Development of an International Standard Set of Value-Based Outcome Measures for Patients With Chronic Kidney Disease: A Report of the International Consortium for Health Outcomes Measurement (ICHOM) CKD Working Group

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Value-based health care is increasingly promoted as a strategy for improving care quality by benchmarking outcomes that matter to patients relative to the cost of obtaining those outcomes. To support the shift toward value-based health care in chronic kidney disease (CKD), the International Consortium for Health Outcomes Measurement (ICHOM) assembled an international working group of health professionals and patient representatives to develop a standardized minimum set of patient-centered outcomes targeted for clinical use. The considered outcomes and patient-reported outcome measures were generated from systematic literature reviews. Feedback was sought from patients and health professionals. Patients with very high-risk CKD (stages G3a/A3 and G3b/A2-G5, including dialysis, kidney transplantation, and conservative care) were selected as the target population. Using an online modified Delphi process, outcomes important to all patients were selected, such as survival and hospitalization, and to treatment-specific subgroups, such as vascular access survival and kidney allograft survival. Patient-reported outcome measures were included to capture domains of health-related quality of life, which were rated as the most important outcomes by patients. Demographic and clinical variables were identified to be used as case-mix adjusters. Use of these consensus recommendations could enable institutions to monitor, compare, and improve the quality of their CKD care.

Complete author and article information provided before references.

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Introduction

Chronic kidney disease (CKD) is an increasingly prevalent clinical and public health problem worldwide, affecting about 8% to 16% of the general population.[1,2] CKD is associated with adverse health outcomes, poor health-related quality of life (HRQoL), and high health care costs[3-5] and contributes substantially to the negative impact of the 4 main noncommunicable diseases identified by the World Health Organization (cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes).[1,3,4] CKD care aims to preserve or restore HRQoL, maintain kidney function and prevent or delay progression to advanced CKD, prevent and manage complications, and, in advanced CKD, manage uremia through hemodialysis (HD), peritoneal dialysis (PD), kidney transplantation, or conservative care (ie, care for patients who, after predialysis counselling, choose not to undergo kidney replacement therapy, as recently defined by KDIGO [Kidney Disease: Improving Global Outcomes][6]). However, significant variation exists in CKD care and treatment practices between institutions and countries.[2,3,7-9]

Value-based health care and shared decision making are increasingly being promoted as a strategy for improving care quality. Based on the principles formulated by Porter and Teisberg,[10,11] value is defined as health outcomes achieved per monetary unit spent: value = outcomes/cost. Shared decision making requires that essential information on patient-relevant outcomes is discussed among the patient and health care professionals so that a given approach to disease will yield a solution aligning as much as possible with the patient's values and preferences. For both value-based health care and shared decision making, defining the outcomes that matter to patients and other stakeholders so they can be collected in a standardized way is the first step.[12]

Although efforts to report outcomes of routine CKD care exist, for example, well-established registries[13] or multinational cohort studies such as the Dialysis Outcomes and Practice Patterns Study (DOPPS),[14] there is no internationally accepted standardized approach to report outcomes of CKD care. Moreover, although survival outcomes and biochemical markers are frequently collected, patients' reports of their HRQoL are still rarely recorded routinely despite increasing recognition of their importance.[15-19] This lack of an agreed standardized approach hinders routine monitoring and benchmarking of different individual clinical practices. To help improve CKD care and shared decision making would require having identical, meaningful, and patient-relevant outcomes of care recorded in routine clinical practice. Furthermore, true comparison would only be possible when correction for case-mix is reliably achieved.

For research, the need for standardization of outcome measurement in CKD was previously recognized by the Standardised Outcomes in Nephrology (SONG) initiative.[20-23] To support the development of a standardized outcome set in CKD for integration into routine clinical practice, the International Consortium for Health Outcomes Measurement (ICHOM; www.ichom.org) convened an international multidisciplinary working group of experts and patient representatives. The aim of the project was to propose a standardized minimum set of patient-centered outcomes for CKD, including patient-reported outcome measures (PROMs) and case-mix factors to increase the usefulness of comparisons across treatment modalities and institutions, targeted for clinical use to enable standardization of health outcome measurement in routine clinical practice in different settings.

Approach

Composition of Working Group

ICHOM, as a not-for-profit activity, has previously developed standardized sets of value-based outcomes for use in routine clinical practice in various medical conditions, such as coronary artery disease,[24] stroke,[25] and cancer (including breast,[26] colorectal,[27] and prostate cancer[28]). To develop a standardized minimum set of health outcome measures for CKD, ICHOM aimed to establish a geographically diverse expert group that covered a broad range of specialties in CKD. The working group started with 22 members, including clinicians (nephrologists and transplantation surgeon), CKD registry experts, epidemiologists, kidney care providers, research scientists, and 2 patient representatives, from 9 countries in Europe, North America, Latin America, the Middle East, and Asia. Five members left the working group. A project team (W.R.V., Z.D.-G., C.R., M.J.S., and W.J.W.B.) guided the efforts of the working group.

Development of the CKD Standard Set

The working group convened using 8 teleconferences between September 2016 and September 2017, following a structured process similar to that of previous ICHOM working groups (Fig 1).[24-28] In brief, the development of the standard set involved several phases: defining scope; prioritizing and defining outcome domains; selecting outcome measures, including clinical data and PROMs; prioritizing and defining case-mix domains; and selecting case-mix measures. Before each teleconference, the project team summarized relevant evidence from the literature and registries and interviewed individual working group members with expertise on specific topics to generate a list of items for discussion. These documents were shared with the working group in advance of each call.

