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## Performance-based risk-sharing agreements in renal care: current experience and future prospects

Michael Drummond <sup>a,b</sup>, Carlo Federici<sup>b</sup>, Ellen Busink<sup>c</sup>, Christian Apel<sup>c</sup>, Dana Kendzia<sup>c</sup> and Werner Brouwer <sup>d</sup>

<sup>a</sup>Centre for Health Economics, University of York, York, UK; <sup>b</sup>Center for Research in Health and Social Care, Bocconi University, Milan, Italy; <sup>c</sup>Health Economics and Market Access EMEA, Fresenius Medical Care, Bad Homburg, Germany; <sup>d</sup>Erasmus School of Health Policy and Management, Erasmus University, Rotterdam, The Netherlands

### ABSTRACT

**Introduction:** Performance-based risk-sharing agreements (PBRsAs), between payers, health care providers, and technology manufacturers can be useful when there is uncertainty about the (cost-) effectiveness of a new technology or service. However, they can be challenging to design and implement.

**Areas covered:** A total of 18 performance-based agreements were identified through a literature review. All but two of the agreements identified were pay-for-performance schemes, agreed between providers and payers at the national level. No examples were found of agreements between health care providers and manufacturers at the local level. The potential for these local agreements was illustrated by hypothetical case studies of water quality management and an integrated chronic kidney disease program.

**Expert opinion:** Performance-based risk-sharing agreements can work to the advantage of patients, health care providers, payers, and technology manufacturers, particularly if they facilitate the introduction of technologies or systems of care that might not have been introduced otherwise. However, the design, conduct, and implementation of PBRsAs in renal care pose a number of challenges. Efforts should be made to overcome these challenges so that more renal care patients can benefit from technological advances and new models of care.

### ARTICLE HISTORY

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### KEYWORDS

Health technology assessment; reimbursement; risk sharing; performance assessment; cost-effectiveness analysis

## 1. Introduction

The notion of payment for performance is gaining popularity in health care worldwide. No longer are health professionals or providers paid for merely delivering a service; payment is based on achieving a given level of performance. In renal care, 'pay-for-performance' schemes exist in a number of settings. The exact nature of these schemes varies from place to place, but in general, they are agreements between providers and payers, with the provider being rewarded for meeting a pre-agreed target, or penalized for failing to meet it [1–3].

For example, in the US, the End Stage Renal Disease Quality Incentive Program (ESRD QIP), the first-ever mandatory federal pay for performance program, was launched in 2012 as the result of an overall reform of payment models for renal care of Medicare patients, mandated by the Medicare Improvements for Patients and Providers Act (MIPPA) in 2008. The MIPPA introduced a bundled prospective payment system for outpatient dialysis services provided to Medicare beneficiaries and legislated that payment would be linked to quality performance measures [1,2]. Within the Quality Incentive Program (QIP), dialysis facilities that do not meet certain standards are subject to a global Medicare payment reduction of up to 2%. The Centers for Medicare and Medicaid Services (CMS) constantly update and expand the quality metrics used to assess providers through an established process. For example, for the payment year 2020, quality measures encompassed both effectiveness

and safety measures, including measures such as standardized readmission and transfusion ratios, dialysis adequacy, hypercalcemia, and vascular access measures, and reporting measures to incentivize facilities to report dialysis-event data [4].

In addition to the QIP, the Comprehensive ESRD Care (CEC) Model, is a specialty-specific payment model launched in 2015, as a five year initiative by the Center for Medicare & Medicaid Innovation, with the objective of improving care and reducing costs for Medicare beneficiaries with ESRD. Within the CEC, dialysis clinics, nephrologists, and other providers join to create ESRD Seamless Care Organizations (ESCOs) and provide coordinated care to their matched ESRD beneficiaries. Like the accountable care organizations (ACOs) introduced by the Patient Protection and Affordable Care Act, ESCOs are held accountable for the clinical and financial outcomes of their beneficiaries [5]. This model is currently undergoing an assessment to determine whether and how it could be implemented as a permanent program. Finally, the ESRD treatment Choice (ETC) model has been proposed but delayed owing to the COVID-19 pandemic. This would provide financial incentives to providers to offer holistic kidney option education, appoint a care coordinator, and would involve a monthly capitation payment, including adjustments based on increasing the share of home dialysis patients and kidney transplants [6].

One feature of pay-for-performance schemes is that they mostly relate to the use of currently accepted treatments and

Article highlights

- Performance-based risk-sharing agreements are attracting considerable interest in health care, as they offer potential benefits to patients, technology manufacturers, health care providers and payers.
- Despite this interest, progress in establishing these agreements has been slow and has been mainly limited to new medicines.
- The field of renal care is a potential candidate for these agreements, since it consists of a range of expensive long-term services, the quality or cost-effectiveness of which could be improved.
- This paper adds to our knowledge by identifying a number of such agreements in renal care, describing their key characteristics.
- Performance-based risk-sharing agreements can be complex in the field of renal care, requiring agreement by payers, providers and technology manufacturers on a number of key issues in the design, conduct and evaluation of schemes.
- These complexities are illustrated by the use of two hypothetical case studies.
- Overall, there is further scope for PBRSA in renal care, providing the main challenges can be overcome.

procedures. The ‘performance’ being assessed relates mostly to the provider’s level of efficiency in providing current care. But what about situations where the choice is whether or not to adopt a *new* treatment or care model? This situation is common outside of renal care, for example, in decisions on whether or not to use an expensive new drug [7]. The drug may increase survival but that is often not known with certainty when it secures a license. In these situations, a different type of performance-based agreement is used, called a *performance-based risk-sharing agreement (PBRSA)* [8] Here, the parties to the agreement share the risk by entering into an interim arrangement to make the new treatment available, while basing the final level of coverage or payment on how well it performs in actual clinical use. (The distinction between the different types of performance-based agreements is illustrated in Figure 1.)

In the case of new pharmaceuticals, and some medical devices, PBRSA are typically between the payer and technology

manufacturer. However, they may also be between the manufacturer and provider, if there is a possibility that the provider can bear the extra cost of adopting the new technology within the current payment (e.g., Diagnosis-Related Group (DRG)). For example, a provider might adopt an expensive new device if it could be shown that it increased the efficiency of providing care. PBRSA are particularly important in facilitating the adoption of new treatments or models of care. A good example is the establishment of the (reformed) Cancer Drugs Fund in the United Kingdom [9]. This has provided a way of making promising, but expensive, cancer drugs available to patients without exposing the payer to considerable financial risk. If the drugs on the scheme are not as effective as was originally thought, the payer has the option to limit their use, or to reduce their price.

PBRSA have been implemented in many areas of health care and the general challenges in the development and implementation of schemes have been discussed [8,10–12]. The purpose of this paper is to explore their potential in the field of renal care. This field is relevant given the high economic burden and the uncertainties surrounding the economic consequences of adopting new technologies in chronic diseases, where expenditure is continuous and ‘savings’ may be hard to realize. First, it reports the results of a literature review, conducted in order to identify any existing PBRSA in the public domain and the opportunities and challenges of these agreements more generally. Secondly, two hypothetical case studies are developed to analyze the applicability of risk-sharing agreements in terms of opportunities and barriers for implementation in renal care.

