

## **Title page**

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## Abstract

Effective policymaking under uncertainty is required for optimal resource allocation in health systems. Over the past 30 years, health technology assessment (HTA), the field for evidence-informed decisions in health, has become increasingly multi-disciplinary. The scope has expanded from medicine reimbursement to informing organisation of health services, evaluation of health promotion programmes, and cross-jurisdictional market shaping. Yet conceptualisations of uncertainty within HTA have not kept pace with this expanded scope.

This thesis develops a multi-disciplinary framework for policymaking under uncertainty, based on an interdisciplinary review, to highlight when standard HTA practice may not be fit-for-purpose and alternative approaches to use. This framework was applied for the 2024 review of the kidney replacement therapy policy in Thailand, comparing the new approaches in the framework to standard HTA practice, and revised based on implementation findings.

Findings suggest that a multi-disciplinary approach does improve policymaking, by broadening and making more systematic projections of policy impact, with low additional resource requirements compared to standard HTA practice. However, implementing approaches with a different philosophical basis to HTA requires time to build capacity and to align new approaches with accepted standards in HTA.

The transition from established practice will likely require an incremental approach, alongside methods to evaluate changes in policymaking practice that are both rigorous and feasible to implement within policy constraints. The thesis explores how approaches from other disciplines, such as system dynamics and futures research, alongside frameworks from implementation science may support this transition. Further work is required to determine policy needs, to define standards in HTA for multi-disciplinary approaches, and to strengthen capacity for a multi-disciplinary approach to policymaking under uncertainty.

## Acronyms

**AIMD:** aims, ingredients, mechanism, delivery framework

**CCC:** comprehensive conservative care

**CFIR:** consolidated framework for implementation research

**CLD:** causal loop diagram

**CQI:** continuous quality improvement

**FTE:** full-time equivalent

**HD:** haemodialysis

**HTA:** health technology assessment

**KPI:** key performance indicator

**KRT:** kidney replacement therapy

**LMIC:** low-income and middle-income countries

**NHSO:** National Health Security Office

**NLEM:** national list of essential medicines

**PD:** peritoneal dialysis

**QA:** quality assurance

**SD:** system dynamics

**THB:** Thai Baht (currency)

**UCBP:** universal coverage benefits programme

**UCS:** universal coverage scheme (the biggest public health insurance scheme in Thailand)

**UHC:** universal health coverage



# Chapter 1 Introduction

## OVERVIEW

All healthcare policies are made under some level of uncertainty. This may relate to disagreement between stakeholders around what the problem is, incomplete or poor-quality data, differences between how a policy is modelled and how it is implemented, or unknowns in terms of future healthcare workforce, technologies, or doctor-patient relationships that may influence policy impact, to name but a few. Currently in healthcare policy, uncertainty is conceptualised as a property of the data, with methods to determine and reduce it. Throughout the course of this chapter, we argue that we are at a turning point requiring a broader view of uncertainty. The mandate of policy bodies for evidence-informed healthcare policy is expanding: agencies that used to address medicine reimbursement decisions are now evaluating health promotion policies to change behaviour and addressing problems related to health system organisation. The type of evidence used for policymaking is similarly diversifying: systematic reviews and economic analyses are increasingly being supplemented by qualitative evidence, ethical analyses, and patient testimonies. There is also increasing formal and informal cooperation across jurisdictions to conduct joint assessments or to adapt assessments to inform policies in settings with different health system organisation, high-level institutions, and socio-cultural context. We illustrate the relevance of a broader view of policymaking under uncertainty for healthcare policy, we contrast it with the narrow view currently taken, and we set out a research agenda for this work.

## BACKGROUND

Universal health coverage (UHC) represents one of the targets of the 2030 Sustainable Development Goals, in which all countries commit to ensuring equitable access to quality health services for the full population [1]. To achieve UHC, governments must optimise the efficiency, equitability, and quality of health programmes according to available resources [2]. Health technology assessment (HTA) is often used as a tool to inform UHC policymaking, by using explicit and multidisciplinary methods to determine the value of a technology, whereby a technology may refer to any intervention, from medicines and diagnostics to health promotion programmes, surgical procedures and systems to organise healthcare delivery [3]. As such, HTA can be considered as a form of policy analysis, defined as a means by which to assess the outcomes of alternative policies [4].

Uncertainty is inherent in any policy analysis, but it has no shared definition either across or within disciplines [5–7]. Uncertainty may be characterised as natural randomness, variability, or imperfect knowledge of a system; different stakeholder problem frames and values; norms around use of evidence for policy; conflicting objectives from higher level institutions; system boundaries that constrain the view of impact; or hidden agendas and inequitable power dynamics that shape problem frames and the solution space, among others [8–13].

Within HTA, policymaking may be conceptualised according to the 3-D framework: data, dialogue, and decision [14]. Data comprises the evidence used for policymaking, influenced by the criteria for decision-making and accepted standards for rigorous, high-quality evidence; dialogue covers the use of evidence to come to a recommendation through a deliberative process representing different stakeholder views; and decision encompasses the institutions for decision-making and governance overseeing how decisions are made and implemented [14]. Across this framework, there is not only uncertainty in the data and its quality, but also in terms of how the evidence will be interpreted, the explicit and implicit decision rules applied, and how the decision will be implemented [9, 10, 15–18]. Governments are accountable to their populations for fair, efficient, and equitable allocation of public resources, which requires effective approaches for policymaking under these varied sources of uncertainty.

In this chapter, we discuss the different sources of uncertainty associated with policymaking under uncertainty in HTA across the 3-D framework. We compare these sources of uncertainty with the conventional view of uncertainty in HTA, showing that HTA primarily conceptualises uncertainty as a methodological issue arising from lack of data. We draw on the philosophical foundations of HTA to discuss the reason for the narrow conceptualisation of uncertainty in HTA, before setting out the research questions related to policymaking under uncertainty in HTA and the structure of this thesis.

## **UNCERTAINTY IN POLICY ANALYSIS: DATA, DIALOGUE, DECISION**

To characterise the breadth of how uncertainty is conceptualised for policy analysis, we conducted an unstructured literature review of the definitions and typologies of uncertainty across disciplines, snowballing from a set of benchmark papers ([9, 10, 18–22]) until we reached saturation in the themes identified (further details are in **Supplement 1**). We have organised our findings according to the 3-D framework described above, in order to facilitate comparison with existing HTA standards in the next section.

**Data.** Uncertainty as a property of data considers our ability to determine the true value [5]. It therefore only covers objective (and not socially constructed) reality. Under this view, uncertainty may arise from inherent randomness (also called stochastic or aleatory uncertainty) or unpredictability of a system, as well as from our inability to measure reality (epistemic uncertainty) [5, 7, 9, 10, 12, 21]. Aside from parameter inputs, data uncertainty may relate to knowledge of a system, in terms of cause-effect relationships or model states [10]. Confidence in the knowledge used for policymaking may also be classified as uncertainty [5, 21]. This may result from internal bias (often described as data quality) or external bias, related to generalisability of data from one setting to another [21, 23].

**Dialogue.** Uncertainty may be considered as a property of how individuals conceptualise and solve a policy problem [5, 12]. According to institutional theory, individuals construct mental models to interpret the environment, which are based on cultural priors from previous learning [24, 25]. These cultural priors influence how individuals bracket relevant information and apply meaning [12], which can lead to uncertainty in a number of ways. Firstly, there is procedural uncertainty from an individual's ability to process a complex environment [26]: when faced with a complex decision problem, how are both the problem itself and the process by which to solve it conceptualised by technocrats [26]? Secondly, differences between the mental models of individuals affect how a problem is framed [5, 12, 27, 28], the value parameters applied in analysis [10], and the decision variables considered to be important [10, 17, 20]. Since each individual has a unique problem frame, even scientific analysis based on rational choice does not consistently lead to a unique answer [29]. It is also possible for individuals to hold seemingly contradictory beliefs or values at the same time, a concept known as ambivalence [30]. During policymaking, there can be communication mismatch between stakeholders, as each individual will interpret information according to their own cultural background [5, 7, 12]. Social learning, in which actors learn from and with each other through interaction, can promote change in both individual and group problem frames [31–33]. The set of stakeholders involved in a decision process and how they interact can therefore influence how a problem will be structured and evidence interpreted to come to a decision [7, 12, 18].

**Decision.** Institutions represent the set of formal and informal rules governing decisions [24, 31, 34]. By restricting the problem space so that there is a lower cognitive demand on actors, and through constraining the interactions and likely actions of stakeholders, institutions may partly reduce representational uncertainty [26, 35]. For example, a policy institution may define the type of evidence collected for a decision, the steps at which stakeholders are engaged, and the criteria used to come to a recommendation, promoting mutually consistent choices and

reducing the cognitive burden to manage the policy process [25]. Conversely, institutions may also lead to greater uncertainty. Institutions impose constraints in terms of time, money, and expertise, which can lead to “closed ignorance” to solve a problem, even though reducible data uncertainty remains [13, 36]. Institutions may have competing short-term and long-term objectives, which can lead to inconsistencies in decision-making [12, 37], such as short-term pressure to reduce spending that overrides use of cost-effectiveness evidence to improve long-term efficiency. They also shape social beliefs and perceptions, including the credibility of evidence from other institutions or appropriate decision rules [13]. Institutions therefore introduce unpredictability when there are competing resources or sources of legitimacy [12, 13], such as conflicting standards between the hierarchy of clinical evidence from global HTA good practice, which emphasises data from systematic reviews, and local policymaker preferences for context-specific studies. Finally, there is uncertainty around the current and future state of institutions, as well as how decisions in one place affect another [34]. For example, a change in tax laws is an external and unpredictable factor that may influence procurement costs for the health sector.

## **CONCEPTUALISATION OF UNCERTAINTY IN HTA**

In this section, we describe the conceptualisation of uncertainty in HTA according to three good practice publications [19, 22, 38]. Although these references only cover evidence synthesis and decision analytic models, a search in PubMed and Web of Science of ((uncertainty) AND (HTA OR “health technology assessment”)), alongside reviews of national HTA guidelines [39–42], did not identify additional conceptualisations of uncertainty in HTA, with the exception of a recent HTAi working group publication [43] that we discuss at the end of this section.

Typologies of uncertainty in HTA predominantly consider uncertainty to be a property of data, at the level of empirical quantities (stochastic uncertainty, parameter uncertainty), model structure (structural uncertainty), and quality of the evidence for policymaking (certainty in the evidence) [19, 22, 38]. There is discussion of modelling choices or values (methodological uncertainty) and problem framing (structural uncertainty in the decision question), but it is disputed in the HTA literature as to whether these represent uncertainty [19, 22, 44].

For empirical quantities, stochastic uncertainty (inherent randomness) is accounted for in patient-level models, such as discrete event simulation and agent-based modelling, to accommodate different disease progression and outcomes due to chance [19]. Epistemic uncertainty (parameter uncertainty reflecting imperfect knowledge) may be accounted for

through deterministic or probabilistic analysis [19, 22]. Uncertainty arising from quality or representativeness of the data is commonly addressed through qualitative analysis, although methods have been developed to parameterise internal and external bias for probabilistic uncertainty analysis and to apply discrepancy approaches which consider distance from the true value [23, 38, 45].

Structural uncertainty considers the extent to which the structure and functions in the model reflect the disease, clinical pathway, or health system being modelled [46]. Structural uncertainty may be parameterised based on expert judgement before undergoing probabilistic sensitivity analysis [44, 47], or addressed through the discrepancy (E-value) approach, which estimates total model error on the basis that all models approximate reality [44, 48]. Both methods may be informed by data but mainly depend on expert opinion [44, 49]. Although the decision problem was originally considered to be a form of structural uncertainty, the consensus is that it represents a subjective choice that should be justified [44].

Methodological uncertainty comprises model domain values (e.g. time horizon) and value parameters (e.g. discount rate or use of QALYs) [22]. These represent choices made by the modeller that may influence model outputs [50]. Within HTA, it is normally recommended to reduce methodological uncertainty through adherence to guidelines [22]. Certain frameworks do not consider it a source of uncertainty, but rather a subjective choice to justify [19].

To summarise, conceptualisations of uncertainty in HTA do not account for representational or institutional uncertainty, yet these reflect many of the current discussions in HTA, including integration of scientific rigour with different views of evidence [51], barriers towards effective stakeholder engagement [52], and institutional risk tolerance [43, 53–55]. Conventional approaches in HTA address uncertainty by seeking to improve knowledge around the “true” value, but this does not align with the increasingly multi-disciplinary nature of HTA, in which a wrong decision does not exist, individual preferences are not constant, and knowledge cannot be separated from the institutions in which it is used [51, 56]. A recent publication following the 2021 HTAi Global Policy Forum does explicitly consider the role of stakeholders and decision-making institutions in policymaking under uncertainty [43], but it has not yet been incorporated into practice and has been (falsely) interpreted as summarising existing methodological guidance [57].

Viewing uncertainty as a property of the data may well be appropriate for medicine reimbursement decisions: medicine effectiveness is generally transferrable across settings [58], drug mechanisms of action and clinical pathways are understood, and well-established

institutions for listing medicines reduce uncertainty in how a reimbursement decision will be implemented [59]. It is, however, inappropriate for the range of policy questions addressed by HTA today. The mandate of HTA agencies is expanding to include policies that depend on people's behaviour and those with system-wide impact, introducing uncertainty that is not related to an objective and measurable reality. Psychosocial and health promotion interventions, for example, depend heavily on the socio-institutional context of an intervention and socially constructed reality becomes just as important (or even more so) than the biological mechanism of action [60–62]. To address this expanding mandate, the types of evidence considered by HTA agencies is diversifying, but different disciplines hold different perceptions around what constitutes relevant and rigorous evidence [51, 56], introducing uncertainty around how these different forms of evidence will be understood and used for decision-making. Finally, as HTA agencies assume greater responsibility, the pressure to provide policy-relevant results within a short timeframe and limited resources becomes even more acute, driving cross-jurisdictional collaboration and adaptation of assessments from other jurisdictions [58, 63–65]. Such collaboration will need to address differences in problem frames, institutional landscapes affecting implementation, and socio-cultural contexts for policy.

## **PHILOSOPHICAL FOUNDATIONS OF HTA AND IMPLICATIONS FOR THE CONCEPTUALISATION OF UNCERTAINTY**

In this section, we review the dominant philosophical paradigm in HTA, in order to evaluate whether current HTA conceptualisations of policymaking under uncertainty described in the section above are aligned with the overarching HTA philosophy. We argue that the field of HTA has transitioned from positivism to critical realism in theory, but that HTA practice, including policymaking under uncertainty, has not yet made the transition.

Positivists assert that an objective reality exists, that this reality may be empirically measured, and that the findings may be extrapolated to produce generalisable theories [66, 67]. This contrasts with interpretivism, in which there are multiple socially constructed realities [68, 69]. For interpretivists, the process of gaining understanding and knowledge can only occur within the frame of an individual's prior experience, perspectives, and goals [70]. Research is therefore subjective. Critical realism is often portrayed as a middle ground between positivism and interpretivism: whilst critical realists believe in an objective reality, they argue that individuals view this reality through their own subjective lens [62, 66]. As a result, research is an inherently values-laden process [62, 71]. Similarly, critical realists seek to identify causal relationships,

much like positivists, but emphasise the importance of context [62, 71, 72]. Perhaps of greatest relevance to HTA, critical realism promotes justice and equality as its central aim [62].

The field of health technology assessment (HTA) first emerged in high-income countries around the turn of the millennium, primarily to support resource allocation decisions for government-funded healthcare schemes [3, 73, 74]. HTA has traditionally drawn heavily from the fields of evidence-based medicine and health economics, both of which emphasise positivist principles of objectivity and replicable empirical measurement [73–78]. However, as HTA has gained prominence as a policy analysis tool for Universal Health Coverage (UHC) decisions globally, there has been increasing attention to criteria outside of efficiency, such as equity and quality [2], as well as the establishment of fair and legitimate processes for decision-making [79, 80], which recognise the inherent subjectivity of making a “right” decision, in line with critical realism principles.

The most recent consensus statement on HTA defines it as a “multidisciplinary process that uses explicit methods to determine the value of a health technology...” [3]. Yet there has been criticism that HTA still fails to look beyond objective, quantifiable research [75, 78]. Recent literature in the field of HTA, for example, calls for “established and codified interpretations of ethical values and norms” [81] and for qualitative studies to show sample representativeness and generalisability [82]. In essence, there is a criticism that HTA is sitting squarely within a positivist paradigm, when in fact another paradigm would be more closely aligned with its goals. In the following section, we discuss the extent to which this assertion is justified, before discussing the implications of HTA’s philosophy for policymaking under uncertainty.

The first question in considering whether HTA follows a positivist paradigm is whether HTA ascribes to ontological realism, or the idea that there is an objective reality. As noted by Sturgiss and Clark, it is difficult to see how any field in health could argue against reality existing independently of the mind: the biological state of a smoker’s lungs, for instance, will exist regardless of a smoker’s knowledge, views, or social interactions [71]. However, it has also been put forward that there are both naturalistic and holistic perspectives of health: the naturalistic view is concerned with physical functioning of the body, while the holistic perspective considers health as the ability of an individual to achieve their goals or avoid harm [83]. The former describes a reality that exists outside of the mind whilst the latter represents a relative reality that is subjective and context dependent. In the same vein, Rawlins and Culyer argue that HTA should separate scientific values to promote truth from socio-ethical values underpinning what is good for society [84]. In this sense, the reality of what constitutes the right decision in HTA is a social

construct, even if the evidence underlying the decision is based on a fixed reality. This reflects Bhaskar's distinction between the world of being and the world of knowing in critical realism [85].

Since it appears that the principle of ontological realism is adhered to either fully or in part by HTA, the next question is whether there is epistemological objectivity: is reality knowable and able to be objectively measured by a researcher (at least in theory) [77]? Two cornerstones of HTA, randomised controlled trials (RCTs) and health economics models, seek to remove bias and standardise measures to objectively quantify reality [77, 86]. It has been argued that the dominance of these disciplines forces HTA reports to be objective [78] and sets an expectation that ethical frameworks for decision-making should be objectively measurable [75] or employ standardised tools for consistent assessment [81]. Cookson and Mirelman went as far as to propose that objective measurements are necessary to consider equity in HTA because "what gets measured gets done" [87]. Yet on the other hand, there is a constant debate in HTA as to whether a model is able to replicate reality, or whether a model instead replicates the values and knowledge of a modeller [50]. Related to uncertainty, this debate is played out in structural uncertainty analysis: can we parameterise uncertainty by assigning a probability distribution to assumptions, or should we recognise that no model structure can ever be correct [46, 48, 88]?

This principle of epistemological objectivity (whether reality may be known and objectively measured) has become increasingly contentious as HTA is applied to a broader scope of interventions beyond high-cost drugs. For many health programmes, outcomes depend not only on the intervention itself, but also on the context in which the intervention is delivered, the nature of social interactions, and the history of the patient, none of which can truly be objectively measured [60, 62, 71]. It has even been argued that overly emphasising objective measurement can lead to a pharmacological bias, as psychosocial interventions that are built around trust and relationships, and developed for specific socio-cultural contexts, are difficult to assess through RCTs [60]. This shift away from epistemological objectivity is demonstrated by a recent framework to guide the inclusion of equity in HTA, which combines quantitative measures with a set of contextual considerations and space to capture "life experiences" [89].

A closely related concept is axiology, or whether values are considered an integral part of research (interpretivism) or a source of bias that can and should be removed (positivism) [90]. It is generally accepted within HTA that appraisal, namely the process of considering the evidence to come to a recommendation, occurs within a framework of values [76]. HTA promotes the use of frameworks such as GRADE, which ultimately depend on expert judgement of evidence quality [38, 91, 92]. Some research does focus on the objective measurement of values in decision-



making, but the prevailing view is that appraisal is a values-laden process requiring context-specific, guiding decision criteria [79, 80, 84, 93]. The first evidence-based supply-side cost-effectiveness threshold, for example, explicitly recognised that some considerations cannot be quantified, including the societal value placed on maternal and child health, as well as intangible benefits realised from mental health programmes [16]. Within the field of HTA, reference cases seek to make explicit and, to a certain extent, standardise the values that contribute to methodological uncertainty [22, 94]. Whilst this may be considered as a mechanism to remove bias, it adheres to the principle put forward by Daniels (and supported by critical realism [62]) that consistent processes are fair [75] and that two policy bodies may legitimately come to a different recommendation for the same question [95]. There has been growing attention to deliberative processes, as a means by which to identify, reflect, and learn about the meaning of social values [96, 97]. Recent HTA literature on deliberation explicitly accommodates different views of what constitutes evidence and considers that individuals may update their beliefs based on social interaction and learning [98–100]. In this way, values are an integral part of evidence-informed policymaking and not a factor to remove.

In conclusion, although positivism was the dominant paradigm in HTA, the expanding mandate of HTA agencies has prompted a shift towards critical realism, to overcome the limitations of solely using objective, generalisable research in understanding the multi-dimensional impact of different policy options. The current conceptualisation of uncertainty in HTA, however, still follows a positivist approach: it assumes there is an objective, measurable reality [66] and uncertainty is viewed as an element that should be reduced as far as possible for good decision-making [5]. This is typical of disciplines based on technical sciences, which seek to develop robust and generalisable estimations of uncertainty that are not context-dependent [11], but it does not recognise the socio-institutional context for policymaking that is now being emphasised in HTA.

Over the past 20 years, HTA has evolved into a reference paradigm that is increasingly multi-disciplinary with stronger links to policy and decision-making [101]. Yet the methods and processes for HTA, including the conceptualisations of uncertainty, have not yet evolved to align with the multi-disciplinary nature of HTA or its critical realist approach. Beyond the theoretical arguments presented, we have highlighted the practical implications of this philosophical misalignment: policies may fail to reach their objectives as they have not accounted for the broader system context [102–106], influence of external factors on policy performance [107, 108], or the role of social interactions [60, 62], among others. Moving forward, a greater diversity

of approaches will be needed for effective policymaking uncertainty to encompass the socio-institutional context of the policy process and impact.

## RESEARCH QUESTIONS

This chapter has indicated that current approaches to policymaking under uncertainty in HTA may not be fit to address important policy questions in public healthcare. Through the course of this thesis, we examine the extent to which the philosophical shift in HTA warrants a re-think in how policymaking under uncertainty is conceptualised and how this may be accomplished. The overarching goal of this work is to improve policymaking under uncertainty in HTA.

We investigated the following research questions.

1. **Research question 1: To what extent does HTA take a multi-disciplinary approach to policymaking under uncertainty?**

Although this chapter argued that HTA should take a broader view of policymaking under uncertainty, our analysis used the typologies of uncertainty used in HTA. It is possible that HTA does, in fact, account for a broader view of uncertainty but does not label it as “uncertainty”. We also argued that a “broader” view should be taken, without specifying what this broader view should encompass. Under research question 1, we conducted a structured review of good practice in HTA, mapped against an interdisciplinary framework of policymaking under uncertainty, to identify which disciplinary conceptualisations of policymaking under uncertainty are both relevant to, and missing from, current HTA practice (**Chapter 2**).

2. **Research question 2: Which approaches to policymaking under uncertainty from other disciplines may address the gaps identified in research question 1?**

Addressing gaps in the conceptualisation of uncertainty in HTA will require the development of approaches and tools to support HTA practitioners to take a broader view of uncertainty. This research question aimed to learn from the experience of other disciplines that have transitioned from positivism to critical realism, in order to map approaches that may be applicable to HTA (**Chapter 2**) and develop a diagnostic framework highlighting when alternative approaches may improve policymaking under uncertainty in HTA (**Chapter 3**).

3. **Research question 3: To what extent do the approaches identified in research question 2 improve policymaking under uncertainty for HTA?**

This research question aimed to understand the utility of the framework, evaluate the transferability of approaches from other disciplines, and identify implementation strategies that may facilitate their integration with HTA practice. We applied a hybrid implementation science study design to address this research question, in order to concurrently evaluate the effectiveness of the framework in improving policymaking, as well as implementation facilitators and barriers towards integrating the framework with HTA practice.

Through a case study, we operationalised the framework for a case study in Thailand (**Chapters 4-6**). We evaluated the extent to which new approaches could improve policymaking, the adaptations required for HTA, and potential implementation strategies for successful integration with HTA practice (**Chapter 7**). Learnings from the evaluation were used to propose modifications to the framework (**Chapter 8**).

While this work is grounded in theoretical analysis of HTA's philosophical evolution, the primary contribution is practical: developing implementable tools to help HTA agencies incorporate social science perspectives into policymaking under uncertainty. It is expected that this work will contribute to the ongoing dialogue around how to operationalise the multi-disciplinary definition of HTA in practice (for example, [43, 98]). Beyond contributing to the literature by mapping gaps and potential solutions, we sought to inform policy and practice by understanding how to implement and evaluate new approaches for better policymaking under uncertainty, especially in light of the philosophical differences between current HTA practice and social science perspectives. We applied management science principles of applying multi-disciplinary approaches for decision-making, illustrating how these may be leveraged and adapted within the field of HTA.

## **STRUCTURE OF THE THESIS**

In **Section I** we review the extent to which HTA takes a multi-disciplinary approach to policymaking under uncertainty and we develop a framework to address identified gaps through an interdisciplinary review of frameworks for policymaking under uncertainty. In **Section II**, we operationalise the framework by trialling it for policymaking in Thailand. In **Section III**, we evaluate the extent to which the framework improved policymaking under uncertainty, compared

with standard HTA practice, in order to propose a research agenda for further work to promote a multi-disciplinary approach to policymaking under uncertainty in HTA.

## SECTION I: FRAMEWORK DEVELOPMENT

In this section, we develop a multi-disciplinary framework for policymaking under uncertainty that could be applied in HTA. In **Chapter 2** we evaluate the extent to which HTA addresses different disciplinary concepts of policymaking under uncertainty and we conduct an interdisciplinary review of approaches to address identified gaps in standard HTA practice. In **Chapter 3** we draw on the findings to develop a preliminary framework for policymaking under uncertainty and we identify a case study to trial the framework.

# **Chapter 2 Which good practice exists for policymaking under uncertainty? An interdisciplinary review with relevance for health technology assessment (HTA)**

## **ABSTRACT**

Appropriate policymaking under uncertainty can lead to better decisions around how constrained resources are used. Although approaches from the technical sciences can provide robust, generalisable uncertainty estimations, they cannot account for the varying social, economic, and cultural contexts in which policies are made and implemented. We evaluated current health technology assessment (HTA) practice, showing limited consideration of social science perspectives, which may be inadequate for policies that influence behaviour, cross jurisdictions, or deal with multiple vested interests. We conducted an interdisciplinary review of frameworks for policymaking under uncertainty, using an iterative approach for cross-disciplinary learning. We applied a comprehensive pearl growing search strategy and conducted inductive analysis combining grounded theory coding with pattern matching. Our analysis identified fourteen approaches to facilitate social science conceptualisations of uncertainty that are currently missing from HTA practice, alongside features of the decision problem and context that influence approach selection. We illustrate the applicability of our findings for three HTA challenges where standard practice is proving insufficient: reducing unnecessary caesarean section, reimbursement of locally manufactured products, and integrating patient voice in policymaking. Beyond the mapping of approaches in this paper, successfully integrating a broader view of uncertainty within HTA will demand capacity building, philosophical alignment, and institutional adaptation. We identify key implementation barriers and recommend empirical effectiveness studies, barrier analysis, and development of guidelines to operationalise an interdisciplinary toolkit for policymaking under uncertainty in HTA.

## **1. INTRODUCTION**

Healthcare policymaking inevitably entails some level of uncertainty. Within health technology assessment (HTA) – the field for evidence-informed decisions in health – this uncertainty may relate to the confidence intervals around an effect size, data quality, and model structure, or it may be broader. For example, policymakers may be considering the impact of a negative

recommendation on future manufacturing and innovation [109]; they may be struggling to select a policy that successfully reduces unnecessary caesarean sections given the wide variation in policy performance between settings [110, 111]; or they may be questioning whether incorporating patient voice in policymaking will improve decisions, due to prevailing views around what constitutes rigorous evidence among policy bodies [51, 56]. In all settings, healthcare resources are finite. Appropriately managing policymaking under uncertainty can lead to better decisions around how constrained resources are used and, ultimately, better health.

HTA has grown from the fields of evidence-based medicine and health economics to become an increasingly multi-disciplinary paradigm [3, 73, 101]. As HTA has become increasingly multi-disciplinary, so too has its view of uncertainty. From the mid-2000s, HTA literature on policymaking under uncertainty predominantly focussed on managed entry agreements, which aim to improve access to expensive technologies with limited information on effectiveness, informed by value of information methods that articulate the value of extra research assuming a risk-neutral decision-maker [112–114]. Within the last 10 years, there has been a shift away from the view of a risk-neutral decision-maker towards variable risk tolerance that can differ by context and setting [53]. Extensions to HTA methods have sought to quantify social values that influence risk tolerance, including the impact on future research and innovation in the UK [115] and severity of disease in the Netherlands [116, 117]. Most recently, alongside increasing emphasis on deliberative processes in HTA [96, 98], there has been a shift towards understanding different stakeholder perspectives for policymaking under uncertainty [43]. This represents a considerable shift from conceptualising uncertainty as a technical construct to a socio-technical one [57].

Similar to the prevailing view that a multi-disciplinary approach is required to determine the value of a technology in HTA [3, 79], a multi-disciplinary approach to policymaking under uncertainty can account for the process and context for decisions, which are absent from technical uncertainty estimations [11]. The process and decision-making context matter, as they shape how the problem is framed, the evidence considered appropriate for a decision, how evidence is interpreted to come to a recommendation, and how that recommendation translates into policy and impact, both for the policy at hand and for future decisions [9, 18, 95, 118]. In the context of regional initiatives for joint HTA assessment [58, 119], this may become even more important, as a single HTA may be applied across multiple settings with varying social, economic, and cultural contexts.

In this review, we aimed to map approaches for policymaking under uncertainty across disciplines, in order to identify approaches that may support HTA practitioners to take a multi-disciplinary view of policymaking under uncertainty. In **Part 2**, we examine the extent to which HTA currently takes a multi-disciplinary approach to policymaking under uncertainty. In **Parts 3 and 4** we outline the methods and results from an interdisciplinary review to synthesise and critically review frameworks for public policymaking under uncertainty, with a broader aim of identifying best practice that could be applied within the field of HTA. We illustrate the applicability of the results from the review to HTA in **Part 5**, before providing concluding remarks on how to integrate multi-disciplinary approaches for policymaking under uncertainty within HTA in **Part 6**.

## **2. EXAMINING THE EXTENT TO WHICH HTA TAKES A MULTI-DISCIPLINARY APPROACH TO POLICYMAKING UNDER UNCERTAINTY**

In this section, we evaluate the extent to which policymaking under uncertainty in HTA is multi-disciplinary, by comparing current HTA practice against the disciplinary concepts developed by Renn [11]. Renn's work identifies how different academic disciplines—from natural sciences to social sciences—conceptualise uncertainty, which types of evidence they consider relevant, and how they approach decision-making under uncertain conditions. By systematically comparing current HTA practices against this spectrum of disciplinary approaches, we can identify which perspectives are well-represented in HTA and which are missing or underdeveloped. We used a framework from the risk literature due to the absence of a multi-disciplinary framework for policymaking under uncertainty in health.

Since definitions of policymaking under uncertainty vary across disciplines [5], we evaluated all HTA practice in this section and not just HTA practice labelled as uncertainty. We have based our assessment on recommended HTA practice from the World Health Organization (WHO) and ISPOR good practice reports [14, 19, 79, 96, 98], on the basis that these represent the standards that many HTA practitioners are working towards, even if implementation varies at the country level.

In the natural and technical sciences, there is an aim to generate robust and universal estimates that represent the best knowledge of impact linked with each policy, without accounting for social or cultural impacts [11]. In HTA, this is analogous to methods to estimate health impact of interventions through evidence-based medicine or models for medical decision-making [38,



120]. These approaches focus primarily on gaps in empirical knowledge that can be addressed through better measurement or more comprehensive evidence synthesis.

Economics accounts for individual preferences through expected utility and discounting [11], as is common practice in decision analytic models for HTA [121, 122]. Although economics includes a broader definition of outcomes, the same unit is applied for all measures of impact (e.g. quality adjusted life years, or QALY) [11]. This approach addresses uncertainty about preferences but still assumes these preferences are stable and can be uniformly quantified.

Psychology, in contrast, accounts for the full set of dimensions of impact and uncertainty that are important to individuals, to provide a more comprehensive set of policy options and criteria [11]. In HTA, psychological perspectives are partially represented through multi-criteria decision analysis, which may be applied qualitatively or quantitatively during topic selection and to formulate a recommendation [93, 123, 124]. This approach begins to address differences in how stakeholders interpret and prioritise different outcomes.

Rational choice theory from the social sciences addresses policymaking under uncertainty by searching for win-win situations across different subjective judgements [11]. Under HTA, processes for stakeholder dialogue and decision rules aims to prioritise policies that are acceptable across stakeholders [14], but a key difference between rational choice theory and HTA practice is that stakeholder dialogue in HTA is confined by set decision options [114], whereas the emphasis of rational choice theory is identification of policies that are agreeable to all stakeholders.

According to critical theory, fair, transparent, and truthful discourse is required to counter power-based decisions in political systems, requiring methodological rigour to address factual uncertainty, truthfulness and openness to address uncertainty in stakeholder responses to policy, and consistency and ethical justification to address normative uncertainty (the application of different rules across decisions) [11]. In HTA, the accountability for reasonableness framework is an ethical framework underlying many policy processes, to promote fair and legitimate decisions [125]. There is separation of methodological rigour in the evidence from the participatory, transparent processes to incorporate values within decision-making [14, 84, 123].

In the theory of modernisation, reflexivity is needed to understand the impact of policies across geographical and socio-cultural boundaries [11]. There is growing evidence that healthcare policies may fail to reach their objectives, or lead to unintended consequences, if they are made

without looking across institutional boundaries [102, 104, 126]. Yet despite this, HTA practice does not incorporate approaches to systematically consider cross-boundary impact of decisions.

Systems theory focusses on how institutional boundaries define what is considered to be a controllable or an uncontrollable source of uncertainty [11]. For HTA, this perspective is particularly relevant when evaluating cross-jurisdictional initiatives or complex interventions that cross traditional healthcare boundaries, such as integrated care models or public health interventions, where success may depend on the perceived level of control across different institutions [127]. Current HTA methods, however, typically treat institutional factors as fixed external constraints rather than sources of uncertainty that can be actively managed.

Under post-modernism theory, hidden power motives enforce the behavioural, moral, and cognitive norms underpinning how uncertainty is perceived and managed [11]. For contentious health policies, actors may exert their influence to shape problem framing, the stakeholders engaged, evidence reviewed, and interventions considered. HTA currently seeks to address these motives through transparency and consistency in the decision process, but governance that allows flexibility to different policy needs whilst preventing undue influence from stakeholders with vested interests is difficult to achieve [128], especially in resource-limited settings [129].

In cultural theory, a defined set of cultural prototypes (e.g. egalitarianism, individualism) shape how uncertainty and its role in policy are perceived [11]. HTA emphasises broad stakeholder dialogue and engagement, but this may not be practical for all decisions [130], particularly in emergency settings [131]. Yet to our knowledge, policymaking under uncertainty in HTA does not use cultural prototypes as a basis for understanding stakeholder views and potential policy reactions.

In summary, although all disciplinary conceptualisations of policymaking under uncertainty may be relevant for HTA, current HTA practice takes a very limited account of conceptualisations from the social sciences (**Table 2.1**). This narrower conceptualisation of uncertainty may be inadequate for complex policy questions that span institutional boundaries, or those that involve significant stakeholder disagreement about problem framing. In the next section we describe the methods for an interdisciplinary review to consider how policymaking under uncertainty is addressed across disciplines. In light of our findings above, we focus on approaches that could address social science conceptualisations of uncertainty.

**Table 2.1** Disciplinary conceptualisations of policymaking under uncertainty, based on [11], and the extent to which they are addressed by current HTA practice.

Discipline	Conceptualisation of policymaking under uncertainty	Relevance for HTA	Extent to which it is addressed in HTA
Technical science	Generates robust and universal estimates that represent the best knowledge of impact linked with each policy, without accounting for social or cultural impacts.	Certain criteria for decision-making, such as efficacy of a medicine or diagnostic test accuracy, are seldom affected by context and can be better estimated with more high-quality data.	Fully addressed - forms the basis of evidence-based medicine (e.g. clinical trials, systematic reviews) and disease impact models.
Economics	Accounts for individual preferences within uncertainty estimates, with the assumption that preferences are stable and can be uniformly quantified across the population.	Resource allocation across different disease areas and technologies can be facilitated by using a common unit that accounts for population-level preferences.	Fully addressed - decision analytic models, incorporating discounting and utility, are commonly used to inform policy.
Psychology	Aims to identify the full set of criteria and policy interventions that are important to individuals to capture impact and uncertainty.	Values applied during decision-making can influence the policy options and evidence considered, as well as how the evidence is used to come to a recommendation.	Partly addressed - multi-criteria decision analysis, applied during topic selection or in formulating recommendations, has the potential to identify important interventions and criteria from different perspectives.

Discipline	Conceptualisation of policymaking under uncertainty	Relevance for HTA	Extent to which it is addressed in HTA
Critical theory	Counters power dynamics in political systems through methodological rigour, truthfulness in communicating uncertainty, and consistent decision rules with ethical justification.	Governments are accountable to the population for allocation of public funds to health services.	Fully addressed - HTA guidelines seek to promote rigorous methods, transparency, and consistency in decision-making, often based on the accountability for reasonableness ethical framework.
Rational choice theory	Aims to reconcile different perceptions of impact and uncertainty by seeking win-win situations across stakeholders.	Governance systems may require consensus for decisions, or implementation of policies may be impossible without the support of key stakeholders.	Limited - may be informally applied through procedures for dialogue and decision at the country level.
Theory of modernisation	Seeks to expand the view of uncertainty and impact across geographical and socio-cultural boundaries through reflexivity.	Policies in complex systems, such as health systems or health promotion, may have unintended consequences or fail to achieve the stated goals without considering system impact.	Very limited – mentioned in health system research studies but not mainstreamed in HTA.
Systems theory	Institutional boundaries determine what is considered a controllable or uncontrollable source of uncertainty.	Successful uncertainty management for cross-jurisdictional policies, or those based on multi-disciplinary	Very limited – may informally be addressed through deliberation in the policy process.

Discipline	Conceptualisation of policymaking under uncertainty	Relevance for HTA	Extent to which it is addressed in HTA
		evidence, can depend on perceived control of different institutions.	
Post-modernism theory	Aims to reveal hidden power motives framing how impact and uncertainty are perceived.	Contentious or high-stakes policies, such as those aiming to address failures within the system, may fail unless they address stakeholder motivations and hidden agendas.	Very limited – may informally be addressed through side discussions of the secretariat or policymakers.
Cultural theory	Characterises perceptions of impact and uncertainty according to cultural prototypes.	Contentious decisions that need to be taken without extensive consultation (e.g. emergency contexts) may still need to account for stakeholder views and reactions.	Not discussed in HTA.

### 3. METHODS: AN INTERDISCIPLINARY REVIEW OF FRAMEWORKS FOR POLICYMAKING UNDER UNCERTAINTY

Uncertainty is conceptualised differently across disciplines and has multiple definitions [5–8]. We therefore employed a semi-systematic methodology, in line with recommendations for conducting an interdisciplinary review [132, 133]. Although a realist review can explore which approaches work in which contexts [134], given the large scope and diversity of this review, we conducted a scoping review as a means by which to map the nature and diversity of available knowledge [135]. Since cultural priors from our respective academic disciplines could shape the way in which information is interpreted [13, 24], we took an iterative approach to allow for learning during the course of the review, and the research team included six members from political science, economics, health policy, and engineering.