Identification of Potential Outcomes and Case-Mix Variables

The project team performed a systematic literature review, following PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) guidelines,[29] of

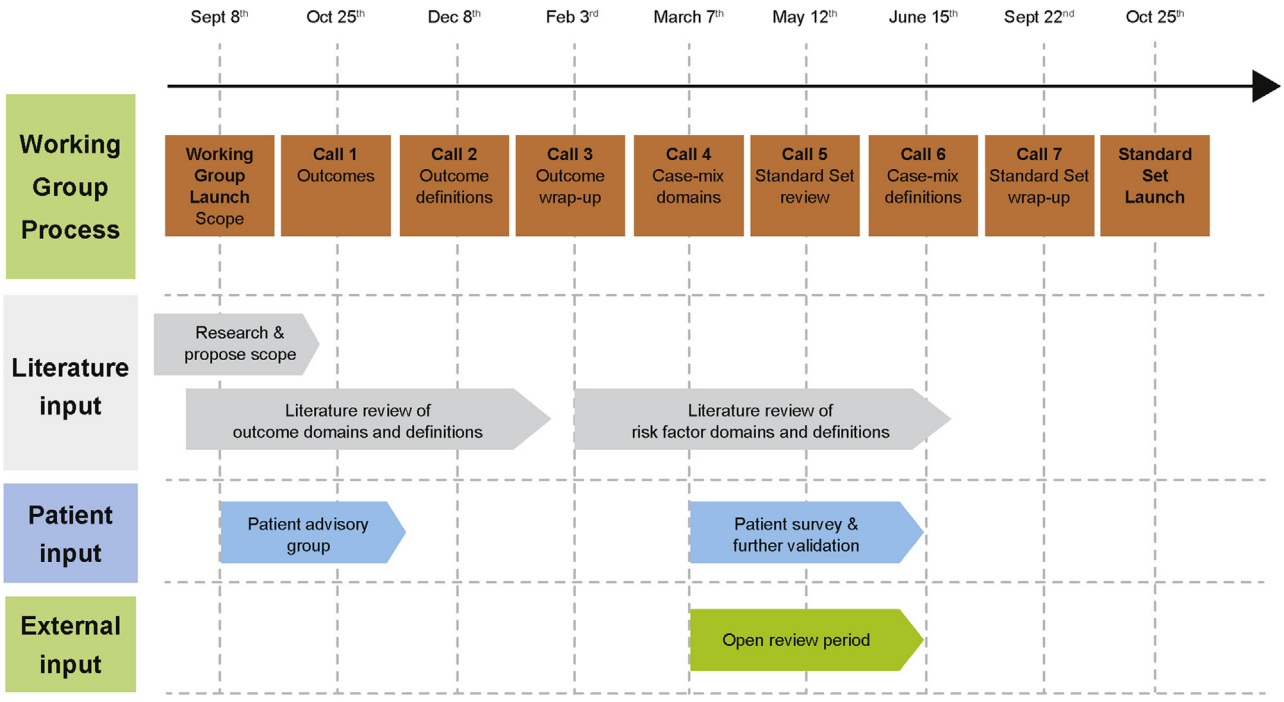

Figure 1. Summary of the development of the chronic kidney disease standard set.

PubMed-indexed articles published January 1, 2005, to September 19, 2016, to identify potential outcome domains, PROMs, and case-mix variables (Item S1). This search retrieved 2,566 articles, of which 1,043 were included for review.

We also reviewed registries of dialysis and kidney transplantation patients for outcome measurement and case-mix adjustment. Registries were identified from a systematic review by Liu et al,[13] by searching links on registry websites, and by internet searches (Item S2). To increase patients' input in identifying potential outcome domains, 5 patients with CKD participated as a patient advisory group in a breakout session using teleconferencing in October 2016 to explore their perspectives on the importance of different outcomes and what affected patients most during their day-to-day activities. We performed an additional literature review to identify studies of patients' perspectives on the most relevant outcome domains in CKD. This search retrieved 1,250 articles, of which 6 were included for review (Item S1).

Consensus Process

Following each teleconference, the project team circulated detailed minutes and an electronic survey to the working group to vote and gather feedback on each key decision point. We used an online 2-round modified Delphi process, following RAND/University of California at Los Angeles methodology[30] and based on literature review,[31] to achieve consensus on which outcomes and case-mix variables should be included (Tables S1 and S2). Inclusion in the standard set required that at least 70% of the working group voted an item as very important (score of 7-9 on a 9-point Likert scale) in either voting round. We used a similar process to agree on which outcome and case-mix measures and PROM tools should be recommended. Results of each vote were reviewed by the working group at the next teleconference. When consensus was not reached by voting, the topic was rediscussed at the following teleconference. The criteria by which we assessed outcome domains for inclusion in the set were: (1) frequency of the outcome, (2) impact on the patient, (3) potential for modifying the outcome, and (4) feasibility of measuring the outcome. Variables to be used as case-mix adjusters were assessed on: (1) relevance, (2) independency, and (3) the feasibility of measurement.