2. Methods

First, a scoping review of the available literature was conducted up until September 2018 using relevant items from the PRISMA checklist as guidance [13,14]. The bibliographic databases searched were Ovid (including Medline), Embase

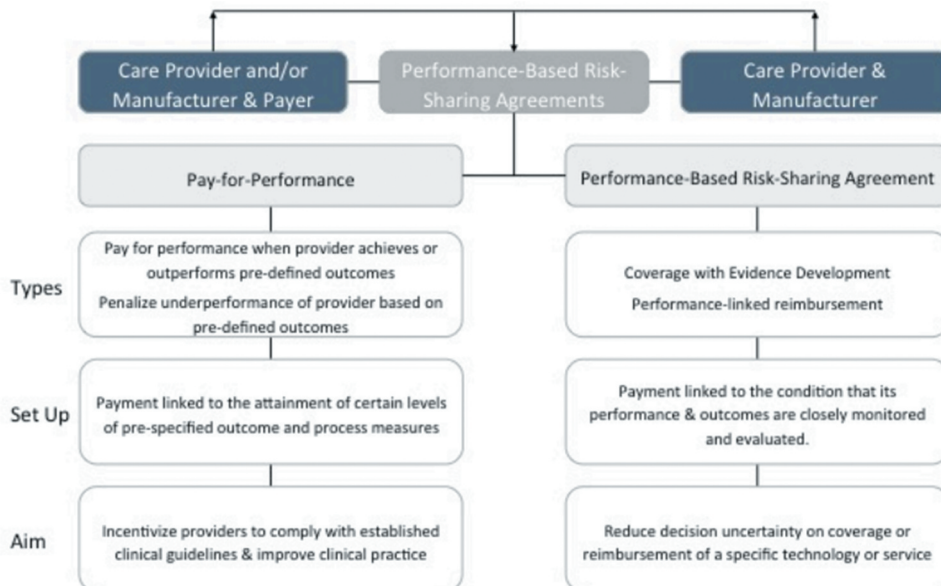


Figure 1. Types of Performance-Based Agreements.

and Web of Science. The eligibility criteria for inclusion were defined as follows: (i) *Condition/disease*: any stage of chronic kidney disease (CKD) and related complications (ii) *Scope*: studies discussing main characteristics, challenges, and/or opportunities of existing performance-based risk-sharing arrangements in renal care, or other schemes where payments for renal care are made conditional on the assessed performance of the technology. All types of studies, except for meeting abstracts, were included if published in English. Editorials were assessed on a case-by-case basis, to determine if they discussed relevant aspects of risk-sharing agreements.

The full strategy used for identifying relevant records is reported in Appendix 1.A search for 'unpublished' or 'gray' literature was also performed on Google using different combinations of the original search terms and the New York Academy of Medicine Grey Literature report. One reviewer performed the literature search, screened the records, and extracted the data from the included studies.

Since there is not always agreement on what constitutes a PBRSA, and these types of schemes are known under many different names, a broad search strategy was adopted encompassing all types of performance-based schemes, including pay-for-performance (P4P) schemes. Subsequently, the types of arrangements discussed in the identified records were classified by the authors as either PBRSA or P4P arrangements. PBRSA were identified using the five criteria proposed in the taxonomy by Garrison et al. [8] (Box1), whereas P4P schemes were defined as schemes whose main objective is to improve quality of care by tying reimbursement to metric-driven outcomes, best practices, and/or patient satisfaction, rather than to reduce decision uncertainty on coverage or reimbursement of a specific new technology or service [15,16].

Data from the identified studies were extracted according to a predefined extraction template, which included the target patient population (e.g. chronic kidney disease (CKD) stage 3 to 5, End-Stage Renal Disease patients); the name and description of any performance-based risk-sharing agreement included; and the country or setting where the scheme was implemented. In addition, information on the challenges or success factors for the schemes was collected including data

#### Box 1. Key Characteristics of PBRSA.

1. There is a programme of data collection agreed between the manufacturer (or the provider, in some instances) and the payer, with the objective of addressing existing uncertainties, e.g., on long term effectiveness, or cost-effectiveness.
2. The data collection is linked to post-launch coverage decisions and is directed at informing payers, providers, and clinicians as decision makers. It is not intended as post-registration licensing requirements for further evidence.
3. The price, reimbursement, and/or revenue for the treatment are linked to the outcome of this programme of data collection, either explicitly by a pre-agreed rule or implicitly through an option to renegotiate coverage, price, or revenue at a later date.
4. The data collection is intended to address uncertainty about the treatment, including, for example, its efficacy or effectiveness in real-world practice; whether health care providers' management of the patient will change the relative benefits and harms under conditions of usual care; or the size and value of cost-offsets, such as due to fewer hospital visits.
5. These arrangements provide a different distribution of risk between the payer and the manufacturer than does the historical manufacturer-payer relationship.

on their desirability/appropriateness, design, implementation, and evaluation of the outcomes obtained.

Second, since the review only identified schemes at the national level, two hypothetical case studies were developed reflecting different situations in which a PBRSA could be relevant locally: (i) an agreement related to the adoption of a new technology or service (Water Quality Management); and (ii) an agreement related to the adoption of a new model of care (Integrated Chronic Kidney Disease Programme). In each case, the opportunities for a risk-sharing agreement and the key features of such an arrangement were discussed, including the outcome(s) to be monitored, the design for data collection, the likely time horizon for the agreement, and the possible financial arrangements.

## 3. Results

### 3.1. Literature review

In total, 1256 non-duplicate records were identified from the selected bibliographic sources, and 99 potentially relevant papers were retrieved for full-text analysis, after the initial title and abstract screening. Of these, 42 records were discarded as they discussed schemes such as disease management or continuous quality improvements, where data collection and performance monitoring were not linked to payment or reimbursement of the technologies or service concerned. Another 20 studies were excluded as they did not discuss any challenges or success factors of the schemes, and a further 19 studies were excluded for not meeting one or more of the other inclusion criteria. The flowchart (PRISMA diagram) of the study selection process is shown in Figure 2. Finally, 18 records met the inclusion criteria and were included in the review. Of these, 16 were classified as discussing P4P schemes, and 2 were classified as discussing PBRSA. Details of all the records identified are given in Appendix 2.

The two papers addressing PBRSA mainly discussed the potential of these schemes to overcome the specific challenges of collecting clinical evidence in nephrology and reducing uncertainty in decision-making concerning the adoption of a specific technology or model of care [17,18]. In both studies, the authors comment that a coverage with an evidence development scheme, where coverage of a technology or service is made conditional on the collection of further clinical data, may be desirable from the perspectives of payers, manufacturers, and patients. In fact, the rationale behind proposing PBRSA in renal care resides in the fact that new treatments may have high potential, but there are both challenges and a lack of encouragement for manufacturers to conduct high-quality studies such as RCTs, particularly those assessing hard clinical endpoints [7,8]. The two papers are summarized in Box 2 below.

### 3.2. Case studies

The literature review outlined a number of the challenges in designing and conducting performance-based schemes in renal care. However, although 18 records in total were identified, only 2 of these discussed PBRSA. All the schemes identified were national schemes, mainly aimed at improving clinical practice and case management by defining a set of financial incentives linked to certain pre-specified process and outcome