For this review, we used the following definitions from the strategy and policy literature:

- **Framework:** “open-ended, purposeful and action-oriented abstractions that identify, define, and structure problem-spaces” [136].
- **Policymaking:** a technical and political process of articulating actions to achieve specific goal(s) [137].
- **Public policy:** measures adopted or endorsed by government [137].

#### Literature search and article selection

We focussed our review on disciplines that have developed from technical science and economics disciplines, including environmental science, engineering, natural sciences, and business. The rationale for this decision was to learn from disciplines that have similar philosophical foundations to health policymaking, but which have since integrated approaches from the social science disciplines, on the basis that these approaches may be more amenable to HTA.

We developed a search strategy using the comprehensive pearl growing approach to facilitate iterative learning and overcome disciplinary biases that commonly affect interdisciplinary reviews [132, 138]. Based on our existing knowledge, we identified a set of benchmark papers related to policymaking under uncertainty from political science, environmental science, health technology assessment, and quantitative sciences. These articles were used to identify appropriate databases and to develop search terms, which were iteratively refined based on relevant search results until no new key words were identified. Articles identified from the

database search were complemented by citation screening of included articles. Further details are available in **Supplement 2.1**.

We established a “learning” approach to selection criteria to accommodate conceptualisations of uncertainty across disciplines, following recommendations for interdisciplinary reviews [132, 139]. Learning while setting the selection criteria involved two researchers with different backgrounds (SB and TC) piloting an initial set of criteria in an iterative process in which the criteria were refined until no new concepts emerged. This process arrived at the following selection criteria:

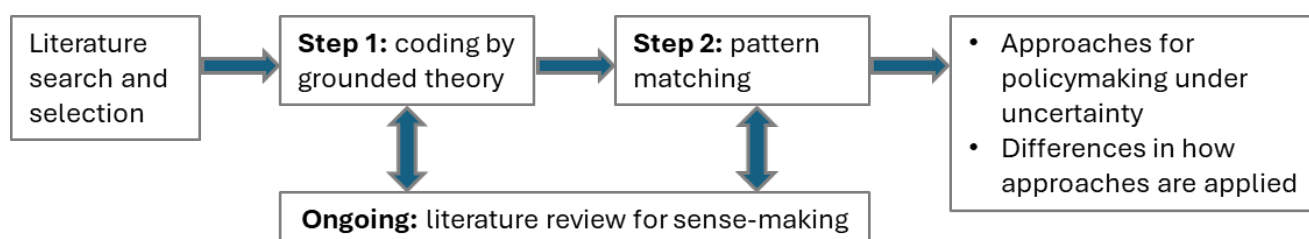
- i) The article describes a framework for public policymaking. We excluded articles restricted to isolated parts of the policy process (for example, those that only discussed evidence assessment), articles that developed a retrospective framework to describe a past policy without broader generalisability to future policies, and those discussing private sector policy.
- ii) The article either explicitly or implicitly considers policymaking under uncertainty. Implicit consideration of uncertainty may include, for example, discussion of problem frames, legitimate process, social learning, or values.
- iii) The article is published in full in a peer-reviewed journal, an official government agency publication, or a book chapter. The purpose of this criterion was to identify good practice, on the basis that these sources have either been upheld to discipline-specific standards or adopted in policymaking.

Both reviewers (SB and TC) independently conducted title/abstract screening followed by full text screening. The resulting list of articles from each reviewer was discussed before coming to a final agreement on the articles to include.

## Analysis

We conducted an inductive analysis with three interconnected steps to avoid imposing discipline-specific views of uncertainty and public policymaking that might limit our findings (**Figure 2.1**): (1) coding by grounded theory to reduce the influence of our discipline-specific knowledge, (2) literature review of methodological approaches to support sense-making, and (3) pattern matching to explore differences between frameworks. A single coder conducted analysis, with review of interim outputs by other team members. The output from the analysis was a set of approaches applied for policymaking under uncertainty across disciplines, alongside a set of factors determining when and how they are used.

**Figure 2.1** Steps in the analysis.



In the first step, we developed an analytical framework of factors influencing approaches for policymaking under uncertainty. We adapted Wolfswinkel’s grounded theory approach for literature reviews, in order to reduce the influence of researcher cultural priors [140]. This entailed open coding to develop an initial set of categories, axial coding to map relations between concepts, and selective coding to test and refine coherence of the codes [140]. Since the purpose of our study was not to develop theory, we did not seek the level of replication between codes normally required in grounded theory analysis and we incorporated other literature, consistent with methods using grounded theory as an analytical starting point [141]. The hierarchy of codes is available in **Supplement 2.2**.

In the second step, we applied flexible pattern matching as an exploratory method by which to test and refine hypotheses [142]. Based on our hierarchy of codes from step 1, we developed the following hypotheses, which we tested through empirical comparison with the articles in our review and theoretical comparison with extant literature:

1. The approaches selected by each framework for policymaking under uncertainty depend on features of the decision problem.
2. The approaches selected by each framework for policymaking under uncertainty are influenced by how the study authors conceptualise uncertainty.

Across both steps of the analysis, we conducted a literature review of methodological approaches described in the included articles, by identifying references cited across multiple articles and by searching for reviews of the method in PubMed (a database aligned with institutional knowledge in HTA) and Web of Science (as a more comprehensive database). The purpose of this step was to increase our understanding of the theoretical basis of methodologies applied in frameworks and possible methodological choices for each.



## Appraisal

The credibility of our results depends on the extent to which we were successfully able to synthesise frameworks from other disciplines. As an indication of whether our domain-specific views had influenced article selection, we reviewed the profile of included studies from our results, in terms of the range of disciplines and disciplinary views of uncertainty included. Another consideration was the construct validity of our study, in terms of whether it was appropriate to learn from frameworks in the published literature, as our analysis could alternatively have been based on theories or review of actual policy processes. To this end, we evaluated the extent to which approaches were aligned with a specific discipline (as opposed to nature of the policy question) and conducted an appraisal of included studies. For the appraisal, we did not identify any framework for evaluating policymaking frameworks and therefore drew on policy theory and governance literature to develop a set of indicators to assess the internal validity, external validity, applicability, and policy implementation of the framework. Full details are provided in **Supplement 2.3**.

## **4. RESULTS FROM THE INTERDISCIPLINARY REVIEW: APPROACHES FOR POLICYMAKING UNDER UNCERTAINTY**

In this section, we discuss the approaches adopted for policymaking under uncertainty identified through our interdisciplinary review. Together, these approaches offer a toolkit that can be tailored to specific policymaking contexts under uncertainty. We review the extent to which approaches in the review facilitate a social science lens to policymaking under uncertainty, before discussing the factors that were found to influence their application and appraising the frameworks.

Extent to which included frameworks supported a multi-disciplinary approach to policymaking under uncertainty

All social science conceptualisations of uncertainty that are missing from standard HTA practice were accommodated under one or more approaches from the review (**Table 2.2**), although whether certain approaches facilitate a social science view may depend on their application. For example, Bayesian networks were used to improve empirical estimates in one framework [143], in line with a technical science perspective, but facilitated the identification of win-win scenarios from the perspective of different stakeholders in another framework [144], in line with rational

choice theory. Further details of each approach and its application in HTA is provided in **Supplement 2.4** and **Supplement 2.5** respectively.

Most frameworks in the analysis combined multiple approaches, allowing a multi-disciplinary approach to policymaking under uncertainty. For example, in order to set water quality limits in a community-based policy process, Lilburne and colleagues incorporated stakeholder analysis to identify how best to engage stakeholders, cognitive mapping to identify how aspirational outcomes from stakeholders were related, scenarios to account for future uncertainty in the natural system and governance processes, and robustness testing to improve proposed policies [145]. To facilitate cross-jurisdictional conservation policy, Mattson and colleagues applied Bayesian networks and value of information analysis to develop a research agenda for adaptive management of a conservation project, alongside structured decision-making to facilitate cross-jurisdictional cooperation [144].

**Table 2.2** Summary of the approaches for policymaking under uncertainty identified in the review. Approaches are not mutually exclusive.

Approach	How it addresses uncertainty	When it is used	Social science conceptualisations accommodated (not exhaustive)
Adaptive governance	Manages uncertainty through iterative learning and adjustment of governance structures based on feedback from implementation.	Very high uncertainty and/or weak institutional arrangements requiring continuous adaptation of governance to be fit for purpose.	<b>Systems theory:</b> incorporates reflexivity to move beyond system-specific conceptualisations of uncertainty. <b>Theory of modernisation:</b> may lead to a broader view of the impact of decisions, through reflexivity and learning.
Adaptive management	Incorporates learning objectives, to iteratively evaluate and revise both policy impact and suitability of the policy process.	Cause-effect relationships are poorly understood, too complex to forecast, and expected to change over time.	<b>Theory of modernisation:</b> incorporates reflexivity to update problem framing, criteria, and evidence for policymaking, supporting an understanding of cross-boundary impact.
Bayesian networks	Represent probabilistic relationships between variables, to infer missing relationships and update conditional probabilities between them with new information.	Missing data or stakeholder disagreement on cause-effect relationships.	<b>Rational choice theory:</b> can represent subjective judgements, to facilitate the identification of policies that are agreeable across stakeholders.
Consequence tables	Summarises the potential outcomes of different policy options under various	Multiple policy goals or resource constraints requiring prioritisation of evidence.	<b>Systems theory:</b> provided that a range of stakeholders are involved in the process, it can highlight institutional differences in what is

	uncertainties for comparison of policy options and evidence prioritisation.		perceived as a controllable source of uncertainty.
Futures science	Constructs images of the future, to explore paths towards a desired future or to understand the policy environment, in the context of uncontrollable, external uncertainty.	Long time horizons or dependence on stakeholder and/or institutional reactions to policy change.	<p><b>Systems theory:</b> the intuitive logics method incorporates multi-dimensional views that prompt reflection around system-imposed views of what constitutes an internal, controllable factors or an external uncontrollable one.</p> <p><b>Post-modernism:</b> scenario thinking seeks to understand the motives of different actors, particularly those with power to influence change.</p> <p><b>Theory of modernisation:</b> scenario thinking takes a cross-boundary view of the impact and people at the end of a chain of events.</p>
Optimisation algorithms	Finds the best policy solution given defined objectives and constraints, by exploring a range of possible outcomes under specified uncertainties.	Cause-effect relationships and goals can be articulated, with fixed stakeholder preferences.	<b>Cultural theory and rational choice theory:</b> worldviews from cultural theory can be included within the optimisation algorithm to identify policies that represent the best option across all worldviews.
Roadmap for institutional change	Identifies steps and strategies to address institutional weaknesses that	Institutional arrangements are inappropriate for addressing a specific policy issue.	<b>Systems theory:</b> incorporates reflexivity in implementation of the roadmap to encourage learning across institutional boundaries.

	contribute to uncertainty in policy implementation.		
Robust decision-making	Prioritises policies that perform well across a range of scenarios, rather than optimising for an expected outcome.	High future uncertainty and/or stakeholder disagreement that cannot be overcome through negotiation.	<b>Rational choice theory:</b> can identify policies that perform well across different stakeholder perspectives of the future or criteria for decision-making.
Soft problem structuring	Defines the problem frame and an appropriate decision process, when the problem is unclear or contested.	Divergent stakeholder views around the problem, responsible policy body, appropriate evidence, or solution space; intangible elements; and uncertainty in outcomes.	<b>Systems theory:</b> structured way to incorporate multiple stakeholder perspectives around the nature of the problem and uncertainty. <b>Post-modernism theory:</b> may surface motivations framing how the problem is presented.
Stakeholder analysis	Identifies and understands the interests, influence, and perspectives of stakeholders, which can be sources of uncertainty in policy outcomes.	Variable levels of technical complexity, public scrutiny, and/or stakeholder dissensus across policy issues.	<b>Post-modernism theory:</b> may be used as a tool to identify hidden power motives of stakeholders (but could also enforce hidden power motives of institutions with control over policymaking)
Structured decision-making	Promotes reflection and iterative learning throughout the policy process to address complex problems.	Learning is important for high-quality decisions, due to high problem complexity and/or collaboration across disciplines or jurisdictions.	<b>Systems theory:</b> incorporates reflection and learning across stakeholders to come to a shared problem frame beyond the institutional view of individual stakeholders.

			<b>Theory of modernisation:</b> may lead to a broader view of the impact of decisions, through reflexivity and learning across stakeholders.
System dynamics	Focuses on understanding interdependencies and feedback loops within a system to identify leverage points and anticipate unintended consequences.	Understanding system boundaries is important prior to decision-making and evidence exists of feedback or adaptation within the system.	<b>System theory:</b> surfaces and reconciles different institutional views around cause-effect relationships in a system.  <b>Theory of modernisation:</b> systematically maps unintended consequences across institutional boundaries.
Transformation	Articulates a transition pathway to change unsuitable norms and practices, to achieve policy goals.	Governance arrangements are inadequate but cannot be changed through conventional means.	<b>Post-modernism theory:</b> systematically reviews stakeholder motivations to develop a pathway for change.
Value of information	Quantifies the potential value of reducing specific uncertainties through further data collection to inform evidence generation priorities.	Evidence generation needs prioritisation, either prior to model development (qualitative) or prior to policymaking (quantitative).	<b>Systems theory:</b> participatory qualitative value of information analysis can identify which sources of uncertainty are perceived to be controllable across stakeholders.

## Factors influencing the approaches selected for policymaking under uncertainty

Our pattern matching analysis revealed that approaches selected for policymaking under uncertainty depend on the nature of the policy question, the policy context, and evidence for decision-making. **Table 2.3** details the specific decision characteristics that influence when each approach outlined in **Table 2.2** is most appropriate, recognising that many policy problems will exhibit multiple characteristics requiring complementary approaches rather than single solutions.

Our hypothesis that frameworks are influenced by how study authors conceptualise uncertainty was found to be true in the choice of approaches to address (1) divergent stakeholder opinions, and (2) unknown cause-effect relationships. To reconcile divergent opinions, frameworks that viewed stakeholder preferences as fixed variables applied optimisation algorithms to identify robust policy options [27, 146, 147], whereas other frameworks applied structured decision-making type approaches to facilitate learning across stakeholders [144, 148–153]. Similarly, although adaptive management was applied across frameworks in settings with complex and poorly understood cause-effect relationships, frameworks that considered there to be an objectively correct answer emphasised learning in the form of data collection [143, 154, 155], whereas other frameworks took a broader view of learning and iteration across problem framing, values, mental models, and implementation strategies [144, 148, 149, 151–153, 156]. Further details on each framework are available in **Supplement 2.6**.

**Table 2.3** Features of the decision question, context, or evidence base that influenced approaches to address policymaking under uncertainty.

Element		Feature	Approach	Example of relevant HTA policy areas
<b>For individual policy questions</b>				
1. Decision question	a) Nature of the problem	i) The policy problem, goals, or process is unclear or contested	Soft problem structuring	Issues proposed by stakeholders through topic nomination channels for technology reimbursement may represent unstructured problems in which the nature of the problem, and whether the topic is related to reimbursement, are unclear.
		ii) Crosses system boundaries, with evidence of feedback and/or unintended consequences	System dynamics	Healthcare delivery organisation crossing public-private sector, administrative levels, or government departments (e.g. health, social care, education).
		iii) Cross-jurisdictional decision-making or implementation	SDM	Long-term care for the elderly, school health programmes, prisoner screening.
	b) Policy goals	i) To change attitudes or behaviour	Futures research	Health promotion policies targeting behaviour of one or more population groups towards a healthier lifestyle.
		ii) To account for high impact, low probability events	Futures research	Pandemic preparedness plans to balance resource allocation between routine needs and resilience to potential future shocks.



	c) Time horizon	i) Long timeline for policy implementation and/or reversal	Futures research	Healthcare infrastructure and workforce planning policies require time to implement and reverse.
2. Decision context	a) Stakeholder interests	i) High level of disagreement among stakeholders regarding important criteria, reliable evidence, and/or future states	Robust decision rules	Contentious issues are likely to be context dependent, but examples may include purchase of high-cost cancer drugs [157] or allocation of resources to health conditions caused by high-risk behaviour [100].
		ii) Strong vested interests across multiple stakeholder groups	Scenario thinking (futures)	Setting quality standards or performance targets when navigation of diverse stakeholder interests is required.
	b) Policy institutions	i) The policy question does not fall under the mandate of existing institutions	Futures research	Integrated care (as it is seldom included under the mandate of a specific policy institution [158]).
		ii) Past decisions and/or institutional mandates impede the policy process or implementation	Roadmap for change and reflexivity	Disinvestment from low value care (as it may be difficult due to past introduction decisions or limited institutional power or knowledge to affect change [159]).
3. Evidence for decision-making	a) Knowledge of cause-effect relationships	i) Goals, causal links, and uncertainty ranges can be defined (from one or multiple perspectives)	Optimisation	Optimisation to design multi-component health programmes or to define optimal sequencing for recommended clinical pathways.

		ii) Missing links or data in causal relationships in the system, requiring inference	Bayesian networks	To update knowledge about comorbidities and risk factors for different populations in national registries and databases, for precision medicine [160]
		iii) Causal relationships are poorly understood	Adaptive management	Local authority plans to improve healthcare utilisation in disadvantaged groups (as groups perceived to be disadvantaged and context-specific factors influencing healthcare utilisation are likely to be multi-dimensional and changing over time).
		iv) Uncertainty in the data or model structure affects the best policy option	Quantitative value of information	Managed entry agreements for high-cost technologies with limited evidence [114]
	b) Type of evidence	i) Multi-disciplinary evidence is being used for policymaking	SDM	Health promotion interventions or psychosocial interventions relying on qualitative evidence and an understanding of context [60].
	c) Resource constraints	i) Constrained resources to collect evidence across multiple criteria	Consequence table	A tool for the secretariat or working group tasked with prioritising and commissioning evidence as part of the policy process.
		ii) Constrained resources to collect evidence for a decision-analytic model	Qualitative value of information	To prioritise evidence collection for decision analytic models in the context of limited time or funding.
	<b>For governance</b>			

Policy questions addressed by a policy institution show high variability in level of contention, decision stakes, and/or available knowledge	Stakeholder analysis	HTA processes with a broad mandate (e.g. to define the full set of preventive and curative interventions across all public health insurance schemes).
Governance arrangements are unfit to handle a type of policy question that regularly comes up, or the mandate of a policy institution changes over time, and governance can be modified on an ongoing basis	Adaptive governance	HTA agencies with a mandate that expands from medicines to health promotion and medical devices.
Governance arrangements are unfit to handle a type of policy question that regularly comes up, or the mandate of a policy institution changes over time, but governance cannot be changed	Transformation	Policy context dependent.

HTA – health technology assessment, SDM – structured decision-making

## Appraisal of included frameworks

An appraisal of included frameworks is provided in **Table 2.4**. Internal validity of frameworks was generally good, with the majority being consistent with the defined aims and worldview of the article. Of the frameworks with lower internal validity, two articles discussed representational uncertainty in the goals but the framework only addressed data uncertainty [143, 154], one framework addressed representational uncertainty quantitatively (ignoring social learning) [27], and one had poorly defined aims [151]. For construct validity, all frameworks were relevant to policymakers and had a theoretical basis. Five frameworks were developed by practitioners to synthesise their expert experience [144, 148, 150, 153, 161] and four were either developed or revised in response to feedback or piloting with the end-user [145, 162–164]. For applicability, all frameworks could be applied to a broad range of policy questions but very few either explicitly accounted for institutional constraints [28, 144, 146, 152, 164, 165] or were developed within the bounds of existing institutions (but therefore with limited transferability to other settings) [145, 163]. Only three studies had been evaluated for useability [144, 152, 153], with all having received a positive response from users [144, 153, 166].

Evidence on effective use in policy was only found for four frameworks. The structured decision-making framework from Gregory et al [148] has been adopted for decision-making by the St’at’imc Nation [167], the New York State Department of Environmental Conservation [168], and for the policy on climate change in Louisiana [169]. For the framework on multi-jurisdictional resource allocation from Mattsson et al, the final recommendation was implemented in one of the case studies but not the other [144]. Although officially required, the guidance to assess and communicate uncertainties developed by the National Institute for Public Health and the Environment [163] was only partially adhered to six years after its introduction [170, 171]. The dynamic adaptive policies framework from Haasnoot et al [172] has been adopted for flood risk management by regional councils in New Zealand [173, 174].

**Table 2.4** Quality of included frameworks, according to the appraisal criteria in Table S2.1.

Author, year	1) Internal validity	2) Construct validity	3) Applicability	4) Effective use in policy formulation
Bond, 2015 [149]	●●●	●●	●	NI
Canessa, 2016 [15]	●●●	●●	●	NI
Cardenas, 2016 [16]	●	●●	●	NI
Castrejon-Campos, 2020 [17]	●●●	●●	●	NI
Conroy, 2011 [154]	●	●●	●	NI
Dandy, 2019 [175]	●●●	●●	●	NI
Furlong, 2016 [164]	●●●	●●●	●●	NI
Giupponi, 2022 [176]	●●●	●●	●	NI
Gregory, 2012 [148]	●●●	●●●	●	●●●
Haasnoot, 2013 [172]	●●●	●●	●	●●●
Halbe, 2019 [165]	●●●	●●	●●	NI
Herman, 2014 [147]	●●●	●●	●	NI
Janssen, 2005 [163] Petersen, 2013 [177]	●●●	●●●	●●	●●
Keller, 2021 [151]	●	●●	●	NI
Kingsborough, 2016 [178]	●●●	●●	●	NI
Klauer, 2006 [162]	●●●	●●●	●	NI
Lempert, 2021 [27]	●●	●●	●	NI
Lilburne, 2022 [145]	●●●	●●●	●●	NI
Mattsson, 2019 [144]	●●●	●●●	●●●	●●
Miller, 2022 [153]	●●●	●●●	●●	NI
Moser, 2010 [152]	●●●	●●	●●●	NI
Ridgley, 2000 [146]	●●●	●●	●●	NI
Stahl, 2013 [150]	●●●	●●●	●	NI
Warmink, 2017 [28]	●●●	●●	●●	NI
Williams, 2018 [161]	●●●	●●●	●	NI

●●● the criterion was fully met, ●● the criterion was partially met, ● the criterion was mostly not addressed, NI = no information

We found that frameworks were often influenced by discipline. For example, adaptive management, structured decision-making, and Bayesian networks were commonly combined in environmental management and conservation articles [143, 144, 148, 150]. Similarly, all frameworks in the review applied futures thinking for policy questions with long lead times and low flexibility, but did not include other types of policy question addressed by futures research (refer to **Table 2.3**) [107, 158, 179, 180]. This supports previous findings that selection of methods may largely be influenced by institutional legacy [181], but none of the frameworks included a reflexive account of the role of institutional legacy in framework development.

In summary, although the review identified many approaches that could broaden the disciplinary view of policymaking under uncertainty in HTA, findings are based on frameworks that are largely untested and mostly adhere to prevailing disciplinary views.

## **5. APPLICABILITY OF FINDINGS FROM THE REVIEW TO HTA**

In this section, we apply findings from the review to the three examples set out in the introduction for which current approaches to policymaking under uncertainty in HTA are insufficient: accounting for local production risk in technology introduction decisions, policies to reduce unnecessary caesarean section, and effectively incorporating patient voice in decision-making. For each example, we identify relevant approaches from the review and compare them with standard practice in HTA to identify whether the approaches could enhance current approaches for policymaking under uncertainty.

### **1) Local manufacturing capacity and benefit package decisions**

Building local manufacturing capacity of healthcare commodities, particularly in low- and middle-income countries, has the potential to strengthen government negotiation power with foreign manufacturers and to improve supply sustainability of products [182, 183]. However, it may require government policies to favour locally manufactured products – even if sub-standard – for sustained investment until a company becomes sufficiently competitive to sell products internationally [184]. Within the context of healthcare, this can introduce tension between a benefit package that optimises population health with one that emphasises the potential for long-term price reductions and sustainable access from supporting local manufacturing capacity. Practically, committees

evaluating a locally manufactured product may be unsure of the result of their deliberations on future manufacturing capacity of the country (for example, the maternal acellular pertussis vaccine in Thailand [185]).

In HTA, considerations around the impact on local manufacture would typically be included in policy committee deliberations to come to a recommendation. Methods are under development to estimate the shared value of new products for government and manufacturers [115], but do not account for external sources of uncertainty (such as ability of local manufacturers to access loans or the market landscape) or divergent stakeholder views around the implications for the local manufacturer of a negative decision.

Results from this review suggest that the following approaches may be appropriate for considering impact of benefit package policies on local manufacture.

- *Scenario thinking (futures science) and robust decision rules*: in many countries, collapse of a local producer could have potentially long-term consequences for building manufacturing capacity, and the factors affecting local producer strategy will depend on many external factors as well as the reaction of many stakeholders to policy decisions (e.g. private sector healthcare providers, investors, government research institutes). Scenario thinking promotes an understanding of the future context and potential implications of a policy, while robust decision rules can optimise the chosen policy to account for this future uncertainty.
- *Adaptive governance*: in most settings, the role of benefit package committees in accounting for local research and development (if any) is not well articulated. Adaptive governance would promote learning to update institutional mandates and procedures over time to reach an appropriate institutional arrangement.

Compared with HTA practice, these approaches would articulate the range of potential impacts of a policy option (scenario thinking), optimise the policy to be robust to a range of potential futures (robust decision rules), and remove institutional uncertainty progressively across decisions by optimising governance arrangements (adaptive governance).

## 2) Reducing rates of unnecessary caesarean section

Many countries have been facing increasing rates of caesarean section, driven by a range of behavioural, psychosocial, health system, and financial factors [111]. Unnecessary caesarean

section is not only expensive for health systems but can also lead to adverse health for the mother and child [186]. Policies to reduce unnecessary caesarean section have shown mixed results [187–189]. Not only are results inconsistent, but often they are contradictory to the proposed policy mechanism of action [187, 188], with evidence that policy success is highly dependent on the socio-institutional context and local market dynamics [110, 190].

While well-suited for evaluating the efficacy and cost-effectiveness of well-defined technologies in stable contexts, traditional HTA methodologies struggle to address complex health system issues [102]. For example, problems like unnecessary caesarean sections - driven by a mix of behavioural, social, and economic factors in dynamic, context-dependent environments [110] - fall outside the core strengths of conventional HTA approaches.

Results from this review suggest that the following approaches may be appropriate for identifying policies to reduce unnecessary caesarean sections.

- *System dynamics*: Evidence suggests that childbirth programmes are characterised by feedback loops that further incentivise or disincentivise caesarean section, which cross the boundaries of multiple systems, including medical profession hierarchies, payment systems of insurance agencies, patient perceptions and religious beliefs, administration systems for public hospitals, and market forces for private service providers [105, 110, 190, 191]. System dynamics could capture context-specific feedback within the system to account for unintended consequences of policy intervention.
- *Scenario thinking*: A policy to reduce caesarean section rates would likely require behaviour change across a number of stakeholders with different financial and non-financial motives, including medical professionals, hospital administrators, and mothers. Applying the critical scenario methods from futures research can anticipate the range of potential responses from different actors and surface motivations, to identify policies that effectively address the motives influencing behaviour.
- *Adaptive management*: It is possible that even at a sub-national level, the factors affecting unnecessary caesarean section vary due to local administration, culture, and market forces. In this case, continued, iterative learning from the success of policies at the local level through an adaptive management approach may support the development of tailored sub-national plans to meet policy goals.



Taken together, an approach that incorporates system dynamics, scenario thinking, and adaptive management could promote a stronger understanding of the socio-technical drivers causing behaviour and system performance in the specific country context, to identify more appropriate policies.

### 3) Effectively incorporating patient voice in policymaking institutions

HTA agencies are increasingly moving towards participatory processes that involve interested parties, patients, and the public alongside policymakers and technical experts [192, 193]. One of the major issues being faced is how to effectively incorporate this broader perspective around what constitutes evidence alongside traditional values of scientific and ethical rigour within policy processes [51, 194], with evidence that the research philosophy of HTA practitioners may be blocking effective patient engagement in policy, as patient lived experience is not valued to the same level as clinical or economic evidence [195].

Three approaches from this study could potentially address this issue.

- *Structured decision making*: Different participants in the policy process have different worldviews, which can shape how they frame the problem and perceive the importance of different stakeholders or evidence. For policies that are made with patient input, structured decision making could facilitate joint learning to come to a shared understanding between technical experts, policymakers, and patients, in order to overcome disagreement around what constitutes a “right” policy process or decision.
- *Futures science*: At a strategic level, efforts to normalise patient engagement in policymaking will need to account for the reactions of different stakeholders within and outside of the process to stakeholder engagement mechanisms (for example, perceived legitimacy of decisions by clinicians and the public, engagement from diverse patient groups, private company strategies to lobby via patient groups). Since the aim is to modify stakeholder interactions in a context of multiple interests and worldviews, applying back-casting approaches from futures research may support the identification of a strategy to successfully engage patients over time that accounts for unknown reactions of other stakeholders, in a process that facilitates joint learning.

- *Adaptive governance*: Since institutional arrangements are not currently fit-for-purpose and may need to continuously be adapted with experience and learning [196], adopting an adaptive governance approach could support learning to identify appropriate governance over time.

Taken together, these approaches could help to move towards a culture of joint learning between stakeholders in the HTA ecosystem to improve processes for patient engagement over time. The key difference with conventional techniques in HTA that rely on good practice from other settings is that there are explicit steps to account for the local context and the approaches institutionalise patient engagement through social norms as opposed to bureaucratic documents and procedures, which are often less effective [25, 31].

## **6. DISCUSSION: INTEGRATING SOCIAL SCIENCE APPROACHES FOR POLICYMAKING UNDER UNCERTAINTY WITHIN HTA**

In this review, we showed that HTA currently takes a limited account of social science conceptualisations of policymaking under uncertainty, which can constrain the view of how policies may perform, especially for policies that influence behaviour, cross jurisdictions, or deal with multiple vested interests. Our findings highlight the benefit of a flexible interdisciplinary toolkit that can be adapted to the needs of the policy question, which is in line with empirical evidence that decision-making strategies are most effective if they align with the task and environment [197].

Mainstreaming a broader view of policymaking under uncertainty within HTA, however, will require more than simply mapping approaches. Uptake of techniques to facilitate an interdisciplinary view of uncertainty will require capacity building to effectively identify the need for and to implement new techniques [198]. It will also require training on the underlying philosophy of social science tools, alignment with current HTA practice, increased resources, and more flexible timelines for the policy process. All approaches identified in this review have already been applied to some extent in healthcare policy research but have not yet been institutionalised, which may be because they do not align with the dominant patterns for decision-making [199]. Furthermore, the philosophical perspectives of study authors in the review shaped how approaches were implemented. This suggests that an interdisciplinary toolkit in itself will be insufficient if the chosen technique is adopted with a positivist mindset. Successful adoption will require adapting new approaches to accepted standards within HTA, whilst maintaining the fundamental principles of the method. In

other fields, adapting governance structures and organisational culture to facilitate social learning, long-term decision making, and cross-jurisdictional cooperation (among others) were found to determine successful adoption of approaches with a social science conceptualisation of uncertainty into technical science domains [179, 200, 201].

This study has highlighted two main areas for further research: (1) increasing our understanding of the benefit of applying a multi-disciplinary approach in different decision contexts, and (2) developing tools to facilitate the integration of interdisciplinary approaches in HTA. We recommend drawing on the principles from evidence-based medicine and implementation science to conduct empirical studies that show the impact of interdisciplinary approaches to decision-making, context and situation-specific effectiveness studies, and studies on barriers and facilitators to adoption. This will not only increase the legitimacy of applying an interdisciplinary toolkit for HTA practitioners but also highlight when and how such a toolkit should be implemented. In practice, few policymaking bodies or secretariats have access to the resources or the flexibility in governance to adopt a flexible multi-disciplinary approach. It is therefore important to understand the situations in which the procedural uncertainty from applying established but inappropriate approaches to policymaking is acceptable, compared to when the time, effort, and resources to broaden the toolkit for policymaking under uncertainty, alongside governance mechanisms to institutionalise use of the toolkit, are justified. To operationalise an interdisciplinary toolkit, we also recommend the development of guidelines and checklists (as is current practice in HTA) to facilitate the uptake of different approaches among the HTA community.

One of the main limitations from our review is that the frameworks identified came from a relatively narrow range of disciplines, predominantly related to environmental science. This suggests that our search strategy may have been biased towards how policymaking under uncertainty is conceptualised within environmental science. The frameworks did, however, cover a wide range of policy questions, research philosophies, and conceptualisations of uncertainty. Another limitation was the lack of structured evaluation of frameworks. Our findings are in line with a previous review on decision-making under deep uncertainty [202] and with HTA practice [130], and highlight the need for established frameworks to appraise frameworks for policymaking, as well as evaluation of any proposed framework for policymaking. Finally, our review was based on academic articles and government guidelines. As noted above, written documents and toolkits in themselves are often

insufficient to change the dominant patterns of decision-making and require concurrent social learning for stakeholders in the policy system to adapt and adopt new ways of thinking [25].

In conclusion, we have illustrated the benefit of adopting a multi-disciplinary approach to policymaking under uncertainty in HTA and suggested some avenues to explore for future research. Although this review only represents a preliminary map of multi-disciplinary approaches, our hope is that it can provide a starting point for future work.

## SUMMARY

In this chapter, we addressed **Research question 1** by evaluating the extent to which HTA takes a multi-disciplinary approach to policymaking under uncertainty. We identified gaps in accommodating perspectives from the social sciences that may be relevant for policy questions with cross-boundary impact or requiring an understanding of stakeholder motivations. We partly addressed **Research question 2** by mapping approaches from other disciplines and features of the decision problem for which these approaches may be appropriate. In the next chapter, we build on the results from this study to develop a framework for HTA practitioners to identify when current HTA practice may be insufficient and which alternative approaches could be applied.

# Chapter 3 Multi-disciplinary framework for policymaking under uncertainty

## OVERVIEW

In this chapter, we describe a multi-disciplinary framework for policymaking under uncertainty, based on results from the interdisciplinary review (**Chapter 2**), and we outline the methodology for evaluating the framework. We first discuss how the framework was developed from the interdisciplinary review finding and describe the components of the framework, before discussing the rationale for selecting an action research approach, evaluation methods, and selection of the case study.

## PURPOSE OF THE FRAMEWORK

The framework has been developed to highlight when standard HTA practice may not sufficiently capture considerations from the social sciences for policymaking under uncertainty. It is intended to be applied by members of an HTA agency or policymaking secretariat, to identify when it may be appropriate to consider alternative approaches, dependent on available capacity, time, and resources. Since the framework is intended to be a diagnostic tool, we do not include operationalisation aspects such as capacity building and integration with existing processes. These are instead considered to be part of the implementation strategy and explored in **Chapter 7**.

The framework is directly based on **Table 2.3** of the interdisciplinary review in **Chapter 2**. To develop the framework, we removed techniques already used in HTA (e.g. quantitative value of information) and revised the organisation/framing of approaches such that a social science lens is always taken (for example, we replaced Bayesian networks and optimisation approaches with cultural prototypes). A full list of changes is provided in **Supplement 3**.

## FRAMEWORK COMPONENTS

This section describes the components of the framework for policymaking under uncertainty, presented in **Table 3.1**. The framework is divided into two sections: considerations for individual

policy questions and considerations for the broader governance of a policy process. For each, the framework lists features of the policy question or governance that may warrant departure from standard HTA approaches. It is not intended to be an exhaustive list, but rather an indicator of when approaches that account for social science perspectives could benefit policy.

**Table 3.1** Summary of the framework for policymaking under uncertainty.

Element		Feature	Approach
<b>For individual policy questions</b>			
<b>1. Decision question</b>	a) Nature of the problem	i) The policy problem, goals, or process is unclear or contested	Soft problem structuring
		ii) Crosses system boundaries, feedback, and/or unintended consequences	System dynamics
		iii) Cross-jurisdictional decision-making or implementation	SDM
	b) Policy goals	i) To change attitudes or behaviour	Futures research
		ii) To account for high impact, low probability events	Futures research
	c) Time horizon	i) Long timeline for policy implementation and/or reversal	Futures research
<b>2. Decision context</b>	a) Stakeholder interests	i) High level of disagreement on important criteria, reliable evidence, or future states	Robust decision rules
		ii) Strong vested interests across multiple stakeholder groups	Scenario thinking (futures)
	b) Policy institutions	i) The policy question does not fall under the mandate of existing institutions	Futures research
		ii) Past decisions or institutional mandates impede policymaking or implementation	Roadmap for change and reflexivity

	c) Urgency	i) Emergency context with insufficient time for stakeholder engagement	Cultural prototypes
3. Evidence	a) Type of evidence for policymaking	i) Multi-disciplinary	SDM
		ii) Complex causal relationships, that cannot be understood ex-ante	Adaptive management
	b) Limited resources for data collection	i) Across multiple criteria	Consequence table
		ii) For a decision-analytic model	Qualitative value of information
For governance			
4. Institution	a) Varied policy questions	i) Dissensus, decision stakes, and/or available knowledge vary across policies	Stakeholder analysis
	b) Unfit governance arrangements	i) Governance can be modified on an ongoing basis	Adaptive governance
		ii) Governance cannot be changed on an ongoing basis	Transformation

#### For individual policy questions

The first part of the framework covers individual policy questions and is intended to be used when a policy problem or question has been assigned to the HTA agency or policy secretariat. It covers considerations related to the decision question, context, and evidence for decision-making. The reference in brackets for each feature of the policy problem below refers to **Table 3.1**.

**Unclear policy problem (1/a/i).** Current HTA approaches are set up to evaluate specific technologies and may therefore struggle to address situations in which potential policy interventions need to be identified. Although literature reviews may identify successful approaches in other settings, they do not account for local context or divergent stakeholder perceptions around what the problem is or how it should be addressed.

For situations in which the policy problem, goals, or process is unclear, soft problem structuring methods can frame the problem, capturing multiple stakeholder perspectives, and articulate an appropriate process to follow for decision-making [203]. Soft problem structuring methods address

uncertainty arising from different stakeholder perceptions of both the problem and the elements of the problem that are controllable. For example, soft problem structuring may be applicable for policies to reduce neonatal mortality rates in countries with fragmented governance for maternal and child health, or for policies to improve healthcare outcomes among marginalised groups.

**Cross-jurisdictional policy problem (1/a/ii).** Many policy questions are not under the mandate of a single agency and require joint decision-making or cooperation with other agencies for implementation. Within health, cross-jurisdictional issues may relate to geographic jurisdictions (for example, provision of health to temporary migrants or nomadic groups in border areas [204]), administrative levels (for example, local authorities and the national health service [205]), or government agencies (for example, addressing child health may require cooperation across ministries of health, education, youth, housing, labour, and immigration, among others [127]). Different jurisdictions may have different formal and informal rules governing how policy problems are perceived and addressed [34], which can make cross-jurisdictional policy difficult [144]. A common way of making cross-jurisdictional policies is by establishing institutions to coordinate between policy bodies [34], but in many cases, no such institution may exist.

When there is no existing mechanism for cross-jurisdictional collaboration, structured decision-making approaches can facilitate joint learning through cyclical discussion and reflection, to bring stakeholders to a common understanding of the policy problem and possible approaches to address it [148, 169]. This manages uncertainty arising from different institutional views of the policy problem between policymaking bodies or between policymakers and implementers.