Selection of PROMs

After the outcomes had been chosen for inclusion in the standard set, we identified the corresponding PROMs from the literature and registry review.[32-37] In targeted searches, the original and validation studies of the instruments were retrieved. We systematically evaluated PROMs for psychometric quality, domain coverage, and feasibility of measurement and implementation using the International Society for Quality of Life Research criteria (Table S3).[38]

Patients' Review of Outcomes

Patients with CKD (n = 358), recruited via national and international patient organizations (Item S3), reviewed the proposed list of outcomes. Participants were asked to complete an anonymized online survey, available in English, Spanish, and Dutch, rating the importance of each proposed outcome on a 9-point Likert scale and indicating whether the list captured the most important outcomes, including the option to suggest additional outcomes in free-text form. The project team performed a qualitative analysis on the free-text responses to identify outcomes missing in the proposed list. The working group discussed all findings and voted on the next steps.

External Input

Health professionals and other interested stakeholders in outcome measurement (n = 70), recruited via professional associations (Item S3), reviewed the final draft of the standard set and provided feedback using an online English-language survey. They were asked to rate their confidence regarding several elements of the set (eg, completeness and implementation feasibility) on a 9-point Likert scale, with an open field for comments. The working group discussed the findings and voted on the next steps.

Findings

Scope

The working group selected adult patients (aged ≥18 years) with a diagnosis of very high-risk CKD, corresponding to KDIGO classification stages G3a/A3 and G3b/A2 to G5, regardless of underlying cause (Fig 2),[39] as the population of interest for the standard set. Treatment modalities that were included were management of pre–end-stage kidney disease (pre-ESKD; defined here as stages of CKD prior to kidney failure, whether or not kidney replacement therapy is planned), HD, PD, kidney transplantation, and conservative care. Patients with acute kidney injury, except those who progressed to very high-risk CKD after 3 months, were not included in the scope of this project because the disease course and care goals are different for acute kidney injury and CKD.

Outcomes

We identified a total of 76 outcome domains from a systematic literature review, assessment of registries, and input from the patient advisory group (Table S1). After a consensus vote, 19 outcome domains were included in the standard set (Table 1): 9 relevant to all patients with CKD, and 10 to treatment-specific subgroups. We categorized these outcome domains into 4 groups: (1) patient survival, (2) burden of disease (eg, hospitalization rates and complications), (3) patient-reported outcomes on HRQoL, and (4) treatment modality–specific outcomes. We pragmatically determined recommended measurement time points

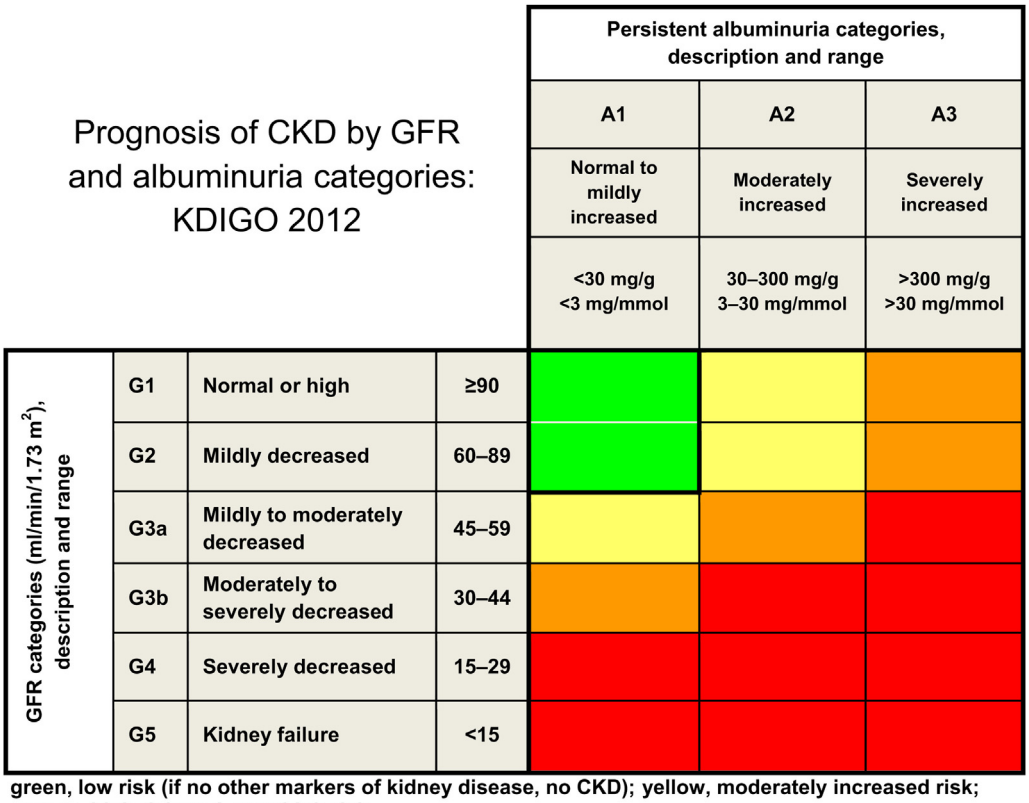

Figure 2. Scope for the chronic kidney disease (CKD) standard set was defined as adult patients (aged ≥18 years) diagnosed with very high-risk CKD, corresponding with KDIGO (Kidney Disease: Improving Global Outcomes) classification stages G3a/A3 and G3b/A2 to G5, regardless of underlying cause. Abbreviation: GFR, glomerular filtration rate. Heat map is copyright 2012 KDIGO; reproduced from the CKD guideline[39] with permission of KDIGO.

of the included outcomes, balancing between meaningful time points when outcomes may be expected to change and the feasibility of data collection (Table 1; Fig 3).