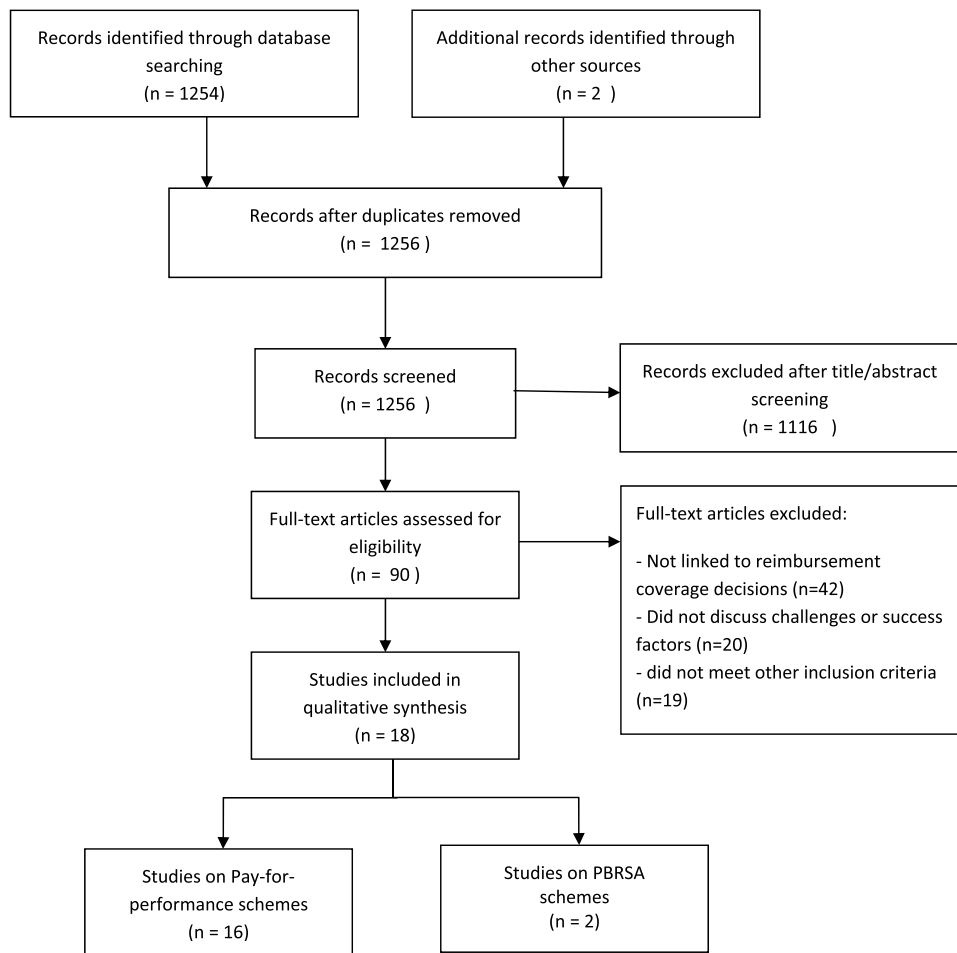


Figure 2. PRISMA Diagram.

Box 2. Structured summary of the papers discussing PBRSA.

**Mendelssohn and McFarlane, 2011 [18]**

**Scope:** to discuss the economic barriers to high-quality evidence generation on the effectiveness and cost-effectiveness of innovations in dialysis

**Main aspects discussed:** There exist economic barriers that act as disincentives to innovation and evidence generation in nephrology. In the US, the cost of dialysis is considered close to the maximum willingness to pay of public funders, so new more expensive therapies would likely be considered not cost-effective, unless they are cost-neutral or even cost-saving. In addition, due to the high budget impact of dialysis, many jurisdictions would not be able to afford an increase in the prevalent dialysis population, which may result from even modest improvements in the mortality in this population. Lastly the ESRD market is considered too small to be appealing for companies unless prices are very high. A small market also acts as a disincentive for well-conducted large randomized clinical trials (RCTs), as this would increase development costs and reduce the time between being granted public funding and patent expiration. At the same time, there are examples, such as Erythropoietin-Stimulating Agents (ESA) where funding decisions have been taken based only on limited evidence, mainly from observational studies, with a level of evidence which was then considered (*ex-post*) to be too premature.

**Role of PBRSA:** For industry, PBRSA offset some of the prohibitive costs and risks associated with developing nephrology products and might make the nephrology research and “marketplace” more inviting. And for payers and governments, it offsets some of the cost and risk of allowing early (and possibly premature) access to promising therapies and delivers the evidence they need to make fair and informed coverage decisions.

**Mendelssohn and Manns, 2011 [17]**

**Scope:** to propose a framework for Improving Evidence Generation in Nephrology through a PBRSA

**Main aspects discussed:** to date, very few RCTs are performed in nephrology. Clinical research in nephrology is challenging for different reasons: Hard-outcome research with survival as the primary outcome in this small population requires multi-center studies with high cost. Proven therapies for non-dialysis related risk factors such as for cardiovascular diseases, may have different effectiveness in dialysis patients and should be retested in this patient population. Lastly, there are only few completely validated surrogate outcomes whose use may reduce study size, complexity, duration and the overall costs of the required trials. Therefore, the difficulties and high costs of conducting RCTs in nephrology may make industry reluctant to engage in the development of new nephrology drugs and treatments.

**Role of PBRSA:** A novel framework based on conditionally funded evaluations may contribute to stimulate renal research such that evidence-based practice in nephrology is enhanced. It may also encourage potential industry partners and satisfy evidentiary need of payers. A framework is proposed through which to identify and assess eligible technologies to PBRSA, conduct clinical studies and update decisions on reimbursement and prices at the end of the scheme.

quality measures. No schemes at the local level were identified where the risk of residual uncertainties in the performance of potentially innovative technologies for renal care is shared between the manufacturer and the payer or health care provider. This may have been because such schemes do not exist in renal care, or because many of the details of schemes agreed between individual manufacturers and providers are confidential, precluding publication. Therefore, we developed two hypothetical case studies based on situations in renal care for which we were aware that schemes existed or were being planned. In selecting the cases we chose one to relate to the introduction of a new technology and service and one relating to the adoption of a new care model. The key characteristics of the two potential schemes are summarized in [Table 1](#).

### 3.3. Water quality management

This is an example of an agreement between a technology manufacturer and dialysis provider concerning the adoption of a new service at the hospital or provider level. Patients undergoing conventional dialysis three times per week are exposed to 300–600 liters of water per week. Dissolved chemical contaminants, or bacterial and/or endotoxin contamination of the dialysis water, and/or dialyzate can threaten the health, or even the life, of a hemodialysis patient [19]. The source of water used in HD consists basically of drinking water, purified by various techniques, whose composition and quality depend on the raw water's parameters. The quality of the water can change from season to season, or even from day to day. Therefore, monitoring the quality of the water used for dialysis is a vital aspect of HD treatment.

From the dialysis provider's perspective, ensuring the quality of the water can be time consuming and, if the quality falls below the acceptable level, this can be disruptive to dialysis services. Therefore, there may be value in a service that guarantees and takes legal responsibility for water quality and assumes the risk of any adverse consequences of poor water quality, for example, by a purification system that incorporates continuous monitoring of water quality, providing the provider with documentation, checking pre-treatment parameters on a daily basis (e.g. chlorine level). Since such a service would only be available at a cost, the dialysis provider would need reassurance that it was good value for money and, as long as that is uncertain, may be hesitant to contract for the service.

The PBRSA could be informed by a health technology assessment undertaken at the hospital level [20]. In order to establish the PBRSA, information would be required on the cost of water testing procedures currently in place in the dialysis center

concerned. In several jurisdictions, testing algorithms have been specified [21]. In addition, data would be required on the probability of disruption and any consequences of problems with water quality. The data on these events may be hard to obtain for a particular dialysis center, given their likely low frequency of occurrence, so estimates may have to be made based on the literature, or on the broader experience of dialysis centers in the location concerned.

In this case, the PBRSA would be between the manufacturer of the water testing system and the provider. There are a number of ways the financial aspects of the PBRSA could be constructed. One option would be a two-part tariff, the first part being a rental charge based on the cost of the water testing system that the service replaces. Then, the second part could consist of a 'bonus' for ensuring water quality during the period of the agreement. Under this approach the water service provider would receive a financial penalty if water quality was not guaranteed.

### 3.4. Integrated Chronic Kidney Disease Programme

The establishment of an Integrated Chronic Kidney Disease (ICKD) program is an example of the adoption of a new care model. As patients progress through the different stages of chronic kidney disease, their quality of life is likely to decrease [22] and the cost of their care is likely to increase [23]. This process may include more frequent hospitalizations, culminating in the need for renal replacement therapy (RRT). Therefore, any intervention that has the potential to delay progression and to reduce complications of disease may be associated with considerable benefits in terms of improved health and, depending on the exact disease and treatment profile, resource savings. The objective of establishing an ICKD program is to reduce hospitalization, delay progression, and ease the transition to RRT by providing more integrated management of care, beginning in the earlier stages of disease [24]. Specifically, an ICKD program could have any or all of the following elements: (i) disease detection and stratification of patients based on their risk of adverse events, to allocate resources efficiently; (ii) patient-centered care management, supported by a care manager to educate, coach, and coordinate; and (iii) monitoring of vital parameters and patient-reported outcomes at home to avoid complications and foster compliance with therapy. Such a program might be offered to patients when they enter CKD stage 3.