**Policy problem crosses system boundaries (1/a/iii).** HTA deals with both complex interventions made up of multiple components and complex systems, which are characterised by adaptation to changes in the environment, non-linear behaviour, and interaction with other systems [103]. While traditional HTA methods are able to address policy questions on complex interventions, they are poorly suited to policy questions that involve complex systems, such as healthcare organisation or healthcare promotion, as conventional HTA evaluations do not account for interactions with the broader system and may therefore lead to policies with limited impact or averse unintended consequences [102, 103].

System dynamics surfaces and maps cause-effect relationships across technical and social spheres, in order to promote an understanding of the system level impact over time [106]. Policy



questions that show evidence of crossing system boundaries, unintended consequences, or feedback are likely to involve complex systems and would benefit from a system dynamics approach. Examples include policies regarding informed patient choice, which may cross system boundaries of patient cultural beliefs, medical professional education, quality assurance regulations, and incentives for service providers, among others; those for which past policies have unintentionally exacerbated the problem, such as investment in health and social care in the UK [104, 126]; and health promotion policies in which the intervention seeks to reinforce healthy behaviour or break a “vicious cycle” of harmful behaviour [206]. System dynamics reduces uncertainty around the impact of policies by systematically mapping causal relationships from the perspective of multiple stakeholders that “see” different parts of the problem.

**Policy aims to change behaviour (1/b/i).** Standard HTA practice projects future conditions from current trends and is poorly able to account for external, uncontrollable factors that may shape future healthcare systems [108]. For policies that either aim to influence behaviour or depend on social interactions, the level of impact from clinical trials only shows effectiveness in a specific time-bound context, which may not be representative of the future in which the policy will operate [107].

Futures research represents a set of methods that constructs images of the future, to gain an understanding of the future environment for policymaking [207]. It addresses uncertainty in future conditions and policy implementation by building an understanding of how external, uncontrollable factors may shape the policy landscape and how the responses of various stakeholders may affect policy impact [30, 207]. It may be appropriate, for example, for policies aiming to influence service utilisation, to evaluate psychosocial interventions (for example, social networking interventions to treat mental health and substance abuse), or market shaping strategies to influence the research and development agenda of manufacturers.

**Policy aims to account for high impact, low probability events (1/b/ii).** Predictive models for HTA are ill-suited to account for high impact, low probability events, such as pandemics, natural disasters, economic collapse, or conflict [108]. Balancing the allocation of resources between routine healthcare provision and measures to increase resilience of the health system to future shocks, however, requires an understanding of what these future shocks may be and the causal relationships underlying them [30, 208].

Futures research provides a structured way to understand how and why future shocks may arise, in order to improve policymaking [209, 210]. It aims to overcome cognitive biases that prevent people from accounting for low probability, high impact events [208]. Within HTA, this may be applicable for identifying strategies to build health system resilience to future shocks that represent good value for money.

**Long timelines (1/c/i).** HTA methods tend to project policy performance based on past trends and current conditions [19, 22]. Whilst this may be acceptable for policies that are flexible to adaptation, such as reimbursement of technologies with a rapid rate of advancement or price negotiation with manufacturers for single year contracts, it may poorly represent the future conditions for policies that have a long time horizon for implementation or reversal, such as healthcare infrastructure or workforce planning [158, 211].

Futures research, as described above, is a structured approach for exploring multiple plausible futures, in order to evaluate the extent to which policy performance may depend on future conditions [30]. It is appropriate for policies with long time horizons that are difficult to change because it accounts for uncertainty in the external environment that can affect policy impact.

**Stakeholder dissensus (2/a/i).** Standard HTA approaches follow optimisation decision rules based on subjective utility [131]. Utility-based decision rules are suitable when cause-effect relationships and uncertainty are well-characterised, but not when stakeholders have different policy goals, prioritise different types of evidence, or hold different values [212]. In HTA, there may be highly contested policies, such as high-cost orphan drugs [213], for which the underlying values of different stakeholder groups cannot be averaged to come to an acceptable agreement. In certain instances, applying utility-based decision rules may jeopardise the ability to take a decision (in governance systems founded on consensus) or implementation of the policy (when key implementation stakeholders oppose the policy).

Robust decision rules prioritise policies that perform at an acceptable level across multiple plausible futures and/or worldviews [214]. They have been successfully applied for issues with high stakeholder dissensus, such as climate change policy in the US [215], as they do not require stakeholders to come an agreement on values, future states of the world, or important evidence, but rather seek to find policies that perform well according to the worldviews of each stakeholder group. In HTA, this approach may be particularly relevant for instances in which the moral values of a health

system are at odds with the social values of the public or other stakeholders engaged in the policy process, such as provision of care to prisoners, drug addicts, illegal immigrants, or other marginalised groups [100]. It represents a structured approach to address uncertainty arising from different worldviews.

**Multiple vested interests (2/a/ii).** Within HTA, the process for evidence generation and policymaking are often meant to be independent and free from conflicts of interest [216, 217]. There is a risk, however, that policies made without an understanding of the underlying motives driving stakeholder behaviour will not achieve the intended impact [179, 215]. Understanding the motivations of public and private sector service providers may lead to more effective control of cost, service quality, and equitable access to healthcare services, for example [129, 218, 219].

Scenario thinking, a branch of futures research that emphasises a multi-dimensional view of impact and the role of stakeholders in shaping the future [220], can surface and identify the influence of stakeholder interests on policy, particularly when coupled with the critical scenario method [30, 221]. It therefore addresses uncertainty in stakeholder reactions to policy that may support or impede the achievement of policy goals.

**No institutional mandate (2/b/i).** Policy institutions, representing the set of formal and informal rules by which policies are made, define the mandate of different policy bodies, their level of authority, and the principles by which decisions are made and implemented [25, 26, 34]. In this way, uncertainty in the normative standards for policymaking is reduced [26]. For policy problems that do not fit under the mandate of an established policy institution, however, there may be lack of continuity in terms of who is tasked with the decision, the rules underlying how the decision was made, and how the decision is implemented. HTA relies on the establishment of institutions for decision-making and is therefore ill-equipped to address policy questions that fall through the gaps of institutional mandates.

Applying futures research for policy questions that do not fit under a specific institutional mandate, such as integrated care, can account for this institutional uncertainty by exploring different future conditions, reactions of different actors, and the range of possible policy impacts with future changes in institutional mandates [158].

**Spatial or temporal jurisdiction impedes policy making or implementation (2/b/ii).** Although institutions can reduce uncertainty by setting up defined procedures [26, 152], the legacy of past

decisions of an institution or institutional mandates may impede the policy process itself or policy implementation [152]. In HTA, this is commonly addressed by constraining the problem space to only include policy interventions for which it is perceived that change is possible. This approach may, however, remove certain high impact options from policy discussions.

Unlike other points in the framework, no accepted practice exists to address this issue, but it has been proposed that an analysis of issues related to the temporal jurisdiction (legacy of past decisions) and spatial jurisdiction (mandates of different agencies) can be used to develop a roadmap, which can be modified over time with reflexivity and learning [152]. Examples of when this may be relevant include value-based pricing in settings with procurement laws set by higher level institutions (which may specify, for example, tendering procedures or use of external reference pricing) or developing a neonatal benefits package for fragmented health programmes and insurance schemes in a country managed across different government ministries and funded through a combination of domestic funding and international donors.

**Urgency of the decision (2/c/i).** Good HTA practice is based on evidence-informed deliberative processes, which engage stakeholders in a dialogue to interpret the evidence to come to a recommendation [96]. However, for urgent decisions, such as emergency contexts, there may be insufficient time for extensive stakeholder engagement, introducing uncertainty in how the decision-maker will interpret evidence and perceived stakeholder pressures to make a decision [131, 201].

In cultural theory, different worldviews across and within a society are conceptualised as a series of prototypes or dimensions, such as level of social cohesion and level of bureaucracy [11]. Applying these prototypes can provide a high-level view of different perspectives of uncertainty and impact that may exist in a society, which can support the identification of policies that are acceptable across members of society, either when analysed qualitatively or when coupled with optimisation algorithms [27].

**Multi-disciplinary evidence (3/a/i).** What constitutes rigorous, high-quality evidence, and perceptions around how evidence-informed policies should be made, differs across disciplines [13]. HTA has been criticised for failing to effectively incorporate perspectives from the social sciences, due to the predominantly positivist mindset of stakeholders involved in the decision process [51, 60, 78, 81].

Structured decision making incorporates social learning for stakeholders to come to a shared understanding [148]. It therefore overcomes uncertainty in whether and how multi-disciplinary evidence will be used, by aligning stakeholders from different disciplines on the scope of the problem, the evidence required, quality standards for that evidence, and how the evidence will inform the recommendation.

**Complex and poorly understood causal relationships (3/a/ii).** The Cynefin framework distinguishes between routine, well understood problems (obvious); problems for which cause-effect relationships are not well understood but can be analysed (complicated); problems that can only be understood by analysing the response to action (complex); and problems for which the cause-effect relationships are not knowable (chaotic) [18]. HTA generally considers problems to be complicated and able to be evaluated ex-ante. However, in certain cases, ongoing learning during policy implementation maybe required to address complex problems. Within health policy, this may be addressed through phased introduction or demonstration projects [222], managed entry agreements with mandatory post-introduction data collection [112–114], or implementation science studies to facilitate implementation of effective approaches [223]. In practice, however, the cyclical link between implementation, learning, and policy adjustment, is seldom present [224, 225].

Adaptive management is a structured approach from the environmental sciences that explicitly incorporates learning in policymaking, in order to inform data collection and to improve the policy process to better address the problem (for example, learning that additional criteria or different stakeholders should be included for decision-making) [161, 226]. It progressively addresses uncertainty over time by adjusting the policy, learning agenda, and policy process with ongoing learning following policy implementation [28, 161, 167].

**Constrained resources for evidence collection (3/b).** Policymaking bodies seldom have access to the human resources, timelines, and budget required to collect the desired evidence for a particular model or set of criteria. Established methods for sensitivity analysis and value of information can identify the importance or missing or low-quality data after decision-analytic model has been developed [19, 22], but data collection during modelling is largely dependent on judgement calls from the analyst and/or policy secretariat [50].

Consequence tables – a soft problem structuring tool – can provide a preliminary view of available evidence across criteria, thereby identifying which evidence is most likely to influence the final

decision, to prioritise data collection [148]. For decision-analytic models, qualitative value of information methods (proposed in the environmental sciences field but still under development) may support a structured approach to prioritising when additional effort should be invested to obtain evidence that is better quality or more representative [227]. These two approaches reduce procedural uncertainty, in which the evidence collected varies dependent on analyst perceptions of the problem.

#### For governance

The governance component of the framework relates to the processes, structures, and institutions that oversee and manage healthcare policymaking. In the framework, there are three main considerations related to governance: (1) the mandate of the policy institution, (2) alignment between existing governance arrangements and the policy questions addressed, and (3) the ability to affect change.

**Mandate of the policy institution (4/a/i).** Standard practice in HTA follows the same principles for stakeholder engagement for each question. However, this may lead to insufficient engagement of affected parties and interest groups for certain questions, whilst creating a burden on limited policy resources for relatively straightforward questions that are technical in nature [130, 228].

For policy institutions with a broad mandate covering policy questions with different levels of public scrutiny and dissensus, stakeholder analysis can identify the perspectives and influence of different stakeholders, in order to tailor the depth and breadth of stakeholder engagement for a given policy [163, 229]. Many policy bodies responsible for drug listing decisions likely fall into this category, as the same committee may be responsible for approving minor packaging revisions as well as reimbursement decisions for high price medicines with extensive media coverage, political pressure, or lobbying from interest groups. Stakeholder analysis can reveal the hidden agendas and motives of different stakeholder groups, leading to more practical policies with less uncertainty around whether and how they will be implemented.

**Suitability of governance arrangements and ability to effect change (4/b).** The mandate of policy institutions can change over time [31]. For example, there may be a change in the types of policy questions addressed, the jurisdictions affected by recommendations (for example, if a committee's remit expands from recommendations to the health insurance agency to also include the public

health agency), or changes from higher level institutions (e.g. level of decentralisation). In HTA, good practice exists for establishing appropriate governance, with recognition that it should be updated (for example [79, 128]), but there is no structured way of doing so and experience suggests that this may, at times, worsen governance as opposed to improving it [130].

In the framework, two approaches are highlighted: adaptive governance if there is the authority and capacity to change governance, and transformation pathways if there is not the ability to effect change. Adaptive governance is an approach that adjusts governance based on iterative learning [230]. It would be appropriate, for example, if the remit of a policy body expands from benefit package decisions to also include evaluation of public health programmes, and the secretariat is able to adjust the evidence requirements, composition of the committee, and steps of the policy process accordingly. If instead multiple institutions need to change accepted ways of making policy, a transformation pathway may be required [165]. Both adaptive governance and transformation pathways aim to reduce uncertainty by aligning policy goals, estimations of impact in the policy process, and impact following implementation.

## **METHODOLOGY TO EVALUATE THE FRAMEWORK**

We selected an action research approach to evaluate the framework. Action research aims to improve practice within a specific context through a cyclical process of evaluation, critical reflection, and change in practice [231]. Action research is not intended to provide generalisable results but rather seeks to understand the complex social context of an intervention and engages in joint learning with practitioners, to identify practical solutions [231–233]. It is therefore relevant for evaluating and integrating improvements to policymaking practice, as the people responsible for overseeing and managing the policy process on a day-to-day basis learn about the new approaches being implemented and use their expertise to identify context-specific adaptations [231, 232]. It aligns with the principles of critical realism as it explicitly recognises the role of social learning in understanding the causal factors influencing change and seeks to use research as a means for positive social change [234].

Within the action research approach, we applied an implementation science framework as a structured, context-specific way by which to evaluate whether an intervention works and how to integrate it into practice. Implementation science aims to improve the quality and effectiveness of

health services by studying methods to promote systematic uptake and routine implementation of evidence-based practices [23]. From this perspective, strategies to improve policymaking practice can be considered as an innovation for implementation. In this study, the innovation was the framework in **Table 3.1**.

Since this study was a preliminary test of the framework in the Thai context, we trialled the framework for a single policy question (the case study detailed below).

### Case study

We applied the framework in **Table 3.1** within the HTA agency in Thailand, to evaluate the extent to which the framework can improve policymaking under uncertainty, and to identify barriers or facilitators associated with its use (further details in **Chapter 7**).

HTA institutions in Thailand align well with the current HTA practice outlined in **Table 2.1** of the interdisciplinary review. Technical science conceptualisations of policymaking under uncertainty form the basis of effectiveness, safety, and budget impact data, with decision analytic models based on economics used to compare effectiveness of policies with high budget impact [235]. Multi-decision criteria analysis is used as part of the topic nomination process [236, 237], but the criteria are determined by operational guidelines and therefore may not capture the full set of criteria that are important to individuals. The HTA methods guide and operational guidelines of policy bodies adhere to the principles of critical theory, by setting methodological standards and following a consistent process for policymaking.

Since HTA in Thailand aligns closely with the global standards for HTA, we did not make any modifications to the framework before applying it to the case study.

### *Rationale for selecting kidney replacement therapy (KRT)*

To pilot the framework, we selected a policy question for which using the framework in a one-off trial was possible and for which the framework was likely to bring added value. Our criteria were as follows:

- there was recognition at the outset that current HTA approaches were not suitable,



- the policy did not fall under the mandate of existing institutions (which have to adhere to operational and methodological guidelines),
- there was available and flexible funding to support the policy process and evidence generation,
- our research group had the mandate to support the policy process, and
- we were able to receive approval from the Chair of the policy process to apply the framework.

The 2024 review of the kidney replacement therapy (KRT) policy in Thailand met our criteria. Since the policy process was not a technology reimbursement decision, it was not addressed through institutionalised benefit package processes, and there was a recognition that standard approaches for HTA in Thailand were not well-equipped to address the social dimensions of the policy question, including factors affecting patient choice and implications of financial incentives on doctor behaviour [238]. Members of our research team were members of the secretariat for the policymaking process, we had flexible research funding available to support evidence generation, and the proposed approaches from the framework aligned well with the Chair's plan for addressing the policy problem.

#### *Scope of the case study*

We identified the following approaches that could supplement standard HTA practice for the KRT case study (**Table 3.2**): scenario thinking (from futures research), system dynamics, and structured decision-making. These approaches were identified as able to accommodate feedback across system and jurisdictional boundaries, path dependency that may shape future policy options, strong vested stakeholder interests, lack of institutional mandate to address the policy question, an aim to change stakeholder behaviour, and use of multi-disciplinary evidence.

We shortlisted scenario thinking and system dynamics for two reasons. Firstly, we had access to subject matter experts in the University of Strathclyde to support implementation. Secondly, we could identify a role for system dynamics and scenario thinking in a plan for policymaking that had already been drawn up by the working group, but structured decision-making would have required a significant change in how the recommendation process was conducted, which was not within our power to influence.

## SUMMARY

In this chapter, we drafted a preliminary framework for policymaking under uncertainty, based on findings from the interdisciplinary review in **Chapter 2**. This addressed **Research question 2**, by providing a structured way in which to select approaches from other disciplines that may address gaps in policymaking under uncertainty following standard HTA practice. We outlined an action research approach to evaluate the framework under **Research question 3**, through conducting a case study applying the framework to the 2024 KRT policy under the NHSO Board in Thailand. The framework suggested that scenario thinking, system dynamics, and structured decision-making could improve policymaking under uncertainty, by addressing features of the policy problem requiring an appreciation of impact across system boundaries, the motivations of different stakeholders, and evidence from other disciplines. Due to available resources and access to expertise, we prioritised future scenarios and system dynamics to test in the case study.

In the following sections, we continue to address **Research question 3** by evaluating the extent to which the framework developed in this chapter improves policymaking under uncertainty in HTA, within the context of the KRT case study. **Section II** reports the results from the scenario thinking study (**Chapter 4**) and system dynamics studies (**Chapters 5 and 6**), while **Section III** evaluates these approaches against standard HTA practice (**Chapter 7**), in order to provide recommendations for improving the framework and suggestions for future research (**Chapter 8**).

**Table 3.2** Applying the framework for policymaking under uncertainty to the 2024 policy for kidney replacement therapy (KRT) in Thailand.

Feature		2024 KRT policy question	Change in approach
1. Decision question			
a) Nature of the problem	i) The policy problem, goals, or process is unclear or contested	Sufficient evidence had been collected to characterise the policy problem, plans existed to define policy goals, and a process had been defined	None
	ii) Crosses system boundaries, with evidence of feedback and/or unintended consequences	Evidence of unintended consequences from the 2022 KRT policy and feedback (e.g. vascular access services and availability of PD nurses)	<b>System dynamics</b>
	iii) Cross-jurisdictional decision-making or implementation	Not all of the issues in the decision problem were under the mandate of the National Health Security Office (NHSO)	<b>SDM</b>
b) Policy goals	i) To change attitudes or behaviour	Increasing rates of PD would require change in patient attitudes	<b>Futures research</b>
	ii) To account for high impact, low probability events	Not the focus of the policy question	None
c) Time horizon	i) Long timeline for policy implementation and/or reversal	Stakeholder consultations had suggested that continued low uptake of PD could lead to collapse of the PD system	<b>Futures research</b>
2. Decision context			

Feature		2024 KRT policy question	Change in approach
a) Stakeholder interests	i) High level of disagreement among stakeholders regarding important criteria, reliable evidence, and/or future states	Unknown at the time of case study selection	None
	ii) Strong vested interests across multiple stakeholder groups	Strong financial incentives for medical professionals and potential changes to funding for healthcare providers	<b>Scenario thinking (futures)</b>
b) Policy institutions	ii) The policy question does not fall under the mandate of existing institutions	The policy question was addressed by an ad-hoc working group as it did not fall under the mandate of existing institutions	<b>Futures research</b>
	iii) Past decisions and/or institutional mandates impede the policy process or implementation	No evidence at the time of case study selection	None
c) Urgency	i) Emergency context with insufficient time for stakeholder engagement	Not an emergency context with resource for stakeholder engagement	None
3. Evidence for decision-making			
a) Type of evidence for policymaking	ii) Multi-disciplinary	A qualitative study based on phenomenology had been conducted alongside quantitative evaluation of registry data	<b>SDM</b>
	iii) Complex causal relationships, that cannot be understood ex-ante	Available quantitative and qualitative evidence of cause-effect relationships	None

Feature		2024 KRT policy question	Change in approach
b) Limited resources for data collection	i) Across multiple criteria	A lot of the evidence had already been collected and additional resources secured for further research	None
	ii) For a decision-analytic model	No decision analytic model was being applied	None

KRT – kidney replacement therapy; PD – peritoneal dialysis; SDM – structured decision-making

## SECTION II: FRAMEWORK OPERATIONALISATION

In this section, we report the results from operationalising the framework in the KRT case study.

**Chapter 4** describes the future scenarios study and evaluates the extent to which the method supported policymaking. **Chapter 5** details the qualitative component of the system dynamics study, comprising causal loop diagram development and archetypes analysis. **Chapter 6** discusses the system dynamics model for the quantitative component of system dynamics.

## **Chapter 4** Accounting for future uncertainty in healthcare policy: a case study integrating scenario thinking with dialysis policymaking in Thailand

### **OVERVIEW**

In this chapter, we demonstrate how scenario thinking and robust decision rules may address uncertainty by promoting a greater understanding of the potential impact of stakeholder motivations and the extent to which factors perceived as external and uncontrollable may be accounted for within proposed policies. We reflect on the experience of applying these methods within HTA and potential adaptations that may be required to apply the methods for future policy questions.

### **ABSTRACT**

**Background:** Healthcare policymaking often struggles to account for complex future uncertainties, particularly for policies affecting healthcare infrastructure or stakeholder behaviour. Scenario thinking is a structured approach for exploring multiple plausible futures. It has, however, been underutilised in healthcare policymaking. We applied scenario thinking to the 2024 dialysis policy in Thailand to characterise and guide policymaking under future uncertainty.

**Methods:** Our study is composed of three parts: scenario development, policy analysis, and evaluation of scenario thinking in the 2024 dialysis policy process. We developed future scenarios using the intuitive logics method, which systematically identifies and explores key uncertainties, and the critical scenario method to evaluate stakeholder responses. Policy options were evaluated for their robustness across future scenarios. We assessed the overall approach according to fitness-for-purpose, influence, and efficiency indicators from established international HTA evaluation frameworks.

**Results:** Four scenarios were developed along the dimensions of kidney transplant accessibility and skilled workforce availability. Approval of patients prior to dialysis initiation and a quality monitoring system were found to strengthen the dialysis programme's adaptability to future change, while considerable uncertainties were identified for performance of service provider payment

mechanisms. Scenario thinking was evaluated to be an efficient method to characterise future uncertainty within the available resources for policymaking.

**Conclusion:** This study demonstrates how scenario thinking can systematically evaluate healthcare policies under future uncertainty, providing a framework for more robust policies. Further research is needed to facilitate its use in healthcare, building on the adaptations developed in this study to bridge scenario thinking with established processes and standards for healthcare policy.

## INTRODUCTION

Healthcare policies have to be made in the context of high uncertainty about the future [22, 239]. Some of this uncertainty is relatively predictable: future disease patterns and life expectancy can be estimated within confidence ranges, for example [107, 240]. There is, however, uncertainty that is harder to predict through conventional models [10, 209], including the nature of doctor-patient relationships [241], technological advancements [30], future healthcare budget allocation [34, 107], and pandemics [208, 242].

Healthcare policy institutions often rely on predictive models to account for future uncertainty [19, 22], but lack systematic, transparent methods to account for the broader context in which a particular health policy operates [108, 243]. Although predictive models work well for evaluating specific technologies with clear timeframes and impacts [209], many healthcare policies require a broader view of uncertainty [107, 215]. This is particularly true for policies with long implementation times [214, 215], such as workforce and infrastructure planning [158, 211]; policies outside established institutional frameworks [158], where lack of defined governance may increase future uncertainty [34, 35]; and policies that aim to influence behaviour or depend on social interaction, such as health promotion interventions [107] or policies to influence supply and demand of health services. It can also be important for policies with multiple strong vested interests and hidden agendas [179, 215].

Futures research takes a fundamentally different approach from standard healthcare policymaking, by constructing “images” of multiple plausible futures rather than seeking to predict a single outcome [207]. These futures are shaped by external sources of change and the potential responses of different stakeholders [209]. Within futures research, scenario thinking is a problem structuring method to systematically explore how policies might perform under different future conditions [244].



The multiple futures are not developed to show what will happen, but rather to illustrate the future uncertainty and how it may shape (and be shaped by) policy or strategic action [30]. This approach aligns with healthcare priority-setting principles of systematic, transparent, and inclusive decision-making [79, 98].

Despite its widespread use in strategic business planning [245, 246], scenario thinking has seen limited application in healthcare policy [243]. While it has informed healthcare workforce planning [158, 211, 247–250], infrastructure decision-making [251], technology evaluation [252], and pandemic planning [253], its adoption faces barriers. Healthcare institutions' reliance on quantitative data and low tolerance for uncertainty have limited uptake [158], with successful applications typically requiring integration with quantitative modelling [211, 247, 248]. Yet few studies have examined how to adapt scenario thinking for healthcare's unique institutional and methodological requirements, or for diverse global contexts.

A broader view of the future may be especially relevant for low-income and middle-income countries (LMICs), where fragmented institutions, political turnover, evolving insurance schemes, and volatile donor funding create additional, external layers of uncertainty in policy success [254]. Scenario thinking has informed health system and palliative care planning studies in Iran [255, 256], community-level integrated health in Vietnam [257], and one of South Africa's national HIV/AIDS plans [258]. However, experience of scenario thinking for healthcare policy in LMICs remains limited, with almost all studies in a handful of high-income countries [243].

In this study, we address this gap by integrating scenario thinking with Thailand's 2024 kidney replacement therapy (KRT) policy. Similar to other countries, Thailand faces a growing burden of kidney failure and increasing demand for KRT [259]. KRT is a life-sustaining but high-cost treatment for patients with kidney failure that diverts healthcare resources away from other disease areas and creates difficult trade-offs between patient needs and healthcare system capacity [260–262]. The policy context exemplified the need for broader future uncertainty analysis, as it carried long-term implications for workforce and manufacturing capacity, aimed to influence both patient and provider behaviour, and involved multiple stakeholders with competing interests outside of established governance frameworks.

Our study demonstrates how scenario thinking can strengthen healthcare policy development while addressing previous barriers to adoption in three ways. Specifically, we show how this method can be adapted to (i) integrate with existing policymaking infrastructure to evaluate policy robustness to

future uncertainty, (ii) anticipate stakeholder responses in this context, and (iii) align with existing knowledge and practice of healthcare policy researchers. Practically, the findings directly informed the 2024 KRT policy in Thailand by identifying potential vulnerabilities in proposed policies and highlighting the importance of system adaptability to maintain equitable access to high quality services.

## **METHODS**

### **Case study: kidney replacement therapy in Thailand**

The study examined the 2024 dialysis policy for Thailand's Universal Coverage Scheme (UCS), a government-funded health insurance scheme that covers around 75% of the population [263]. The rest of the population is covered by public health insurance schemes for government or private sector employees [264]. Although all public health insurance schemes in Thailand cover KRT [265], most patients receive dialysis, due to a shortage of centres providing kidney transplant (particularly outside of Bangkok), limited infrastructure for organ procurement, and laws around organ donation [265–267]. Dialysis is provided as peritoneal dialysis (PD), which the patient administers at home, or as haemodialysis (HD), which is provided by specialised nurses in healthcare centres. In Thailand, PD is only provided by public hospitals, whereas around 80% of HD patients registered under UCS receive services in private hospitals or private HD clinics [268].

Prior to 2022, unless contraindicated, dialysis patients registered under UCS could only access PD for free, whereas the other two insurance schemes fully reimbursed both PD and HD [238]. A 2022 policy change allowed UCS patients to choose between PD or HD [238], but concerns around financial sustainability and system capacity to provide high-quality services led to re-visiting the policy in 2024 [269]. This research was conducted to inform recommendations of the National Health Security Office (NHSO) ad-hoc working group on KRT.

### **Methodological approach**

Our study is composed of three parts: scenario development, policy analysis, and evaluation of scenario thinking in the 2024 KRT policy process. The timeframe for the futures analysis was defined as 5-10 years, to reflect potential healthcare workforce and infrastructure consequences, whilst recognising health technology's rapid advancement. The scenarios were developed from June to

September 2024, alongside other research informing the 2024 KRT policy [207]. Our research team was composed of medical professionals, political scientists, and public health researchers, most of whom participated as members of the secretariat for the NHSO ad-hoc working group (**Table S4.1a**).

### *Scenario development*

In futures research there are two broad methods for scenario development: descriptive methods that seek to provide the context for policy action and normative methods that describe the ideal future to shape policy action [207]. Since the goal of the 2024 dialysis policy was to realise immediate change, we applied descriptive methods, to understand how different policy options may perform over the next 5-10 years in different future contexts. We followed the intuitive logics method, as it is multi-dimensional (i.e. able to explore many types of impact that may be important to different stakeholders) and considers how stakeholders will act to preserve or enhance their own interests [245]. We included the critical scenario method as part of scenario development, as a means by which to explicitly account for stakeholder interests and mechanisms of power [30]. This was particularly important for our policy question, as exploratory research had highlighted that the motivation for the 2022 policy change and its unintended consequences were largely driven by stakeholder actions to protect their interests [238].

We followed the steps of the scenario thinking method developed by Cairns and Wright [30], with adaptations for healthcare policymaking in Thailand (**Table 4.1**). Briefly, we first determined a preliminary list of exogenous factors affecting the dialysis programme in the past, present, and future from secondary data of 20 in-depth interviews with policymakers, service providers, and medical associations as well as a focus group discussion with 12 patients (**Table S4.1b**), which had been collected to understand the rationale for the 2022 policy change. We conducted secondary thematic analysis according to the PESTEL framework (political, economic, social, technological, ecological and legal) to identify exogenous factors and the causal relationships between them, from the perspective of interviewees and focus group participants [30].

This initial set of exogenous factors was reviewed during a half-day stakeholder workshop with 21 participants comprising dialysis nurses, nephrologists, patients, government payers, and suppliers (**Table S4.1c**). Participants were selected to represent a range of perspectives of the KRT programme (for example, by including both junior and senior healthcare professionals as well as participants from different provinces). During the workshop, participants grouped related factors into clusters

based on causal relationships and identified extreme outcomes from each cluster. Although it is recommended to have heterogeneous groups [244, 245], we separated senior nephrologists into a separate group to account for hierarchical power structures and instead tried to improve heterogeneity by sharing ideas across teams via facilitators (**Table 4.1**). We had included “remarkable thinkers” (individuals with knowledge that can challenge business-as-usual and perceptions around the future [270]) in two of the groups to overcome myopic views of the future that have been well-documented in research studies [244, 245] but we faced challenges in encouraging group discussion around input from the remarkable thinkers.

The research team therefore further elaborated workshop inputs before classifying each cluster according to its potential impact and level of uncertainty. We conducted a quasi-anonymous ranking Delphi survey with a panel comprising two members of the KRT secretariat, two researchers supporting the KRT policy, and one researcher from the health technology assessment agency. Following an initial 1-hour training session, panellists anonymously ranked the uncertainty and impact of each cluster with a rationale, until reaching consensus on the two clusters with highest combined impact and uncertainty. For each round, participants received a template matrix to complete via email, together with an anonymised file containing all participant responses to the previous round (example provided in **Figure S4.3b**). Consensus (unanimous agreement) was reached after two rounds, with two days for the first round and five days for the second round. We then placed extreme outcomes from the selected clusters in a 2x2 matrix to define four scenarios.

We used the critical scenario method to identify how different actors would perceive each future and actions they may take to protect their own interests, forming the basis of scenario narratives. Given the research team’s predominant affiliation with Thai policy institutions, an external team member (AC) reviewed outputs to challenge assumptions and check narrative consistency.

Scenarios were validated by argumentation, reviewing consistency of storylines, ensuring consistency both within each scenario (internal) and with established facts (external), and seeking transparency throughout scenario development process [207]. Narratives were reviewed by the research team according to established principles [244]:

- scenarios are multi-dimensional,
- scenarios challenge implicit assumptions about what may change in future, and
- narratives are engaging and promote understanding.

**Table 4.1** Summary of steps to develop the scenarios, challenges encountered, and adaptations made to better align with institutions for healthcare policymaking in Thailand.

#	Step in the basic method[30]	Issues encountered	Adaptations
0	Cross-cutting: stakeholder engagement	<ul style="list-style-type: none"> <li>Limited time to engage different participants alongside other activities for the policy process.</li> <li>The research team and secretariat had observed that power structures were preventing participants from sharing divergent opinions during policy meetings.</li> </ul>	<ul style="list-style-type: none"> <li>An existing stakeholder meeting was leveraged to collect input on external factors that may impact the KRT programme; the research team conducted all subsequent steps.</li> <li>Groups in the stakeholder workshop were purposefully chosen to minimise power relationships. Since this limited heterogeneity in each group, workshop facilitators shared ideas between groups.</li> </ul>
1	Set the context and scope	<ul style="list-style-type: none"> <li>Policy working group focus on the issue at hand, not the ideal future.</li> </ul>	<ul style="list-style-type: none"> <li>Preliminary list of exogenous factors developed from secondary interview data.</li> </ul>
2	Determine external factors, driving forces, and extreme outcomes	<ul style="list-style-type: none"> <li>“Myopia”, as widely documented for scenario studies [244], led to discussions centring on solutions to current issues in the system (e.g. increasing subscription to kidney transplant waiting list).</li> </ul>	<ul style="list-style-type: none"> <li>Facilitators asked participants to consider an extreme situation in 10 years’ time related to the issue being discussed (e.g. kidney transplant programme) and why that future</li> </ul>

		<ul style="list-style-type: none"> <li>• Unlike business studies [245], the inclusion of participants known to challenge business as usual (“mavericks”) was largely unsuccessful due to power structures.</li> <li>• Participants wanted a definition of “plausible future”, which is generally advised against for scenario studies [207].</li> </ul>	<p>may arise. This technique was only successful to a limited extent.</p> <ul style="list-style-type: none"> <li>• Preliminary inputs from the workshop were elaborated with the “mavericks” by the research team, which had a flat hierarchy.</li> <li>• Since participants were focussing on business-as-usual scenarios anyway, facilitators advised the group not to overly focus on the requirement of “plausible futures”.</li> </ul>
3	Identify the two factors with highest potential impact and greatest uncertainty	<ul style="list-style-type: none"> <li>• Participants were uncomfortable with the concept of “multi-dimensional” impact.</li> <li>• Limited time for face-to-face meetings and high level of disagreement among group members.</li> <li>• The concept of high uncertainty was poorly understood among team members. Early discussions focussed on the perceived</li> </ul>	<ul style="list-style-type: none"> <li>• Defined as financial sustainability and health/social impact, consistent with concepts in economic evaluation known to participants.</li> <li>• A Delphi process was used to come to consensus, as reported in previous studies [271, 272].</li> <li>• The first meeting was held face to face to clarify the purpose of the step. A familiar example (epidemiology of chronic kidney disease) was used to illustrate the concept.</li> </ul>

		likelihood of a scenario as opposed to uncertainty in the potential impact.	All team members were requested to give a full explanation of the rationale for ratings to check understanding.
4	Scenario narratives	<ul style="list-style-type: none"> <li>• Insufficient time for role-play in critical scenario method.</li> <li>• Scepticism within the team around the purpose of scenario narratives in the policy process and mixed opinions around the plausibility of scenarios.</li> </ul>	<ul style="list-style-type: none"> <li>• Research team individually analysed which actors may be affected by each future and their potential reactions.</li> <li>• In the final analysis and presentation to the working group, scenarios were presented as representations of the future with varying workforce capacity and kidney transplant accessibility. This is in line with narratives from other futures studies used in health policy [211, 247, 248].</li> </ul>

### *Policy analysis*

We analysed seven policies already proposed by the NHSO working group (**Table 4.2**), which were informed by qualitative research, literature reviews, and budget projections of the KRT programme [238]. We applied robust decision analysis, which evaluates policy options under multiple plausible futures, to identify policies that are likely to be successful despite considerable future uncertainty [209, 212]. We defined robust as policies that performed better in futures with system strain, moderately robust as policies that performed similarly across all futures, and not robust as policies that had variable performance depending on future conditions. The critical scenario method assessed the role of different actors on policy success. We considered policies to be vulnerable to stakeholder responses if the policy could be overturned or ineffective, moderately vulnerable if the scale of impact depended heavily on stakeholder responses, and not vulnerable otherwise. Two analysts independently evaluated the policies under the base case future and the four future scenarios, for analyst triangulation.

**Table 4.2** Policies evaluated in this study.

#	Policy	Description
1	Doctor fee restrictions	Regulations restricting financial payments to nephrologists from private dialysis providers, so that payment is only allowed for dialysis sessions attended by the nephrologist.
2	Pre-authorisation	Approval from a provincial committee is required prior to dialysis initiation. The committee reviews patient profile to ensure that timing and type of treatment are appropriate for the patient. In the context of HD supply constraints, the committee will prioritise patients for HD based on need.
3	Patient education	Prior to kidney failure, patients are educated by a multi-disciplinary team of healthcare professionals on available treatment options.
4	CCC protocols	Protocols and prompting questions are provided to nephrologists for assessment of patients prior to dialysis initiation. The protocols aim to



		identify patients who would have best quality of life with comprehensive conservative care (CCC).
5	CQI system	A continuous quality improvement (CQI) system to monitor quality of dialysis services, overseen by a working group to identify and resolve issues with dialysis service quality.
6	Global budget	The total available budget for payment of dialysis service providers is capped each year, meaning that an increased number of dialysis patients leads to decreased service fee per patient.
7	Bundle payments	Service provider payments for HD, PD, and CCC are provided as a payment per dialysis patient, adjusted for the patient case mix.

CCC – comprehensive conservative care, CQI – continuous quality improvement, HD – haemodialysis, PD – peritoneal dialysis

#### *Evaluation of the role of scenarios thinking in the policy process*

We evaluated how scenario thinking informed the 2024 KRT policy using established health technology assessment (HTA) evaluation frameworks, comprising a framework to evaluate the impact of HTA systems [273] and outcome indicators for deliberation in HTA [98]. We adopted elements of the frameworks that were applicable to futures research and relevant for single studies (**Supplement 4.2**).

The resulting evaluation framework (**Table 4.3**) assessed fitness-for-purpose, influence, and efficiency of the futures study in the policy process. Fitness-for-purpose evaluates whether the futures study provided relevant information for decision-making that would otherwise have been missing from the policy process (1a), and whether the futures study fulfilled its purpose, in terms of increasing understanding of future uncertainty (1b) and the role of actors in impeding or enhancing whether a policy achieves the expected goals (1c). For this study, the comparator to assess whether futures analysis provided additional relevant information was other research being undertaken to inform the policy, namely two literature reviews and a system dynamics modelling study [238]. Influence considers the extent to which results from the futures study shaped the final policy that was recommended and approved (2a) and the plan for policy implementation (2b). Efficiency

provides a qualitative assessment of the value for money of the study, in terms of the resources required to complete the study relative to the benefits (3a).

## Ethics

The Ethics Committee of the Institute for the Development of Human Research Protections (IHRP) Thailand approved the sub-study for interview data collection on February 22nd, 2024 (COA No. IHRP2024025; IHRP No.002-2567).