Patient Survival

We selected patient survival (determined by assessing overall survival time and cause of death) for inclusion. Identified problems in collecting data for cause of death included the validity of such data and the practical implications of detailed data collection, but we believed that cause of death is a key factor in understanding long-term outcomes of CKD care. We recommend use of a simplified version of the coding standard for causes of death from the ERA-EDTA (European Renal Association–European Dialysis and Transplant Association) Registry, which was developed by the Scottish Renal Registry.[40]

Burden of Disease

Hospitalization and cardiovascular events were selected as measures of burden of disease. We decided to define hospitalization as the number of admissions and of days spent in hospital, rather than by collecting dates of each admission and discharge. Dialysis-free time was considered as an additional outcome relevant to HD patients, but we noted that not all health services are able to provide frequent dialysis, so dialysis-free time may not be an accurate representation of better health. Cardiovascular events of interest included acute myocardial infarction, stroke, and limb amputation. We decided not to include side effects of medication, primarily because side effects are specific to different drugs and lack standardized assessments.

Patient-Reported Outcomes for HRQoL

The working group prioritized 6 patient-reported outcome domains for HRQoL: general HRQoL, pain, fatigue, physical function, depression, and daily activity (Table 1). The final voting result on depression was inconclusive, but we decided to include depression because it was given a high rating of importance by the patient representatives (Table S1). Our aim was to select a PROM with good psychometric performance that would capture all 6 outcome domains for HRQoL and provide scores for each individual domain while minimizing respondent and administrative burden. Of 41 PROMs identified,[32-36] the

Table 1. Summary of Outcomes for the CKD Standard Set

Patient Population	Measure	Details	Timing	Data Source
Survival				
All pts	Survival	Date and cause of death	Ongoing	Clinical or administrative data
Burden of Disease				
All pts	Hospitalization	No. of admissions, days in hospital	Annually	Administrative data
	CV events	AMI, stroke,[a] limb amputation[b]	Annually	Clinical or administrative data
Patient-Reported Outcomes for HRQoL				
All pts	HRQoL	Tracked with SF-36, RAND-36, or PROMIS Global Health + PROMIS-29	6-monthly: HD, PD, & conservative care pts; Annually: pre-ESKD & KT pts	Patient reported
	Pain			
	Fatigue			
	Physical function			
	Depression			
	Daily activity			
Treatment Modality–Specific Outcomes				
Pre-ESKD & conservative care pts	Kidney function	eGFR[c] and/or Scr	6-monthly	Administrative data
Pre-ESKD, KT, & conservative care pts	Albuminuria	UACR or UPCR in spot urine	Annually	Administrative data
HD, PD, & KT pts	Bacteremia	Positive blood culture with clinical signs	6-monthly	Clinical data
HD pts	Vascular access survival	Tracked with status of vascular access	6-monthly	Clinical or administrative data
PD pts	PD modality survival	Tracked with status of PD modality	Annually	Clinical or administrative data
	Peritonitis	Clinically suspected and/or culture proven	6-monthly	Clinical data
KT pts	Kidney allograft function	eGFR[c] and/or Scr	6-monthly	Administrative data
	Kidney allograft survival	Tracked with status of transplant	Annually	Clinical or administrative data
	Acute rejection	Clinically suspected and/or biopsy-proven[d]	6-monthly in first year, then annually	Clinical data
	Malignancies	Solid tumor, skin cancer, & hematologic malignancies	Annually	Clinical or administrative data

Note: A detailed definition of each outcome can be found in the online reference guide (freely available at www.ichom.org/medical-conditions/chronic-kidney-disease/).

Abbreviations: AMI, acute myocardial infarction; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; CV, cardiovascular; eGFR, estimated glomerular filtration rate, HD, hemodialysis; KT, kidney transplantation; PD, peritoneal dialysis; PROMIS, Patient-Reported Outcomes Measurement Information System; HRQoL, health-related quality of life; Scr, serum creatinine; SF-36, 36-Item Short Form Health Survey; UACR, urinary albumin-creatinine ratio; UPCR, urinary protein-creatinine ratio.

[a]Excluding transient ischemic attack.

[b]Limb amputation not due to traumatic injury.

[c]eGFR calculated using the CKD-EPI creatinine equation (preferred) or other equations.