However, such a program would incur costs, including the appointment of a care manager, the resource implications of care and services prescribed under the program, educating patients, and negotiations with existing staff about new methods of

**Table 1.** Key characteristics of potential schemes.

Technology or Model of Care	Value Proposition	Parties to the PBRSA	Possible Study Design for the PBRSA	Possible Financial Arrangements
Water Testing System	Guaranteed water quality eliminates the need for regular water testing and reduces the probability of a disruption to dialysis services	Technology manufacturer and dialysis provider	Matched comparison of dialysis units with and without the testing system, or prospective study in a single unit with historical control	Annual payment plus annual bonus for maintaining water quality for the year
Integrated Chronic Kidney Disease Programme	Coordinated, holistic care improves patient quality of life, reduces the frequency of hospitalizations and delays transition to renal replacement therapy	Dialysis provider and payer	Cluster randomized trial involving several dialysis units, or prospective study in a given unit with historical control	Annual payment for care based on the cost-effectiveness of the ICKD programme

**Table 2.** Roles and Responsibilities in PBRsAs.

Role	Manufacturer	Provider	Payer	Patient
<b>Establishing value proposition</b>	X			
<b>Identifying Outcomes of interest</b>	X	X	X	X
<b>Determining study design</b>	X	X	X	
<b>Defining data collection and monitoring</b>	X	X	X	X
<b>Determining actions following the scheme</b>	X	X	X	
<b>Financing the scheme</b>	X	X	X	

working, e.g. telemonitoring. Of course, depending on the effectiveness of the new model, these costs could potentially be offset by reductions in hospitalizations, delays in the transition to RRT, and smoother transitions when a patient is in need of RRT. There is some evidence suggesting the existence of these benefits [25–27], but dialysis providers may still be uncertain that they would be realized in their setting. Moreover, providers reimbursed through fee-for-service may not be sufficiently incentivized to implement this program without a change in payment arrangements (e.g. to prevent income losses). Therefore, ICKD programs could be candidates for a PBRSA, in order to gather evidence to convince both dialysis providers, patients, and payers.

The design of the PBRSA could be based on a traditional prospective randomized controlled trial, with patients being assigned to the ICKD program or not. However, given the time and cost of conducting an RCT, it is more likely that such a PBRSA would be based on a before/after study, whereby historical data on costs and outcomes would be gathered and compared with data gathered in a prospective study after the implementation of the ICKD program. The ‘before’ cohort could be constructed using the records of patients reaching Stage 3 over the past 2–3 years and extracting data on the subsequent interventions received, hospitalizations incurred, time to RRT, and successfully adhering to that RRT. The ‘after’ cohort could be constructed by following patients enrolled in the ICKD program and collecting the same data prospectively, over the same 2–3 year period. In addition, quality of life could be measured as the patient’s health state changed. Such a study design would pose challenges, in matching, or adjusting for differences in, the two cohorts and taking account of any other changes in service provision over time that might affect the comparison.

As in the previous examples, the detailed financial aspects of the PBRSA would have to be negotiated and would depend on who is bearing any increased cost of the ICKD program. Therefore, it would be important to assess the costs and benefits from different perspectives, such as the payer, provider, and patient. This is because costs and savings might accrue to different parties. For example, the provider may incur the costs of implementing the ICKD program, but may not save costs if the hospitalizations fell on another budget. The analysis would help determine whether any financial transfers would be necessary to implement the ICKD program on an on-going basis. Specifically, if the reduction in hospitalizations benefited the payer but not the provider adopting the CKD program, it may be worthwhile for the payer increasing the level of reimbursement to the provider of the renal care to encourage that provider to implement the program. This would also be the case if the payer could be convinced of the quality of life benefits of integrated care, through both delaying RRT and in easing the transition to RRT. Therefore, in this case the PBRSA would most likely be an agreement between the provider and

the payer, with the payer providing temporary reimbursement and agreeing to increase the level of reimbursement permanently if it could be demonstrated that there were cost offsets, or improvements to the quality of care.

#### 4. Discussion

Performance-based risk-sharing agreements can work to the advantage of patients, health care providers, payers, and technology manufacturers, particularly if they facilitate the introduction of technologies or systems of care that might not otherwise have been introduced [8]. However, they require careful design and implementation [12]. No performance-based risk-sharing arrangements (PBRsAs) were found in the renal care literature and only two papers discussed the potential for such schemes. This may be because many of these arrangements are agreed at the local level between health care providers and technologies manufacturers. They may also involve confidential elements and therefore the incentives to publicize them may be low.

In order to illustrate the potential and challenges of PBRsAs, we developed two hypothetical case studies. These illustrated a number of issues that have been discussed in the literature outside renal care. First, PBRsAs can potentially involve a number of key parties, including the technology manufacturer, health care provider, and patient. In order for these arrangements to be successful, the various parties need to work together to address the following challenges: defining the value proposition for the new technology or system of care, identifying the outcome(s) of interest, determining the study design, defining the data collection and monitoring arrangements, determining the actions following the conclusion of the scheme and financing the scheme. Table 2 indicates the roles and responsibilities of the various parties.

There is no doubt that the design, conduct, and implementation of PBRsAs in renal care pose a number of challenges [10], but these have been overcome in other areas of health care [7]. Therefore, efforts should be made to overcome these challenges in renal care, so that more patients can benefit from technological advances and new models of care, while protecting the interests of payers, health care providers, technology manufacturers, and patients. This will require more discussions between the three major parties in these agreements (payers, providers, and technology manufacturers), about the potential benefits to be obtained and the incentives required to implement them.

#### 5. Expert opinion

There is a growing interest in the use of performance-based risk-sharing agreements (PBRsAs) in all fields of health care.

These agreements are particularly useful in situations where there is uncertainty about the effectiveness or cost-effectiveness of a new technology, treatment, or care plan. Under these arrangements a new treatment can be funded on the condition that further data are collected to demonstrate the effectiveness or cost-effectiveness of the treatment concerned. The potential advantage of these arrangements is that patients can obtain early access to promising new treatments or technologies, because the risk to the provider or payer of health care is minimized, by making future payment or approval of the new intervention dependent of the results obtained in practice.

However, although our review of the renal care literature found many examples of pay-for-performance schemes relating to improved performance in *existing* care, but there was little discussion of PBRsAs relating to the introduction of *new treatments or care plans*. One potential reason for this could be that, unlike the PBRsAs concerning new medicines which typically involve the manufacturer and national payer, agreements in renal care also involve the provider. Local agreements between the manufacturer and provider are unlikely to be published in the literature. However, the issues in developing and implementing these schemes can be illustrated by hypothetical case studies. For example, as in the case of Water Quality Management, the arrangement could be between the manufacturer and provider alone and be agreed at the local level. Such agreements are unlikely to be published in the literature. Alternatively, in the case of an Integrated Chronic Kidney Disease Programme, the agreement could potentially involve all three parties, or be between the provider and payer. This complicates matters if a manufacturer has to convince a provider of the advantages of a new treatment or care plan, who then has to bear any additional cost of the new intervention unless the payer can be convinced to increase the payment bundle to fund it.

This points to another possible reason why PBRsAs are less common in renal care than for medicines; the way new treatments of care plans are funded. In the case of a new medicine, if a payer, being convinced of the additional benefit, feels that a drug should be made available to patients, an additional payment can be made to include it on the national or local formulary. However, in the case of new treatments or care plans in renal care, the increase in funding would have to be through a revision of the bundled payment to the provider. These payments are not easily increased to accommodate changes in the model of care, especially if it is not clear what proportion of the benefits of the new intervention go to the provider in terms of cost-offsets, or to patients in terms of improved patient care, which the payer may consider worth paying for.

Therefore, in developing PBRsAs in renal care several complexities need to be addressed, including (i) establishing the value proposition underlying the new treatment, technology, or care plan, (ii) identifying the outcomes, in costs and effects, that will be measured, (iii) agreeing the arrangements for data collection and analysis, (iv) financing the study, and (v) determining the roles and responsibilities of the various parties to the agreement.

Despite the challenges, the potential benefits from establishing PBRsAs in renal care are considerable. Therefore, health care partners, providers, and payers with an interest in these schemes should benefit from the findings of this research,

with the hope that a number of such arrangements will be developed in the future. The major beneficiaries of such a collaboration will be patients, who would benefit from access to new technologies, treatments, and services.