**Table 4.3** Framework to evaluate the role of scenario thinking in the 2024 KRT policy.

#	Goal	Indicator	Data source(s)
1	Fitness for purpose	a) The level of additional information/insight from the futures study, beyond other research conducted for the policy.	Comparison with the results from other research studies for the 2024 KRT policy (literature review and system dynamics modelling) [238]
		b) The research team had an expanded view of future uncertainty.	Materials from research team meetings and correspondence
		c) The research team had a greater understanding of the interests of different actors and how their responses may shape the future.	
2	Influence	a) The futures study influenced policy.	Minutes from the NHSO working group and NHSO Board
		b) The futures study influenced planning for implementation (for example, stakeholder engagement and risk mitigation plans).	Minutes from the NHSO Board
3	Efficiency	a) The human and financial resources to conduct the futures study were justified given the additional insight.	Timesheets; reflection from team members

KRT – kidney replacement therapy; NHSO – National Health Security Office

## RESULTS

### Scenario development

During the scoping stage, the research team identified the following themes as exogenous factors that could shape the future of the KRT programme: marketing strategies of dialysis service providers, which could affect behaviour of doctors, nurses, and patients; inequality between the benefit package of public health insurance schemes, leading to patient dissatisfaction and advocacy; dialysis reimbursement policies in neighbouring countries, affecting local manufacturing investment and supply chain; technological advancements in kidney transplant and dialysis; the success of community health promotion and prevention activities to reduce the burden of non-communicable diseases; and changes in the culture of medical professions to shift towards shared decision making with patients.

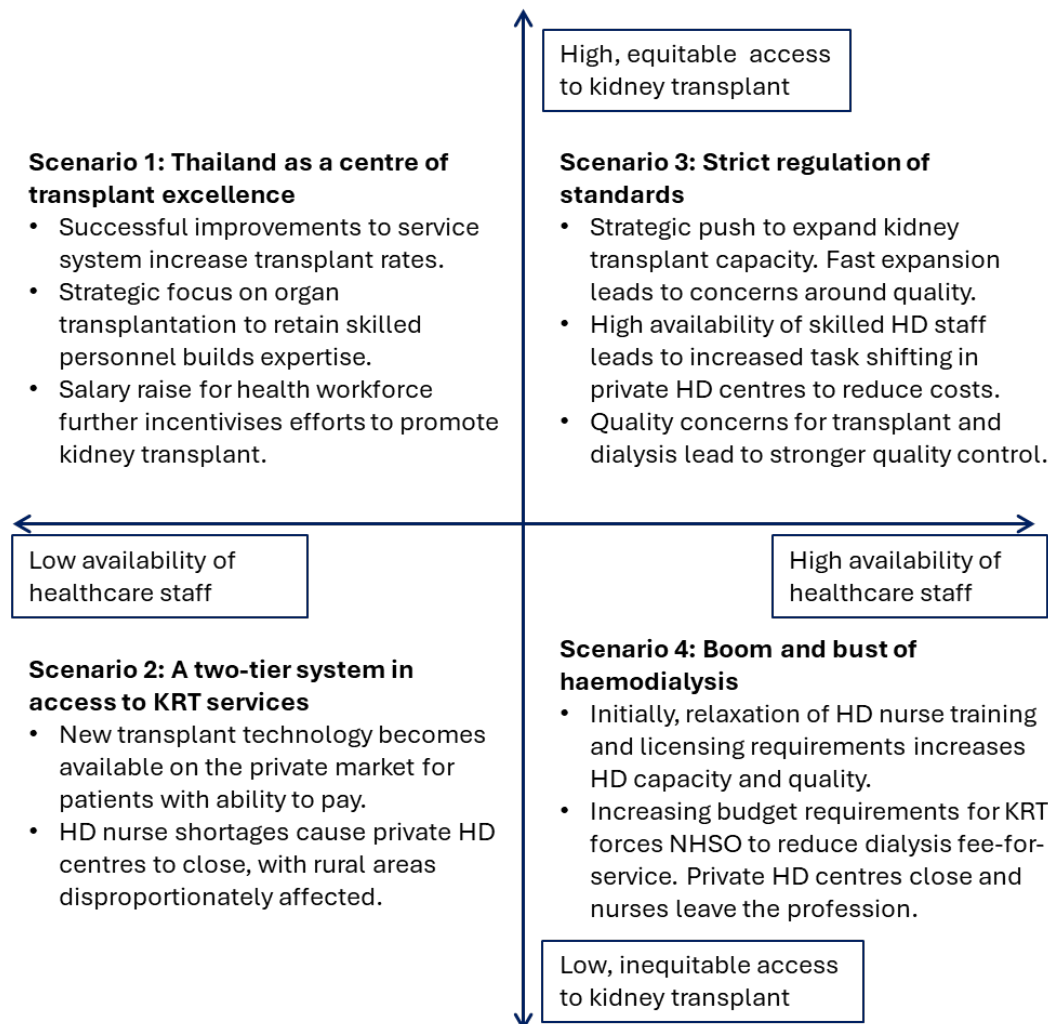
Through stakeholder workshops and analysis, these factors were consolidated into seven clusters of driving forces: (1) viability of the dialysate manufacturing plant in Thailand; (2) accessibility of kidney transplant; (3) kidney failure burden; (4) level of alignment across the three health insurance funds; (5) quality of utilities (including water and electricity supply); (6) private HD centre business viability; and (7) the size and capabilities of the dialysis workforce. The causal links between driving forces and extreme outcomes for each cluster are shown in **Figure S4.3a**.

Of these clusters, two were judged to have both high impact and high uncertainty within the 5-10 year timeframe of this study: (3) the accessibility of kidney transplant and (7) the size and capabilities of the dialysis workforce. The impact of kidney transplant accessibility could vary based on new technological advances, investment in the service system, or legal changes. Workforce capacity impact would depend on government and service provider responses to workforce shortages, such as quality assurance requirements, salary increases, or training programmes. While other factors like the burden of kidney failure, viability of the dialysate manufacturing plant, and private HD centre business viability could have significant impact, the magnitude of impact considered more predictable (and therefore low uncertainty).

The two key uncertainties formed the basis for four scenarios (**Figure 4.1**), representing different combinations of kidney transplant accessibility and workforce constraints. These scenarios represent possible futures and are not intended to depict what would happen with a particular level

of workforce availability or transplant access, nor the likely or preferable future. The full narrative for each scenario is provided in **Table S4.3**.

**Figure 4.1** Overview of the four high impact high uncertainty scenarios, which were developed around different levels of equitable access to kidney transplant and workforce constraints.



HD – haemodialysis; KRT – kidney replacement therapy; NHSO – National Health Security Office

## Policy analysis

The policy analysis firstly considered how the future may be shaped by actor responses to each policy, before evaluating the policy performance across future scenarios (**Table 4.4**). A description of each policy and the full policy analysis is provided in **Supplement 4.4**.

Our analysis highlighted that the success of three policies (restricting payments of the doctor fee, global budget, and bundle payments) depends heavily on private service provider responses. Bundle payments attempt to equalise financial incentives across all treatment options, namely HD, PD, and comprehensive conservative care (CCC, an approach for patients unsuitable for dialysis, comprising interventions to delay disease progression and minimise complications, with shared decision making and planning, alongside psychologic and family support) [274]. However, their effectiveness depends on private service providers diversifying their portfolio to include PD and CCC. Otherwise, private HD service providers are still motivated to attract more HD patients and financial incentives will likely remain. Similarly, global budget implementation may severely decrease accessibility and quality of HD services if private service providers consider the business case to be too risky. Such a policy may require strong regulatory oversight and measures to guard against geographical inequity in access to HD services, such as bus services for HD patients in rural areas. The performance of a continuous quality improvement (CQI) scheme was judged to be highly dependent on support from other government departments and medical associations. The pre-authorisation system, which requires patients to be approved by regional committees before dialysis can start, could risk being overturned if patients and doctors perceive it as a barrier to service access. Patient education could have broader benefits if used to increase awareness of available services, including transplant options and medications that should be provided for free.

We rated pre-authorisation and CQI as highly vulnerable to future stakeholder actions, as the policy could be overturned or ineffective (**Table 4.4**). Global budget, bundle payment, and patient education were rated as moderately vulnerable, since private service provider reactions could greatly impact the scale of change achieved. Restrictions in the doctor fee and implementation of a CCC protocol were rated as low vulnerability.

In the robustness analysis, pre-authorisation, a CCC protocol, and a CQI scheme all showed similar or improved performance in the future scenarios, as they had broader systemic benefits. Pre-authorisation puts in place a system that allows prioritisation of patients according to need in the context of resource constraints or when expanding access to new services; CQI puts in place a

system to uphold service quality during periods of system strain or introduction of new technologies; and the CCC protocol is likely to encourage strengthening of palliative care services, with benefits for other disease areas such as cancer. Global budget, however, could make the KRT programme vulnerable to future shocks, as the business case for private centres is already precarious and any change prompting closure of private HD centres could force a higher percentage of patients into comprehensive conservative care, particularly in rural areas.

**Table 4.4** Summary of the policy analysis of policies proposed by the NHSO working group. Methods for scoring are described in the Methods section and the full analysis is provided in **Supplement 4.4**.

Policy option	Vulnerability to actor response	Robustness (performance relative to base case)			
		Scenario 1	Scenario 2	Scenario 3	Scenario 4
1) Doctor fee	Low	=	=	=	+
2) Pre-authorisation	Very high	+	+	=	+
3) Education	Medium	=	=	+	-
4) CCC protocol	Very low	=	+	=	+
5) CQI	High	+	+	+	+
6) Global budget	Medium	-	-	=	=
7) Bundle payment	Medium	=	=	=	=

**Vulnerability:** level of uncertainty in policy performance due to potential responses from different stakeholders to protect their interests. **Robustness:** change in the performance of a policy option in different scenarios, relative to the base case future.

+ indicates better performance than the base case future; = indicates similar performance to the base case; - indicates worse performance than the base case.

CCC – comprehensive conservative care, CQI – continuous quality improvement, NHSO – National Health Security Office.

## Evaluation of scenario thinking within the KRT policy process

The evidence used for the assessment of each indicator is shown in **Table S4.5**. In terms of fitness for purpose, we found that the futures analysis revealed insights that were not identified through other analyses conducted for the 2024 KRT policy. Results from a literature review had recommended patient education, bundle payments, and CCC protocol, on the basis that similar policies had improved uptake of PD and CCC in other countries [275, 276]. Subsequent system dynamics modelling had shown that these policies do not address specific drivers in the Thai context and that the doctor fee, pre-authorisation, or global budget may be required to meet policy goals [277]. It had also highlighted the risk of reduced access to services with global budget. However, the conventional methods of literature review and modelling did not identify the importance of private service provider response on the performance of bundle payments and education, as there was no structured method to account for potential stakeholder responses in the Thai context, and did not identify the broader systemic strengths of pre-authorisation and a CQI system, as literature review outcomes were based on a single indicator (as opposed to multi-dimensional impact explored by the futures analysis) and the system dynamics model projections did not account for external change to the system.

In terms of policy influence, draft recommendations from the working group were revised following presentation of the futures analysis, placing greater emphasis on pre-authorisation and CQI, with less prominence for bundle payments and education. We had updated the system dynamics modelling to account for uncertainty highlighted by the futures analysis, and this prompted significant discussion within the working group meeting around why bundle payments did not achieve the policy goals despite evidence from the literature review. The findings from our analysis related to the importance of securing support from different stakeholder groups for the implementation of pre-authorisation and CQI were not explicitly discussed in the NHSO Board meeting. However, since the Board established a permanent working group to oversee policy implementation, our study is unlikely to have accurately measured this indicator.

From the perspective of efficiency, resource requirements for the scenario thinking exercise were modest. We estimate that staff time required to complete the study was less than 10% of that ordinarily spent developing an economic evaluation to inform policy, which is likely justified for policies that would benefit from a broader view of future uncertainty.



## DISCUSSION

This study illustrated the potential benefits of scenario thinking to account for future uncertainty in healthcare policy. Our analysis for the 2024 KRT policy in Thailand highlighted social dimensions of uncertainty that are typically absent from decision analysis in healthcare and identified the broader health system impact of policies. This provided an expanded view of decision risk by bridging between decision analysis and implementation planning, which are traditionally separate functions in the governance of healthcare systems.

Consistent with the literature, we faced challenges in applying scenario thinking for healthcare policy [108, 158]. Since most members of the research team and working group come from clinical or economics backgrounds, there was tendency to judge the likelihood of each scenario or to provide a strict definition of impact. There was also scepticism around the role of narratives and stakeholder analysis, which were not perceived to be rigorous methods compared with systematic reviews or economic evaluation studies. Similar cultural barriers have been found in other scientific disciplines [179, 180, 200, 278] and studies from South Africa and Iran have similarly highlighted policymaker preference for quantitative data in scenario planning [255, 258]. We additionally found that cultural dynamics of policy processes influenced whether points made in group discussion were elaborated further by the group or ignored, making it difficult to achieve productive discussion among a heterogeneous group with out-of-the-box thinkers, as recommended by the future scenarios literature [244, 245]. Although quality of scenario studies depends on challenging the status quo [243], long timeframes with continued engagement are needed to encourage participants to question assumptions about the future [107], which may not be possible in policy environments [158].

Based on our findings, we propose three key adaptations to better integrate scenario thinking with existing healthcare policy processes. Firstly, although the results of any policy analysis will ultimately be discussed and used in hierarchical policy processes, we propose that the core analytical steps be conducted within a group without a rigid hierarchical structure, utilising common methods in healthcare policy analysis such as literature review and key informant interviews to identify important external factors, as opposed to workshops. This is particularly important in setting with prominent hierarchical structures, such as LMICs government agencies. Since policy stakeholders may be involved to a lesser extent in the scenario development process, transparent reporting is encouraged to maintain trust.

Secondly, scenario thinking outputs should be presented in formats familiar to healthcare policymakers, to allow them to better understand implications of the research [199]. Although the scenario analysis literature emphasises the importance of rich scenarios for storytelling, this is not consistent with views around rigorous science in healthcare policy [51]. We found greater success linking scenario insights to quantitative modelling results, using the scenario insights to highlight which outcomes may be affected by uncertainty in future conditions or stakeholder actions. This is consistent with other scenario studies used to inform health policy from Australia, Belgium, the Netherlands, and the UK, which conducted scenario analysis alongside quantitative modelling [247, 248, 252]. It does, however, place greater importance on the role of the research team in effectively synthesising key policy implications from the futures analysis, as quantitative analysis is unlikely to capture the rich multi-dimensional insights gained from scenario thinking.

Thirdly, we recommend facilitating use of the method by developing tools to support researchers informing healthcare policy. Within healthcare, adherence to checklists and guidelines is commonly upheld as a standard of quality. Although qualitative researchers caution against the use of checklists on the basis that they may constrain insights [279–281], we recommend the development of a set of guiding principles at the global level to lay out what constitutes a high-quality scenario thinking study in healthcare. For the reasons provided above, these standards should emphasise policy implications rather than scenario storylines. At the country-level, use of scenario thinking may be better accepted and utilised if incorporated within existing national guidelines, following good practice to develop guidelines for evidence-informed decision-making [282].

This study has a number of limitations. Firstly, stakeholder engagement challenges may have limited our view of future uncertainty, and it could be questioned whether our research team was able to accurately anticipate the future actions of actors given our institutional view of the health system and policymaking. Since the purpose of scenario analysis is not to predict what would happen, but rather to question assumptions around future uncertainty, the main risk of this limitation is that we may have a constrained view of the level of future uncertainty associated with each policy option. However, we believe that this is still more informative than conducting no analysis at all. Perhaps the most important limitation of the study is that our proposed adaptations to the methods and evaluation of the policy process are derived from a single case study. Further research is needed, particularly in LMICs, to understand which adaptations are broadly applicable to healthcare policymaking versus context-specific. With respect to our evaluation framework, the timeline of this

study was too short to capture the role (if any) of this study on policy implementation. Finally, we were unable to differentiate whether the benefit of scenario thinking was specific to scenario thinking as an approach, or whether other structured methods to investigate future uncertainty would have provided similar or greater insight. Methods for futures research have been categorised across three dimensions: quantitative to qualitative, participatory to expert-based, and imagination to evidence-based [210]. Understanding which futures research methods may be most appropriate for different types of health policy questions, and adaptations required for the healthcare field for each method, is an area for further research.

Our study was conducted in a setting with established governance structures for healthcare decisions and therefore may not be representative of settings with ad-hoc decision-making. We cannot, for example, determine the extent to which influence of this study on policy was due to trust in the research team that has been built up over more than 15 years in Thailand. Furthermore, some members of the research team are part of the implementation process. We argue that this is a strength of our study, as policy research is inherently embedded within policy structures, but it may limit generalisability of findings.

In conclusion, our study found considerable benefit in expanding the view of future uncertainty for the 2024 KRT policy in Thailand. We proposed adaptations to the scenario thinking method to better align with power structures in government institutions and to present results in a way that is perceived as credible and relevant to healthcare policy institutions. The proposed adaptations aim to make scenario thinking more accessible and relevant for healthcare institutions while maintaining its core benefits. We recommend that further research: (1) articulate which healthcare policy questions would benefit from an expanded view of future uncertainty and support healthcare policy researchers to navigate between available futures study methods; (2) develop a set of principles and quality standards for the application of scenario thinking for healthcare policy; and (3) conduct evaluation of scenario thinking methods across a broader set of contexts to identify adaptations that are general to healthcare policy and those that may depend on the local setting.

## **SUMMARY**

This chapter represents the first of three studies in which we operationalise the framework from **Chapter 3**. Scenario thinking had been identified for the KRT case study for the following reasons:

long-term consequences of the KRT policy may be difficult to change, there were multiple vested interests, the policy needed to account for behaviour of patients and service providers, and no policy institution existed in Thailand for addressing questions around policy failure. According to the review in **Chapter 2**, these factors suggested that policymaking may benefit from accounting for uncertainty around what is considered an external, uncontrollable source of uncertainty (systems theory) and the hidden motives of actors in the system (post-modernism).

In this chapter, we illustrated how scenario thinking may (1) promote a greater understanding of stakeholder reactions to protect their interests and the impact on policy options, and (2) identify policy options that strengthen the system to withstand sources of uncertainty that would typically be considered in HTA as uncontrollable. In **Chapters 5 and 6**, we apply system dynamics as part of the same case study, illustrating in **Chapter 6** how the insights from scenario thinking supplemented system dynamics modelling.

# **Chapter 5** Understanding Healthcare Demand and Supply through Causal Loop Diagrams and System Archetypes: Policy Implications for Kidney Replacement Therapy in Thailand

## **OVERVIEW**

In this chapter, we developed a causal loop diagram to systematically map different stakeholder perspectives around the cause-effect relationships influencing the impact of the 2022 KRT policy. This addressed uncertainty arising from perceived system boundaries, in order to account for consequences across institutional boundaries and feedback loops crossing system boundaries. We applied system archetype solutions to identify policy interventions that could effectively address this uncertainty.

## **ABSTRACT**

**Background:** Systems thinking approaches can determine system interdependencies to guide effective policymaking but have been underutilised in health policymaking, particularly for policies related to access and delivery of health services. In Thailand, a policy changing access to dialysis services for patients with kidney failure in 2022 had resulted in an unexpected surge in patients, mortality rate, and budget overspend. This study applied systems thinking to characterise the dynamics underlying the unforeseen impact of the 2022 policy, in order to propose context-specific policy interventions.

**Methods:** We developed a causal loop diagram through iterative stakeholder engagement, to understand the drivers for supply and demand of dialysis under the 2022 policy in Thailand. Since systems thinking was considered a new tool for policymaking, we used system archetypes as a means by which to collapse down the complexity of causal loop diagrams into simple narratives for policymakers. Confidence-building (validation) was conducted through triangulation across data sources and steps to facilitate stakeholder critique throughout the process.

**Results:** Chronic underinvestment in peritoneal dialysis had failed to capitalise on improvements in expertise and quality of services, while a series of short-term measures to overcome constraints in

haemodialysis supply had unintentionally increased haemodialysis demand in the long-term, increasing strain on the healthcare system. By applying generic solution archetypes, we identified a series of measures to balance demand for services with system capacity, including better alignment of incentives with health system goals, proactive planning to anticipate future supply needs, and regulatory mechanisms to moderate demand according to available supply.

**Conclusions:** A major implication of this research is that changes to healthcare access and delivery require multi-stakeholder engagement and whole system thinking, as even small changes can have potentially vast consequences. Applying a systems thinking lens not only communicated the reasons for unintended impact of the 2022 policy, but also identified interventions absent from the literature that were unique to the drivers of demand and supply in Thailand.

## BACKGROUND

Globally, there is increasing adoption of systematic, evidence-informed priority-setting mechanisms for health [283, 284], with growing evidence of positive impact across multiple dimensions of decision-making [285–287]. Although traditionally focussed on which technologies and services to cover under publicly funded health systems or health insurance schemes [283, 288], the remit of systematic, evidence-informed priority-setting mechanisms is expanding to address issues such as organisation of healthcare delivery and health system interventions to address supply and demand of services [3, 289].

The evaluation of system interventions requires different priority-setting methods and processes [102, 103]. Technology assessment starts with an intervention, whereas system interventions often start with a context-specific issue: there may not be a clearly defined set of policy interventions or there may be questions around the transferability of successful programmes from other settings [106]. Conventional methods for priority-setting in health do not account for changes in actor behaviour or responses in other areas of the system, such as feedback loops between government sectors [61, 104], the effect of incentives on actor behaviour [290, 291], or changes in population values following system change [103], yet these are often key factors influencing impact of system interventions.

Healthcare systems show the features of complex systems: behaviour of the system as a whole cannot be predicted from its components; there is feedback, meaning that change can reinforce or

balance further change; and adjustments to the system can modify system behaviour (adaptation) [102, 103, 292]. Furthermore, health system policy questions often exhibit the features of an unstructured problem, defined as problems with divergent stakeholder perspectives and interests, intangible elements, and uncertainty [203]. Multiple problem frames may exist, with stakeholders disagreeing about whether there is a problem, the underlying reasons for the problem, which policy body is responsible and the scope of its mandate, the solution space to explore, the evidence that should be considered, and/or appropriate stakeholders to involve for a recommendation [33]. Failing to account for system complexity or multiple problem frames can lead to policy interventions that have limited impact, or worse, exacerbate the problem in the long run [102, 104, 293].

System dynamics is an established approach to problem-solving that determines and communicates “complex feedback structures to facilitate system change” [104]. The premise is that understanding inter-dependencies endogenous to the system and mapping a holistic view of the system from multiple stakeholder perspectives guides effective policy and decision-making [104, 294, 295]. Given the complexity of health systems, it has been proposed that system dynamics can improve health service design [102, 104, 292, 296].

Within system dynamics, causal loop diagrams (CLDs) are used as an analytical tool to surface and understand the mental models of different stakeholders about how the system works [297]. CLDs illustrate the inter-dependencies in a system, representing the collective knowledge of a group [298]. They are often used as an evolving thinking tool to structure problems, to facilitate joint stakeholder learning about complex systems and alternative problem frames, and to identify and address unintended consequences of past or future policies [148, 293, 299]. Interest in CLDs to inform healthcare policy is growing [300, 301]. CLDs have been used to explore multi-faceted healthcare problems, including inequity, provider payment, and governance [61, 290, 302]; to support health system planning [301, 303–305]; and for programme evaluation [291]. Archetypes represent common structures (combinations of loops) within a CLD that characterise behaviours that are consistent across disciplines and settings [294]. Archetypes thus support development of narratives to understand and communicate the complexity captured by a CLD [293]. For example, the *underachievement* archetype describes a CLD structure for policy actions that do not achieve the expected impact due to a delayed reaction from another area of the system. This archetype may describe, for example, a policy research institute aiming to improve its policy relevance by producing research reports in a shorter timeframe, but subsequently experiencing a loss of reputational trust

from stakeholders who valued the institute's scientific rigour. Although archetypes have been applied to a certain extent to understand dynamics of health and social care in the UK [104], their application remains limited within health priority-setting globally.

In 2024, our research team was tasked with generating evidence for a policy recommendation to the National Health Security Office (NHSO) Board in Thailand regarding the kidney replacement therapy (KRT) policy, an issue that showed the features of a complex, unstructured health system problem. In Thailand, there is well-established governance to assess technologies (medical devices, surgical procedures, health promotion programmes, diagnostics, etc) for inclusion under the Universal Coverage Scheme (UCS) benefit package. The process includes stakeholder nomination of technologies and conduct of additional studies (for example, economic evaluation for high-cost interventions or feasibility studies) to inform the final policy recommendation [306]. NHSO provides funding to public and private healthcare providers for services provided in the benefit package, which are provided free at point of care to registered beneficiaries [307]. There is, however, no formal governance for policies related to changes in service delivery or coverage.

Due to limited infrastructure for transplantation and legal restrictions on organ donation, most patients with kidney failure in Thailand receive dialysis as a life-sustaining treatment until the end of life. The KRT programme under NHSO is funded by its own budget, due to the significant costs: over 5% of the total NHSO budget is allocated each year to treat the 0.1% UCS beneficiaries with kidney failure, and this figure is expected to rise given increasing rates of chronic kidney disease [262]. Treatment of KRT complications is funded separately through an inpatient budget. Dialysis providers are paid by fee-for-service, with a higher fee for HD services. Peritoneal dialysis (PD) is provided solely by public hospitals, while haemodialysis (HD) is provided by both public and private centres. Registration and quality assurance requirements differ between public centres, private hospitals, and private clinics, with very limited regulation of private provider use of the fee-for-service.

A change to the KRT policy had been implemented in 2022, based on an estimation of marginal budget increase and minor system disruption [238]. However, contrary to expectations, the budgetary and health system impact was substantial. The budget doubled to represent 10% of the total NHSO budget for all health conditions, and by 2024 mortality rates were still 50% higher than expected deaths [308]. Initial research indicated that lower quality of care and workforce shortages were being mutually reinforced and that actors had changed their behaviour following the policy change. This suggested the presence of feedback loops and system adaptation, typical of a complex



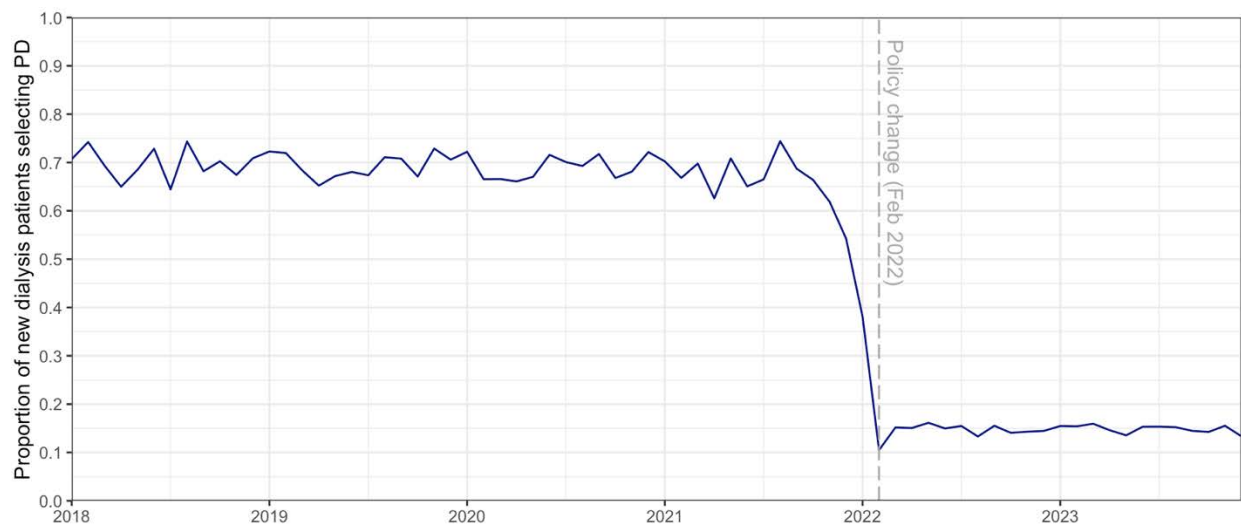
system, which had not been accounted for in the policy design. Moreover, the reasons underlying the increased number of patients and mortality rates were contested, particularly due to the highly political nature of the policy change.

In this study, we applied system archetypes, an under-used tool within healthcare policy, to understand the supply and demand dynamics in a middle income setting with mixed public-private healthcare service provision. By applying a systems thinking lens, this study aimed to: (1) identify the causal relationships driving the demand and supply for KRT services under the 2022 policy in Thailand and (2) identify policies that are likely to have greatest impact on quality of care and financial sustainability of the KRT programme.

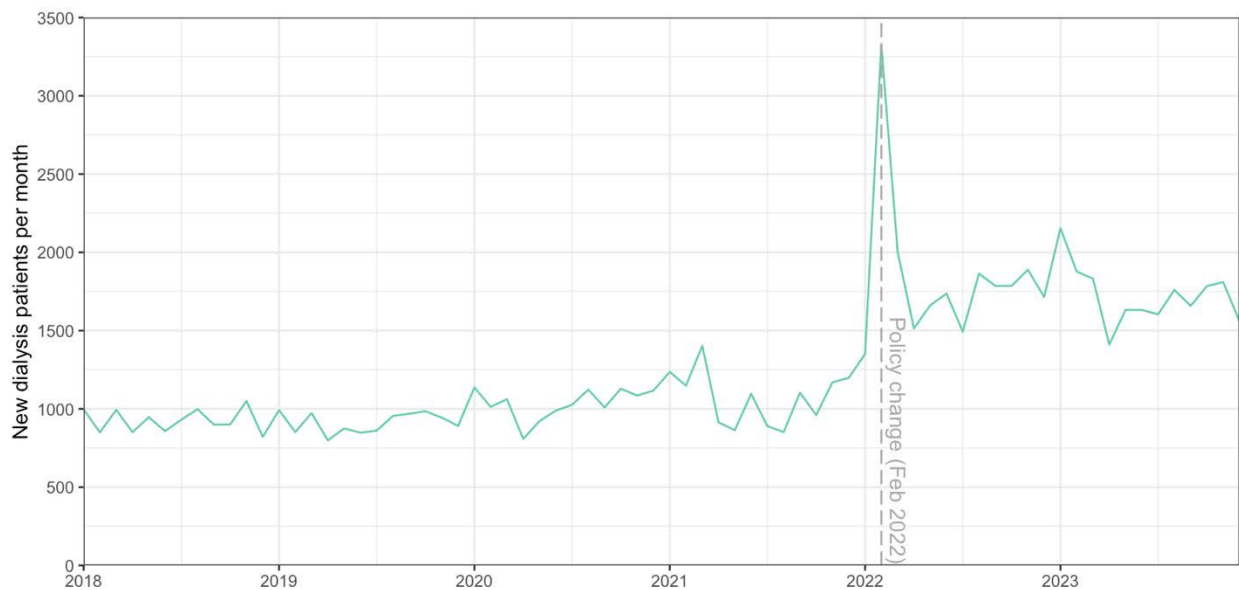
## METHODS

There were two specific dynamic problems that this study aimed to explore. The first was the rationale for the steep decline in proportion of patients selecting PD following the policy change, from around 70% before the policy change to around 15% after the policy change, which was far greater than had been anticipated (**Figure 5.1**). The second problem was the increase in incident dialysis patients after the policy change. Although number of new dialysis patients per month had been steadily increasing over time due to rising chronic kidney disease incidence, there was a jump in new dialysis patients per month after the policy change, which remained above 1500 per month two years later (**Figure 5.2**).

**Figure 5.1** Proportion of new dialysis patients selecting PD, before and after the 2022 policy change.




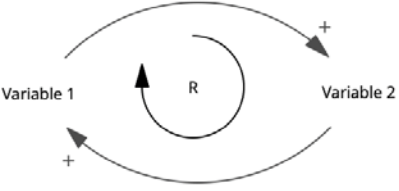
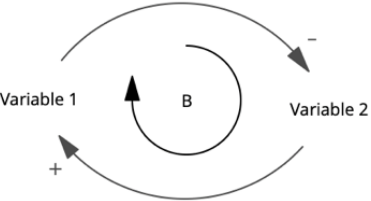
**Figure 5.2** Incident (new) dialysis patients per month, before and after the 2022 policy change.



We developed a CLD through an iterative process with stakeholders from June to October 2024, in order to inform the policy recommendations of a working group under the NHSO Board in Thailand. The decision to use a CLD as an approach was based on early discussions and research indicating the presence of feedback loops, system adaptation, and multiple stakeholder frames [308]. Although the CLD outlined in this paper was primarily used as an exploratory thinking tool, the CLD later formed the basis of a system dynamic model, which quantitatively modelled policies. An overview of the components of a causal loop diagram is provided in **Table 5.1**.

**Table 5.1** Elements of a causal loop diagram, based on [297, 298, 300].

Component	Example	Description
Positive arrow	A $\xrightarrow{+}$ B	The plus (+) sign indicates that an increase (or decrease) in A results in a value of B that is greater (or less) than it would have been otherwise.
Negative arrow	A $\xrightarrow{-}$ B	The minus (-) sign indicates that an increase (or decrease) in A results in a

		value of B that is less (or greater) than it would have been otherwise.
Delay	A  B	The delay sign (parallel lines) shows that there is a delay between a change in A and an associated change in B.
Reinforcing loop		In a reinforcing loop, there are an even number of negative arrows, typically leading to exponential increase/decrease over time.
Balancing loop		In a balancing loop, there are an odd number of negative arrows, typically leading to stabilising behaviour over time.

## Study setting

The setting for this study was the KRT programme under the Universal Coverage Scheme (UCS) in Thailand. From 2008 to 2022, the UCS KRT programme required all KRT patients eligible for home-based peritoneal dialysis (PD) to receive PD; only those with health or social contraindications for PD could receive haemodialysis (HD) at a hospital or registered private centre [269]. This was known as the “PD-first” policy. Although the PD-first policy was successful in allowing UCS patients to access dialysis in the context of constrained resources, patient groups were increasingly vocal in demanding access to HD, particularly as the public health insurance schemes covering civil servants and private sector employees did not restrict HD access [238]. On 1<sup>st</sup> February 2022, in response to patient advocacy, eligibility criteria for HD were removed, with the intention that this would improve patient choice and reduce out-of-pocket spending by allowing all KRT patients to access either HD or PD without co-payment [309].

## Boundaries of analysis

We considered the drivers leading to changes in the number of registered HD and PD patients following implementation of the 2022 policy, covering both demand-side (number of patients) and supply-side (availability of services) factors. Our scope was dynamics that have an effect at the national level under routine implementation of the 2022 policy, without shocks to the system, from 2022 to 2029. As the study took place from June to October 2024, this timeframe was selected to understand influential factors that had shaped the system response to the 2022 policy, as well as how those dynamics may play out over the next 5 years, to inform future policy interventions to control the impact on budget expenditures and mortality.

Since we were considering routine implementation, we excluded shocks to the system such as flooding, infectious disease outbreaks, or closure of manufacturing plants. We additionally assumed that there would be no significant change in prevalence of kidney transplantation or advancements in dialysis technology that would displace HD or PD within the study timeframe.

## Steps to develop the CLD

The process to develop the CLD covered the following five steps: (1) development of cognitive maps from secondary interview data, (2) synthesis of cognitive maps and definition of problem boundaries, (3) development of a core CLD with analysis of system archetypes, (4) stakeholder critique of draft CLDs and revision, and (5) identification of potential solutions to improve quality of care and financial sustainability of the dialysis programme. These steps are broadly based on [297], with the addition of system archetypes as an analytical tool for sense-making [293]. Each step is described below.

### *Step 1: Cognitive maps from secondary interview data*

Cognitive maps are often used as a preliminary step to developing a causal loop diagram, to represent the mental models of individuals before engaging in a process of group sense-making [310]. We developed cognitive maps from secondary interview data from 20 informants and a focus group discussion with 12 patients, which had been conducted as part of a prior qualitative study. Informants had been selected to understand the rationale and implications of changes to Thailand's

KRT policy over the past 20 years and comprised policymakers, public and private sector healthcare professionals, manufacturers, academics, and patient representatives (**Table S5.1**). Interviews had stopped when data saturation was reached, which the researchers had defined as the point when no new themes emerged from interim analysis. Interviews had been conducted using a narrative interview style [311], in which the interviewee was encouraged to share their background and perspectives in an unstructured interview. The amount and depth of content relevant to our research question therefore varied, but the interviews served as a helpful means for the researchers to learn about the primary issues, map variables and dependencies, and highlight areas for further stakeholder discussion.

The cognitive maps were exploratory in that they helped to understand perceptions of the problem before defining the scope of subsequent analysis. We used uncoded transcripts to develop the cognitive maps for two reasons: firstly, bounding the system too early can risk loss of contextual information, and secondly, we found that many interviews required the analyst to read between the lines [312]. Use of non-standardised processes can, however, lead to cognitive bias, arising from the analyst interpretation of both what constitutes important information and when an informant is implying causality [312]. For this reason, the preliminary causal map developed from combining all cognitive maps was first reviewed by the research team conducting the qualitative interviews before proceeding to broader stakeholder critique and review.

### *Step 2: Synthesis of cognitive maps*

Cognitive maps developed from interview data were merged into a single causal loop diagram. This process was interpretivist as opposed to using a rule-based approach for two reasons. Firstly, the use of secondary data meant that we could not account for linguistic uncertainty by prompting stakeholders to clarify definitions, meaning, or implied causality. As a result, the analyst had to consider alternative frames based on contextual information in each interview. Secondly, since the interview data had been collected for a separate research question, we considered this step to be a broad mapping of the problem space to build researcher understanding and facilitate subsequent stakeholder discussions, as opposed to an accurate representation of the system.

At this stage, if there were discrepancies between cognitive maps in terms of the relationships between variables (or multiple possible pathways if implied causality from interview data was

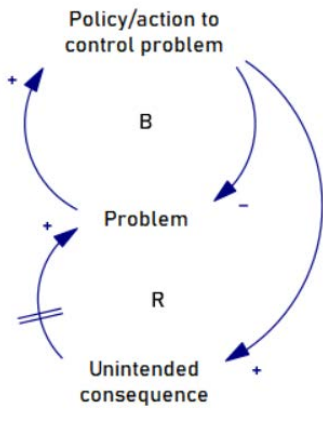
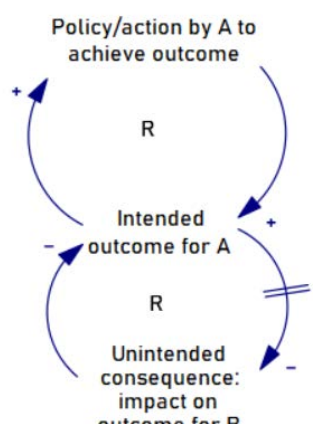
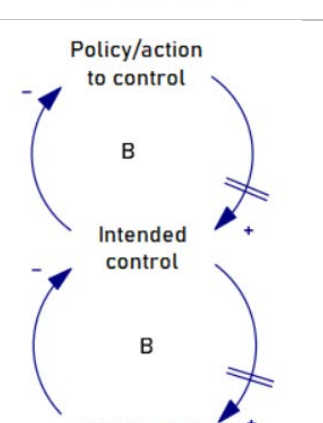
unclear), we maintained both pathways. In cases where there were differences between cognitive maps in terms of granularity, we included the more granular version. To focus on the elements of the system causing dynamic behaviour, we removed any sections of the resulting causal loop diagram for which there were both no feedback loops present and the research team could not identify potentially missing feedback loops. Presence of team members with experience researching health systems in other settings and conducting research on dialysis in Thailand supported this step. We also explicitly defined the boundaries at this stage to focus on factors affecting number of registered HD and PD patients under UCS.