[d]Biopsy-proven acute rejection according to Banff classification category 2, 3, or 4.[50]

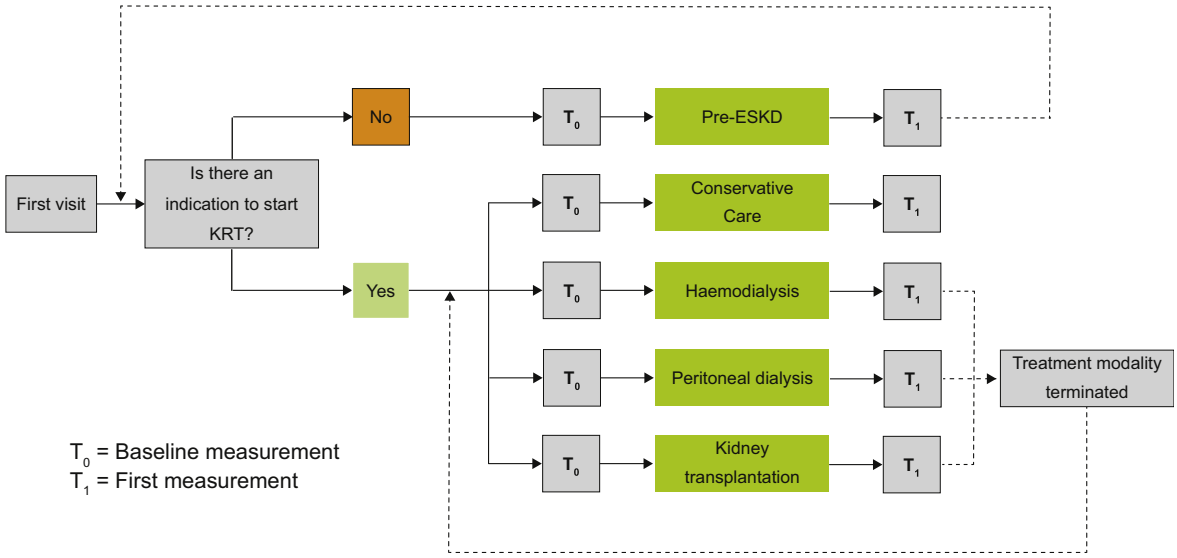

Figure 3. Algorithm for measurement time points of the chronic kidney disease (CKD) standard set. Abbreviations: ESKD, end-stage kidney disease (ie, non–kidney failure CKD); KRT, kidney replacement therapy.

16 most commonly used PROMs were reviewed (Table S3), discussed by the working group, and voted on. We recognized that a generic PROM could be used to measure all 6 HRQoL domains rather than one specific to CKD or a particular treatment. A major advantage of a generic PROM is that such tool could be used across treatment modalities and across other diseases, which is relevant in the CKD population, and recommended for multimorbid patients.[41]

Despite extensive evaluation and discussion, the working group did not reach consensus on a single preferred instrument because each PROM was believed to have its own merits and limitations, so 3 tools were recommended: the 36-Item Short Form Health Survey (SF-36) version 2,[42] RAND-36,[43] and the combination of the Patient-Reported Outcomes Measurement Information System (PROMIS)-Global Health and PROMIS-29.[44] The SF-36 is widely used and well validated, but its use requires a license fee.[32-36] RAND-36 is an older version of the SF-36 without a license fee, but is only available in English and Arabic. The 2 PROMIS tools are both short forms based on extensive item banks, are available in paper and electronic versions, and have been validated in general populations.[45,46] CKD validation studies are currently being performed.[47] The disease-specific Kidney Disease Quality of Life (KDQOL) measures were not preferred because the KDQOL Short Form (KDQOL-SF) contains substantially more questions than strictly needed to measure the 6 HRQoL domains, while the 36-Item KDQOL (KDQOL-36) provides only 2 summary scores on physical and mental health. Each recommended PROM can be completed in about 10 minutes and provides scores for all 6 outcome domains of interest and 2 overall scores of physical and mental health. To enable comparisons among the PROMs, most measures of the same outcome domain can be translated into a common metric, developed by PROsetta Stone (www.prosettastone.org). We decided that it was most important to recommend use of a selection of PROMs rather than 1 specific PROM; because the field is rapidly changing, other PROMs may be considered in revisions of the standard set.

Treatment Modality–Specific Outcomes

Kidney function, or kidney allograft function, and albuminuria were included as measures of disease control for patients with pre-ESKD CKD, conservative care patients, and kidney transplantation patients. Recognizing that measurement of these outcome domains varies across institutions (eg, use of different equations for estimated glomerular filtration rate), we decided to include several measurement methods and selected a preferred option for comparison purposes, based on KDIGO guidelines[39,48]: estimated glomerular filtration rate calculated using the CKD-EPI (CKD Epidemiology Collaboration) creatinine equation for kidney/kidney allograft function and urinary albumin-creatinine ratio in spot urine specimens for albuminuria. Because different laboratories use different measurement techniques, we recommend to assess type of serum creatinine and albuminuria assay and whether isotope-dilution mass spectrometry calibration standardization is used.[49]

We considered infections as an important outcome domain in all patients undergoing kidney replacement therapy. Due to lack of standardized assessments, the domains for assessment of these outcomes were restricted to bacteremia in HD, PD, and kidney transplantation patients (positive blood culture with clinical signs, excluding contamination) and peritonitis in PD patients (clinically suspected and/or culture-proven infection). We also included outcomes of treatment modality survival: PD

modality survival in PD patients and kidney allograft survival in kidney transplantation patients. Vascular access survival was voted to be a relevant outcome for HD patients. Surgical complications, such as complications after vascular access surgery, PD catheter surgery, and kidney transplantation, were not included in the final set because of lack of standardized assessments of these complications. Acute rejection of a kidney transplant (clinically suspected and/or biopsy-proven acute rejection according to Banff classification category 2, 3 and 4[50]) and malignancies were included as important measures of treatment complications for kidney transplantation patients.

