRQOL, perception of their symptoms, and impact of the dialysis treatment regimen should be an integral part of care, as discussed earlier. It is important to provide psychosocial and educational support for both patients and their caregivers with home-based therapies, such as PD. Psychosocial factors account for a significant percentage of HD transfers, in part because psychosocial factors and mental health issues, such as depression, have been associated with worse outcomes, such as peritonitis.[74,75] Thus, integrating strategies to address psychosocial issues for patients, as well as caregivers, is an important aspect of care that needs to be developed.

Conclusion

Substantial heterogeneity in practice patterns around the world has resulted in wide variations in the quality and type of dialysis care delivered, particularly in countries without universal standards of care and governmental (or other organizational) oversight. The implementation and oversight of basic standards of care requires sufficient infrastructure and appropriate workforce and financial resources to support the basic levels of care and safety practices. Standards of care that have been developed in HICs may present challenges in terms of implementation in LMICs, depending on the available resources and finances to realize these standards. This requires a dialogue within each country or region to decide which standards are both reasonable and achievable and support a basic level of acceptable care. The ISN has created a task force to develop recommendations and guidance documents outlining basic safe and minimum standards of care for hemodialysis and peritoneal dialysis, which can help guide the implementation of such standards in LMICs in the context of local health systems. This will be one of the policy and advocacy priorities of the ISN.

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