### *Step 3: Analysis of archetypes*

System archetypes were used to analyse the resulting causal loop diagram, in order to develop the narrative for stakeholder consultation. System archetypes are composed of two or more loops representing an intended consequence with a delayed unintended consequence, which is hidden by an organisational boundary from the view of those instigating the change [293]. **Table 5.2** provides an overview of system archetypes.

**Table 5.2** Overview of system dynamics archetypes, based on [293].

#	Archetype	Diagram	Description
1	Underachievement		A policy or action does not achieve its intended impact because of an unintended consequence. This archetype consists of a reinforcing loop (planned action/policy) and a delayed balancing loop (unintended consequence of the outcome).

2	Out-of-control		A policy or action aiming to control a problem unintentionally makes the problem worse. This archetype consists of a balancing loop (policy/action) and a delayed reinforcing loop (unintended consequence of the policy/action).
3	Relative achievement		A policy or action achieves its intended impact at the expense of other policy initiatives. This archetype consists of a reinforcing loop (action/policy) and a delayed reinforcing loop (another policy/action that is undermined as a result).
4	Relative control		A policy or action aiming to control a problem undermines other policies or initiatives moderating the problem. This archetype consists of two balancing loops, representing the intended policy/action and another policy/action that is unintentionally affected. Either or both balancing loops may have a delay.

#### Step 4: Stakeholder critique and revision

The preliminary causal loop diagram was reviewed by stakeholders during a half-day workshop on 9<sup>th</sup> July 2024. The workshop was attended by 21 participants, four of whom had already been interviewed. Compared to the interviews, the workshop included greater representation from

nephrologists, dialysis nurses, and patients (**Table S5.2**). During the workshop, participants were separated into three groups. The composition of each group aimed to encourage participation, by separating individuals from the same profession with different levels of seniority, whilst also including a diverse set of perspectives (for example, nephrologist, health insurance agency, manufacturer, patient). All workshop participants had been selected as stakeholders with knowledge or lived experience of the 2022 policy change and its implications. Each group reviewed the CLD (shown in **Figure S5.1**) with two facilitators, in order to provide comments on the accuracy of connections and any missing elements. At least one facilitator in each group was conducting research into the impact of the 2022 policy.

The revised causal loop diagram was reviewed by workshop facilitators after the workshop to ensure that all contributions from their group had been sufficiently captured. Since there was conflicting information around the supply of HD services (particularly factors that influence opening of new clinics in the public and private sectors, as well as payment of a doctor fee for patient referral), we additionally circulated an anonymous survey to directors of HD centres in the public (n=3) and private (n=4) sector. We selected HD centre directors with at least 3 years of experience in the role (median 10, range 3-22) who were known to members of the research team or policy working group. For public sector centres, we only selected centres that also provided PD, and for the private sector, we chose two clinics and two hospitals. Size of HD centres in the sample ranged from 16 to 64 beds (median 20). Respondents were paid 500 THB for completing the questionnaire. All directors approached by the research team completed the survey in full. Questions included in the survey are detailed in **Table S5.3**.

#### *Step 5: Policy solutions*

Once the CLD had been finalised, we identified potential policy solutions from generic solution archetypes in the literature [293]. At the time of analysis, the working group under the NHSO Board had already started to discuss potential policy solutions based on literature reviews of experience in other countries and quantitative analysis of changes in number of patients, patient outcomes, and financial expenditures following the 2022 policy [275, 276, 308]. Initially, we checked to see whether any of the proposed policies aligned with generic solution archetypes in the CLD. If no appropriate policy had yet been proposed, we proposed an additional policy intervention to align with the archetype [46]



## Confidence-Building

We sought to enhance validity of the CLD through triangulation across data sources (interviews, group workshop, anonymous survey, and literature review) and through steps to enhance stakeholder dialogue and understanding. During the workshop, we built up model structure sequentially, with the group facilitator providing an explanation (or “storytelling”) for each view and highlighting key parts of the diagram [300, 313]. Following the workshop, the research team reviewed external validity of the CLD (when possible) by comparing with the literature, to verify whether the structure adhered to existing knowledge about the KRT system in Thailand [314].

## Ethics

The Ethics Committee of the Institute for the Development of Human Research Protections (IHRP) Thailand approved the sub-study for interview data collection on February 22nd, 2024 (COA No. IHRP2024025; IHRP No.002-2567).

## RESULTS

Our analysis highlighted three main dynamic interactions influencing demand and quality of care following the 2022 policy change: (1) shifts in quality of HD service provision caused by short-term coping mechanisms to deal with the surge in HD demand; (2) mechanisms to address workforce shortages that inadvertently exacerbated system strain; and (3) development of infrastructure for HD at the expense of the PD service system. In the following sections we outline the causal relationships underlying each of these components, applying system archetypes to identify potential solutions. Feedback loops in the CLD are summarised in **Table 5.3** and system archetypes with potential solutions in **Table 5.4**.

Coping measures to deal with the surge in demand for HD lowered quality standards and induced further HD demand

The 2022 policy change removed eligibility criteria determining which patients could be fully reimbursed for HD. As a result, there was a surge in demand for HD, placing pressure on vascular access services (required before patients can initiate HD) as well as HD centres. A series of short-

term measures were taken by the public health insurance agency (NHSO), private HD centres, and doctors to cope with the increase in demand. However, as shown in **Figure 5.3a**, certain key measures had unintended consequences that controlled the problem in the short-term but exacerbated the supply constraints in the long-term. These measures are characteristic of the *out-of-control archetype* (B1/R1, B2/R2, B3/R3, and B4/R4), in which a balancing loop is counteracted by a delayed reinforcing loop, and that of the *relative-control archetype* (drifting goal as a special case, B1/B2).

The first coping measure had been taken by NHSO prior to 2022. Regulations to approve a new HD centre were relaxed, allowing HD centres to provide services without Thailand Renal Replacement Therapy (TRT) certification (balancing loop B1), in order to accelerate approval of new HD centres given the limited capacity for quality assurance (QA).

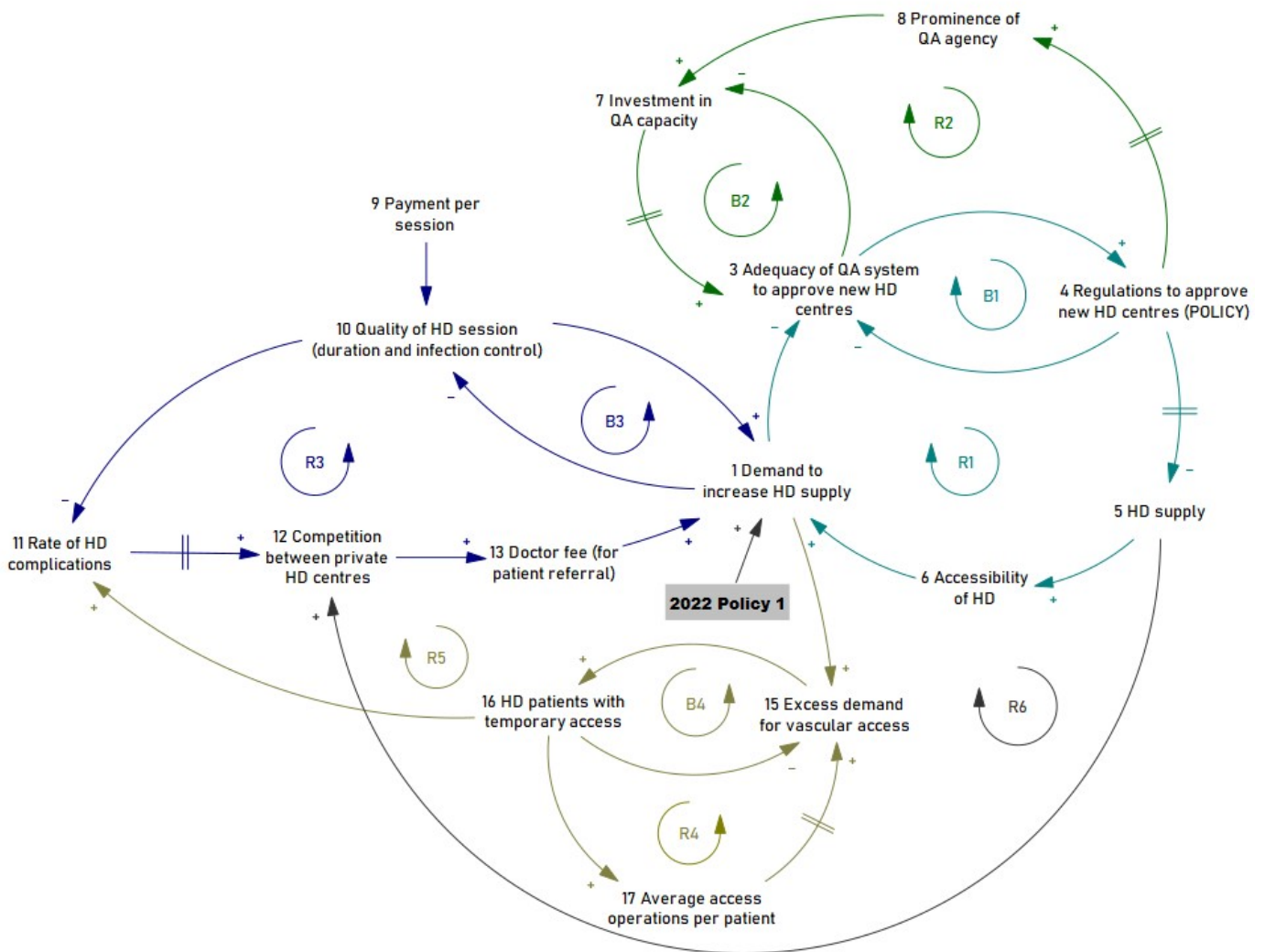
“ปี 63 ยกเลิกใช้ใบ ตรต. ทำให้มีหลายที่ไม่ได้ขึ้นทะเบียนหน่วย และเข้า สปสช. ได้เลยในบางเขต ทำให้มีปัญหาในเทศบาล ที่จะตั้งเป็น รพ. ที่จัดตั้งไม่ได้ ไม่มีคนช่วยดูการขึ้นทะเบียน ถ้า outsource ไม่ยื่นตรวจ ตรต. ก็จบ”

“In 2020, the requirement for TRT certification was abolished, causing many centres to provide services to NHSO without TRT registration. [The TRT certificate] had been causing problems in certain municipalities that were setting up hospitals that could not be established as there was no one to facilitate the registration. If the centre manager did not submit a TRT registration report, it was over.”

*Kidney Association representative (the Kidney Association is responsible for the management of TRT), workshop on 9<sup>th</sup> July 2024*

However, this policy unintentionally increased demand for HD: the opening of private HD clinics meant that more patients could access HD, putting pressure on NHSO to maintain the lower QA standards (reinforcing loop R1). Perhaps more importantly, B1 and B2 form a *relative control archetype*, in which actions to control the inadequate QA system distracted away from investment in QA capacity to regulate the growing number of HD centres. This illustrates the archetype of *drifting goals* (i.e. a special case of *relative control archetype*), in which targets are lowered for short-term impact instead of addressing the fundamental problem (inadequate QA capacity). In the longer term, this could lower the perceived importance of regulatory mechanisms (reinforcing loop R2), leading to chronic underinvestment in QA. This is a case of *shifting the burden* archetype, in which the short-term fix undermines fundamental solutions.

**Figure 5.3a** Dynamics causing shifts in quality of HD service provision caused by short-term coping mechanisms to deal with the surge in HD demand.



HD – haemodialysis, QA – quality assurance

The second set of measures to address the surge in HD demand was taken by private HD centres. HD centres are reimbursed per HD session [315], creating a system in which the goal is to increase number of HD sessions per centre. To address the high demand for HD, certain private centres reduced the length of HD sessions and cut back on infection prevention and control measures (balancing loop B3). As a result, the rate of complications among HD patients increased. Although patients with complications receiving HD at public or private hospitals can be treated in the same hospital, patients in private HD clinics have to transfer to a hospital. High complication rates can

therefore increase the number of transfers from private HD clinics to hospitals. Beyond increasing burden on hospitals, this reduces the number of clients in private HD clinics and increases competition for clients. Private HD centres can attract new patients by remunerating doctors referring patients to their HD centre. This fee (referred to as the doctor fee) is paid per patient per session. In the private centres surveyed, 3 out of 4 paid a doctor fee, which varied between 150 and 250 THB per session.

“ค่า DF

เนี่ยมันเกิดขึ้นเนื่องจากว่าโรงพยาบาลหรือเอกชนเนี่ยไปออกแบบเองเพื่อที่จะดึงคนไข้แล้วก็อาจจะให้หมอโรคไตชักจูงให้หมอโรคไตส่งคนไข้เนี่ยไปให้เขา นี่ก็ออกใหม่ครับ ส่งคนไข้ไปให้เขาถ้ายังส่งมาเขาก็มีค่าตอบแทนกลับไปของหน่วยบริการนะ”

“The DF [doctor fee] was designed by hospitals and private companies to attract patients and to persuade nephrologists to refer patients to them. Do you understand? If you refer patients to them, the more patients you send, the more compensation you will receive from the HD centre.”

*Nephrologist 1 interview*

Increased competition for HD patients can raise the doctor fee, increasing the financial benefit for doctors to recommend HD to their patients (or even to initiate HD prematurely), further increasing number of new HD patients and maintaining demand to increase HD supply (reinforcing loop R3). This is an example of *setting the wrong goal archetype*, in which the incentives in the system lead to agents following a goal that is not aligned with the broader health system objectives.

The final coping mechanism in this section concerns vascular access, which is required before patients can initiate HD. The surge in HD patients meant that there were long waiting times for vascular access. Many doctors therefore initiated patients on HD with temporary access (balancing loop B4). Although this temporarily relieved pressure on vascular access services, it is another example of the *fixes that fail archetype* (a special case of *out-of-control archetype*), in which a delayed reinforcing loop unintentionally exacerbates the problem, as HD patients with temporary access are more likely to need multiple vascular access operations, leading to a growth in demand for vascular access services over time (reinforcing loop R4).

“อย่างเช่นเส้นเลือดอย่างเช่นตรงอะไรอย่างเงี้ยมันก็ไม่ทันครับมันก็ไม่ทันเพราะมีการ shift

พอสมควรเลยก็ต้องไปใช้เส้นเลือดชั่วคราวเยอะขึ้น”

“For example, things like blood vessels are not ready in time. It’s not in time and because there’s quite a lot of shifting, we have to use more temporary vessels.”

*Nephrologist 1 interview*

HD patients with temporary access have a higher rate of complications [316], leading to a net increase in the average doctor fee, due to previously described mechanisms (reinforcing loop R5).

“คนไข้ต้องไปใช้เส้นเลือดชั่วคราวนะครับซึ่งมันมีเสี่ยงมากเลย เสี่ยงต่อการติดเชื้อ”

“The patient has to use temporary blood vessels, which are very risky and risk infection.”

*Nephrologist 1 interview*

#### *Policies to ensure adequate supply whilst maintaining quality of care*

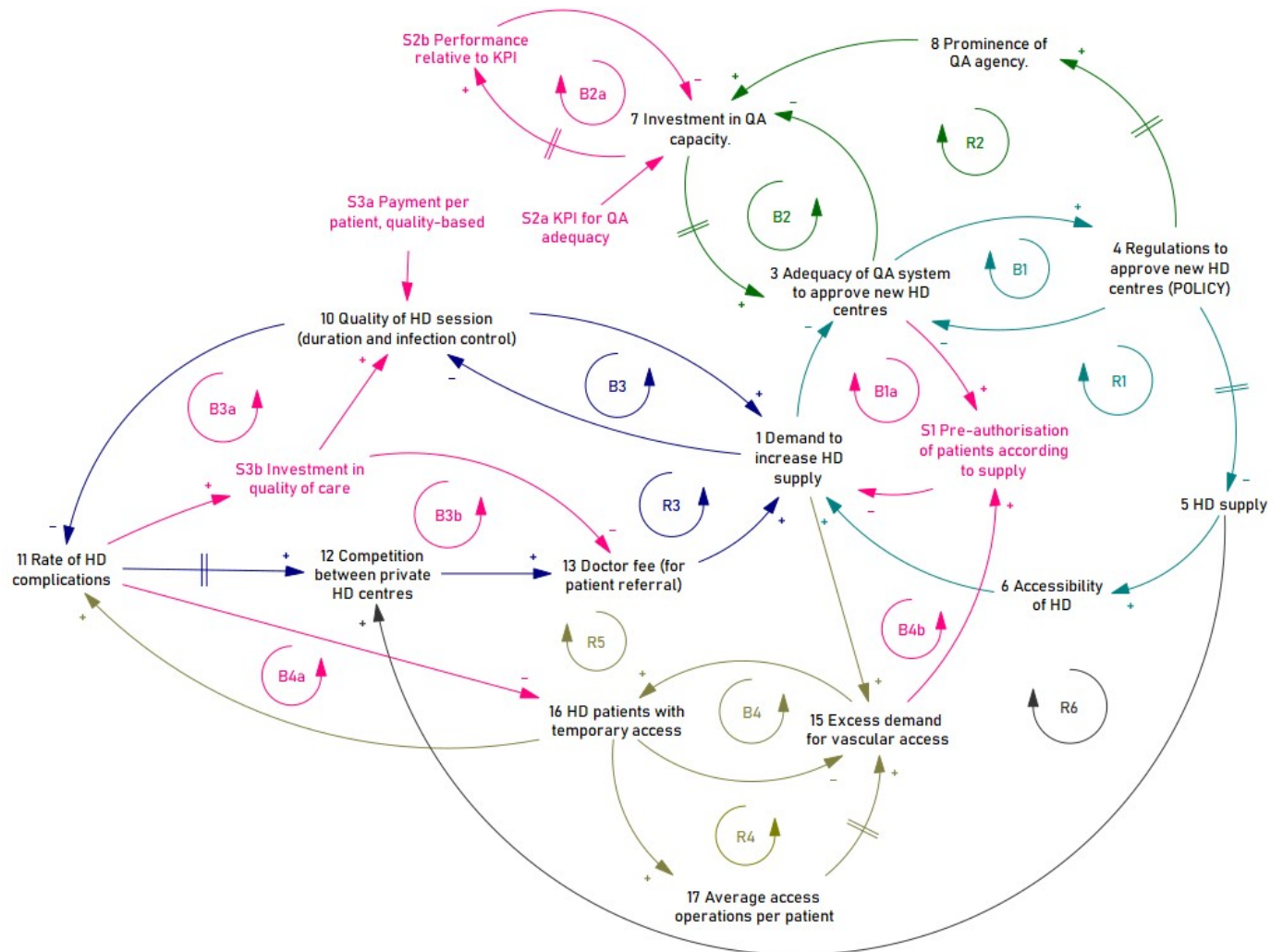
Our analysis of system archetypes identified the following policy interventions: (1) pre-authorisation of new HD patients that accounts for availability of vascular access and HD services, (2) key performance indicators (KPI) related to number and competence of QA staff in relation to number of HD centres, and (3) changing the payment mechanism from fee per service to quality-based payments per patient. **Figure 5.3b** depicts the potential impact of these policies on the causal loop diagram.

A pre-authorisation system would require each patient to be approved by an oversight board at the regional level before they are able to access dialysis services. A similar system had been in place prior to the 2022 policy change. However, unlike the 2008-2022 policy, the pre-authorisation system would allow patients who prefer HD to access HD, provided that: (1) timing to initiate HD is appropriate given the patient’s kidney function, (2) the patient would not have better quality of life with another treatment, and (3) there is available HD supply. In the context of constrained HD supply, patients requesting HD who are not contra-indicated would be required to start dialysis on PD. This solution aims to reduce induced demand for HD, including premature HD initiation, by replacing reinforcing loops R1/R6 and R5 with balancing loops B1a and B4b respectively. In balancing loop B1a, pre-authorisation phases the increase in HD patients at a rate that is constant with regulatory approval of new HD centres. In balancing loop B4b, excess demand for vascular access beyond system capacity is similarly moderated. This solution had already been proposed by the policy working group prior to our analysis.

The intention of a key performance indicator for QA staff would be to set a goal (for either the Ministry of Public Health or NHSO) that maintains investment into the QA system independent of measures to relax/heighten regulations. Such a measure aims to guard against a loss of capacity and maintain perceived importance of QA, by triggering investment when capacity is insufficient (balancing loop B2a).

Changing the payment mechanism from fee per session to patient-level payments contingent upon quality indicators aims to better align goals of service providers with those of the health system. Instead of increasing number of HD sessions, the emphasis is shifted to improving quality of patient outcomes. Reinforcing loop R3 is closed by balancing loops B3a and B3b, since higher complication rates trigger measures to improve quality of care (balancing loop B3a). This in turn reduces the funding available to pay for the doctor fee (balancing loop B3b). Patients with temporary access are expected to decrease also, in an effort to reduce complications (balancing loop B4a).

**Figure 5.3b** Potential solutions (in pink) to address the problems in Figure 5.3a, based on generic solutions for out-of-control and relative control archetypes.

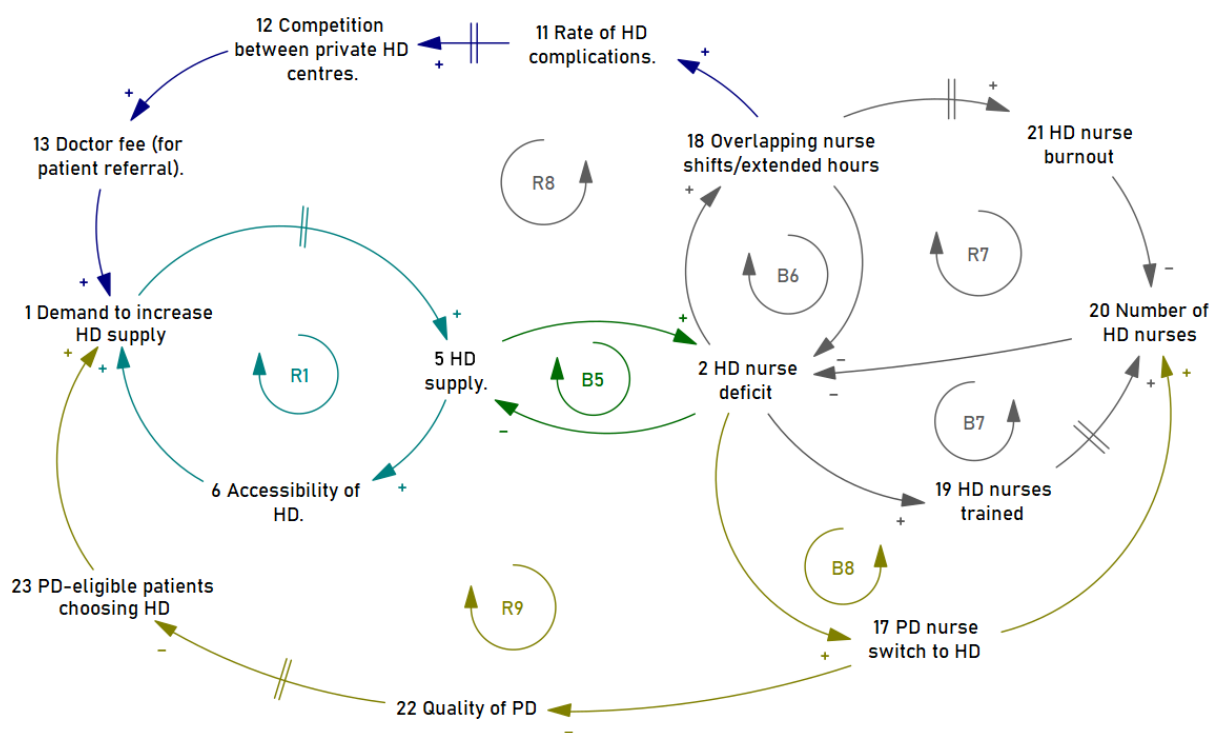


HD – haemodialysis, KPI – key performance indicator, QA – quality assurance

Mechanisms to address HD nurse shortages compromised quality of care and placed increased pressure on the HD nurse workforce

One of the factors counterbalancing the increase in HD supply is the availability of HD nurses, which acts as a limit to HD growth (loops R1/B5). As shown in **Figure 5.4a**, number of HD nurses can be increased through additional training, according to annual quotas determined by the Nursing Council. Short-term responses to overcome nurse shortages temporarily relieved system pressure, but compounded deficit of HD nurses in the long-term, either by increasing demand for HD (*out-of-control archetypes* B8/R9 and B6/R8) or by decreasing number of HD nurses (*out-of-control archetype* B6/R7 and *relative control archetype* B6/B7).

**Figure 5.4a** Dynamics affecting availability of HD nurses relative to demand.



HD – haemodialysis, PD – peritoneal dialysis



In the current system, HD nurses have opportunities for career progression and recognition that are not available to PD nurses. There is therefore an ongoing transition of PD nurses to HD, which tends to be the more experienced nurses.

“Career pathway ผลตอบแทนพิเศษ แรงจูงใจ ไม่มีให้พยาบาล PD”

“PD nurses do not have a career pathway, special compensation, or incentives.”

*Nephrologist 1, workshop on 9<sup>th</sup> July 2024*

“Mindset คนไทยให้ของขวัญพยาบาลไตเทียมเยอะ มี social recognition”

“It is in the mindset of Thai people to give lots of gifts to haemodialysis nurses. They have social recognition.”

*Nephrologist 2, workshop on 9<sup>th</sup> July 2024*

With the sharp increase in HD nurse deficit following the 2022 policy change, one of the system responses was an increase in the rate of PD nurses transitioning to HD (balancing loop B8), which had implications for patient decisions between PD and HD (reinforcing loop R9). One of the main factors influencing patient decisions between PD and HD is perceived risk of infection on PD:

“[The three patient representatives] mentioned that they may not fully understand the concept of quality or survival outcomes, but they focus on the side effects and complications of dialysis, such as infections [...] Complications seem to be one of the main factors that concern some patients.”

*Observations of patient inputs, workshop on 9<sup>th</sup> July 2024*

Although there are complications for HD too, the symptoms are often difficult to attribute directly to HD (for example, sepsis or cardiovascular disease), whereas the cause of peritonitis and other PD complications is less ambiguous.

As more PD nurses switch to HD, risk of infection for PD patients increases due to the higher ratio of PD patients per nurse [317] and loss of experienced PD nurses.

“More experienced nurses tend to move to the private sector. The government setting has to train new, less experienced nurses, which may affect the quality of service.”

*Observations of nurse inputs, workshop on 9<sup>th</sup> July 2024*

As a consequence, the proportion of PD-eligible patients choosing HD increases. This is another example of the *out-of-control archetype*, as the short-term counteracting measure exacerbates

demand for HD nurses in the long-term. Although PD nurses switching to HD is not an intentional action (which is a common feature of archetypes), we have nonetheless included it within the CLD, as it is influenced by the compensation and professional hierarchy within the Ministry of Public Health system.

The second mechanism to control the deficit in HD nurses was implemented by HD centres. HD nurse training takes 4-6 months (or longer for specialised HD nurses), represented by the delay in balancing loop B7. Many centres therefore implemented short-term measures to address workforce shortages (balancing loop B6): more HD nurses worked overtime or extended their hours to cover more shifts and some private HD centres registered the same nurse in two centres with overlapping shift times. As a result, more HD nurses had high workload, experienced burnout, and left to other professions (reinforcing loop R7).

“The increase in salary is not due to the amount of money but because of the increased workload (number of sessions and patients). This causes the number of nurses to decrease because it affects their quality of life.”

*Observations from public sector nurse input, workshop on 9<sup>th</sup> July 2024*

Short-term coping mechanisms not only distracted away from HD nurse training programmes (*relative control archetype*, B6/B7), but also reduced training programme impact, as HD nurse turnover had increased (*out-of-control archetype*, B6/R7). Quality of HD services also decreased. Similar to reinforcing loop 3, this can lead to an increase in financial incentives for HD, exacerbating HD nurse shortages in the long term (reinforcing loop R8).

#### *Policies to sustainably address shortages in HD nurse workforce*

We identified the following potential solutions to the deficit in HD nurses, based on the system archetypes: (1) quality-based payments per patient as opposed to payment per HD session, (2) setting a KPI for the Ministry of Public Health or the Nursing Council related to number of registered HD nurses relative to HD patients, and (3) enforceable regulations defining maximum HD patients and/or hours per HD nurse. The modified CLD with solution archetypes is shown in **Figure 5.2b**.

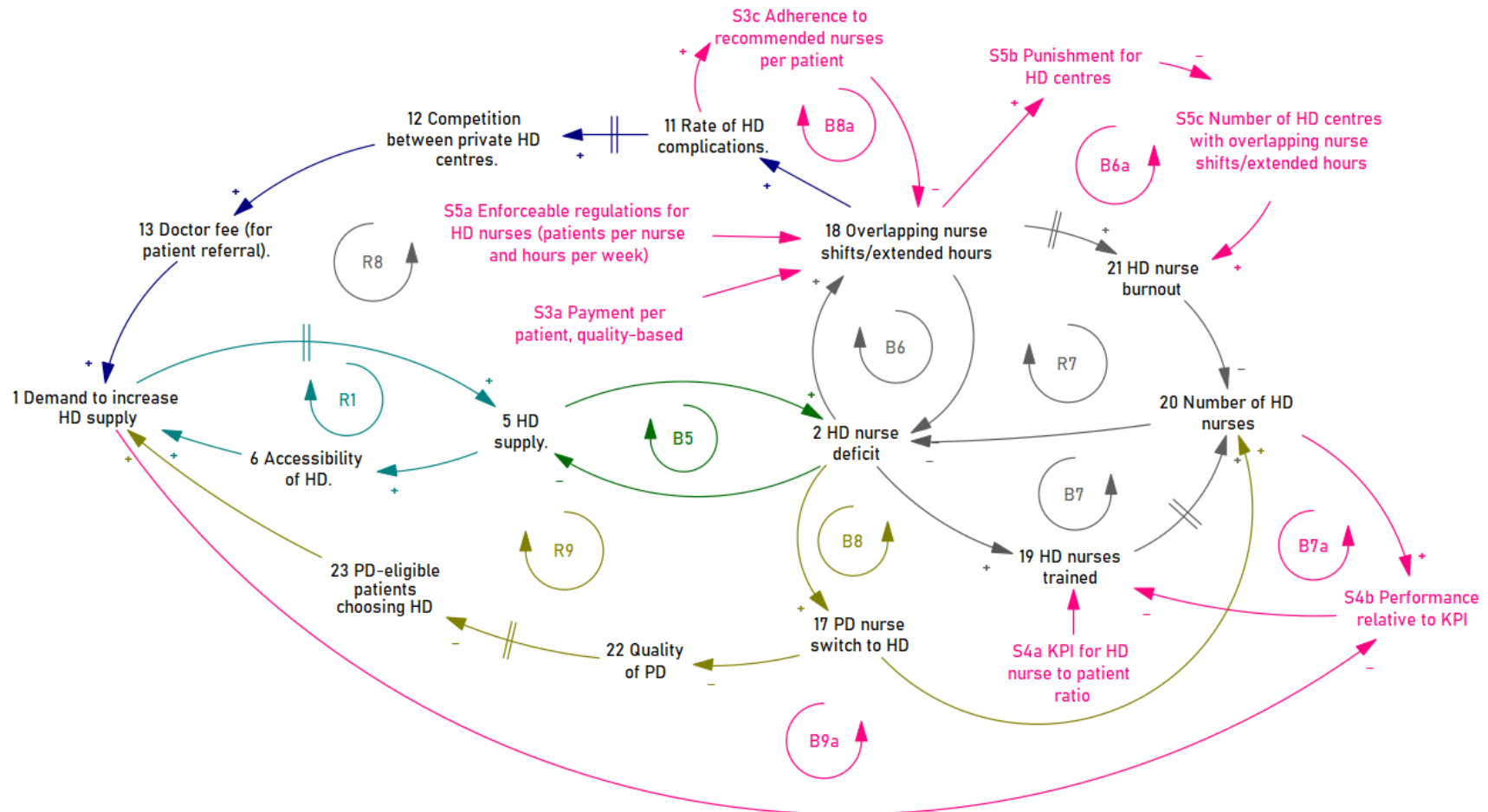
Quality-based payments per patient aim to change the incentive for healthcare providers towards increasing patient quality of life. This closes reinforcing loop R8, as it is expected that HD centres are

more likely to adhere to the recommended number of nurses per patient, in order to manage complication rates (balancing loop B8a).

Setting a KPI for the HD nurse to patient ratio aims to fix number of nurses trained according to actual need (nurse to patient ratio) and not perceived need, which may be obscured by temporary coping mechanisms. This provides a holistic solution to the *relative control archetype* in loops B6, B7, and B8, as the fundamental solution to HD nurse shortages (training) is moderated relative to KPI performance (B7a and B9). This KPI is not at the level of individual centres (who face severe nurse shortages) but at the national level. It would require, however, regular censoring of HD nurses in active employment, which does not currently exist, and measures to address regional health workforce inequities.

Enforceable regulations around maximum workload for HD nurses (in terms of patients and/or hours per week) aim to reduce burnout of HD nurses. The structure of loop R7 is changed to a balancing loop (B6a), controlling HD nurse burnout by punishing HD centres exceeding the permissible weekly HD nurse workload.

**Figure 5.4b** Potential solutions (in pink) to address the problems in Figure 4a, based on generic solutions for out-of-control and relative control archetypes.



HD – haemodialysis, KPI – key performance indicator, PD – peritoneal dialysis

Underinvestment in PD capacity coupled with increasing investment in HD has led to a decline in PD uptake

In contrast to the HD system, the system for PD is characterised by archetypes that limit its growth (**Figure 5.5a**). In the *growth and underinvestment archetype* (special case of the *underachievement archetype*), an initial improvement in performance is limited by a resource constraint, and the resulting drop in performance discourages further investment [293]. In the case of PD, as number of PD patients increases, so does experience and size of PD centres, improving the quality of PD services [317, 318] (reinforcing loop R10). However, quality is also dependent on the availability of PD nurses [317, 318], which decreases with more PD patients (balancing loop B9). Expansion of PD capacity (including number of PD centres and PD nurses) is dependent on perceived investment need by hospital directors. There is a delay between perceived investment need, investment, and increase in capacity, due to the time to train nurses and open PD centres (balancing loop B10). As a result, increases in infection from lack of capacity can lead to fewer patients choosing PD, which disincentivises further PD investment.

“If the number of PD patients decreases, hospital directors may not perceive the importance of PD nurses and may not support their training.”

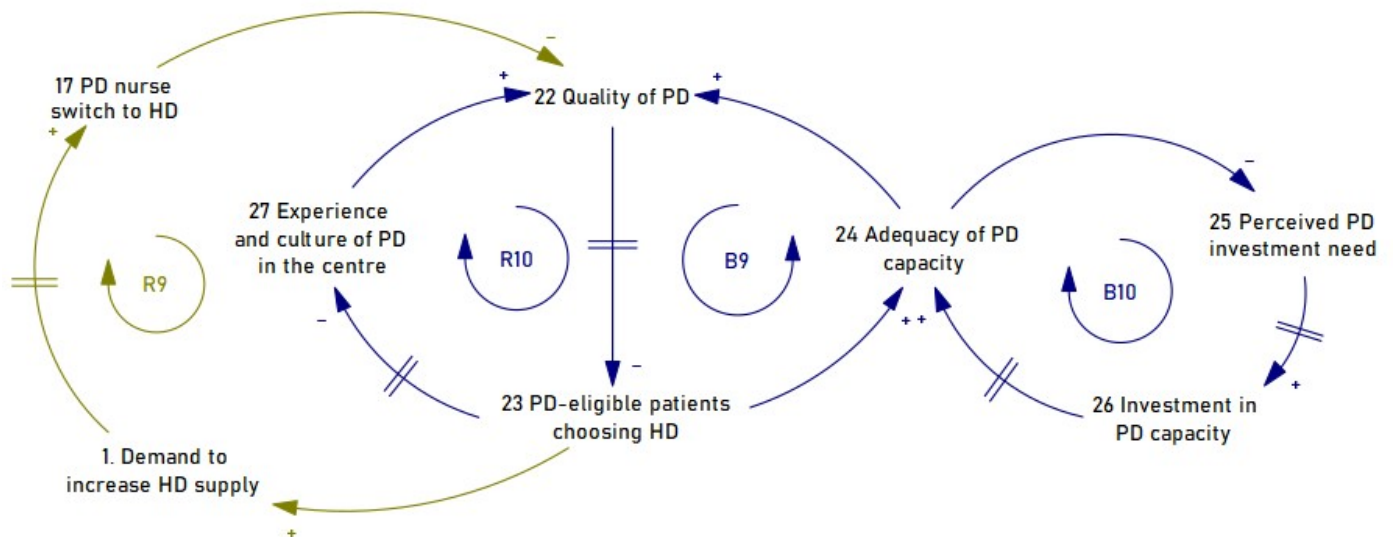
*Observations from nephrologist input, workshop on 9<sup>th</sup> July 2024*

The second archetype constraining growth of PD is the success to the successful, or *relative achievement archetype*. In reinforcing loop 9, an increase in PD nurses switching to HD led to fewer patients selecting PD. When combined with reinforcing loop R10, this leads to a loss in the experience and culture of PD in public hospitals providing PD services. The growth of HD is therefore achieved at the expense of the PD system.

#### *Policies to maintain capacity for PD*

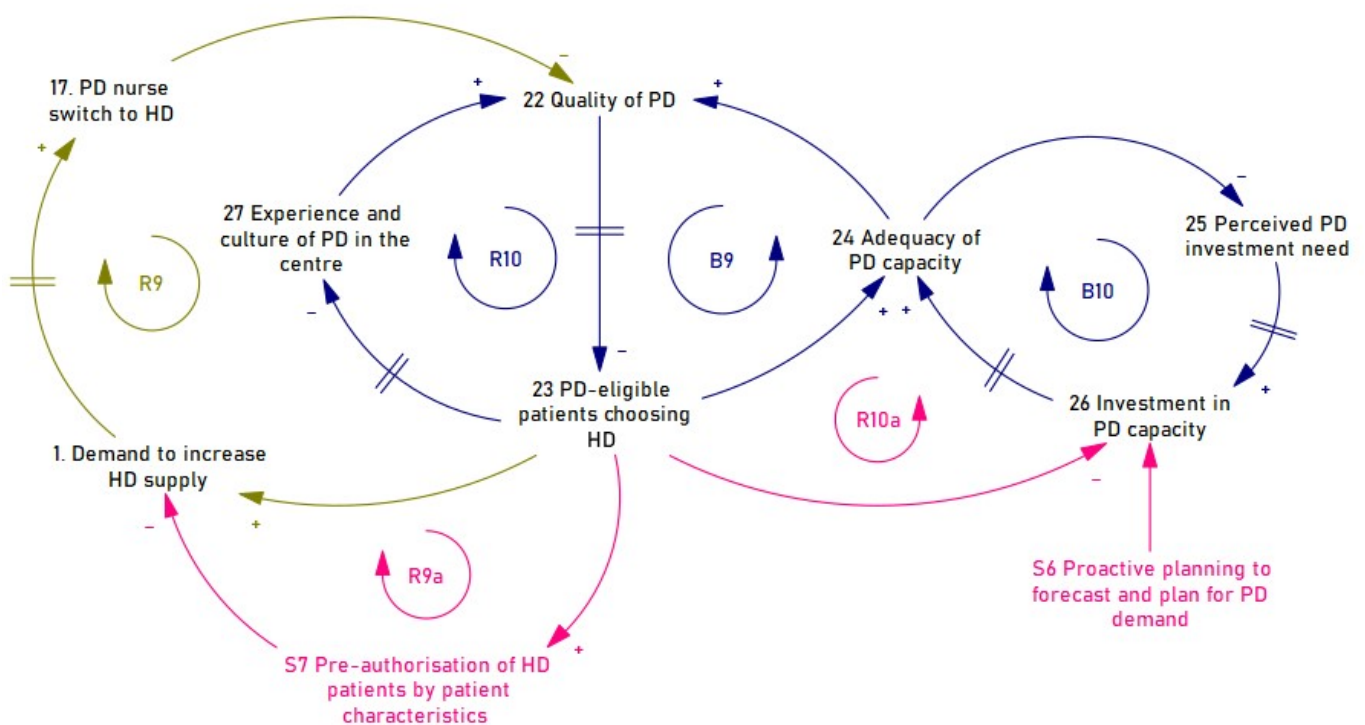
The solution archetype for underachievement involves development of a proactive plan, and the solution archetype for relative achievement entails external regulation[293]. As shown in **Figure 5.5b**, proactive planning to scale PD investment relative to projected PD demand addresses underinvestment in PD (reinforcing loop R10a), while an independent pre-authorisation system to approve patients initiating HD according to patient characteristics would maintain the number of patients selecting HD at a level that is sustainable for the system (reinforcing loop R9a).