Looking to the future, it might be possible to change the focus of some of the existing pay-for-performance schemes to encourage the adoption of new treatments of care plans if these have the potential to improve the quality of care. Some of the schemes could be designed as PBRsAs, where the bundled payment is increased on the condition that data are collected to establish whether health outcomes are improved, or cost offsets are generated. These data could then be used to determine the revised payment level at the end of the scheme. This would bring renal care more into alignment with other fields of health care, where ways are being found to make promising new treatment available, while sharing the financial risk between payers, providers, and manufacturers.

## Notes

1. <https://www.govinfo.gov/content/pkg/FR-2016-11-04/pdf/2016-26152.pdf> and <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2020-Final-Rule-NPC-v10.pdf>; <https://innovation.cms.gov/initiatives/comprehensive-esrd-care/>
2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5647921/pdf/bjgpnov-2017-67-664-e775.pdf>
3. <https://www.nice.org.uk/standards-and-indicators/qofindicators>
4. <https://www.england.nhs.uk/wp-content/uploads/2018/07/quality-outcome-framework-report-of-the-review.pdf>
5. <https://www.govinfo.gov/content/pkg/FR-2016-11-04/pdf/2016-26152.pdf> and <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2020-Final-Rule-NPC-v10.pdf>; <https://innovation.cms.gov/initiatives/comprehensive-esrd-care/>
6. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5647921/pdf/bjgpnov-2017-67-664-e775.pdf>
7. <https://www.nice.org.uk/standards-and-indicators/qofindicators>
8. <https://www.england.nhs.uk/wp-content/uploads/2018/07/quality-outcome-framework-report-of-the-review.pdf>

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Peer reviewers on this manuscript have no relevant financial relationships or otherwise to disclose.

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## Declaration of interest

Ellen Busink, Christian Apel, and Dana Kendzia are employees of Fresenius Medical Care. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

## ORCID

Michael Drummond  <http://orcid.org/0000-0002-6968-4610>  
Werner Brouwer  <http://orcid.org/0000-0002-0476-8397>



## References

Papers of special note have been highlighted as either of interest (\*) or of considerable interest (\*\*) to readers.

1. Gupta N, Wish JB. Do current quality measures truly reflect the quality of dialysis? *Semin Dial.* **2018**;31(4):406–414.
2. Weiner D, Watnick S. The ESRD quality incentive program—can we bridge the Chasm? *J Am Soc Nephrol.* **2017**(28): 1697–1706.
3. Desai AA, Garber AM, Chertow GM. Rise of pay for performance: implications for care of people with Chronic Kidney Disease. *Clin J Am Soc Nephrol.* **2007**;2(5):1087–1095.
4. CMS.Org - Laws & Regulations [Internet]. [cited 2020 Dec 30]. Available from: [https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/05\\_LawsandRegs](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/05_LawsandRegs)
5. Pham HH, Cohen M, Conway PH. The Pioneer Accountable Care Organization Model: improving Quality and Lowering Costs. *JAMA.* **2014**;312(16):1635.
6. Executive Order on Advancing American Kidney Health [Internet]. **2019**. Available from: <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/> (Accessed 05 February 2020).
7. Dabbous M, Chachoua L, Caban A, et al. Managed Entry Agreements: policy Analysis From the European Perspective. *Value Health.* **2020**;23(4):425–433. .
8. Garrison LP, Towse A, Briggs A, et al., Performance-Based Risk-Sharing Arrangements—Good Practices for Design, Implementation, and Evaluation: report of the ISPOR Good Practices for Performance-Based Risk-Sharing Arrangements Task Force. *Value Health.* **16**(5): 703–719. **2013**..
- **The seminal paper on issues with the development and implementation of PBRsAs in health care.**
9. NHS England Cancer Drugs Fund Team. Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund) - A new deal for patients, taxpayers and industry [Internet]. NHS England; **2016**. Available from: <https://www.england.nhs.uk/wp-content/uploads/2013/04/cdf-sop.pdf>(Accessed 05 February 2020).
10. Reckers-Droog V, Federici C, Brouwer W, et al. Challenges with coverage with evidence development schemes for medical devices: A systematic review. *Health Policy Technol.* **2020**;9(2):146–156. S2211883720300137. .
- **The most recent review of the challenges of implementing these schemes.**
11. Stafinski T, McCabe CJ, Menon D. Funding the Unfundable: mechanisms for Managing Uncertainty in Decisions on the Introduction of New and Innovative Technologies into Healthcare Systems. *PharmacoEconomics.* **2010**;28(2):113–142.
12. Drummond M. When do performance-based risk-sharing arrangements make sense? *Eur J Health Econ.* **2015**;16(6):569–571.
13. Tricco AC, Lillie E, Zarin W, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): checklist and Explanation. *Ann Inter Med.* **2018**;169(7):467. .
14. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *BMJ.* **2009**;339(jul21 1):b2535–b2535. .
15. Mannion R, Davies HTO. Payment for performance in health care. *BMJ.* **2008**;336(7639):306–308.
16. Hahn jim. Pay-for-Performance in Health Care. Washington DC. Congressional Research Service (CRS); **2006**.
17. Mendelssohn DC, Manns BJ. A Proposal for Improving Evidence Generation in Nephrology. *Am J Kidney Dis.* **2011**;58(1):13–18. .
- **One of only two discussions of PBRsAs in renal care found in the literature.**
18. Mendelssohn DC, McFarlane P. Conditionally Funded Field Evaluations-A Solution to the Economic Barriers Limiting Evidence Generation in Dialysis?: FIELD EVALUATIONS IN DIALYSIS. *Semin Dial.* **2011**;24(5):556–559. .
- **One of only two discussions of PBRsAs in renal care found in the literature.**
19. Boccato C, Evans DW, Lucena R, et al. Water and dialysis fluids. a quality management guide; **2015**.
20. AdoptHTA. The AdHopHTA handbook: a handbook of hospital-based health technology assessment [Internet]. **2015**. Available from: [www.adhophta.eu](http://www.adhophta.eu).(Accessed 05 February 2020).
21. British Columbia Provincial Renal Agency (BCPRA) Hemodialysis Committee. In: *Dialysate Water System Microbiology & Endotoxin Sampling*. Vancouver: British Columbia Provincial Renal Agency (BCPRA); **2016**.Pages 1-8
22. Nguyen NTQ, Cockwell P, Maxwell AP, et al. Chronic kidney disease, health-related quality of life and their associated economic burden among a nationally representative sample of community dwelling adults in England. In: Bolognino D, editor. *PLOS ONE*. Vol. 13. **2018**. doi.org/10.1371/journal.pone.0207960.
23. ReNe (Renal Lombardy Network), Additional contributors from ReNe Network, Roggeri A, Roggeri DP, Zocchetti C, et al. Healthcare costs of the progression of chronic kidney disease and different dialysis techniques estimated through administrative database analysis. *J Nephrol.* **2017**;30(2):263–269.
24. Kalantar-Zadeh K, Kovesdy CP, Streja E, et al. Transition of care from pre-dialysis prelude to renal replacement therapy: the blueprints of emerging research in advanced chronic kidney disease. *Nephrol Dial Transplant.* **2017**;32(suppl\_2):ii91–ii98. .
25. Fishbane S, Agoritsas S, Bellucci A, et al. Augmented Nurse Care Management in CKD Stages 4 to 5: A Randomized Trial. *Am J Kidney Dis.* **2017**;70(4):498–505. .
26. Hopkins RB, Garg AX, Levin A, et al. Cost-Effectiveness Analysis of a Randomized Trial Comparing Care Models for Chronic Kidney Disease. *Clin J Am Soc Nephrol.* **2011**;6(6):1248–1257. .
27. Chen PM, Lai TS, Chen PY, et al. Multidisciplinary Care Program for Advanced Chronic Kidney Disease: reduces Renal Replacement and Medical Costs. *Am J Med.* **2015**;128(1):68–76. .