Case-Mix Variables

After voting (Table S2), we selected a minimum set of case-mix variables to enable meaningful comparisons across treatment modalities and institutions (Table 2).

Demographic factors included age, sex, and education level. We selected education level (defined as the highest level of schooling attained) as a surrogate for socioeconomic status, being easily obtainable and internationally comparable,[51] in line with previous ICHOM work. The prohibition against collecting data for race or ethnicity in several countries and the lack of an internationally standardized method for collecting these data led to the decision to exclude race or ethnicity as a case-mix factor from the current set.

Clinical factors included smoking status, nutritional status by body mass index, comorbid conditions, primary kidney disease, baseline kidney/kidney allograft function, baseline albuminuria, and characteristics of previous and current treatment modality. Comorbid conditions of interest were based on the Charlson Comorbidity Index,[52] Davies comorbidity score,[53] and Khan index.[54-57] Primary kidney diseases were based on a simplified version of the ERA-EDTA coding system.[58]

Table 2. Summary of Case-Mix Variables for the CKD Standard Set

Patient Population	Measure	Data Source
Demographic Factors		
All pts	Age	Patient reported
	Sex	
	Education level[a]	
Baseline Clinical Factors		
All pts	Comorbid conditions[b]	Clinical abstraction
	Smoking status	
	Body mass index	
	Primary kidney disease[c]	
Pre-ESKD & conservative care pts	Baseline kidney function	
Pre-ESKD, KT, & conservative care pts	Baseline albuminuria	
HD, PD, KT, & conservative care pts	Previous treatments	
HD pts	Vascular acces type[d]	
KT pts	Baseline kidney allograft function	
KT pts	Transplant type[e]	

Note: A detailed definition of each case-mix variable can be found in the online reference guide (free available at www.ichom.org/medical-conditions/chronic-kidney-disease/).

Abbreviations: CKD, chronic kidney disease; ERA-EDTA, European Renal Association–European Dialysis and Transplant Association; HD, hemodialysis; KT, kidney transplantation; PD, peritoneal dialysis; pt, patient.

[a]Education level defined as highest attained education. Level of schooling defined in each country according to the International Standard Classification of Education.

[b]Comorbid conditions include hypertension or use of antihypertensive medication, diabetes mellitus, chronic lung disease, chronic liver disease, cardiovascular events, and malignancies.

[c]Primary kidney diseases according to categories based on simplified ERA-EDTA coding system: uncertain cause, diabetes mellitus, glomerulonephritis, hypertension, polycystic kidney disease, pyelonephritis, kidney vascular disease, or other (indicate).

[d]Vascular access type includes arteriovenous fistula, arteriovenous graft, and catheter.

[e]Transplant from living or deceased donor.

Patients' Review of Outcomes

Of the 358 patients who participated in the online review survey between March and June 2017, a total of 75% (270) believed that the proposed list of outcomes captured the most important outcomes. Patients ranked the HRQoL domains as most relevant (Fig 4); 115 respondents provided free-text responses, in which health literacy and ability to work were the most frequently raised additional outcomes (Table S4). However, we could not find validated or freely available measurement tools for these outcome domains and recommend developing such tools as a research priority. If such tools become available, health literacy and work ability should be reconsidered for inclusion in the standard set.

Stakeholder Consultation

The health professionals and care providers (n = 70) who completed the online survey on the proposed standard set were confident that the set represented a comprehensive view of the most essential outcomes for patients with CKD and about the feasibility of data collection in routine clinical practice (Table S5; mean score, 6.9 on a 9-point Likert-type scale). Their main concerns were related to challenges around implementation of the standard set, availability of data, and the number of measures included in the set (see next section).

Data Collection and Implementation

Concerned about the standard set's length and potential difficulties in implementation, we reconsidered the outcomes included in the set and decided to group the outcomes into 2 tiers: an essential tier, which includes the PROMs, and an important tier (Fig 5). Health care providers implementing the set should focus on monitoring outcomes in the essential tier and include the important tier if feasible.

A reference guide is freely available on ICHOM's website (www.ichom.org/medical-conditions/chronic-kidney-disease/), including a data dictionary for all variables, potential data sources, and recommended timelines for data collection.