**Figure 5.5a** Dynamics affecting availability and quality of PD services.



HD – haemodialysis, PD – peritoneal dialysis

**Figure 5.5b** Potential solutions (in pink) to address the problems in Figure 5.5a, based on generic solutions for underachievement and relative achievement archetypes.



HD – haemodialysis, PD – peritoneal dialysis

**Table 5.3** Overview of reinforcing loops and balancing loops in the causal loop diagram. For each loop it is noted whether the loop describes an intended or unintended consequence of a policy/action, or an initiative beyond the organisational boundary of stakeholders implementing a particular policy or action.

Loop	Variables	Description
Balancing loops		
B1	3 → 4 → 3	Stringency of regulations to approve new HD centres determine pressure on the registration system (intended control measure).
B2	3 → 7 → 3	Investment in quality assurance capacity affects the adequacy of the quality assurance system (initiative outside organisational boundary).
B3	1 → 10 → 1	Quality of HD services (predominantly session length and adherence to infection control measures) is influenced by level of demand for HD services (intended control action).
B4	15 → 16 → 15	Providing HD patients with temporary access (via a catheter) affects demand for vascular access (intended control action).
B5	5 → 2 → 5	Changes in supply of HD services affect the deficit of HD nurses (unintended consequence).
B6	2 → 18 → 2	The magnitude of the HD nurse deficit influences the level of overlapping nurse shifts and overtime work for HD nurses (intended control action).
B7	2 → 19 → 20 → 2	Number of HD nurses trained depends on demand for HD nurses (initiative outside of organisational boundary).
B8	2 → 17 → 20 → 2	Deficit of HD nurses affects the rate at which PD nurses switch to HD (system control measure).
B9	23 → 24 → 22 → 23	Adequacy of the PD system for number of PD patients affects PD quality of care (system response to changes in number of PD patients).
B10	24 → 25 → 26 → 24	Investment in PD capacity depends on perceived adequacy of PD system (intended control action).
Reinforcing loops		
R1	3 → 4 → 5 → 6 → 1 → 3	Changes in regulations to approve new HD centres can induce demand for HD services (unintended consequence).

R2	3 → 4 → 8 → 7 → 3	Changes in regulations to approve new HD centres influence investment in quality assurance capacity (unintended consequence).
R3	1 → 10 → 11 → 12 → 13 → 1	Quality of HD service provision affects financial incentives for doctors to refer patients for HD (unintended consequence)
R4	15 → 16 → 17 → 15	Number of HD patients with temporary access alters long-term demand for vascular access services (unintended consequence)
R5	15 → 16 → 11 → 12 → 13 → 1 → 15	Changes in number of patients with temporary HD access influences financial incentives for doctors to refer patients for HD (unintended consequence).
R6	3 → 4 → 5 → 12 → 13 → 1 → 3	Changes in HD supply influence financial incentives for doctors to refer patients for HD (unintended consequence).
R7	2 → 18 → 21 → 20 → 2	Measures to cope with HD nurse deficit affect rates of HD nurse burnout (unintended consequence).
R8	2 → 18 → 11 → 12 → 13 → 1 → 5 → 2	Measures to cope with HD nurse deficit influence financial incentives for doctors to refer patients to HD (unintended consequence).
R9	2 → 17 → 22 → 23 → 1 → 5 → 2	Rate at which PD nurses switch to HD influences level of demand to increase HD supply (consequence of system change).
R10	23 → 27 → 22 → 23	Quality of PD depends on level of experience and culture for PD (system response).
Solution loops		
B1a	3 → S1 → 1 → 3	Pre-authorisation of patients according to available supply controls pressure on regulatory system.
B2a	7 → S2b → 7	With key performance indicators (KPI) for the adequacy of quality assurance mechanisms, adequacy of registration systems to meet demand affects level of investment in quality assurance mechanisms.
B3a	10 → 11 → S3b → 10	With quality-based payments per patient to HD service providers, rate of complications affects level of investment in quality of care.
B3b	1 → 10 → 11 → S3b → 13 → 14 → 1	Investment in quality of care affects financial incentives for doctors to refer patients to HD.



B4a	16 → 11 → 16	With quality-based payments per patient to HD service providers, rate of complications regulates number of HD patients with temporary access.
B4b	15 → S1 → 1 → 15	Pre-authorisation of patients according to available supply controls pressure on vascular access services.
B6a	2 → 18 → S5b → S5c → 21 → 20 → 2	With enforceable regulations restricting HD patients per nurse and HD nurse maximum hours per week, punishment for HD centres not adhering to the rules regulates level of HD nurse burnout.
B7a	19 → 20 → S4b → 19	Performance indicators linked to availability of trained HD nurses for the Ministry of Public Health regulate HD nurse training relative to nurse deficit.
B8a	18 → 11 → S3c → 18	Demand forecasting for HD nurse training by the Ministry of Public Health changes nurses trained according to anticipated demand for HD services.
B9a	2 → 17 → 22 → 23 → 1 → S4b → 19 → 20 → 2	With a KPI target for HD nurse to patient ratio, changes in HD demand influence HD nurse training.
R9a	23 → S7 → 1 → 17 → 22 → 23	Pre-authorisation of patients initiating HD provides external regulatory control to the balance of PD to HD patients.
R10a	23 → 26 → 24 → 22 → 23	Proactive forecasting for PD capacity links investment in PD infrastructure and nurses to anticipated need.

**Table 5.4** Summary of problem archetypes and potential solutions (see text for details).

#	Problem	Archetype	Loops	Potential solutions	Solution loop(s)
1	Short-term fix to overcome bottlenecks in registration of private HD centres lowers quality and increases demand	Fixes that fail (out of control)	B1, R1, R6	<b>S1:</b> Pre-authorisation of new HD patients according to supply availability	B1a
		Drifting goal (relative control); Shifting the burden (out of control)	B1, B2, R2	<b>S2a:</b> Key performance indicators for regulatory capacity based on availability and competence of staff	B2a
2	Payment mechanism incentivises volume, not quality, of HD sessions	Seeking the wrong goal (out of control)	B3, R3	<b>S3a:</b> Payment per HD patient based on quality indicators	B3a, B3b
3	Short-term fix to address bottlenecks in vascular access exacerbates demand	Fixes that fail (out of control)	B4, R4, R5	<b>S1:</b> Pre-authorisation of new HD patients according to supply availability <b>S3a:</b> Payment per HD patient based on quality indicators	B4a, B4b
4	System response to address HD nurse deficit amplifies HD demand	Out of control	B8, R9	<b>S4a:</b> KPI for HD nurse to patient ratio	B9a
5	Short-term response to HD nurse deficit increases HD demand	Out of control	B6, R8	<b>S3a:</b> Payment per HD patient based on quality indicators	B8a

6	Short-term fixes for HD nurse deficit distract from investment in HD nurse training and exacerbate the problem over time	Drifting goals (relative control)	B6, B7	<b>S4a:</b> KPI for HD nurse to patient ratio	B7a
		Shifting the burden (out of control)	B6, B7, R7	<b>S5a:</b> Enforceable regulations for HD nurses (patients per nurse and hours per week)	B6a
7	High quality of PD services reduces perceived need for investment in PD, limiting future growth of PD	Growth and underinvestment (underachievement)	R10, B9, B10	<b>S6:</b> Proactive plan for investment in PD capacity relative to projected demand	R9a
8	Growth of HD occurs at the expense of PD	Success to the successful (relative achievement)	R9, R10	<b>S7:</b> External regulation of patient eligibility for PD/HD, via pre-authorisation	R10a

## DISCUSSION

In this study we applied systems thinking to understand the dynamics underlying demand and supply for KRT services following the 2022 policy in Thailand, which lifted restrictions to certain services but also unintentionally increased registered patients, expenditures, and patient mortality. Our analysis suggests that these unintended consequences arose from reactive actions that did not account for long-term consequences. Underinvestment in PD from demand-based (as opposed to proactive) planning failed to capitalise on prior gains in expertise and quality of PD services. For HD, a series of short-term measures to overcome supply constraints had the unintended consequence of increasing long-term demand, degrading the quality of both HD and PD services.

By applying generic solution archetypes, we identified a series of measures to balance demand for services with system capacity: (1) changing payment mechanisms from fee-per-service to quality-based fee-per-patient; (2) putting in place an external regulatory mechanism (pre-authorisation) to approve dialysis initiation according to patient profile and available supply; (3) using data from the regulatory mechanism to proactively project demand and invest in future capacity for KRT services and quality assurance mechanisms; (4) introducing key performance indicators linked to adequacy of the nurse workforce and quality assurance bodies; and (5) introducing and enforcing regulations around workload of HD nurses. Overall, these measures seek to align incentives within the system with those of the health sector, as well as shifting from reliance on market forces to proactive planning and external regulation.

Our findings reflect recommendations from a strategic health workforce planning group model building exercise in Thailand, which found that investment in hospitals and measures to increase the hospital workforce not only amplified shortages in healthcare staff and investment at lower levels of the healthcare system, but also further amplified demand for hospital services [305]. Through quantitative system dynamics modelling, study authors similarly propose a shift away from reactive measures aimed at increasing system capacity towards proactive planning and system re-design [305].

Since our study was exploratory in nature, we focussed on policy interventions with the highest potential to improve quality and financial sustainability, but success will depend to a large extent on how each policy is implemented. For example, the success of quality-based provider payments can depend on whether the selected KPIs fully capture quality from a clinical and patient perspective, timeliness of provider payments, and mechanisms to account for social determinants of health in the populations served by different providers [319–321]. To address

this, we propose that the CLD continue to be updated throughout policy planning and implementation to facilitate learning. CLDs are best used in policy when iteratively updated to integrate new information and inform programme design as new insights emerge [299]. The NHSO Board has established a permanent policy working group on kidney disease, tasked with setting up a monitoring system and conducting periodic review of data to propose refinements to the policy. The CLD could support this working group to prioritise research and to refine the policy as further knowledge emerges. Beyond improving KRT policy roll-out, this would have the additional benefit of building capacity for systems thinking within NHSO policy processes, supporting future institutionalisation of evidence-based processes for policies related access and delivery of services, which will need to account for system complexity.

A strength of our study is that we applied system archetypes to understand and narrate the complexity of the CLD, which has been underutilised in similar studies (for example [290, 291, 322–325]). However, it is possible that the reliance on system archetypes constrained the solution space of our proposed policy interventions. A policy proposed by the policy working group that was not identified by system archetypes approach was abolishing financial incentives for doctors. Instead, our proposed solutions to change payment mechanism (solution loop S3a) and external regulation (solution loops S1 and S7) indirectly affect the same issue. It is unclear whether the solutions identified by archetypes may be more robust (stakeholders mentioned, for example, that more aggressive marketing or gifts to doctors could replace the doctor fee, if abolished), or whether it would have been prudent to take a more comprehensive approach to identify solutions beyond focussing on system archetypes. Similarly, the working group proposed patient education by multi-disciplinary teams and protocols to evaluate new patients for comprehensive conservative care, as effective approaches that had reduced demand for HD in other countries [275, 276]. Neither of these policies changed the structure of loops in the CLD and were therefore not proposed by our analysis. We argue that they may be an example of interventions that have limited transferability across different health system contexts – which systems thinking methods intend to explore – but verifying this hypothesis is important for evaluating the applicability of general solution archetypes. We plan to explore both of these questions further through system dynamic modelling of interventions (both those proposed in this paper and others nominated by stakeholders) and through longer-term monitoring of the final policy change. If solutions outside of generic archetype solutions do appear to offer important benefits, we would propose coupling archetype-based solutions with other established techniques to identify policy interventions from CLDs from system-wide leverage points. These techniques include disrupting or strengthening individual loops by modifying loop

structure and targeting high impact nodes (for examples see [61, 326]), as opposed to “closing” archetypes.

Other limitations of our study primarily arose due to time and resource constraints, which is often a feature of studies conducted to directly inform policy [13, 36]. The CLD was developed by a single researcher, which could have led to cognitive bias in interpreting relevant information in causal links. We believe that this limitation was overcome by review from other researchers who were conducting concurrent studies aiming to understand factors influencing the rise in number and death rate of patients on HD, with access to official databases [238], as well as from critique during a stakeholder workshop. However, the workshop was only half a day, which was sufficient for gaining feedback and input from all stakeholders, but not for coming to a shared understanding across the different groups. More importantly, we did not have the opportunity to present back proposed solutions to workshop participants, which would have identified whether our view of the system led us to ignore potential consequences, including range of possible stakeholder responses [325]. We did, however, follow-up regularly with the secretariat coordinating all research projects for the 2024 KRT policy for their review of interim drafts, as secretariat members had a broad knowledge of different stakeholder perspectives and the body of research on KRT in Thailand. Finally, although CLDs are typically developed through open discussion to improve joint learning, certain information in the CLD is based on an anonymous survey with a small sample size. Yet since we were requesting sensitive information, we felt this was necessary, as use of anonymous surveys has been found to improve validity of participant answers [271].

Incorporation of this analysis within official policy processes of the NHSO improved the legitimacy of the study, as evidenced by a high level of engagement from all stakeholders approached throughout the analysis, and also allowed us to leverage data and insights from other commissioned research studies. Perhaps unsurprisingly for a new approach being introduced into established policy institutions, stakeholder understanding of the CLD itself was low, and we relied heavily on storytelling to receive their feedback and input. Applying system archetypes did, however, identify additional policy solutions and highlighted which of a long list of proposed policy interventions were most likely to be successful in the Thai context.

To our knowledge, this is the first study to illustrate the use of causal loop diagrams within established health priority-setting policy mechanisms. We show how systems thinking can surface and integrate different perspectives around cause effect relationships to address uncertainty in cross-boundary impact, which may lead to unintended consequences through

feedback loops across system boundaries. Beyond this specific policy, a major implication of this research is that more detailed planning, multi-stakeholder engagement, and consideration of potential consequences are required before changing policies around healthcare service access and delivery. Due to complexity of healthcare systems, even small changes could have potentially vast consequences. Although policy institutions that evaluate the impact of technology introduction decisions are well-developed in countries such as Thailand [79], mechanisms to evaluate access and delivery of services have yet to be defined. In setting up such mechanisms, it will be important to consider when existing methods and processes can be adapted and when introduction of approaches such as systems thinking is warranted, as well as the level of capacity building required. Given limited resources and technical expertise in many settings, further research into this area could help to make the best use of priority-setting resources.

## CONCLUSIONS

We used causal loop diagrams and system archetypes to understand the complexity driving supply and demand of HD and PD services under a government-funded health insurance scheme. We found that short-term fixes to cope with high demand for HD were unintentionally increasing future demand and decreasing service quality, while underinvestment in PD had limited the impact of achievements in building PD capacity and expertise. Overall, our results emphasise the importance of aligning incentives with health system goals, undertaking proactive planning based on forecasted demand, and putting in place regulatory mechanisms to balance supply and demand according to available health sector resources.

## SUMMARY

This was the second chapter in which we operationalised the framework from **Chapter 3**. System dynamics had been selected due to preliminary evidence of feedback across system and jurisdictional boundaries, suggesting a need to account for uncertainty from different institutional views of cause-effect relationships (systems theory) and unintended consequences across institutional boundaries (theory of modernisation). We applied qualitative system dynamics methods to develop a CLD, illustrating how this was able to integrate different perspectives to explain the reason for the unintended impact of the 2022 policy and propose policy solutions. In **Chapter 6** we develop a system dynamics model, based on the structure of

the CLD, to project the impact of continued implementation of the 2022 policy and proposed policy options, integrating findings from **Chapter 4** to inform projections.



## Chapter 6 Balancing patient choice and health system capacity: a system dynamics model of dialysis in Thailand

### OVERVIEW

In this chapter, we developed a quantitative model based on the structure of the causal loop diagram in **Chapter 5**. The causal loop diagram addressed uncertainty by surfacing different stakeholder views around cause-effect relationships and by systematically mapping the unintended consequences across system boundaries. However, it was unable to reconcile the most influential factors driving system behaviour or to project the relative impact of different policies over time. The system dynamics model developed in this chapter enabled us to systematically explore the implications of uncertainty in the data, model structure, policy implementation, and stakeholder reactions to policy change, in order to propose policies that were most likely to achieve policy goals.

### ABSTRACT

**Background:** As universal health coverage schemes mature, governments often seek to improve patient choice, but carefully designed policies are needed to ensure that variation in care results from patient preference and not supply-side factors. Policy levers to manage supply and demand for services have shown mixed results across contexts, highlighting the complex interactions and feedback effects that shape health system behaviours. To address these complexities, we developed a system dynamics model of dialysis demand and supply in Thailand, to explore the impact of proposed policies on dialysis services while accounting for considerable uncertainty in how these policies may work.

**Methods:** Model structure was based on a causal loop diagram developed in consultation with stakeholders and iteratively refined through testing, calibration, and validation. The resulting model projected profile of dialysis patients over a 10-year time horizon (2025-2034) under the current policy alongside policy interventions proposed by a working group under the National Health Security Office. We conducted structural and parameter uncertainty analysis to account for uncertainties in the base model and in the mechanisms of action of proposed policy interventions.

**Results:** The base case projected that over a third of new dialysis patients would be inappropriate dialysis initiation, under the current policy. None of the proposed policy interventions, either alone or in combination, achieved the defined policy target of 50% new dialysis patients on peritoneal dialysis within 3 years, with a maximum of 45% achieved from combining policies. Performance of all policies decreased over time unless the policy was able to progressively reduce financial incentives paid by private dialysis centres to physicians.

**Conclusions:** Regulating financial incentives in the Thai health system offered the greatest potential to reduce inappropriate dialysis initiation and increase peritoneal dialysis uptake. The system dynamics model showed that coupling policies with complementary mechanisms could address key uncertainties and amplify their impact. We suggest that policymakers incorporate quality of care and time-dependent performance into policy goals to achieve sustainable improvements. Overall our findings highlight the value of a systems approach to account for evolving feedback effects in health system policy design.

## **BACKGROUND**

Universal Health Coverage (UHC) either implicitly or explicitly involves rationing access to health services [327]. Explicit measures include definition of a benefit package (i.e. which services are provided, under which eligibility criteria, and with which level of co-payment) based on available financial and human resources, whereas implicit rationing occurs when the benefit package is either undefined or more generous than available resources allow [328]. This is particularly true of high-cost interventions such as kidney replacement therapy (KRT). KRT is the only available treatment to keep patients with kidney failure alive, but it places a disproportionate strain on the budget and workforce of the health system, with many settings spending over 5% of the healthcare budget on KRT provision for less than 0.5% of the population [262].

On the path to UHC, governments can build towards universal coverage by progressively increasing the proportion of patients with access to affordable and high-quality services [327, 329]. Policies may initially entail strict eligibility criteria and limited patient choice [262, 328], but over time improvements in system capacity and health system resources may justify preference-sensitive care, in which patient choice increasingly determines the services provided [218]. Within the context of KRT, this may mean shifting from policies that dictate the type of KRT patients can access towards policies allowing patient choice between services.

The transition from essential care to patient choice needs to be carefully managed, particularly in systems with heavy reliance on private service providers. Strict conditions to access health services implicitly regulate the private sector [330], but increased patient choice requires strong regulatory frameworks to address information asymmetry between patients and healthcare providers [129]. In the case of KRT, such regulation needs to effectively manage diverse stakeholder interests, including patient demand for optimal treatment with limited knowledge, resource constraints of public hospitals, private centre incentives to maximise profits, and the tension between good clinical practice and financial incentives for healthcare professionals. Such regulatory structures are, however, often weaker in low-income and middle-income countries (LMICs) [129]. Even in high-income countries with well-developed governance systems, patient choice often does not explain variations in care between settings, which may instead be explained by supply-side factors, including financing mechanisms (e.g. fee-for-service or per capita payments) and geographic location of services [218, 219].

A range of policy levers exist to regulate demand and supply, such that incentives within the system align with health system goals. Such levers may include varying provider payment mechanisms, setting targets, putting in place transparent reporting systems, developing clinical practice guidelines, or introducing decision aids for patients [219]. Yet the performance of the same policy levers can be highly variable, even in supposedly similar contexts. Taking the example of dialysis, there is a growing body of evidence that fee-for-service payments can result in unnecessary healthcare visits and treatments, similar to other hospital-based services [331, 332]. However, payment mechanism reforms show heterogeneous performance that is difficult to explain and appears to be highly context-specific [187, 331–335]. Similarly, educational services have successfully increased uptake of home-based dialysis services in countries with public sector service provision, but performance remains mixed in other settings [276].

Given this complexity and the context-specific nature of policy performance, a system-level perspective can disentangle the feedback loops and emergent behaviours that shape policy outcomes. There is growing application of SD modelling in healthcare, with studies on patient flow, public health interventions, medicine supply, infectious diseases, and workforce demand [336, 337]. Healthcare service provision is well suited for SD modelling as it exhibits a number of features of a complex adaptive system, including feedback between supply and demand, delayed and unintended consequences of interventions that targeted one part of the system in isolation, and system-wide adaptation driven by stakeholder reactions to change (for example, service providers and patients). Within the context of UHC, SD is particularly useful to show how

organisational design and financing mechanisms impact access and quality of healthcare services [338].

In this study, we build on the causal loop diagram developed in **Chapter 5**. Initial evaluation of the 2022 policy had suggested strong presence of supply-sensitive care, driven by financial incentives for various actors within the system as opposed to true patient choice, which was leading to high programme costs and low quality of dialysis [269]. We illustrate the application of SD as an exploratory tool to test how different policies to manage supply and demand may perform in a specific context. We aimed to identify which of a set of proposed policies could reach the defined policy goals and key sources of uncertainty that could determine policy success. Our two research objectives, based on targets and timeframes established by policymakers [238], were as follows: (1) to identify which policy options could achieve the goal of 50% new dialysis patients selecting PD within 3 years, and (2) to characterise the impact of these policies on total number of dialysis patients and dialysis-related mortality over a ten-year period.

## METHODS

### Model context

Most kidney failure patients in Thailand are treated by dialysis, due to limited capacity for kidney transplant [265, 267]. Not all patients with kidney failure receive KRT: selected patients, particularly those with short life expectancy, may have better quality of life with comprehensive conservative care (CCC) than dialysis [339, 340]. Under CCC, patients receive holistic, person-centred care to delay disease progression and manage symptoms [341]. PD, HD, and CCC are free at point of care for patients, as mandated for all services provided under UCS [342]. Although PD is administered by the patients themselves, PD nurses provide regular training and follow-up, with evidence that more patients per nurse can increase rates of peritonitis, one of the main complications for PD [317].

Prior to initiation of dialysis, PD patients require PD catheter insertion and HD patients require a vascular access operation, both of which are reimbursed under UCS. Vascular access for HD may be long-term or temporary, with temporary vascular access associated with higher risk of complications and shorter timeframe until a subsequent vascular access operation is required [343, 344].

Dialysis providers (i.e. hospitals or private HD centres) are reimbursed by fee-for-service, with a higher reimbursement rate for HD. There is limited regulation of how service providers spend the

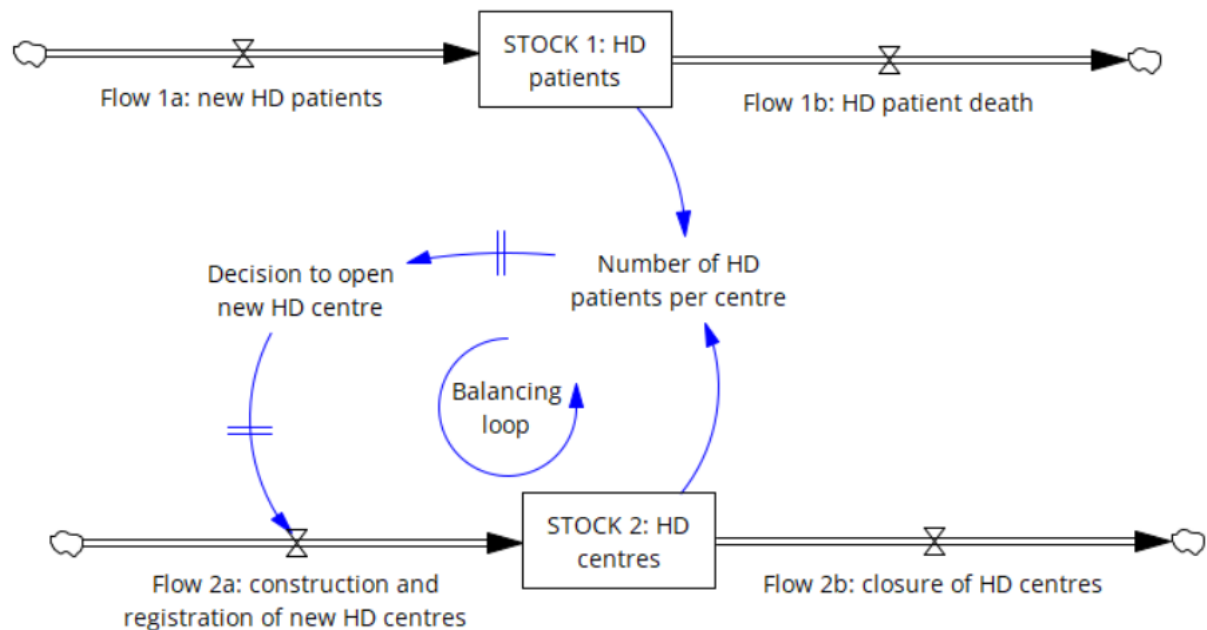
fee-for-service, with many private providers paying a “doctor fee” to nephrologists to encourage patient referral [345]. The doctor fee is paid to each referring nephrologist per dialysis session and is estimated to account for approximately 10-17% of NHSO reimbursement for dialysis services [238]. Complications arising from dialysis are covered under a separate budget line.

We developed a SD model to evaluate the impact of proposed policies on the dialysis system, according to the goals set by the 2024 ad-hoc working group on KRT. We selected a SD model due to the presence of feedback mechanisms between supply and demand, as well as delays between cause and effect. For instance, we had evidence that rising demand for HD led to the opening of new private HD centres (a delayed process), while those centres then stimulate further demand by offering doctors financial incentives for patient referral.

### *System dynamics modelling*

In SD, the behaviour of organisational or social systems is conceptualised as a series of accumulations influenced by feedback mechanisms within the system [346]. An illustration of SD model structure is shown in **Figure 6.1**. Accumulations are represented as stocks, which can be increased or decreased by flows [347]. In **Figure 6.1**, number of HD patients is a stock that increases according to incident HD patient inflow and decreases with HD patient death outflow. These stocks interact through feedback loops, some of which are reinforcing (positive feedback) and can accelerate growth, while others are balancing (negative feedback) and constrain system expansion once resource limitations are reached [298]. The example in **Figure 6.1** illustrates how new centres may be built to respond to unmet demand for HD, which in turn reduces unmet demand, slowing further construction of HD centres through a balancing loop. Stocks are sources of delay as any change in these flows will not instantaneously shift the stock level; instead, the effects accumulate over time, creating the observed delay [348]. In **Figure 6.1**, it takes time to construct, furnish, and register a new HD centre. If decisions to open new HD centres are based on information about the current gap between supply and demand, this dynamic can lead to a period of undersupply followed by oversupply.

**Figure 6.1.** Illustration of a simple system dynamics (SD) model. The rectangular boxes are stocks, representing number of haemodialysis (HD) patients and centres, respectively. The double arrows represent flows that increase or decrease the stocks. The blue arrows represent a balancing feedback loop, characterised by delays (blue arrows with a double line).



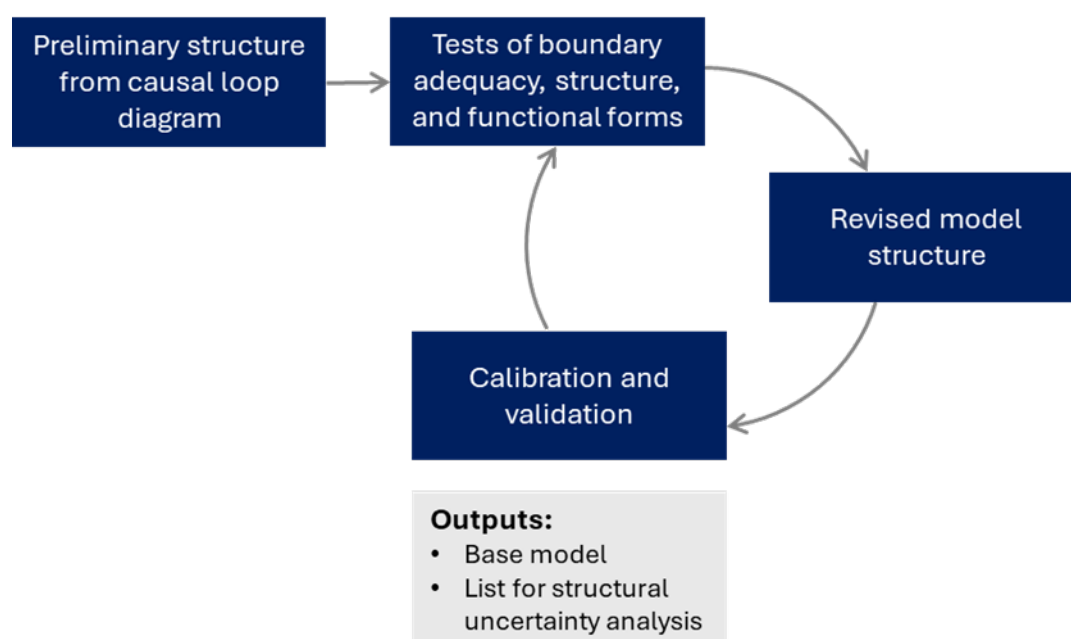
#### Process to develop model structure

The preliminary model structure was based on the causal loop diagram from **Chapter 5**. In line with the policy goals defined by the working group, which related to financial sustainability and maintaining system capacity for PD, the boundary of the SD model was defined as factors influencing the change in number of dialysis patients and proportion of new dialysis patients selecting HD after the 2022 policy change. We therefore did not include components of the causal loop diagram related to quality assurance changes or for PD system investment prior to the 2022 policy change.

Incidence of chronic kidney disease in the Thai population was modelled as an exogenous variable. Patient choice between HD, PD, and CCC, timing of dialysis initiation, and death rate of dialysis patients were all influenced by feedback loops within the model related to supply constraints for HD (including vascular access services), competition between private HD centres, and availability of dialysis nurses.

The preliminary model went through an iterative process of testing the boundaries, structure, and functional forms; calibration and empirical validation of model behaviour; and revision of model structure until the resulting model structure and parameter sets were both logical based on existing knowledge and coherent with renal registry data (**Figure 6.2**). Due to challenges of reconvening large groups of stakeholders, we consulted the literature and the secretariat of the policy working group during each model iteration to ensure coherence with existing knowledge.

**Figure 6.2.** Process to iteratively develop model structure.



During this iterative process, the main changes made were related to the supply components, with three major changes implemented. First, we removed the stocks for HD centres and HD nurses after extreme values and boundary adequacy testing showed that this had negligible impact on total number of HD patients over a 5-year time horizon. In the revised model, HD systems stress is modelled as proportional to the rate of change in HD patients, rather than absolute capacity, reflecting the observation that system stress arises from adaptation to changes rather than static supply constraints. Second, we removed the stocks for PD centres and PD nurses from the model, as this was the only structural or parameter analysis that removed model behaviour that was not consistent with pattern of the data. The final model structure assumed that chronic underinvestment in the PD nurse workforce was reflected in the baseline PD death rate, consistent with findings from the causal loop diagram [345]. Finally, we added a separate stock for HD patients with temporary vascular access, due to the presence of

a reinforcing loop and strong influence of vascular access rates on total HD patients. A full summary of the changes made to the model structure and testing of alternative functional forms are detailed in **Table S6.1a** and **Table S6.1b** respectively, with the preliminary and revised model structure in **Figures S6.1a** and **S6.1b**.

### Model structure

The structure of the model is illustrated by the stock and flow diagram in **Figure 6.3**. We modelled the key accumulations as stocks: (1) the financial incentive paid per patient per session to physicians (“doctor fee”), (2) number of HD patients, and (3) number of PD patients. To capture important clinical factors that affect outcomes, we further divided HD patients into sub-stocks based on two factors: type of vascular access (temporary or permanent) and clinical suitability for CCC (patients who would have a higher quality of life on CCC are referred to as “CCC suitable”). This structure allowed us to better model HD death rates, which depend on proportion of patients with temporary vascular access and proportion of CCC suitable patients receiving HD.

Prior to the 2022 policy, the model includes two types of incident dialysis patients: PD-eligible and HD always. PD-eligible patients receive PD while patients that are not eligible for PD (“HD always”) receive HD. There is net switch of patients from PD to HD at a fixed baseline rate, due to health reasons such as catheter failure, infection, or dialysate leakage [349]. A proportion of new HD patients (and PD patients switching to HD) initiate HD with temporary vascular access. The proportion of HD patients with temporary vascular access depends on a fixed proportion of urgent start patients and a variable proportion that depends on strain on the vascular access (VA) system, caused by a higher rate of change in patients with temporary access compared to a reference time point in the past. Patients with temporary access require another vascular access operation after a fixed length of time, whereas the model assumes that patients with permanent access (arteriovenous fistula or graft) will not need a subsequent vascular access operation. HD death rate depends on the proportion of patients with temporary vascular access as well as strain on the HD system (described previously). Both HD death rate and HD supply are modelled to change the average amount paid for the doctor fee, due to increased competition between private HD centres. Changes in HD supply affect relative risk of peritonitis and death rate of PD patients, to reflect the increased rates of PD nurse transition to HD.





Following the 2022 policy change, there are two main changes in the model related to incident dialysis patients and HD death rate. Firstly, PD-eligible patients may initiate dialysis on either HD or PD. The proportion of PD-eligible patients selecting HD in the model depends on a fixed preference for HD or PD that is not modified by other components of the model, as well as a modifiable component that depends on relative risk of peritonitis and the doctor fee. Rate of PD to HD transitions is similarly moderated by peritonitis risk and the doctor fee. Secondly, there are three additional sources of new HD patients: CCC-suitable patients selecting HD, premature HD initiation patients (“HD premature”), and HD incident patients that would not have registered for dialysis under NHSO prior to the 2022 policy change (“HD other”). The proportion of CCC-suitable patients selecting HD depends on fixed patient preference for CCC or HD and a modifiable component that depends on the doctor fee. Premature HD initiation scales directly to the doctor fee, whereas HD other is a fixed percentage of baseline dialysis incidence. Proportion of HD patients that are CCC-suitable affects the HD death rate.

### Functional forms

Functions in the model are detailed in **Table S6.1c**. Rates of change were calculated by time delays in the model and modifiable patient choice was modelled as a sigmoidal curve, under the assumption that at very low or very high values, there is smaller impact from incremental change in a factor influencing choice (e.g. financial incentives or peritonitis rates). Equations were solved using the dede solver from the deSolve package in R, using the lsoda method [350]. Since the purpose of the model was to provide 10-year projections, in line with policy goals, the unit of time was months. Time steps of 0.25 months were used, which represents one quarter of the smallest delay in the model. Discontinuities in the model from switching on/off parts of model structure following policy change were handled using the approxfun interpolation function in R and spikes in number of new HD patients on 1<sup>st</sup> February 2024 were added as events. All code is available in the Zenodo repository: <https://doi.org/10.5281/zenodo.14987793> [351].

### Parameter estimation and calibration

The model was populated with data from national registries, published literature, and expert opinion (**Table S6.2a**). Since incidence of chronic kidney disease is projected to increase over time [352], we estimated baseline dialysis incidence coefficients through linear regression of renal registry data from 2016-2021. Time delays for changes in HD supply were estimated by

optimising the fit between number of HD patients and number of HD centres between 2018 and 2022 from a national database [268]. Methods for all parameter estimation are provided in **Table S6.2b**.

Calibration estimated factors in the model that could not be estimated from empirical data, such as factors to scale the relationship between two variables. We conducted calibration for sub-models where possible [353]. For the main calibration, parameters were calibrated to datasets related to the main policy goals, namely total dialysis patients and proportion of incident dialysis patients on PD. Factors affecting total dialysis patients were calibrated first, since factors affecting PD-eligible patient choice have minimal impact on total number of patients.

**Table S6.2c** shows the calibrated parameters and calibration datasets. Calibration was conducted using the modCost and modFit algorithms from the FME package in R [354], following the steps outlined by Duggan [355]. In all instances, model calibration was run multiple times with variations in the starting value and upper/lower bounds. If the calibrated value was not stable to the calibration starting conditions, we used grid search and conducted hand calibration to identify alternative calibration sets.

We calibrated parameters from parts of the model structure that were switched on prior to the 2022 policy change first using data from 2019-2021 (Calibration period 1) and parameters that were only active after the policy change from March 2022 to February 2023 (Calibration period 2). Vascular access data has only been reported from 2020 and is reported quarterly, so we calibrated using the full dataset up to the end of 2022.

## Validation

A number of steps were taken to validate the model. Face validation of the model structure, parameters, and outputs was conducted by members of the policy working group secretariat. During model development, boundary adequacy, extreme conditions, and behaviour sensitivity tests were used to validate model structure [313, 314]. Model behaviour was validated by empirical comparison with the data from March 2023 to February 2024 (the period directly after model calibration), for pattern anticipation [314]. Model behaviour was compared with data for the two outputs of interest: total dialysis patients and proportion of incident dialysis patients on PD. Since the goal was to inform policy over the next 10 years, we did not look for the model to capture monthly oscillations but instead checked for overall direction and magnitude.

## Policy projections

The model projected number of HD and PD patients over a 10-year time horizon (2025-2034) under the 2022 KRT policy (base case) and under alternative policy scenarios. The primary metrics used to compare policies were percentage of new dialysis cases selecting PD after 3 years, total dialysis patients over 10 years, and HD death rate over 10 years. Only HD death rate was explicitly modelled as it was a major concern following the 2022 policy change [238]. We also reported profile of new HD patients (e.g. PD-eligible, premature initiation) to show the extent to which each policy improved appropriate dialysis initiation.

A set of twelve policy interventions had been proposed from research projects to inform the working group recommendations, including literature reviews [275, 276], causal loop diagram [345], and situational analysis of changes after the 2022 policy in Thailand [308]. For each of the proposed policies, we modified the model diagram to show the theory of change. Since the model diagram does not show the relative magnitude or importance of loops [356], we conducted the base case analysis (i.e. continuation of the 2022 policy) to identify structures in the model that were most likely to affect achievement of the policy goal to have 50% new patients selecting PD. We then shortlisted the proposed policy interventions that targeted high-impact structures in the model.