## Appendix 1 Search terms

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- #12 (#7 OR #11) AND #8 *DocType = All document types; Language = All languages;*
- #11 #10 OR #9 *DocType = All document types; Language = All languages;*
- #10 TS = (quality NEAR/1 (compensation OR incentive) OR (quality NEAR/1 outcome NEAR/1 framework) OR (continuous NEAR/1 quality NEAR/1 improvement)) *DocType = All document types; Language = All languages;*
- #9 TS = ((Disease NEAR/1 management) OR (integrated NEAR/1 care)) *DocType = All document types; Language = All languages;*
- #8 TS = (dialysis OR h\*emodialysis OR (renal AND care) OR (kidney AND failure) OR CKD OR (chronic NEAR/1 kidney) OR (renal NEAR/1 disease)) *DocType = All document types; Language = All languages;*
- #7 #6 OR #5 OR #4 OR #3 OR #2 OR #1 *DocType = All document types; Language = All languages;*
- #6 TS = (pay\* NEAR/1 (model OR system)) *DocType = All document types; Language = All languages;*
- #5 TS = (pay\* NEAR/2 Performance OR P4P) *DocType = All document types; Language = All languages;*
- #4 TS = ((performance OR outcome\* OR value) NEAR/2 (based) NEAR/2 (contract\* OR partnership\* OR agreement\* OR arrangement\*)) *DocType = All document types; Language = All languages;*
- #3 TS = (adaptive NEAR/1 (licensing OR reimbursement OR pathway\*)) *DocType = All document types; Language = All languages;*
- #2 TS = (payment NEAR/1 result\* OR (risk OR cost\*) NEAR/2 sharing AND (agreement\* OR deal\* OR scheme\* OR contract\* OR arrangement\*)) OR (performance NEAR/1 based NEAR/1 risk NEAR/1 sharing NEAR/1 (agreement\* OR deal\* OR scheme\* OR contract\* OR arrangement\*)) OR managed NEAR/1 agreement\* OR (money NEAR/1 back NEAR/1 guarant\*) *DocType = All document types; Language = All languages;*
- #1 TS = ((Coverage NEAR/1 evidence AND development) OR ((only OR accept) NEAR/1 research) OR (conditional NEAR/1 treatment NEAR/1 continuation) OR (conditional NEAR/1 coverage) OR (outcome\* NEAR/1 guarantee\*) OR (outcome\* NEAR/1 based NEAR/2 (contracting OR agreement\* OR arrangement\* OR contract\*)) OR (payment NEAR/1 result\*) OR access NEAR/1 evidence) *DocType = All document types; Language = All languages;*
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## Appendix 2 Details of the Performance-Based Schemes Identified in the Review

In the review, four countries were identified where P4P schemes have been implemented in renal care, namely the US, the UK, Australia (state of Queensland) and Taiwan. In the US, the ESRD Quality Incentive Program (QIP) was introduced in 2011 by the Medicare Improvements for Patients and Providers Act (MIPPA) together with a bundled prospective payment system for renal dialysis services provided to Medicare beneficiaries. Within the QIP, dialysis facilities that do not meet certain standards in a particular year are subject to a global Medicare payment reduction of up to 2% in the 'payment year,' which is 2 years after the year of assessment [9]. The Centers for Medicare and Medicaid Services (CMS) constantly update and expand the quality metrics used to assess providers through an established process. For example, for the payment year 2020, quality measures encompassed both effectiveness and safety measures, including measures such as standardized readmission and transfusion ratios, dialysis adequacy, hypercalcemia, and vascular access measures, and reporting measures to incentivize facilities to report dialysis-event data. There are 36 ESRD Seamless care Organizations (ESCOs) in the US participating in the Comprehensive ESRD Care Model, which is designed to identify, test, and evaluate new ways to improve care for Medicare beneficiaries with end-stage renal disease.<sup>1</sup>

In the UK, the Quality and Outcomes Framework (QOF) was introduced in 2004 as part of the General Medical Services Contract for primary care providers (PCPs). The QOF is a voluntary reward and incentive program rewarding GP practices for delivering interventions and achieving patient outcomes using evidence-based indicators developed by the National Institute for Health and Care Excellence (NICE)<sup>2</sup>. QOF indicators also include four qualities and reporting measures for patients with chronic kidney disease (CKD), including incentives to establish the development of a register of patients with CKD (categories G3aA1 to G5A3 – previously stage 3–5); promote improved BP control, and treatment with renin-angiotensin system antagonists where appropriate [10]<sup>3</sup>. Recently, the QOF has undergone a review process with the ultimate aims of determining future priorities of the scheme, and developing proposals for reform that may help to address these priorities<sup>4</sup>. Future changes in the scheme have been announced including a revision of existing indicators.

In the Australian state of Queensland, the Clinical Practice Improvement Payment Project (CPIP) was a P4P program introduced by the health authority in 2008 and terminated in 2013 after the project underwent an external review. The program awarded clinical units that achieve pre-specified process and outcome targets including vascular access management with functional arteriovenous fistula, arteriovenous graft, or Tenckhoff catheter, and patients screening and treatment for dialysis or transplant-related infections. Notably, payments to individual renal units were to be used for investments in quality improvement, education, training, and research.

Finally, in Taiwan, a nationwide pre-ESRD P4P care program was launched in 2006 to provide more comprehensive care to patients with advanced CKD through a multidisciplinary integrated care model [11]. Under the pre-ESRD P4P scheme, health care providers receive additional bonus payments for attaining a set of pre-specified process and outcome indicators related to patient enrollment, comprehensive patient education, annual evaluation, and four types of case management (CKD patients at stage 3b-4, CKD

patients at stage 5, patients with proteinuria, and continuous case management for all CKD patients and those with proteinuria). Process indicators include the provision of physician care, nursing care, dietician services, and data management at patient enrollment, the provision of comprehensive education and dietician services at each follow-up visit, and the provision of annual physical examinations. In addition, providers are encouraged to achieve minimal levels of quality indicator targets (e.g. blood pressure < 130/80 mmHg, total cholesterol/triglyceride < 200 mg/dL, serum albumin > 3.5 g/dL, HbA1c < 7.5%, and hematocrit > 28%). Outcome indicators, depending upon the health status of an enrolled patient with CKD, include reductions in the estimated values of glomerular filtration rate (eGFR), time to initiating dialysis or receiving kidney transplantation, use of erythropoietin, peritoneal dialysis, and outpatient dialysis, creation of vascular access before dialysis, and achievement of complete remission of proteinuria (UPCR < 200 mg/g) [12].

Since the aim of the described schemes is to improve clinical practice by financially rewarding good performers (or by penalizing bad performers), a general concern reported in the identified studies was about whether the schemes would be able to achieve their objectives without resulting in distortions in care, or unintended negative consequences. For example, in the US QIP, a recurrent challenge referred to the possibility that, in the absence of an adequate case-mix adjustment mechanism, providers would game the scheme by 'cherry-picking' healthier patients for whom the expected financial gains would be maximized. In addition, the appropriateness of the quality measures used to determine payment was another recurrent topic. Particularly, measures were required i) to be underpinned by solid clinical evidence; ii) to be correlated with final health outcomes and to reflect patient preferences (e.g. survival, but also patients' comfort, satisfaction with care, and quality-of-life); iii) to be actionable by or directly attributable to the recipients of the financial incentives; iv) to be independent from other processes and not leading to unintended consequences; and v) to be easily measurable with the available data sources and data infrastructure.

Further aspects concerning the design of the schemes related to the appropriate size of the incentives or penalties that would be required to prompt a change in clinical practice; the choice of the target recipient of the incentives, for example, the individual providers or facility/organization level; or the need for alignment of the incentives across the different specialties involved in the process of care beyond nephrologist and dialysis facilities (e.g., endocrinologists, cardiologists, vascular surgeons, and participating caregivers including nurses, dieticians, social workers, and pharmacists) [13].

For example, in ESRD care, clinical investigations are often hampered by the relatively low number of patients treated in individual dialysis units, resulting in the need for high-cost multicenter studies to provide evidence on final clinical outcomes, such as survival [8]. In addition, the lack of validated surrogate outcomes predicting survival limits the possibility to decrease study size, complexity, duration, and therefore the high cost of the required clinical studies. Lastly, ESRD patients are exposed to both traditional risk factors (e.g. cardiovascular risk) and non-traditional uremia or dialysis-related risk factors, so that single interventions that work very well in non-dialysis patients may not be effective in dialysis patients. This in turn requires that interventions that have been proven to be successful in the general population should generally be retested in dialysis patients.