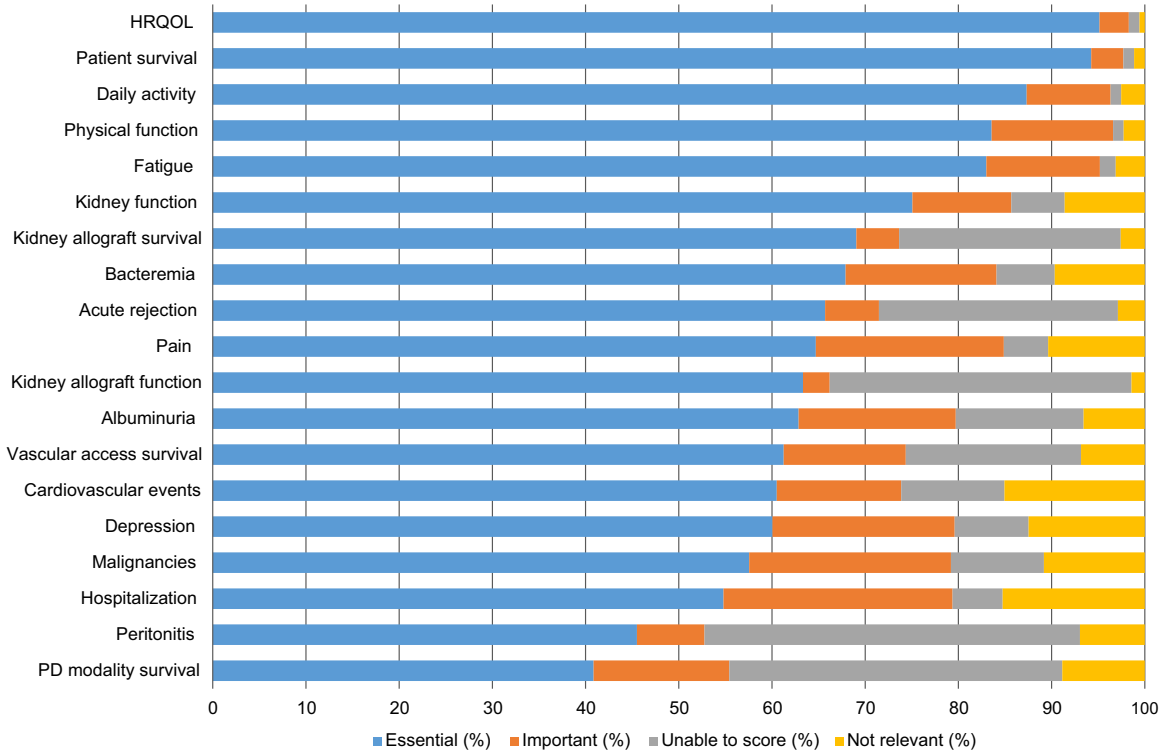

Figure 4. Results of the online review survey among patients with chronic kidney disease (n = 358) on the proposed outcomes. The survey included all outcomes with supporting definitions. Respondents had to rate the importance of each outcome on a 9-point Likert scale (7-9, "essential"; 4-6, "important"; and 1-3, "not relevant"). The response option "unable to score" was included, for example, for patients having no experience with specific treatment modalities (eg, hemodialysis, peritoneal dialysis [PD], or kidney transplantation). Abbreviation: HRQoL, health-related quality of life.

Discussion

On the basis of patient input, literature reviews, assessment of registries, and expert consensus, an international multidisciplinary working group defined a minimum set of patient-centered outcomes for CKD that should be recorded in routine clinical practice to support the shift toward value-based health care in CKD and improve shared decision making. The working group focused on outcomes relevant to patients with very high-risk CKD (stages G3a/A3 and G3b/A2 to G5, including HD, PD, kidney transplantation, and conservative care) and to treatment-specific subgroups. The set includes outcomes that are important to patients but that are less routinely collected, such as HRQoL, and a minimum of demographic and clinical factors to be used for case-mix adjustment across treatment modalities and institutions.

In nephrology, data collection of health outcomes in routine clinical practice has been performed by well-established regional, national, and international registries and in studies such as DOPPS.[13,14] These efforts have

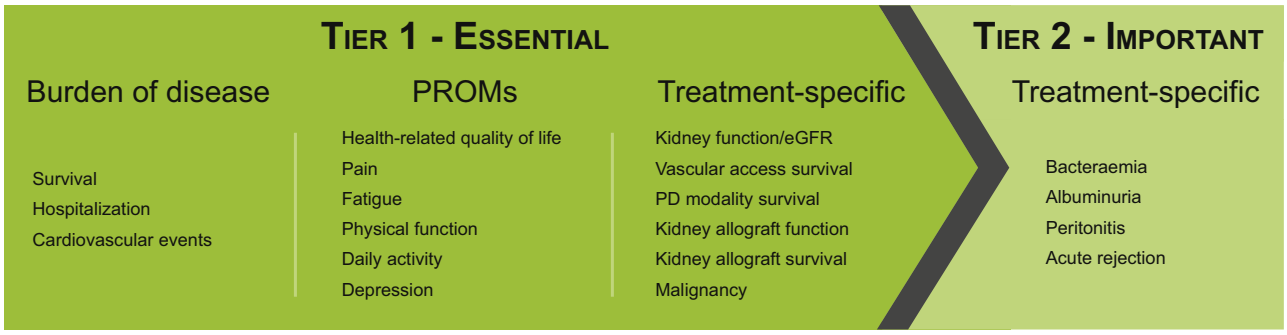

Figure 5. Outcomes of the chronic kidney disease standard set divided into 2 tiers, covering essential and important outcomes, to guide implementation. Abbreviations: eGFR, estimated glomerular filtration rate; PD, peritoneal dialysis; PROM, patient-reported outcome measure.

provided the foundation for quality improvement in CKD care in many countries; for example, after observing differences in health outcomes across different care settings.[8,59-61] However, comparisons and data sharing across health systems have been restricted to the involved institutions and countries and (in addition to mortality) to intermediate and process outcomes of CKD care, such as biochemical parameters, that are most easily accessible.[15] Furthermore, most data collection has focused on patients undergoing dialysis or kidney transplantation, which misses opportunities to optimize care at an earlier stage to prevent or delay CKD progression. Standardization of outcome measurement in clinical practice based on outcomes that matter to patients is needed as a first step to enable benchmarking and quality improvement in CKD care on a larger scale and improve shared decision making.[62,63] Such standardization of outcomes was previously recognized for research by the SONG initiative.[20-23] Our work is a multinational effort to recommend a standardized minimum set of health outcome measures for use in routine clinical practice across different settings worldwide, incorporating PROMs that are important to a broad spectrum of patients with CKD, including those with pre-ESKD stages.