**Figure S6.3a to S6.3k** show the modified model structure for each of the twelve proposed policy interventions. Given the profile of new patients selecting HD in the base case analysis, the research team shortlisted policy interventions for further analysis if they either (1) prevented premature HD initiation, or (2) reduced proportion of incident HD patients across at least three categories (e.g. PD-eligible, CCC-suitable, and HD other). According to these criteria, we selected the following five policies (**Table S6.3**).

- **Pre-authorisation:** approval of patients by provincial committees prior to dialysis initiation.
- **Doctor fee regulation:** restrictions on private service provider payments to nephrologists for HD patient referral.
- **Education:** patient education by multi-disciplinary teams to support patients to select an appropriate treatment for kidney failure, initiated during chronic kidney disease stage 4.
- **Quality-based HD payment:** change from fee-for-service, in which service providers are reimbursed per HD session, to quality-based payments per HD patient.

- **Global budget:** total budget for dialysis provider payment is capped per year, so that fee per patient decreases as total dialysis patients increases.

### Uncertainty analysis

We conducted several types of analyses to assess the robustness of model results. For the base case, we conducted deterministic sensitivity analysis of parameter uncertainty using confidence intervals from the literature or plausible ranges from expert opinion (**Table S6.2a**). Since we had insufficient data to estimate priors for all model inputs, we conducted global sensitivity analysis using Latin hypercube sampling as an efficient method by which to consider total parameter uncertainty [357]. We conducted structural uncertainty analysis related to the influence of the doctor fee and peritonitis rates on patient choice, as these functions were identified as having a potentially important impact during model development (**Table S6.1b**). For each structural change, we re-calibrated the model (**Table S6.2d**).

For each of the policy interventions modelled, we assessed uncertainty through three complementary approaches. Firstly, we compared policies under the alternative base model structures described above, to see whether model structure could affect the best performing policy option. Secondly, we conducted one-way deterministic sensitivity analysis to identify which parameter uncertainty could influence whether or not the policy targets were met. Thirdly, we conducted scenario analysis to model different implementation of each policy option. Scenarios were informed by a scenario thinking study [358] and literature relevant to the policy proposal in question.

## RESULTS

### Base case (2022 policy)

The base case projection estimated approximately 117,000 dialysis patients by the end of 2029 under the 2022 policy (**Figure S6.4a**). Between 2025 and 2029, an average of 12% of patients were projected to select PD at the time of dialysis initiation, 32% of new dialysis patients were estimated to initiate HD prematurely, and 6% of patients were projected to have a higher quality of life on CCC (**Figure S6.4b**). Similar to the structural analysis (**Tables S6.1a and S6.1b**), parameters affecting the doctor fee, temporary vascular access rates, and PD-eligible patient choice were most influential on model outcomes (**Figures S6.4c and S6.4d**). Results from the Latin hypercube sampling are shown in **Figures S6.4e and S6.4f**, showing a high level of

variability that tends towards a lower projection of total dialysis cases and a steeper decline in proportion of new dialysis patients selecting PD over time.

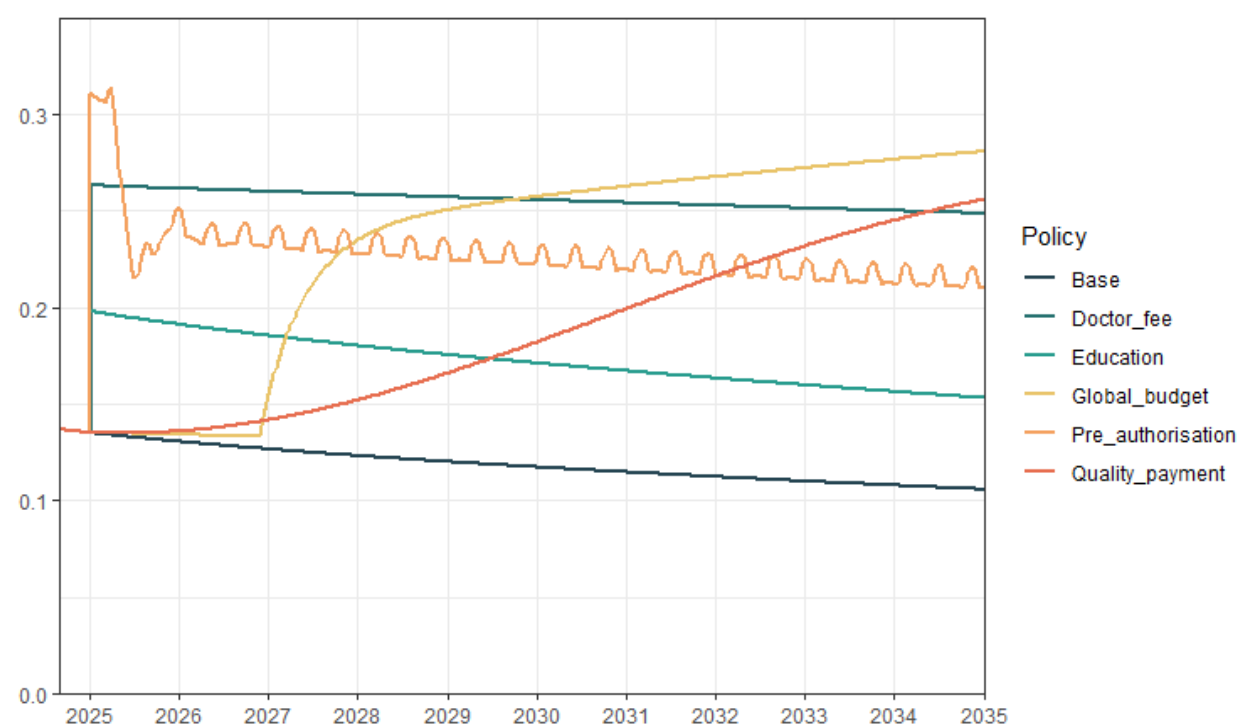
## Comparison of policy interventions

### *Proportion of new dialysis patients selecting PD*

None of the five proposed policy interventions reached the target of 50% incident dialysis patients on PD by the end of 2027 (**Figure 6.4** and **Table S6.5a**). The best performing policy option was restricting payment of the doctor fee, which was projected to result in 26% of incident patients selecting PD, followed by global budget and pre-authorisation (23% each). Restricting the doctor fee was the best performing option across all structural analyses, though none of the policies achieved proportion of PD incidence above 30% (**Table S6.5b**), increasing confidence in model findings that no single intervention can achieve the policy target but restricting the doctor fee is likely most effective [346]. In the one-way sensitivity analysis, only two parameters increased proportion of incident dialysis patients on PD to above 30%: inherent preference for HD among PD-eligible patients that is not modified by peritonitis risks or the doctor fee (for pre-authorisation and doctor fee regulation) and the starting value of the doctor fee in the model (for the education policy) (**Table S6.5c**).

Although the doctor fee showed the strongest immediate impact, our temporal analysis revealed important differences in how policy effectiveness evolved over time (**Figure 6.4**). Global budget and quality-based payments were the only policies projected to show an increase in proportion of new dialysis patients selecting PD over time, with both projected to outperform doctor fee regulation over a 10-year period. The scenario analysis suggested that performance of all policies would decrease over time unless the policy either prevented increases in financial incentives to doctors and healthcare workers, through strict regulation of financial incentives or successfully limiting available funds to pay the doctor fee, or inadvertently restricted access to HD (global budget) (**Supplement 6.6**). To illustrate, a highly effective abolition of financial incentives was modelled to improve doctor fee regulation performance over time, approaching 30% within 10 years, whereas quality-based payments that led to private providers selecting healthier patients as opposed to changing spending patterns could lead to fewer dialysis patients selecting PD over time, approaching 10% over 10 years.

**Figure 6.4.** Projected proportion of new dialysis patients selecting peritoneal dialysis (PD) between 2025 and 2034, under alternative policy interventions.



#### *Total dialysis patients and HD death rates*

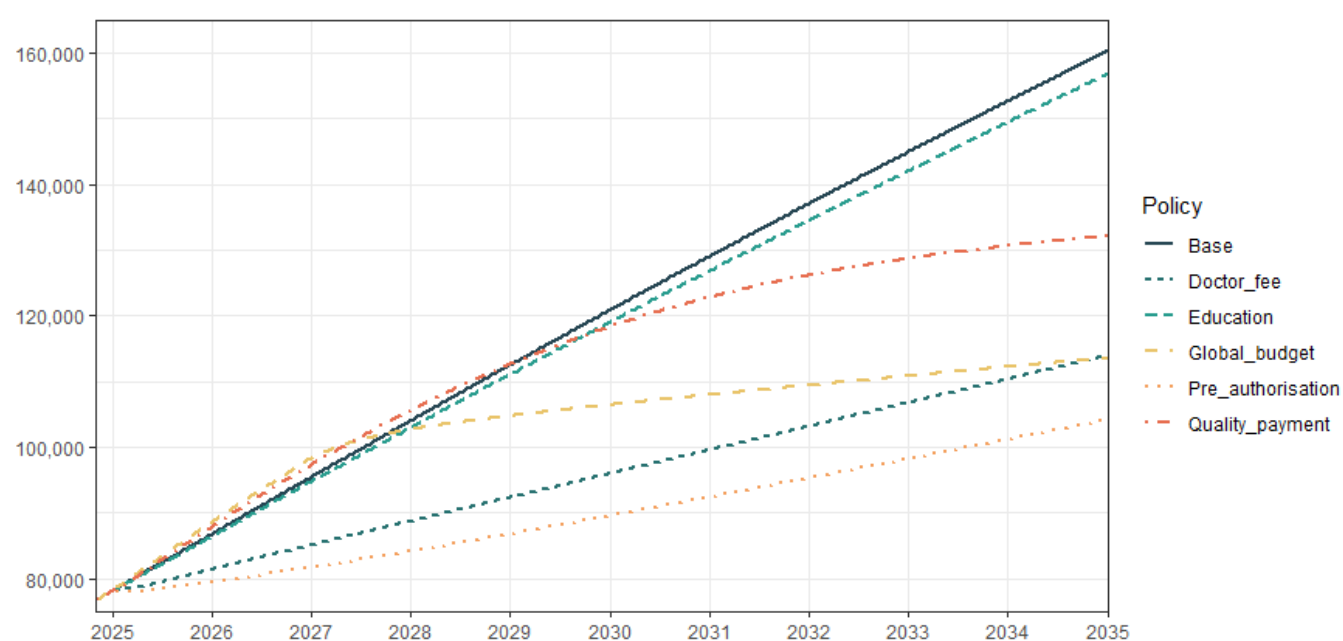
Projected total dialysis patients and death rates over 10 years are shown in **Figure 6.5** and **Figure 6.6** respectively. Pre-authorisation is modelled to bring the greatest reduction in total dialysis patients across all time periods modelled, as it is the only policy to prevent inappropriate HD initiation (**Figures S6.5a and S6.5b**). Over a 10-year period, a pre-authorisation system is also modelled to have the lowest HD death rates, as it is the only policy to prevent CCC-suitable patients from initiating HD and it has low strain on the HD and vascular access systems due to a slow rate of increase in total HD patients.

The next greatest reductions in total dialysis patients are observed with doctor fee regulation and global budget policies. For doctor fee regulation, the reduction predominantly comes from a marked reduction in premature initiation of HD. HD death rates show an initial drop but are very slightly higher than the base case after 10 years due to a higher percentage of CCC-suitable patients (**Figures S6.5a and S6.5b**). For global budget, once HD demand exceeds available supply, the model projects a high increase in HD death rates, from strain on the system, alongside reduced access to dialysis services, making it the only policy to decrease proportion of HD always patients (**Figure S6.5b**). Of note, unless private centres stop paying a doctor fee,

global budget is still modelled to have a high level of inappropriate dialysis initiation (**Figures S6.5a and S6.5b**).

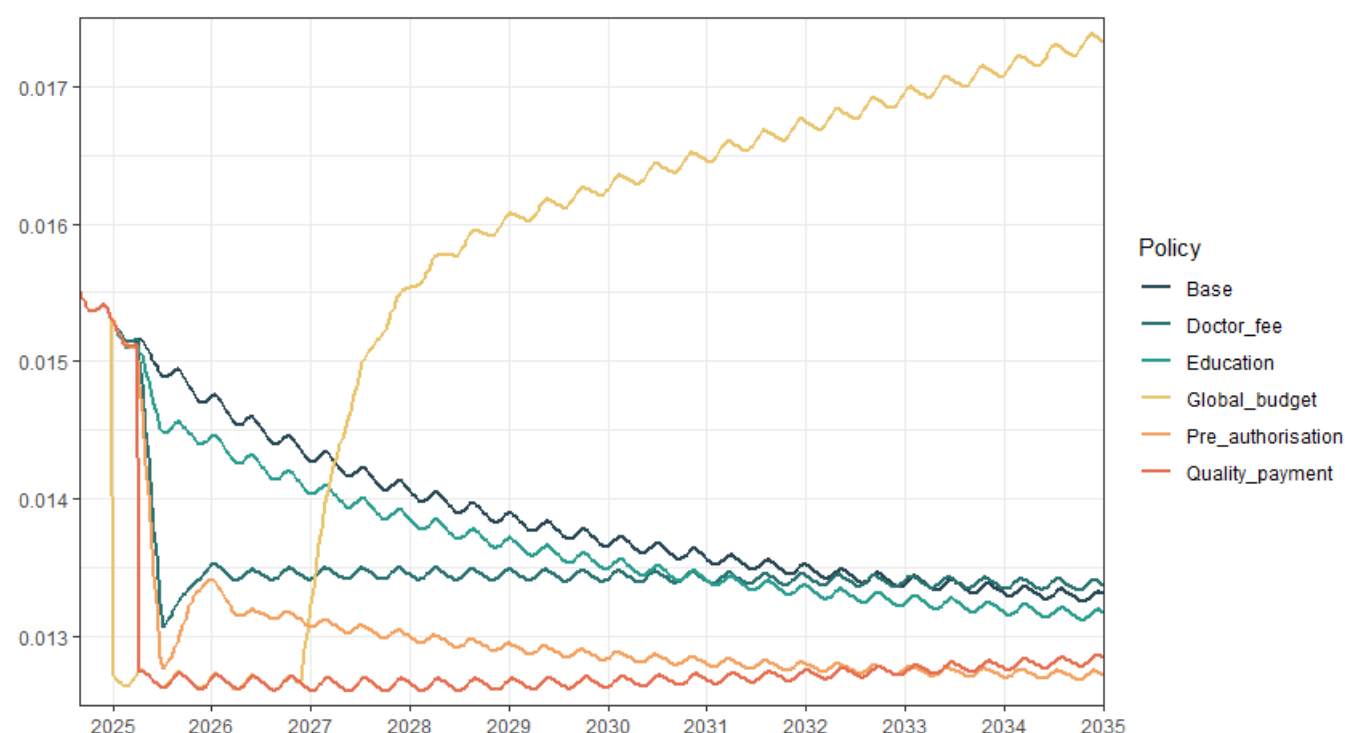
Although quality-based payments may slightly increase total dialysis patients in the short-term, due to lower death rates, the progressive reduction in the doctor fee over time to maintain quality standards is modelled to have a more pronounced effect over 10 years, reducing total dialysis patients by around 30,000 whilst also maintaining low HD death rates. By contrast, education shows minimal impact on total patients or death rates, although the scenario analysis suggested that this reduction could be greater if there is some level of reduction in financial incentives for healthcare professionals.

**Figure 6.5.** Projected total dialysis patients between 2025 and 2034, under alternative policy interventions.





**Figure 6.6.** Projected death rate (% per month) of HD patients between 2025 and 2034, under alternative policy interventions.



### Combinations of policy interventions

Combining multiple policy options improved outcomes but still fell short of the 50% policy target (**Table S6.5a**). The most effective policy combination was joint implementation of pre-authorisation, doctor fee regulation, education, and quality-based payment, which resulted in 45% incident patients on PD by the end of 2027, a total of 102,000 dialysis patients by the end of 2029, and an average HD death rate of 0.012% per month (which was the lowest death rate of any policy combination). Over time, proportion of new dialysis cases selecting PD increased while death rate of HD patients decreased. Under all structural and parameter sensitivity analyses, proportion of new patients selecting HD within 3 years was between 40% and 50%, with the exception of HD preference among PD-eligible patients, which varied between 34% and 61% at extreme parameter values, dependent on model structure (**Table S6.5e**).

### Model validation

The results from model calibration and validation are presented in **Figures S6.7a and S6.7b**. Overall, the model effectively captured the long-term dynamic behaviour trends. The main

variations from renal registry data occurred during the calibration periods. During calibration period 1 (prior to the 2022 policy change), the model did not pick up fluctuations in baseline dialysis incidence in 2021 (as it is treated as exogenous to the model) or a decrease in proportion of incident patients selecting PD prior to the 2022 policy change. During calibration period 2, the model did not show a stagnation in total dialysis patients around 2 months after the 2022 policy change. Since number of new dialysis cases from the model is in line with renal registry data, this suggests that the model may poorly represent short-term changes in death rates after shocks to the system but effectively generates long-term behaviour.

## **DISCUSSION**

In this study, we developed a SD model to evaluate which policy interventions could achieve a set of targets to balance dialysis supply and demand in Thailand. A system dynamics lens allowed us to address different conceptualisations of uncertainty by incorporating different views around cause-effect relationships in the system (most notably the role of the doctor fee in influencing physician behaviour) and modelling feedback loops that cross institutional boundaries.

Our results suggest that co-implementation of pre-authorisation, doctor fee regulation, education, and quality-based payment policies could increase the proportion of new dialysis patients selecting PD to over 45% within the next 3 years and decrease total dialysis patients by 60,000 within the next 10 years whilst decreasing HD death rates. Comparing individual policies, restricting payments of the doctor fee would have greatest impact in increasing the proportion of dialysis patients selecting PD over the next 3 years, and this finding was consistent when testing different model structures. The most important source of uncertainty in our analysis was the factors affecting payment of the doctor fee and factors driving PD-eligible patient choice. Coupling education interventions with the doctor fee regulation effectively addresses this uncertainty, as factors decreasing the effectiveness of doctor fee regulation are countered by improvements in the effectiveness of education and vice versa.

Our findings are not aligned with a review of policies to increase uptake of PD, which did not identify moderation of financial incentives to individual doctors or pre-authorisation mechanisms as effective policy levers [276]. This is likely because the review mainly included studies from tax-funded public health systems with minimal private service provision and the majority of studies were from high-income countries that likely have stricter regulation of informal payments. From a theoretical perspective, our findings are consistent with the

framework for variations in healthcare put forward by Wennberg et al [218], as the proposed bundle of policies addresses effective care, by preventing dialysis initiation in unsuitable patients (pre-authorisation) and preference-suitable care, by moderating financial incentives for doctors (doctor fee regulation) and addressing information asymmetry between patients and providers in private healthcare systems (education). Our findings are also consistent with studies from the US linking physician behaviour with financial incentives provided by private companies [359–361]. This suggests that context-specific factors influencing patient and provider behaviour should be considered alongside literature review when identifying potential policies to address health system problems.

One of the strengths of the study is that our projections of policy performance were coupled with a scenario thinking analysis to broaden our view of potential stakeholder actions [358], and revisions to model structure to reflect impact of policies in the Thai context (which may have different mechanisms of action to those described in the literature). The model results initially presented to the working group, based on secretariat hypotheses about how the policy may work, were more optimistic in terms of policy performance than the results presented in this paper [238]. Our revised approach provides greater information on implementation uncertainty and risk to policymakers, allowing for better policy decisions.

Another strength is that we used a variety of approaches to identify potential policy interventions, comprising literature reviews, situational analysis, and causal loop diagram (CLD) archetype solutions (a tool from systems thinking). Our results suggest that the combination of literature review and situational analysis identified the highest impact combination of policies. Although the solutions identified from CLD archetypes were generally less relevant, there are a number of reasons as to why this may be. Firstly, solutions to the CLD archetypes had been identified to address unintended consequences of policy changes in the dialysis system and was not targeted to proportion of PD patients, unlike the literature review. Secondly, during model development, populating the model with data challenged some of the assumptions in the CLD and exploratory modelling highlighted loops that were more influential on model results than others. Even in settings with limited time and capacity for SD simulation, our findings suggest that it may be beneficial to conduct exploratory modelling of the CLD in freely available software to iteratively improve model structure before conducting an analysis to identify archetype solutions.

Our study has a number of limitations, many of which are inherent to the purpose of system dynamics. Firstly, we made changes to model structure so that supply was not modelled in terms of absolute number of centres and nurses. Although this showed a better fit to the data at the

national level, it is known that there is substantial heterogeneity in availability of dialysis centres and nurses between provinces [268], which could be affected unequally by different policies. A second limitation is that model calibration suggested our model may be poorly able to account for short term increases in death rates following shocks to the system. This is most relevant for global budget, which may have higher death rates in the first few years of implementation than we have modelled. Moreover, the main source of uncertainty in the model was patient choice among PD-eligible patients, which may be better modelled through agent-based, bottom-up models than system dynamics.

Despite these limitations, our analysis suggested high confidence in our finding that combining policies to regulate doctor fee payments, approve dialysis initiation (pre-authorisation), patient education, and quality-based payments would have the greatest impact. In the model, strict regulation of the doctor fee was the only way to prevent proportion of PD patients from progressively decreasing over time. It has been found that speaker and consulting fees for specialists can have a similar (albeit reduced) effect to direct financial payments to physicians [361]. We therefore recommend a holistic approach to abolishing unregulated payments within the system, similar to the principles to manage conflicts of interest within policy processes [216, 217, 362], to encourage culture change over time.

Another recommendation from our research regards the policy goals. We showed that performance of policy options may substantially improve or worsen over time, suggesting that policy goals should monitor targets on an annual basis as opposed to setting a one-off target, with governance mechanisms in place to adapt the policy over time as new knowledge is gathered. Furthermore, the current policy goals aim to reduce total number of dialysis patients without compromising on patient quality of care, and have therefore been framed around total incident patients and total budget [238]. However, our analysis showed that the current targets could lead to prioritisation of policies such as global budget, which could worsen patient outcomes. Including a specific target around quality of care or death rates could better align the stated targets with actual policy goals.

Our finding that none of the policy combinations would achieve the 50% PD utilisation target presents policymakers with a fundamental dilemma: pursue imperfect improvements within the current patient choice framework or return to the original PD-first policy, despite its restrictions on patient choice. This decision involves weighing competing values of patient autonomy, system efficiency, and equitable resource allocation. The data provides some justification for reconsidering a PD-first approach. A study in Thailand estimated that there is 10% leakage within

UCS, meaning that UCS beneficiaries receive 10% of their healthcare services outside of UCS (most often through out-of-pocket spending) [263]. Data from patients switching to NHSO following the 2022 policy change suggests that under the PD-first policy, there was less than 10% leakage for dialysis, and most likely less than 5% [363]. From this perspective, the 2008 KRT policy was aligned with service provision among other disease areas of UCS and it may therefore be justified to return to the PD-first policy for equitable allocation of resources between the KRT programme and other disease areas [261].

## CONCLUSIONS

The most effective policies in this analysis had been identified from situational analysis of the Thai context, highlighting the limitations of relying on experience of health system policies from other jurisdictions, particularly in settings with unregulated financial incentives and practices. We showed that coupling policies with complementary mechanisms of action could both increase policy impact and effectively address the key sources of uncertainty in our analysis. Our study also highlighted that different policies show different trends in performance over time, suggesting that policy goals and targets should not be set for single time points. Our findings demonstrate the value of systems thinking for health policy design, offering policymakers an approach to navigate the complex interplay between financial incentives, provider behaviour, and patient choice that shapes healthcare outcomes beyond what conventional policy analysis can achieve.

## SUMMARY

In this chapter, we drew on findings from the scenario thinking analysis in **Chapter 4** and the causal loop diagram in **Chapter 5** to project the impact of policy options using a system dynamics model. We illustrated how this approach was able to accommodate multiple views of cause-effect relationships, cross-boundary impact, and potential stakeholder reactions to policy change, in order to propose a set of policy interventions able to account for this broader view of uncertainty.

Through operationalising the framework, we have partially addressed **Research question 3** regarding the extent to which the framework improves policymaking under uncertainty in HTA. We have demonstrated proof-of-concept by showing that the framework was able to address the social science conceptualisations of uncertainty from **Chapter 2**, within the context of the KRT

case study. In the next section (**Section III**), we conduct a structured evaluation of the framework from the perspective of whether it improved policymaking under uncertainty and feasibility of implementation, applying principles from implementation science. We discuss the generalisability of our findings to other policies in Thailand and to other HTA agencies globally, in order to propose revisions to the framework and future research directions.

## SECTION III: FRAMEWORK EVALUATION

In this section, we evaluate the preliminary version of the framework and propose modifications based on learnings from the case study. In **Chapter 7** we describe the methods applied to evaluate the framework, we discuss the extent to which the framework improved policymaking under uncertainty for the case study, we identify potential barriers and facilitators to its implementation in Thailand, and we provide suggestions for future evaluation of policymaking frameworks. In **Chapter 8** we draw on our findings from the KRT case study evaluation to revise the framework.

## **Chapter 7: Improving policymaking practice: an implementation science informed evaluation of a multi-disciplinary policymaking framework in Thailand**

### **OVERVIEW**

In this chapter, we describe our approach to evaluate whether the multi-disciplinary framework from **Chapter 3** had improved policymaking in the KRT case study, the adaptations required for HTA, and potential implementation strategies for successful integration with HTA practice (in line with research question 3). We discuss implications for future implementation of the framework and highlight a broader need for methods to evaluate changes to policymaking practice.

### **ABSTRACT**

**Background:** Successful policymaking requires ongoing “learning by doing” to ensure that institutions for evidence-informed policymaking stay relevant and effective. Currently, policy institutions are seeking to become more multi-disciplinary, but there is a lack of structured approaches by which to evaluate, tailor, and encourage adoption of changes to policymaking practice. In this study, we applied an implementation science framework within action research to evaluate a locally developed multi-disciplinary framework for policymaking under uncertainty in Thailand. We aimed to evaluate the effectiveness of the framework, develop an implementation strategy for adoption, and explore whether implementation science frameworks could accommodate the timelines, resource constraints, and vested interests inherent in policy environments.

**Methods:** We conducted a type-1 hybrid implementation study using the Consolidated Framework for Implementation Research (CFIR) to evaluate effectiveness of the framework, with a secondary aim of assessing barriers and facilitators to adoption. We adopted action research to enable stakeholders involved in policymaking processes to iteratively evaluate and improve practice. The study comprised three phases: case study selection using CFIR indicators, real-time adaptation of the innovation during implementation, and an evaluation of innovation effectiveness, opportunity cost, and implementation. Outcomes were analysed qualitatively from archival, observational, and interview data.



**Results:** We selected the 2024 kidney replacement therapy policy in Thailand as a case study, due to trialability, relational connections, available funding, and tension for change. We adapted the new approaches identified by the multi-disciplinary framework (system dynamics and scenario thinking) to align with norms for policymaking, to address short timelines, and to allow all stakeholders to contribute. Compared to standard practice, the new approaches provided a systematic approach to articulate the broader impact of policy options, with minimal opportunity cost. We developed an implementation strategy that emphasised collaboration with motivated leaders, tailoring strategies to align with current practice, and building capacity.

**Conclusions:** We demonstrated that minor adaptations to implementation science methods can provide a structured framework to evaluate, adapt, and implement changes to policymaking practice within the constrained timelines and resources of policy environments. These methods can support further refinement of the framework and implementation strategy to promote multi-disciplinary policymaking in Thailand.

## **BACKGROUND**

Improving population health relies on having evidence-informed policies that have been made through fair and legitimate processes [2]. Successful policymaking requires ongoing “learning by doing” to ensure that institutions for evidence-informed policymaking are well-adapted for the types of policy questions addressed and suited to local context [196, 282]. However, such learning by doing requires structured approaches for continuous improvement and systematic evaluation, which are currently lacking [130].

Health technology assessment (HTA) agencies, tasked with establishing and managing institutions for evidence-informed public health policy, regularly update their guidelines and processes [364]. These updates are commonly made by subject matter experts and the secretariat for the policy body, with varying levels of stakeholder engagement [42, 282]. Yet there is limited evaluation of whether changes to the policymaking process actually lead to improved policymaking [130, 282] and a gap between what is written in the guidelines and how policies are made in practice [282]. Experience is showing that revisions to policymaking based on global good practice or stakeholder input alone are insufficient: modifications to England’s National Institute for Health and Care Excellence (NICE) procedures may have weakened the fairness and legitimacy of decisions [130] and globally promoted methods for adaptive HTA (in which assessments from other jurisdictions are contextualised to the local setting) have performed poorly in empirical comparison with standard HTA methods [65], for example. Local innovation

and adaptation are required for strong policy institutions, but we lack a structured approach to implement and evaluate changes to policymaking procedures.

Strategies to improve policymaking practice face different evaluation and implementation challenges than strategies to improve clinical practice. A pathway exists to assess the efficacy and effectiveness of a clinical intervention before developing and adapting implementation strategies for successful uptake [365]. For changes to policymaking practice, establishing whether a change in practice works and identifying mechanisms to encourage its uptake are less obvious: we lack controlled environments for piloting, there is no agreed set of outcome measures, and implementation takes place in a context of strong vested stakeholder interests, political timelines that may not align with research timelines, and very limited possibility for iteration. Whilst this may highlight why structured evaluation of changes to the policymaking process are not the norm, it also emphasises the need for tailored approaches to evaluate not just clinical interventions, but also the policymaking process itself.

As discussed in earlier chapters, one of the major transitions in HTA that is proving challenging to implement in practice is a shift towards a multi-disciplinary approach [51, 78, 366], including around how uncertainty is conceptualised and addressed. HTA has traditionally relied on evidence-based medicine, economics, and policy processes founded on the principles of the accountability for reasonableness framework [79, 101, 367]. Whilst this approach to policymaking has proven successful for medicine reimbursement decisions, other policy questions regarding the organisation of healthcare systems, health promotion interventions, and cross-jurisdictional policies need to account for the broader social context in which policies are made and implemented [60, 104, 107, 126]. Policymaking under uncertainty in HTA is now much broader than data quality: the problem frames for policy questions may be unclear, policy impact may be multi-dimensional or cross jurisdictions, and stakeholders may disagree about relevant evidence or stakeholders[43, 98, 102, 158].

Our team developed a framework for policymaking under uncertainty in HTA, which highlighted features of the policy question, context, or governance that may warrant departure from standard HTA practice, to better incorporate a social science lens for policymaking. Although the framework was based on an interdisciplinary review of established practices from other disciplines, we were seeking to understand whether and how the framework could be integrated with existing HTA institutions in Thailand, but we lacked the tools to do so in a systematic manner.

Implementation science aims to improve the quality and effectiveness of health services by studying methods to promote systematic uptake and routine implementation of evidence-based

practices [223]. From this perspective, strategies to improve policymaking practice can be considered as an innovation for implementation. Strategies to promote evidence-informed policymaking are, however, under-researched in implementation science [368], as policy research questions may not align with implementation science “ways of thinking” [369], requiring adaptation to address differences between clinical and policymaking practice.

In this study we applied implementation science as a means by which to evaluate improvements to policymaking practice in a structured manner, in order to evaluate the added value of the change in practice and to adapt the practice to the policymaking context, to promote its uptake. Since changes to policymaking practice are most often made by stakeholders managing the policy process, we applied an implementation science framework within an action research approach, in which members of the HTA agency in Thailand were core members of the research team.

Our study had the following objectives: (1) to evaluate the extent to which a multi-disciplinary approach improves HTA policymaking under uncertainty in Thailand, (2) to develop an implementation strategy to promote integration of the multi-disciplinary approach into policymaking practice, and (3) to explore the benefit of applying an implementation science framework within an action research for promoting improvements to policymaking practice. This study demonstrates how implementation science frameworks may be adapted to evaluate innovations in policymaking practice, providing insights to adapt policymaking institutions in a structured manner, within the resource and time constraints typical of policy environments.

## **METHODS**

### **Study design**

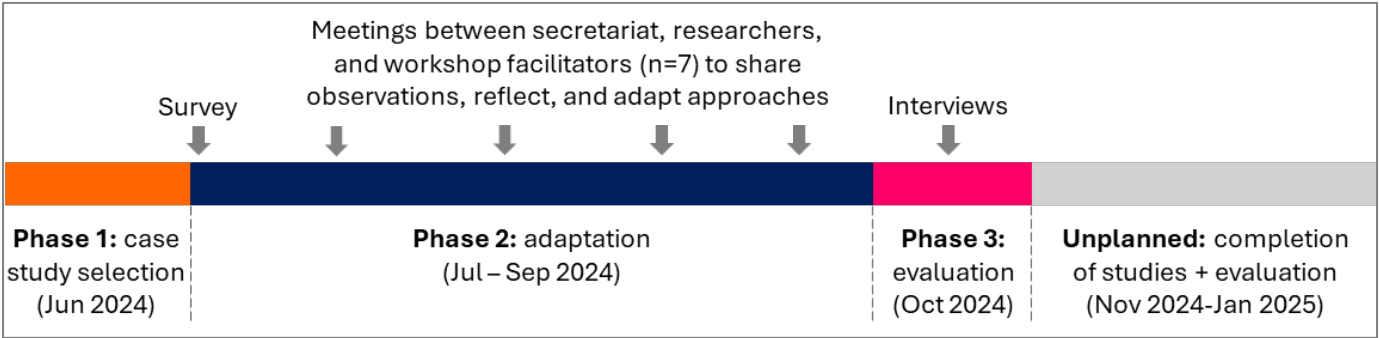
We conducted a type-1 hybrid implementation study, which simultaneously evaluates effectiveness of an innovation, how it needs to be adapted, and the barriers and facilitators to adoption, in order to develop an appropriate implementation strategy [370, 371]. Given the complex, real-world context of policymaking, a hybrid type-1 design allowed us to evaluate the effectiveness of the multi-disciplinary framework while exploring factors influencing its implementation. The study was composed of three stages: (1) identification of an appropriate case study (according to pre-defined criteria), (2) adaptation based on reflection and learning (without pre-defined indicators), and (3) evaluation of the effectiveness and barriers/facilitators

to implementation (according to indicators defined a priori) (**Figure 7.1**). Further details are provided in the **Outcomes and analysis** section.

[231][231–233][231, 232]

We follow reporting standards for qualitative research (COREQ) and for initiatives to improve healthcare (SQUIRE 2.0) [372, 373] (**Supplements 7.1 and 7.2**).

**Figure 7.1.** Overview of steps of the study and timeline.



Context

Evidence-informed policymaking has been well-established for benefit package decisions in Thailand since 2008 [237, 374, 375]. There is separate governance for the National List of Essential Medicines (NLEM) and Universal Coverage Benefits Package (UCBP), although both follow recommended steps for health policy recommendations, comprising topic nomination by defined stakeholders, topic selection through a multi-criteria analysis approach, identification of the need for and conduct of additional studies (e.g. economic evaluation or feasibility), and recommendation by a sub-committee of members appointed on fixed terms [79, 237, 375]. Although not legally binding, internal operational guidelines and publicly available HTA methodological guidelines define steps of the process and methods for both policy processes, with good adherence. HITAP is a semi-autonomous organisation within the Ministry of Public Health that supports the process, research, and development of HTA infrastructure for UCBP, NLEM, and other policy research in Thailand [376].

HTA in Thailand is characterised by a learning culture, with regular review and revision of processes. In recent years, changes have been made to incorporate structured criteria for rapid HTA and to define separate requirements for technologies addressing rare diseases, for example.

This is facilitated by long-term funding, close relationship between HITAP and policymakers, and cross-country collaboration. Thai government multi-year funding provides support for HITAP to strengthen and advance evidence-informed policy in Thailand (and is separate to grants for research studies). Within Thailand, members of the HITAP Board and leadership team have served as members of the sub-committee and working groups for NLEM and UCBP for over fifteen years, building close relationships. Outside of Thailand, HITAP has established regional and global networks of HTA agencies and academia to promote cross-learning and sharing of best practice between stakeholders, which is leveraged to inform improvements to HTA in Thailand [376, 377].

## Intervention

We implemented a framework to improve policymaking under uncertainty (referred to herein as “the framework”). The full framework, with an explanation of how it differs from standard HTA practice, is included in **Chapter 3**. Since the intervention for this study supports evidence-informed policymaking, we report the framework according to the Aim, Ingredients, Mechanism, Delivery framework (AIMD) [378]:

- **Aim:** The framework aims to improve public health policymaking under uncertainty, by highlighting when it may be appropriate to depart from standard HTA practice. It facilitates a multi-disciplinary approach by emphasising situations in which a social science lens could improve policymaking.
- **Ingredients:** The framework lists features of the policy question, decision context, available evidence, and institutions for decision-making for which standard HTA practice may be insufficient and lists alternative approaches to apply. The framework is not intended to be exhaustive or prescriptive, but rather a diagnostic tool.
- **Mechanism:** The framework was developed from an interdisciplinary review of frameworks for policymaking under uncertainty and is composed of established methods from other disciplines [379].
- **Delivery:** The framework has been developed for use by focal points in an HTA agency or government policymaking secretariat (for example, in the Ministry of Health). It is intended for use in settings with established HTA institutions.

Since this study was a preliminary test of the framework in the Thai context, we trialled the framework for a single policy question. A lead researcher from HITAP implemented the

framework and new approaches identified, with guidance from subject matter experts at the University of Strathclyde. Researchers from HITAP and the secretariat team supported research activities and communicated outputs to policymakers. Policymakers were briefed on the new approaches during the first policy meeting (for approval), before requests for their input, and before presentation of results. A summary of terms used is provided in **Table 7.1**.

**Table 7.1.** Summary of terms used in this manuscript.

Term	Meaning
The framework	A multi-disciplinary framework for policymaking under uncertainty in HTA (the <i>innovation</i> for this study).
New approaches	Multi-disciplinary approaches for policymaking under uncertainty identified from the framework, which were trialled in this study.
Standard HTA practice	Current HTA practice in Thailand.

## Outcomes and analysis

The timeline for evaluation stretched from Working Group initiation (June 2024) until the decision of the National Health Security Office (NHSO) Board (November 2024). Since results from the new approaches were not ready by the Board decision, we continued the evaluation until January 2025 to identify additional information for policymaking that would have been available, had the new approaches been completed in time (**Figure 7.1**).

We considered the framework as successful if it provided additional insight for policymaking beyond standard HTA practice, and implementation as successful if the additional insights informed the Board decision. We selected the Consolidated Framework for Implementation Research (CFIR) as the basis for our analysis, since it has been developed to understand the barriers and facilitators for an intervention, it is able to account for group interaction and context, and it can be implemented with constrained time and resources [380, 381]. We deliberately selected CFIR as a flexible framework, rather than frameworks developed for specific technologies or clinical settings [380]. CFIR comprises a set of concepts related to the following domains: innovation, outer setting, inner setting, individuals, and the implementation process [380]. **Supplement 7.3** details which CFIR indicators were applied at each phase of the study.

### *Part 1: selection of an appropriate case study*

The case study for implementing the framework was selected according to criteria that were later mapped to elements of CFIR (**Supplement 7.3**). Briefly, we selected a case study for which:

- there was recognition at the outset that current HTA approaches were not suitable,
- the policy did not fall under the mandate of existing institutions (which must adhere to operational and methodological guidelines),
- there was funding to support the policy process and evidence generation,
- our research group was mandated to support the policy process, and
- we were able to receive approval from the working group Chair (or equivalent) to apply the framework.