The 18 studies are summarized in Table A2.1 below.

Table A2 .1. Details of the schemes identified

Study (year)	Target condition	Programme name	Country	Type of scheme	Issues with appropriateness/desirability, design, implementation and evaluation of the schemes
Gupta and Wish (2018) [1]	ESRD	ESRD QIP	US	Pay for Performance	<p><b>Appropriateness/desirability of the scheme:</b> Inappropriately vetted or case-mix adjusted quality measures may lead to cherry picking and providers trying to “game” the scheme.</p> <p><b>Design of the scheme:</b> Quality measures may be inadequate because: 1) there is a lack of evidence of their correlation with final health outcomes; 2) they do not reflect what patients care the most; 3) they are not actionable by or directly attributable to providers; 4) are not appropriately case-mix adjusted to avoid cherry picking</p> <p><b>Evaluation of the scheme:</b> A number of confounders make attribution of effect of schemes challenging, including other programmes and plans affecting the quality measures used.</p>
Haarsager et al. (2018) [2]	ESRD	Queensland's Clinical Practice Improvement Payment Project (CPIP)	Australia	Pay for Performance	<p><b>Design of the scheme:</b> 1) The period of accountability for each patient eligible to the scheme must be defined. This requires a pre-defined starting point (e.g. a prognosis of less than one year) and an ending point (the death of the patients, or his/her withdrawal from the scheme), and can be defined both prospectively or retrospectively; 2) Serious illness care (including ESRD care) may be oriented toward increasing patients' comfort, satisfaction with care, quality-of-life, and quality of death, rather than solely on prolonging life. This orientation often requires novel data, including patient registries and surveys of patients and caregivers; 3) Measures should be chosen based on their reliability, validity, clinical relevance, and feasibility to collect; 4) different mechanisms to link spending and quality indicators exist: unconditional, conditional, quality hurdle and cost hurdle models are mentioned.</p> <p><b>Design of the scheme:</b> Success factors that explain positive impact of the scheme may be: the requirement for physician to adhere to international guidelines (K-DOQI), with links to quality incentives; the multidisciplinary of the team in the program (physicians, nutritionists, nurses, case managers and pharmacists) that guarantee immediate integrated care services; frequent nephrology visits for the patients enrolled.</p>
Ryan and Rodgers (2018) [3]	ESRD	Comprehensive ESRD Care Model	US	Pay for Performance	<p><b>Design of the scheme:</b> Critical features remain in creating quality measures that are patient-centered and reflect health-related quality of life, end of life and advance care planning, and patient engagement in their medical care. Many of the measures included in the QIP are not supported by enough evidence. The QIP is devoid of patient-centered measures (although with some late improvements). Improved survey incorporating patient preferences and patient-relevant symptoms may provide more patient-centered information.</p>
Hsieh et al. (2017) [4]	CKD stage 3-5	Taiwan pre-ESRD P4P program	Taiwan	Pay for Performance	<p><b>Design of the scheme:</b> Practices are free to choose which metrics to be evaluated on. Only a few of the metrics available are specific to nephrology. Therefore, poorly performing nephrologist may not be noticed as the practice scores are built using quality metrics from better performing specialties; a good balance between quality and costs is needed to avoid patients undertreatment (if costs control prevails) or exorbitant bills (if quality metrics prevail).</p> <p><b>Evaluation of the scheme:</b> Metrics are risk adjusted, however, statistical models cannot completely eliminate normal fluctuations in costs and quality. Providers with small populations could be penalized even if they are high-performer, due to few outliers (CMS exempt providers with low patient or payment volume, but medium size providers may be affected). Many providers may consolidate to mitigate risk exposure, and in large and medium population areas, small private practice nephrology might become financially untenable.</p>
Weiner and Watnik (2017) [5]	ESRD	ESRD QIP	US	Pay for Performance	<p><b>Design of the scheme:</b> ESRD QIP rewards absolute performance rather than relative improvement. Thus, facilities in deprived neighborhood may receive a low performance score even if they had the greatest improvement compared to the previous year.</p> <p><b>Evaluation of the scheme:</b> other clinical and regulatory forces make difficult to estimate the effects of the programme (e.g. change in clinical guidelines).</p>
Lin et al. (2017) [6]	CKD (not specified)	P4P programme introduced by the Medicare Access and Children's Health Insurance Program Reauthorization Act (MACRA)	US	Pay for Performance	<p><b>Design of the scheme:</b> ESRD QIP rewards absolute performance rather than relative improvement. Thus, facilities in deprived neighborhood may receive a low performance score even if they had the greatest improvement compared to the previous year.</p> <p><b>Evaluation of the scheme:</b> other clinical and regulatory forces make difficult to estimate the effects of the programme (e.g. change in clinical guidelines).</p>
Saunders et al. (2017) [7]	ESRD	ESRD QIP	US	Pay for Performance	<p><b>Design of the scheme:</b> ESRD QIP rewards absolute performance rather than relative improvement. Thus, facilities in deprived neighborhood may receive a low performance score even if they had the greatest improvement compared to the previous year.</p> <p><b>Evaluation of the scheme:</b> other clinical and regulatory forces make difficult to estimate the effects of the programme (e.g. change in clinical guidelines).</p>

(Continued)

Table A2 .1. (Continued).

Study (year)	Target condition	Programme name	Country	Type of scheme	Issues with appropriateness/desirability, design, implementation and evaluation of the schemes
Diamond and Howard (2016) [8]	ESRD	ESRD QIP	US	Pay for Performance	<p>The majority of metrics in current use in the QIP are not evidence based. Four characteristics for quality metrics are required: 1) the care process results in improved outcomes, 2) the measure captures provision of these processes, 3) the measure is independent from other processes and 4) the measure will not lead to unintended consequences. None of the actual measures of the QIP meet these criteria.</p> <p><b>Evaluation of the scheme:</b> dialysis facilities load the data that are used for quality measures manually into the data platform (CROWNWeb), favouring data entering errors; congestion of CROWNWeb has been another issue, given the amount of data entered daily; there is high frequency of missing data and the pattern of different organizations, and end-users interpreting business rules differently (e.g. starting and ending point of a measure), resulting in inconsistent and frequently inaccurate data; there is a lack of reports for users to run and use CROWNWeb; Administrative claims data is a second source for quality measures, however, since they go through in depth audit and adjudication phases, there is generally a delay in getting a full data set for purposes of calculating measures of dialysis facility performance, making this data source challenging to use for rapid cycle quality improvement; another source of data is the CDC-NHSN on infections and infections-related events. Again, variability of input is an issue, especially due to the high dialysis facility staff turnover rates leading to significant variability in data entry.</p>
Kliger (2016) [9]	ESRD	ESRD QIP	US	Pay for Performance	<p>The current measures included in nephrology Clinical Performance Measures (CPMs) identifies several desired intermediate outcome and process measures, but some challenges are outlined: measures could be unreliable because of poor correlation with truly important clinical outcomes; measures of the patient experience and quality of life are still missing. In fact, although the In-Center Hemodialysis (ICH) Consumer Assessment of Healthcare Providers and Systems (CAHPS) has been included among performance indicators, they have only measured use of the ICH CAPHS tool, and not actual patient responses; lastly individual patients may have different preferences and goals for therapy which may not be aligned to the population-based clinical process and outcome improvements underlying actual CPMs (e.g. patients who come to dialysis as part of a palliative care plan have different goals than patients seeking life-prolonging treatment).</p>
Moss and Davison (2015) [10]	ESRD	ESRD QIP	US	Pay for Performance	<p>QIP measures have been criticized, because they are largely disease oriented and use easy-to-obtain laboratory-based indicators, such as Kt/V and hemoglobin, that do not reflect outcomes that are most important to patients and have had a minimal effect on survival or quality of life. Whereas none of the actual or proposed measures assess patient-reported quality of life; among the measures included in the CMS National Quality Strategy, three measures—patient experience and engagement, clinical care, and care coordination—are particularly relevant to quality care in the ESRD Program. However, in the 2014 ESRD QIP, none of the 6 measures included provide data from a patient-centered perspective.</p>
Saunders and Chin (2013) [11]	ESRD	ESRD QIP	US	Pay for Performance	<p>P4P might be ineffective in improving quality of care or, worse, have unintended negative consequences.</p> <p><b>Design of the scheme:</b> The money at risk could be not sufficient to encourage dialysis facilities to improve quality; P4P could also increase ethnic and socioeconomic disparities because of patients self-selection and “cherry picking” from dialysis facilities</p> <p><b>Evaluation of the scheme:</b> It is not clear whether the reported improvement in anemia overtreatment (reduced % of patients on ESAs with Hgb &gt;12 g/dL) was mainly a consequence of the concomitant incentives of P4P, anticipation of bundled payment for ESAs, and mounting clinical evidence of the potential harms of ESAs; the likelihood of a facility receiving any payment reduction increased as proportion of African Americans in the neighborhood increased, even after controlling for neighborhood poverty.</p>

(Continued)

Table A2 .1. (Continued).