It is important to recognize that this standard set does not include all outcomes that may matter to patients and other stakeholders. Our aim was to define a minimum standard set of health outcomes relevant to patients with CKD while balancing the practicalities and burden of data collection, finding the most appropriate PROMs and case-mix variables, and recommending meaningful but feasible measurement time points. Specific for the recommended PROMs, the prioritization of the 6 HRQoL domains and the subsequent assessment of domain coverage per PROM substantially guided our selection. Generic PROMs appeared to be the most appropriate, which is somewhat contrary to existing recommendations for HRQoL measurement in CKD that propose to combine generic and kidney disease–targeted components.[64-66] However, in such recommendations, domain coverage is often missing as a selection criterion or is not needed due to a difference in purpose. We encourage care providers to measure additional outcome domains, use additional PROMs (eg, more detailed symptom- or treatment-specific instruments) or case-mix adjusters (eg, race/ethnicity), and measure at more frequent time points to meet their specific requirements.

As with any process of standard set development, there are limitations to our approach. The current recommendations reflect the opinion of a selected group of experts and patient representatives. We informed our discussions by evidence reviews and aimed to collect as much feedback as possible from patients, health professionals, and other relevant stakeholders. We sought to achieve a high level of transparency by using a modified Delphi technique to document our decision-making process. Feedback from the online review surveys suggested that patients, health professionals, and other stakeholders were confident that the standard set included the most important outcomes. However, we were not able to include health literacy and work ability, which had been identified as important outcome domains in the online review survey of patients, because of the lack of valid or freely available assessment tools. Our results include some similar outcome domains to those from the SONG initiative on defining core outcomes for nephrology research[67-69] and to results from studies of patients' outcome priorities.[70-72] In the SONG initiative, patients rated aspects of HRQoL as more important than survival. Our patient reviewers rated HRQoL as important as survival. We recommend that the current set be used as a starting point for standardized registration and collection of patient-centered outcomes in CKD care. A steering committee, made up of a subgroup of the working group including a patient representative, will convene annually to review new evidence and expertise, including new developments in the field of PROMs, and continue to refine the standard set.

We recognize that implementation of the standard set in routine clinical practice may be challenging in many settings because it may require investment in resources for collection of data (including PROMs) and infrastructure development (including linkages with administrative data sources), as well as alignment with existing registries and outcome measurement efforts. Moreover, as patients wish to discuss individual outcomes and PROM results to guide their treatment, which was explicitly expressed by the patient representatives in our working group, new practice patterns would need to be developed to do so.[73,74] For these reasons, we consider the standard set as a goal rather than a threshold.

We envision that implementation involves 4 phases: (1) preparation, to engage clinical leaders and set up an appropriate governance process; (2) diagnostic, to determine current measurement practices and gaps and develop strategies for collecting clinical data and PROMs at suitable time points, (3) roll-out, to use pilot sites to test strategies including for data collection, and (4) measurement, to determine how to relay the data back to the clinical teams and patients (Fig S1). To facilitate implementation, we divided the list of outcomes into an essential tier and an important tier, stressing the need to focus on the PROMs, and added references on barriers and facilitators of implementing PROMs in clinical practice.[64,66,75-77] The near-term goal will be to partner with pilot institutions to implement the set as a proof of concept, which has been successfully applied for other standard sets.[78-80] The experience and lessons learned in this pilot testing will be documented, and the steering committee will use feedback from this phase to refine the CKD standard set and prepare it for widespread implementation.

To conclude, we have developed a consensus recommendation for a standardized minimum set of health outcomes that are deemed most important to patients with CKD targeted for integration into routine clinical practice. Use of the standard set enables institutions to monitor, compare, and improve the quality of their CKD care.

Supplementary Material

Figure S1: Phases involved in implementation of the CKD standard set.

Item S1: Literature review to identify potential outcomes, PROMs, and case-mix variables in CKD studies to be considered for inclusion in the CKD standard set, and to identify studies studies determining CKD patients' perspectives on the most relevant outcomes in CKD.

Item S2: Registry review to identify potential outcomes, PROMs, and case-mix variables in registries to be considered for inclusion in the CKD standard set.

Item S3: List of patient and professional organizations involved in recruitment of patients, health professionals, and other stakeholders for participation in the online review surveys.

Table S1: Voting results of 2-round modified Delphi process by working group on outcomes.

Table S2: Voting results of 2-round modified Delphi method by working group on case-mix factors.

Table S3: Overview of the review on PROMs for the included outcome domains, and overview of domain coverage of PROMs.

Table S4: Results of the qualitative analysis on free-text responses about missing themes reported by CKD patients participating in the online review survey.

Table S5: Results of online review survey on the proposed CKD standard set by health professionals, care providers, and other stakeholders interested in outcomes measurement.

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