Study (year)	Target condition	Programme name	Country	Type of scheme	Issues with appropriateness/desirability, design, implementation and evaluation of the schemes
Karunaratne et al. (2013) [12]	CKD stage 3-5	Quality and Outcomes Framework (QOF)	UK	Pay for Performance	<b>Design of the scheme:</b> Linking blood pressure targets (BP) to payments in the QOF may distort the recording of BP and lead to an over-representation of BP just below target when compared with just above target.
Fishbane et al. (2012) [13]	ESRD	ESRD QIP	US	Pay for Performance	<b>Design of the scheme:</b> Measures should address a process for which there is evidence showing a link with improved clinical outcomes; measures should capture whether evidence-based care has been delivered; they should measure a process as close as possible to the outcomes of interest and should have minimal or unintended consequences. All three quality measures used for QIP in 2013 (patients with High >12 g/dl; patients with urea reduction ratio - URR of $\geq 65\%$ and type of Vascular Access) violate at least one of these principles. Also, for URR, levels of achievement are already very high so that the measure can't really differentiate between providers nor incentivize performance.
Mendelshon and McFarlane (2011) [14]	ESRD	NA	US	Coverage with evidence development (CED)	<b>Appropriateness/desirability of the scheme:</b> CED may be desirable from the perspectives of payers, manufacturers and patients; because in renal care new drugs and technologies have often high potential, but there are challenges and lack of incentives for manufacturers in conducting clinical evaluation studies. For industry, CED offsets some of the prohibitive costs and risks associated with developing nephrology products and might make the nephrology research and "marketplace" more inviting. And for payers and governments, it offsets some of the cost and risk of allowing early (and possibly premature) access to promising therapies, and delivers the evidence they need to make fair and informed coverage decisions.
Mendelsohn and Manns (2011) [15]	NA	NA	NA	Coverage with evidence development	<b>Appropriateness/ desirability of the scheme:</b> Clinical research in nephrology is challenging for several reasons: 1) given the low prevalence of ESRD patients, hard- outcome research with survival as the primary outcome in this small population requires multicenter studies with high cost; since cardiovascular mortality is the major cause of deaths in ESRD patients, much attention has been focused in identifying and modifying risk factors for cardiovascular diseases; 3) Therapies that works well in non-dialysis patients have not been effective in dialysis patients, hence, interventions tested in the general population should be re-tested in dialysis patients; 4) there are no completely validated surrogate outcomes that can substitute for survival outcomes in ESRD to decrease study size, complexity, duration, and the high cost of the required trials.
Parker (2011) [16]	ESRD	ESRD QIP	US	Pay for Performance	<b>Design of the scheme:</b> nephrology has many very rich observational databases, which can be used for hypothesis generation and guidance on care processes. <b>Implementation of the scheme:</b> nephrologists and/or patients might opt in for a CED scheme, but then not really promote the trials <b>Appropriateness/desirability of the scheme:</b> In poorly designed pay-for-performance schemes in ESRD in which case mix adjustments are not adequate, rational self-interest could lead nephrologists toward cherry picking dialysis patients. This carries more consequences and distortions on the distribution of rewards across physicians.

(Continued)



Table A2 .1. (Continued).

Study (year)	Target condition	Programme name	Country	Type of scheme	Issues with appropriateness/desirability, design, implementation and evaluation of the schemes
Himmelfarb and Kliger (2007) [17]	ESRD	General discussion (previous to ESRD QIP)	US	Pay for Performance	<p><b>Appropriateness/desirability of the scheme:</b> Evidence that payment-for-performance strategies improve health care outcomes is sparse following elements: 1) robust epidemiological data; 2) robust data collection vehicles; 3) available evidence-based clinical practice guidelines (CPGs) to develop payment incentives; 4) a culture of payment for quality in dialysis facilities. In the US, epidemiological data is provided by the Dialysis Outcomes Practice Pattern Study and large dialysis organizations. Data collection is allowed through the Standardized Information Management System (a national information infrastructure that electronically links all 18 ESRD Networks with the CMS). Evidence based CPGs are provided by the National Kidney Foundation guidelines. Finally culture of payment for quality already exists in dialysis facilities linking payments of medical directors to outcomes measures. However, critical aspects are outlined: evidence used in the CPGs comes mainly from epidemiological studies rather than RCTs so that there is a risk for biased results. There is no evidence on what is the best P4P design (e.g. same small set of quality measures or rotating measures?) and whether P4P schemes ultimately improve health outcomes</p> <p><b>Implementation of the scheme:</b> Individual nephrologists often take care of &lt;60 patients and this challenges the capability to reliably assess individual performances (the same applies to small dialysis centres). Cherry picking is another challenge with small numbers that need to be addressed. This is generally guarded against by case-mix adjusting, but Medicare's current approach to case-mix adjustment is clearly inadequate. In addition frequent and timely feedback on performance to physicians and providers are required, but the CMS to date has not been able to digest and report information in a sufficiently timely fashion. Computer systems required for data collection are often unavailable in individual physician offices or group practices. A reduction in payment for economically marginal facilities that are not meeting quality targets might lead to unit closure in already underserved communities, thereby leaving patients with less overall access to dialysis care.</p> <p><b>Evaluation of the scheme:</b> In the dialysis population, despite the identification of a number of laboratory, demographic, and morbidity-associated data predictors of patient outcomes, unknown and unmeasured variables account for the bulk of patient outcomes. Facility-specific data also suggest that incomplete case-mix adjustment may account for much of the observed difference in facility-specific outcomes.</p>
Desai et al. (2007) [18]	ESRD	Not specified	US	Pay for Performance	<p><b>Appropriateness/desirability of the scheme:</b> Incentives systems need to be perceived as fair: paying too much for some patients, paying too little for others, or penalizing providers for the poor care of others—may result in “cherry picking” behaviour by providers and facilities.</p> <p><b>Design of the scheme:</b> Schemes need to incentivize adoption and use of data-infrastructures linking renal care facilities to the ESRD network and CMS; Financial incentives need to be appropriately sized to prompt change in clinical practice; also choosing the target recipient of the incentive, i.e. whether individual providers or facility/organization level is important to stimulate structural changes in the care delivery process and align incentives for all providers involved (dialysis facilities, nephrologists, and other practitioners); incentives may be designed in order to promote an integrated process of care from early stages of CKD to ESRD and dialysis: P4P programs that target nephrologists or dialysis facilities and ignore other physicians (e.g., endocrinologists, cardiologists, vascular surgeons) and participating caregivers including nurses, dieticians, social workers, and pharmacists may fail to align incentives adequately across the spectrum of care.</p> <p><b>Evaluation of the scheme:</b> Clinical relevance of quality targets is important. For example, facility-level mortality continues to vary significantly despite improvements in dialysis adequacy and anaemia process measures; Accountability of the identified measures is also an issue: for example, many areas of ESRD care are multidisciplinary in nature and therefore, it is difficult to assign accountability (e.g., failed vascular access).</p>