We analysed the selected case study against the framework to identify alternative approaches suitable to address the policy question (“new approaches”). We prioritised which new approaches to implement based on access to relevant knowledge from experts at the University of Strathclyde.

### *Part 2: iterative learning and adaptation*

Throughout the policy process, we adapted the new approaches based on observations and informal interactions. Specifically, we convened researchers and policy secretariat members before and after stakeholder meetings to reflect on implementation challenges, facilitators, and points for improvement. We had originally planned for the research team to collect structured field notes, but we found that it was not feasible alongside other tasks. We therefore collected team member impressions and insights for ongoing iteration in an unstructured way. This may mean that adaptations reflect our framing of how policies should be made to a greater extent than adaptations based on structured field notes.

Reflection and discussion around adaptations to the framework were led by the lead researcher, who was a PhD candidate working as a Researcher at HITAP with brief training in ethnographic methods. Meetings were attended by the secretariat lead (a HTA leader in Thailand and globally); members of the secretariat (clinical and policy experts); and researchers from HITAP. All meetings therefore included participants with varied expertise in standard HTA practice, strength of relationships with policymakers, and knowledge of the new approaches.

*Part 3a: evaluation of effectiveness and cost outcomes*

Outcomes were selected to (1) measure the extent to which the framework identified approaches that improved policymaking within existing resource constraints, and (2) evaluate the barriers and facilitators to implementing these new approaches.

The first set of outcome measures sought to identify the additional benefit (if any) of applying the framework and additional resources required for its implementation. These factors map to the effectiveness, comparative advantage, and innovation cost components of the CFIR framework (**Supplement 7.3**). Specifically, we measured the following outcomes, which map to established evaluation frameworks in HTA [98, 273]:

1. **Additional policy-relevant information.** This measure was used as a proxy for framework efficacy. We compared results and recommendations from standard HTA practice (detailed in the results) with those from the new approaches. Since the new approaches aimed to encourage a multi-disciplinary approach, we did not define indicators for what constitutes “policy-relevant” information a priori. In terms of construct validity, we assumed that as HTA researchers, we can judge what constitutes policy-relevant information, in line with an action research approach.
2. **Use of outputs by policymakers.** For this indicator, we tracked recommendations throughout the process to compare the extent to which the final policy leveraged insights from standard HTA practice, the new approaches, and/or other factors. We documented the recommendations from: (i) individual working group members at the start of the policy process (survey sent to working group members via email), (ii) secretariat recommendations presented to the working group, (iii) official recommendation from the working group to the decision-maker (from meeting minutes), and (iv) the Board decision (published on the NHSO website). We assumed there was no cross-learning that modified outputs from the standard HTA approach.
3. **Staff time to apply the framework.** This indicator was measured by timesheets circulated to members of the research and secretariat teams, to account for additional activities conducted for the new approaches, beyond standard HTA practice.

For outcome 2, use of outputs by policymakers depends on many factors, including familiarity with the new approaches and trust in the evidence. For outcome 3, we did not account for policymaker time or activities that served both standard and new approaches. We sought to address these limitations through the qualitative analysis in step 3b.



### *Part 3b: evaluation of barriers and facilitators to implementation*

To evaluate implementation barriers and facilitators, we conducted a qualitative analysis of archival, observational, and interview data. We did not measure pre-defined indicators due to limited evidence on factors influencing successful change to policymaking practice. Data sources comprised meeting minutes, interviews, and adaptations from Part 2. Minutes from working group meetings (n=5) had been taken by members of the secretariat and covered the main discussion points and conclusions. Meetings lasted 3 hours and were held in a hybrid format with in-person and online participation by working group members and the secretariat. We analysed the version of the minutes approved by the working group. Minutes were translated into English using Gemini, alongside ChatGPT and Google Translate if the Gemini translation was unclear, and reviewed against the original by a native Thai speaker.

Interviews were conducted within two weeks of the final working group meeting. We invited all working group members to interview as well as members of the secretariat team involved in framework implementation. Requests to interview were sent electronically by the secretariat with one follow-up request. Of working group members, 2 out of 18 accepted to be interviewed (although 1 did not return the consent form and their interview was removed from the analysis) and 1 sent a written response to interview questions. For the research team, 3 out of 4 agreed to be interviewed. Although response rate for working group members was low, this is in line with other studies [382] and had been expected given busy schedules and the requirement for interviews to be conducted in English.

Interviews were conducted via Zoom in English by the lead researcher and another member of the research team, both of whom were HITAP staff members with training and experience conducting interviews. Both interviewers had established relationships with the interviewees and interviewees were aware of research goals. We asked open-ended questions about the overall process following an interview guide (**Supplement 7.4**). Due to limited time to pilot the guide, the first interviews were conducted with members of the research team. Interviews lasted 20-60 minutes and were recorded and transcribed for analysis. We circulated transcripts and preliminary findings to all interviewees for review, with two follow-up emails.

All data was thematically analysed by one researcher according to codes from the CFIR framework [381]. The CFIR codes structured narratives which were used to synthesise relationships between the codes. No commercial software was used.

## Ethics

This study was approved by the Management Science Department Ethics Committee of the University of Strathclyde. The main ethical issues identified were potential identification of participants, misrepresentation of what interviewees wanted to convey, and a risk that trust in HTA may be undermined. Alongside data privacy procedures and sharing transcripts with interviewees, we circulated draft results to all interviewees and the research team to ensure that none of the results could present a reputational risk to individuals or organisations. Following interviewee review, all quotes and the narrative analysis were removed from the manuscript as interviewees highlighted potential reputational risk to individuals and organisations (even with anonymised quotes).

## RESULTS

### Part 1: selection of an appropriate case study

We applied the framework during a review of the kidney replacement therapy (KRT) policy in 2024. In Thailand, KRT had been included in the benefits package since 2008 [383]. A policy change in 2022 to the eligibility conditions for KRT had resulted in an unexpected increase in budget expenditures and death rates, prompting a review of the policy by the NHSO Board [238]. Thailand has established HTA institutions for technology inclusion decisions, but not for problem-oriented questions around why a policy did not achieve its intended results. To address the 2024 review of the KRT policy, an ad-hoc working group was therefore formed under the NHSO Board with a dedicated secretariat to coordinate research activities [238]. The secretariat was led by researchers from HITAP alongside researchers from Thai universities and government institutions.

The KRT policy met our selection criteria (as mapped to the CFIR framework) for the following reasons. Firstly, the policy process was not governed by existing guidelines (2E, policies and laws), so the framework could be tested without requiring endorsement or large-scale change (1E, innovation trialability). Secondly, members of our research team had been nominated to the working group secretariat, had previously worked with members of the working group, and included opinion leaders for both HTA and KRT in Thailand (3B, relational connections; 4C, opinion leaders). Finally, it had been recognised that standard HTA practice was insufficient to address the policy question and innovation was needed (3E, tension for change), with flexible research funding already secured (3J1, available funding).

### *Application of the framework for policymaking under uncertainty*

The research plan for the 2024 KRT policy, based on standard HTA practice, included: (1) projection of KRT patients and budget impact using a cohort Markov model [384], which adhered to recommended practice [385]; (2) a qualitative phenomenology study to understand motivations for the 2022 policy change [386]; and (3) literature reviews of the effectiveness of policies to increase uptake of comprehensive conservative care and home-based dialysis [275, 276].

As detailed in **Chapter 3**, we identified the following new approaches that could be beneficial for this policy question.

1. Future scenarios: there could be long timeframes to reverse impact of the 2022 policy and there were multiple vested interests.
2. Structured decision-making: cross-disciplinary evidence was being used.
3. System dynamics: initial evidence suggested the presence of feedback loops.

Applying our prioritisation criteria for implementation, we selected future scenarios and system dynamics, as guidance and training was available from the University of Strathclyde (3K, access to knowledge and innovation), and these approaches aligned with the existing working group plan (3F compatibility).

### *Part 2: iterative learning and adaptation*

Adaptations made to system dynamics and future scenarios are detailed in **Supplement 7.5** and **Chapter 4**, respectively. The main issues encountered were: (1) lack of familiarity, which challenged stakeholder engagement and lowered perceived credibility; (2) short timelines; and (3) power dynamics. To address lack of familiarity, we modified our communication to follow formats used in HTA. A key learning was that short training sessions were insufficient for policymakers and workshop participants to effectively contribute. Instead, we received more constructive input when asking for feedback on “assumptions” or “potential impact”. The short timelines meant that we could only engage a diverse set of stakeholders once. Leveraging the secretariat, who oversaw the research and policy process, allowed us to understand diverse stakeholder perspectives and ensured our work was aligned with current knowledge. Finally, due to vested interests and professional hierarchies, we shifted the goal of stakeholder engagement towards capturing the diversity of perspectives, as opposed to coming to a shared vision.

## Part 3a: effectiveness and cost outcomes

### *Additional policy-relevant information*

Compared to standard practice, new approaches showed (1) more systematic estimation of impact based on behaviour change or healthcare system performance, and (2) more dimensions of impact (**Supplement 7.6**). Under standard HTA practice, working group members estimated percentage of patients selecting peritoneal dialysis, directional mortality rate, and impact on equity through discussion. The new approaches identified the causal mechanisms influencing these factors, to estimate impact over time (system dynamics) and account for potential stakeholder actions to protect their interests (future scenarios) [358, 387]. Regarding dimensions of impact, future scenarios highlighted the impact in strengthening (or weakening) the system to withstand future shocks [358]. System dynamics identified policies that addressed underlying issues beyond the immediate problem (e.g. long-term investment) or under the jurisdiction of other bodies (e.g. quality assurance bodies and the nursing council) [345]. In contrast, standard HTA approaches focussed on interventions provided by healthcare personnel (e.g. patient education and triage protocols) or financing mechanisms (e.g. bundled payments).

As discussed previously, most of the policy-relevant information highlighted above was not available by the time of policy decision, due to the short timelines for evidence generation, and could not inform the working group recommendation.

### *Use of the outputs by policymakers*

The policy options under consideration by the working group increased over the recommendation process (**Table 7.2**). All working group members surveyed after the first working group meeting either selected the previous or current policy when asked which policy should be made. In the opening of the second meeting, the chair proposed a set of five policy interventions, all of which were reflected in the final seven policy options proposed to the Board. The new approaches were referenced but not incorporated into final working group recommendations. The final decision from the Board adopted two of the seven policy interventions proposed by the working group.

**Table 7.2.** Tracker of policy proposals throughout the process.

Date	Stage of process	Preferred policy
Jun 2024	1 <sup>st</sup> working group meeting	Survey to collect individual working group member opinions on the best policy to make (6/18): <ul style="list-style-type: none"> <li>• PD-first, policy from 2008-2022 (n=2)</li> <li>• Free choice, policy from 2022 (n=3)</li> <li>• None specified (n=1)</li> </ul>
Jul 2024	2 <sup>nd</sup> working group meeting	Policy interventions proposed by the chair in the meeting opening: <ul style="list-style-type: none"> <li>• Pre-authorisation</li> <li>• Counselling to inform patients of KRT options</li> <li>• Process to identify patients for palliative care</li> <li>• Regulation, monitoring, and audit</li> <li>• Payment mechanisms</li> </ul>
Oct 2024	Final working group meeting	Official recommendation: <ul style="list-style-type: none"> <li>• Pre-authorisation</li> <li>• Patient education (counselling)</li> <li>• Protocol to identify patients for palliative care</li> <li>• Quality monitoring system</li> <li>• Global budget (a type of payment mechanism)</li> <li>• Restricted payments of the doctor fee</li> <li>• Working group for monitoring and evaluation, supported by establishment of a data system linked to existing databases</li> </ul>
Nov 2024	NHSO Board	Decision: <ul style="list-style-type: none"> <li>• Pre-authorisation</li> <li>• Reimburse conservative care as a KRT option under the benefit package</li> <li>• Working group established to develop the system and monitor quality of KRT services</li> </ul>

KRT – kidney replacement therapy; NHSO – national health security office; PD – peritoneal dialysis

### *Staff time associated with applying the framework*

Only one team member completed the timesheet. The team member was one of the most active members of the research team and was accustomed to completing worklogs. Additional time for this team member, beyond existing research and secretariat activities, totalled 34 hours over four months, equivalent to 0.06 FTE (full time equivalent). If we assume that all team members allocated a similar length of time, this would equate to 0.3 FTE over four months in addition to 0.6 FTE from the lead researcher over six months.

### Part 3b: barriers and facilitators to implementation

This section summarises the barriers and facilitators related to the framework, its implementation, and the context that influenced the extent to which the new approaches influenced policymaking. Beyond barriers and facilitators, the interviews highlighted two success outcomes that we had not included in our analysis: (1) impact of the policy process on stakeholder knowledge and practice (regardless of the final policy), and (2) adoption of the approaches for future policymaking. The narrative analysis, with interview quotes, was removed following interviewee review, to adhere with ethical clearance.

Overall, our findings suggest that the working group and secretariat did see the new approaches as filling a gap, but there was insufficient working group engagement for the results to effectively inform policy. As summarised in **Table 7.3**, attitudes and partnerships in the outer setting (policy institutions), alongside structural characteristics of the inner setting (the KRT policy process), shaped the inner setting relational connections, communication, and culture, in ways that were both positive and negative for promoting change in policymaking practice. Individuals had high capability to fulfil their role, but limited motivation to challenge the status quo. Highly motivated leaders were able to promote uptake of the new approaches (secretariat leadership) and to create an environment to accommodate different types of evidence (working group leadership). Successful adaptations included tailoring approaches to be compatible with existing patterns for policymaking and give a broader range of stakeholders the opportunity to contribute. The evaluation highlighted the need to build capacity of the research team, secretariat, and policy body to use the new approaches, through repetitive use over time (research team and secretariat) and regular discussion prior to policymaking (policy body).

Our analysis suggests that an implementation strategy to integrate the framework with HTA practice in Thailand should include the following features: (1) collaboration with HTA leaders to

tailor and implement the framework; (2) initially applying the framework for policies with leaders that are motivated to incorporate different types of evidence and stakeholder inputs; (3) tailor approaches prior to implementation to align with HTA standards and allow input from diverse stakeholders; and (4) build capacity of HTA researchers in Thailand to apply the new approaches and effectively communicate outputs to policymakers.

**Table 7.3.** Factors that were barriers or facilitators to the implementation of new approaches for policymaking under uncertainty and how they were addressed. The code in the Consolidated Framework for Implementation Research (CFIR) is provided after each statement. We have removed all interview quotes to adhere to ethical clearance.

Factor	How it behaved as a facilitator	How it behaved as a barrier	Approach to address
Strong institutions for evidence-informed policy (II Outer Setting: <i>B Local Attitudes</i> )	<ul style="list-style-type: none"> <li>Trust between the secretariat and the working group (III Inner Setting: <i>B Relational connections</i>)</li> <li>Secretariat expertise in developing evidence-based policy (IV Individuals: <i>B Capability</i>)</li> </ul>	<ul style="list-style-type: none"> <li>Established views around what constitutes acceptable evidence for policy (III Inner Setting: <i>D Culture</i>)</li> </ul>	<ul style="list-style-type: none"> <li>Leadership from a HTA expert built trust in the new approaches (IV Individuals: <i>A High-level Leader + C Opinion Leader + D Motivation</i>)</li> <li>Adaptations aligned new approaches with established ones (III Inner Setting: <i>F Compatibility + V Implementation process: E Tailoring strategies</i>)</li> </ul>
Stakeholders in the policy process were not independent (II Outer Setting: <i>D Partnerships and connections</i> )	<ul style="list-style-type: none"> <li>Incorporated lived knowledge, experience, and vested interests (IV Individuals: <i>I Innovation recipients + B Capability</i>)</li> <li>Impact on practice outside of the policy sphere</li> </ul>	<ul style="list-style-type: none"> <li>Reluctance to change or criticise the status quo (IV Individuals: <i>I Innovation recipients + D Motivation</i>)</li> <li>Power dynamics from hierarchies outside of the policy process</li> </ul>	<ul style="list-style-type: none"> <li>Leadership from senior nephrologists to challenge the status quo (IV Individuals: <i>A High-level Leader + C Opinion Leader + D Motivation</i>)</li> <li>Workshops designed to capture multi-vocality (IV Individuals: <i>C Opportunity + V Implementation process: E Tailoring strategies</i>)</li> </ul>



	(III Inner Setting: <i>C Communications</i> )	(III Inner Setting: <i>B Relational connections</i> )	
Policy question did not align with institutions for decision-making (III Inner setting: <i>A Structural characteristics</i> )	<ul style="list-style-type: none"> <li>New approaches could be trialled (<b>I Innovation: <i>E Innovation trialability</i></b>)</li> </ul>	<ul style="list-style-type: none"> <li>Mandate and expectations of the working group from the Board were unclear (<b>III Inner setting: <i>C Communications</i></b>)</li> </ul>	<ul style="list-style-type: none"> <li>Networks leveraged during the policy process promoted awareness outside of the policy sphere (<b>IV Individuals: <i>A High-level Leader + C Opinion Leader + D Motivation</i></b>)</li> </ul>
Novelty of the innovation ( <b>I Innovation: <i>C Innovation relative advantage + F Innovation complexity</i></b> )	<ul style="list-style-type: none"> <li>Stakeholders in the working group and secretariat perceived a need for the new approaches (<b>IV Individuals: <i>A Need</i></b>)</li> </ul>	<ul style="list-style-type: none"> <li>Low knowledge about the approach, couple with limited time, limited inputs from stakeholders (<b>IV Individuals: <i>I Innovation recipients + B Capability</i></b>)</li> <li>The secretariat was learning while doing, so results were available only at the end of the process (<b>IV Individuals: <i>E Implementation leads + B Capability</i></b>)</li> </ul>	<ul style="list-style-type: none"> <li>Members of the secretariat were consulted for input on stakeholder perspectives (<b>IV Individuals: <i>F Implementation team + B Capability</i></b>)</li> <li>Plan to build capacity in the HTA agency for future implementation (<b>IV Individuals: <i>A High-level Leader + C Opinion Leader + D Motivation</i></b>)</li> </ul>

## DISCUSSION

Transformative change to policymaking practice often hinges in the collective efforts of committed leaders and engaged stakeholders [54]. Our study underscores this reality. We evaluated a multi-disciplinary framework for policymaking under uncertainty that we had developed at the HTA agency in Thailand. Although our results show a gap in policymaking practice that was filled by the framework, reluctance to deviate from established procedures and entrenched perceptions around how policies “should” be made required strong leadership and proactive stakeholder action. We illustrated the benefit of implementation science to characterise and address these dynamics within the unique pressures and constraints of a policy environment.

A strength of this study is that we articulated methods to assess the effectiveness of changes to policymaking practice that can be conducted alongside standard HTA. Our findings suggest that the multi-disciplinary framework was successful in improving policymaking, by systematically evaluating the impact of policy options over time for factors that would rely on unstructured expert opinion following standard HTA practice. It is, however, difficult to generalise the findings from this study across policy decisions, as we only applied 2 out of 14 approaches in the framework during this case study, and the framework therefore requires further empirical testing.

Despite a perceived need for the framework and relevance of the outputs for policymaking, we experienced challenges in promoting its adoption. This is in line with experience in the literature: a framework for environmental policymaking under uncertainty in the Netherlands found mixed levels of use, despite widespread training and dissemination [163, 170]; and the new approaches in this study (system dynamics and future scenarios) have often been proposed for health promotion policymaking [102, 107, 346], but have experienced limited uptake [102, 108, 296]. This aligns with institutional theory that formal rules alone (e.g. operating manuals and policies) are insufficient to promote a change in practice without a concurrent change in the informal social rules and norms that guide policymaking [25], and highlights the relevance of implementation science in articulating how to bridge the gap to routine use for new policymaking practice.

By analysing the barriers and facilitators to use of the framework through an implementation science lens, we identified the following features influencing successful implementation: (1) motivated senior leadership, from the secretariat to use the framework and from the policy body to accept new forms of evidence; (2) ongoing capacity building of the research team, secretariat, and policy body; and (3) tailoring new approaches for compatibility with existing institutions for decision-making. Our

findings are similar to a case study on factors influencing evidence-informed policymaking for health and social care policy in Sweden, which highlighted the role of actors and capacity building in bringing about change [388], and reflects one of the only examples of successful integration of system dynamics and future scenarios with healthcare policy, in which results were presented in line with standard HTA practice [211].

Practically for our HTA agency, the analysis of barriers and facilitators highlights three important features of an implementation strategy. Firstly, in terms of sustainability, it is unlikely to be feasible to simultaneously build capacity to implement all 14 approaches in the framework. Collaborating with HTA leaders to identify which approaches are highest priority to implement, based on the profile of upcoming policy questions that cannot be addressed with standard HTA practice, may allow a stepwise approach to gradually build capacity to implement the framework. This aligns with the policy theory of incrementalism, in which successful policies make incremental change to existing operational procedures and norms [118]. Secondly, support for each new approach can be built by purposely selecting policies for which there is recognition that standard HTA practice is not suitable and for which there are strong leaders to facilitate use of outputs from social science based approaches. Finally, we found that established norms and beliefs can affect the credibility of evidence, in line with the literature [12, 13]. Tailoring each approach to standard HTA practice may better support acceptability.

This study extends implementation science by demonstrating how hybrid designs can evaluate policymaking innovation, adapting CFIR for institutional rather than clinical contexts. This provided a structured way to articulate the benefit of the framework, assess the opportunity cost, and develop an implementation strategy. Applying implementation science within action research may be particularly relevant for LMICs, in which members of HTA agencies often wear multiple hats and possess fewer resources for the policy process or its evaluation, requiring structured action research for continuous improvement. We did, however, come up against common challenges in policy settings when evaluating the framework: team members had insufficient time to complete structured field notes or timesheets, policymakers were reluctant to be interviewed, and we could not separate which insights from the new approaches were researcher dependent. Some of these limitations may be addressed by putting in place procedures for action research in HTA agencies, to reduce the burden to simultaneously implement and evaluate changes to policymaking practice. Developing procedures to reduce the risk to policymakers of engaging in research will also be

important, to extend learning beyond the research team and secretariat. Finally, although we applied CFIR, other implementation science frameworks may prove better suited for improvements to policymaking practice. Further research to adapt implementation science techniques for HTA is needed.

## CONCLUSIONS

Policymaking practice is not static and continues to evolve. Particularly with the transition to a multi-disciplinary approach in HTA, we require structured methods to evaluate the benefit of changes to policymaking practice and to develop implementation strategies for their successful uptake. In this paper, we took a novel approach by applying an implementation science framework as part of action to research to address this challenge.

Our study provides preliminary evidence that the multi-disciplinary framework for policymaking under uncertainty in HTA, developed by our team, does improve policymaking, by broadening and making more systematic projections of policy impact, with low additional resource requirements compared to standard HTA practice. We articulated an implementation strategy to address the barriers and facilitators from this study, entailing a stepwise approach to capacity building focussed on policies with the greatest unmet need, enlisting motivated leaders, and adapting new approaches to align with HTA standards. Ongoing evaluation is required to evaluate and adapt this implementation strategy over time.

We demonstrated that minor adaptations to existing implementation science methods can provide a structured framework to evaluate, adapt, and implement changes to policymaking practice within constrained timelines and resources. Further work could better articulate a set of tools that can be routinely used by HTA agencies to systematically improve policymaking in an evidence-based manner.

## SUMMARY

In this chapter, we addressed **Research question 3**, by considering the extent to which the framework improves policymaking under uncertainty in HTA, within the context of the KRT case study. Based on the findings from this study, we propose changes to the framework in **Chapter 8** and

describe further research needed to validate the framework for use in Thailand and globally in **Chapter 9.**

## Chapter 8: Updated framework for policymaking under uncertainty

### OVERVIEW

In this chapter, we draw on learnings from the evaluation in **Chapter 7** to propose changes to the framework for policymaking under uncertainty from **Chapter 3**. We illustrate how the revised framework could inform strategic choices around capacity building for multi-disciplinary approaches in Thailand, we outline an implementation strategy to encourage the evaluation and integration of new approaches, and we highlight areas for further research related to the revised framework.

### MODIFICATIONS TO THE FRAMEWORK

One of the main learnings from the case study is that time is required to (1) build capacity across local researchers and the policy secretariat to apply each new approach, (2) iteratively adapt and evaluate the new approach to be compatible with existing HTA practice, and (3) to progressively institutionalise a new approach through consistent application across policy questions. In response, we have modified the primary aim of the framework to be a strategic tool to support HTA agencies, or equivalent bodies, to identify new approaches that are high priority to implement in their context, and to outline the steps by which to develop an implementation plan for these approaches.

**Table 8.1** summarises findings from the case study evaluation and revisions to the framework.

**Table 8.1** Summary of findings from the implementation study in Chapter 7 and changes made to the framework for policymaking under uncertainty from Chapter 3.

#	Finding	Revision to the framework
1	Time is required to build the capacity of the researchers and secretariat to implement new approaches.	Capacity cannot be built simultaneously for all new approaches: revise the aim of the framework to be a strategic tool identify high-priority approaches to introduce into the HTA system.
2	Repetition can increase familiarity and understanding of new techniques.	

<b>3</b>	Aligning the communication of results to align with standard HTA practice is more effective than brief training session for policymakers to use results.	Include a step in the framework to develop (and iteratively revise) an implementation strategy that explicitly adapts the approach to existing HTA practice.
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## UPDATED FRAMEWORK

The main changes to the framework are presented according to the AIMD framework in **Table 8.2**. The revised framework is intended to be used as a strategic tool to decide when and how to incorporate approaches that support a social science lens to policymaking under uncertainty within existing HTA systems. The framework is comprised of four steps, which are detailed below and summarised in **Table 8.3**. Although steps 1 and 2 can be modified to fit with available time and resources, it is anticipated that some level of capacity for monitoring and evaluation may be required for steps 3 and 4.

### Step 1: identify where existing HTA practice is insufficient

Using the original framework from **Chapter 3**, this step entails a review of recent and upcoming policy questions being addressed by the HTA agency, to identify which of the listed approaches in **Table 3.1** may be relevant for improving HTA practice. Relevant considerations at this stage include the stakeholders to include in discussions, the depth of analysis (for example, based on expert opinion or structured review of each past, ongoing, and upcoming policy question), and how the scope of upcoming policy questions will be defined (for example, by reviewing policy questions addressed by neighbouring countries and other horizon scanning activities, or expert opinion based on past questions and knowledge of local institutions and politics).

### Step 2: prioritise which new approaches to implement

Each new approach will require capacity building, adaptation, and evaluation to successfully implement. It is unlikely to be feasible to introduce multiple new approaches into HTA practice at the same time. This step applies indicators from the Common Framework for Implementation Research (CFIR, [381]) to prioritise across new approaches identified in step 1:

1. **Relative priority** (3G): For which approaches identified in step 1 is there greatest need, either in terms of frequency of policy questions and/or insufficiency of current HTA practice?
2. **Compatibility** (3F): To what extent is the new approach compatible with existing HTA philosophy, ways of thinking, and HTA procedures in the country? An incremental approach would initially prioritise approaches that are better aligned with current HTA practice [118], to gradually transition towards a social science lens for policymaking over time.
3. **Structural characteristics** (3A): To what extent does the HTA agency (or equivalent) have the authority to implement the new approach? Approaches that would require change outside of the mandate of the HTA agency may require extended timelines for implementation and may benefit from learning acquired through implementing other approaches first.
4. **Access to knowledge and information** (3K): Does the HTA agency (or equivalent) have access to training, networks of experts, or other forums to build capacity of the researchers and secretariat team?

These indicators have been proposed based on the analysis in **Chapter 7** and may need to be tailored to the local context.

**Table 8.2** Modifications to the framework for policymaking under uncertainty, reported according to AIMD [378].

	Original framework (from Chapter 3)	Revised framework
<b>Aim</b>	The framework aims to improve public health policymaking under uncertainty, by highlighting when it may be appropriate to depart from standard HTA practice. It facilitates a multi-disciplinary approach by emphasising situations in which a social science lens could improve policymaking.	The framework is a strategic tool to prioritise and implement changes to HTA practice for improved policymaking under uncertainty.



	Original framework (from Chapter 3)	Revised framework
Ingredients	The framework lists features of the policy question, decision context, available evidence, and institutions for decision-making for which standard HTA practice may be insufficient and lists alternative approaches to apply. The framework is not intended to be exhaustive or prescriptive, but rather a diagnostic tool.	The framework is composed of four steps: (1) identification of policy questions or contexts for which <b>current HTA practice is inadequate</b> , (2) <b>prioritisation of new approaches</b> to integrate with HTA practice, (3) development of an <b>implementation strategy</b> for each prioritised approach, and (4) <b>action research</b> to iteratively adapt, implement, reflect, and revise the implementation strategy.
Mechanism	The framework was developed from an interdisciplinary review of frameworks for policymaking under uncertainty and is composed of established methods from other disciplines [379].	The framework was developed based on an interdisciplinary review [379]. It is composed of established methods from other disciplines and informed by implementation science frameworks.
Delivery	The framework has been developed for use by focal points in an HTA agency or government policymaking secretariat (for example, in the Ministry of Health). It is intended for use in settings with established HTA institutions.	The framework has been developed for use by focal points <b>responsible for strategic decisions</b> in an HTA agency or government policymaking secretariat. It is intended for use in conjunction with standard good HTA practice.

### Step 3: develop an implementation strategy for each prioritised approach

An implementation strategy defines how the approach will be integrated with existing HTA practice. Appropriate implementation strategies will likely vary across settings and according to whether the approach relates to evidence generation, the policy process, or governance structures. Frameworks from implementation science can support development and tailoring of an implementation strategy.

The below factors (mapped to CFIR indicators) were found to be important in Thailand for approaches related to evidence generation.

1. **Policies and laws** (2E): HTA guidelines, present in many settings, outline how policies should be made in a country [282]. Well-established policymaking institutions may equally have unwritten codified procedures for addressing policies [25]. Initially implementing new approaches for policy questions outside of these institutions not only demonstrates their applicability in addressing questions that existing practice cannot address, but also gives the flexibility to trial new approaches without disrupting (or requiring approval to deviate from) existing procedures.
2. **Motivation - HTA leaders** (4D): Motivated HTA leaders, with the reputation and connections to influence change, can build trust in and acceptance of the new approaches.
3. **Motivation - policy leaders** (4D): Many of the new approaches in the framework require input from a broad range of stakeholders, which may be challenging in settings with rigid hierarchies or cultures with perceptions around which stakeholders hold more valid knowledge or opinions than others. Motivated policy leaders who are open to use evidence from the social sciences can encourage use of outputs from the new approaches in policymaking.
4. **Assessing needs – capacity building** (5B): The ability to implement the new approaches to high quality depends on the capacity of the researchers and secretariat. Identifying training and capacity building needs can support implementation for individual policy questions and build institutional capacity for the new approach over time.
5. **Engaging - policymakers** (5F): Planning the policy process so that there are multiple engagements with policymakers to discuss interim results can promote joint learning, in which the policymakers understand how the new approach can support policymaking and the secretariat and research team gain a better understanding of how to tailor the analysis and communication of results to align with policymaker needs.
6. **Adapting** (5I): Understanding the outputs from the new approaches and how they can be used to inform policymaking increases the cognitive load of policymakers, particularly if the new approach is perceived to be complex [35]. There may additionally be reluctance to use outputs from the new approaches if they adhere to quality standards from the social

sciences that are not aligned with standards for HTA [51]. Making adaptations to how the results from the approach are presented to align with established practice in HTA, without losing the additional insight from social science lens, can reduce the cognitive burden for policymakers and align with perceptions around rigorous science, for more effective use of the approach in policy.

#### Step 4: action research approach to implementation

The overarching goal of implementing the new approaches is to improve policymaking under uncertainty. It is therefore important to ascertain: (1) whether the insight from the new approach supports policymaking, (2) whether additional resources to implement the approach are justified, and (3) which implementation strategy may best support successful integration of the approach with existing HTA practice. Implementation science frameworks applied within an action research approach can determine the value of the new approach and how to encourage its institutionalisation, by promoting ongoing evaluation and improvements by HTA practitioners. A fundamental part of this step is accommodating staff time and ongoing activities in a way that reduces the additional burden for staff whilst also facilitating learning and evaluation.

**Table 8.3** Summary of the components of the updated framework.

#	Key actions	Main considerations
1	Review recent and upcoming policies against the framework ( <b>Table 3.1b</b> ) to identify policy needs	<ul style="list-style-type: none"> <li>• Who to involve</li> <li>• Depth of analysis</li> </ul>
2	Prioritise new approaches identified in step 1 for implementation	<ul style="list-style-type: none"> <li>• Criteria for prioritisation</li> </ul>
3	Develop an implementation strategy for the prioritised approach	<ul style="list-style-type: none"> <li>• Implementation science framework and/or CFIR indicators to apply</li> </ul>
4	Action research approach to implementation	<ul style="list-style-type: none"> <li>• How to integrate action research with minimal additional staff burden</li> </ul>

## APPLYING THE REVISED FRAMEWORK

We applied the revised framework to our HTA agency in Thailand, to illustrate how it may be used to identify, prioritise, and develop an implementation strategy for broadening the view of policymaking under uncertainty in HTA, although it was beyond the scope of this research to implement the revised framework.

### Step 1: identify where existing HTA practice is insufficient

We identified the following eight approaches that are highly relevant for policy questions being addressed by the HTA agency: system dynamics, future research, structured decision-making, adaptive management, consequence table (from soft problem structuring), qualitative value of information analysis, stakeholder analysis, and adaptive governance (**Table S8.1**). These approaches were identified due to: (1) increasing policy questions related to organisation of system delivery and health promotion (system dynamics, futures research); (2) policies with unachieved goals or unintended consequences (system dynamics, adaptive management), (3) increasing use of multi-disciplinary evidence in policy (structured decision-making), (4) constraints in time and resources for evidence collection in policy (consequence table, qualitative value of information); (5) varied levels of contention in the main policy processes applying HTA (stakeholder analysis); and (6) lack of established institutions to address health system or programme design questions (adaptive governance).

### Step 2: prioritise which new approaches to implement

Of the approaches that were considered to be most relevant for HTA in Thailand from Step 1, one of the approaches (futures research) has very different quality standards and methodological basis compared to current HTA practice in Thailand and was therefore de-prioritised (**Table S8.1**). The HTA agency has greatest ability to influence introduction and uptake of system dynamics and qualitative value of information analysis (**Table S8.1**), as compared to other approaches, which would require leadership from other institutions. For both system dynamics and qualitative value of information analysis, there is access to available knowledge, through network collaborations in the case of system dynamics and through published studies in the case of qualitative value of information analysis (which is similar to existing HTA practice and therefore requires less capacity building).

These two approaches would be highest priority to first implement to improve policymaking under uncertainty for HTA in Thailand.

### Step 3: develop an implementation strategy for each prioritised approach

Since an implementation strategy for system dynamics has been outlined in **Chapter 7**, we focus on an appropriate implementation strategy for qualitative value of information analysis, according to the CFIR indicators outlined above.

Qualitative value of information (VOI) analysis is a structured way in which to prioritise the level of resources assigned to data collection [227] (for example, whether to collect utility data for a model from a primary study in the population of interest, a systematic review of the literature, or by borrowing the value used in a study from a neighbouring country). It addresses critical theory perceptions of policymaking under uncertainty, by introducing consistency in how data is prioritised, alongside systems theory, by using participatory approaches to determine what is controllable or uncontrollable uncertainty from the perspective of different stakeholders.

As outlined in **Table 8.4**, a different set of CFIR domains may be important for implementation of qualitative VOI than for system dynamics and scenario thinking. Aligning with existing policies (2E) and motivating leaders to support the approach (4D) will depend on the evidence base to support the innovation (1B), as it is a less well-established approach. First evaluating the effectiveness of qualitative VOI, in terms of whether it can identify the most influential sources of uncertainty prior to model development, can identify whether to pursue its implementation and provide justification for HTA leaders and to policy bodies for applying the approach (if found to be effective). Capacity building of the research team and secretariat (5B), engaging policymakers (5F), and adapting the approach (5I), although necessary, are likely to require less time and effort than system dynamics and scenario thinking, since the approach shares the same basis as established HTA practice. Instead, tailoring implementation strategies (5E) that allow participants to fully contribute, so that a social science lens is reflected in the method, is likely to be more important. This suggests that a separate implementation strategy may be required for each approach implemented.

**Table 8.4** Application of the CFIR indicators representing barriers/facilitators from the case study, in order to inform an implementation strategy to introduce qualitative value of information analysis into HTA practice in Thailand.

CFIR indicator	Relevance	Implementation strategy
<b>Policies and laws (2E)</b>	HTA guidelines lay out preferred evidence for decision analytic models [389]. A Health Economics Working Group reviews adherence for established processes.	For trialling the approach, conduct both qualitative VOI prior to evidence collection and quantitative VOI after model completion.
<b>Motivated leaders (4D)</b>	Supportive leadership from the HTA agency and Health Economics Working Group is needed for acceptance of the approach.	Demonstrate proof-of-concept for qualitative VOI by applying it retrospectively for past decisions with quantitative VOI results.
<b>Assessing needs (capacity building) (5B)</b>	Qualitative VOI uses the same principles as quantitative VOI in standard HTA practice, so less training for researchers may be required.	Training for researchers based on quantitative VOI principles.
<b>Engaging policymakers (5F)</b>	Less relevant – engaging participants contributing to qualitative VOI estimates will be more important.	Develop materials to support stakeholder participation, with iterative evaluation and refinement.
<b>Adapting (5I)</b>	Cognitive burden will be greatest in understanding how to conduct the approach, as opposed to understanding outputs (which are similar to current HTA practice).	Limited adaptation of the approach itself; the emphasis is on tailoring the implementation strategy to support stakeholder participation.

HTA – health technology assessment; VOI – value of information

## **SUMMARY**

In this chapter, we revised the framework to be a strategic tool to identify approaches to address gaps in current HTA practice, to prioritise implementation of those approaches, and to develop and refine implementation strategies to promote their integration with standard HTA practice. We illustrated proof of principle of the framework, but further research is required to test its usefulness and applicability, which we discuss in **Chapter 9**.

## **Chapter 9: Discussion**

### **OVERVIEW**

In this section, we draw together learnings from each chapter to summarise our findings and discuss implications for policy and practice. Based on a critical reflection of the role of the researcher, interpersonal connections, and context on our findings, alongside a discussion of limitations, we examine the extent to which this thesis addressed the original research questions and propose an agenda for future research.

### **SUMMARY OF FINDINGS**

In this body of work, we set out to examine whether current practice for policymaking under uncertainty in HTA can address policy needs, in light of the expanding mandate of HTA agencies and the progressive shift towards a multi-disciplinary approach. Our findings suggest that current practice in HTA takes limited account of uncertainty conceptualisations in the social sciences, and that a broader view of uncertainty may be relevant for policy questions that influence behaviour, cross jurisdictions, or deal with multiple vested interests. We developed a framework for policymaking under uncertainty, based on findings from an interdisciplinary review, which identified features of the policy question, decision context, or governance for which alternative approaches to standard HTA practice may be more suitable. Applying the framework to the 2024 KRT policy in Thailand provided a systematic way in which to identify and estimate the impact of policy options across technical and social dimensions, through system dynamics and scenario thinking, which were absent from standard HTA approaches. The case study highlighted, however, the significant capacity building and adaptation required to integrate new approaches with current HTA practice. In response, we modified the framework to be a strategic tool for HTA agencies, or equivalent bodies, to identify and prioritise where to build capacity to improve policymaking under uncertainty.

### **IMPLICATIONS FOR POLICY AND PRACTICE**

Findings from this work suggests that, in order to address current and future policy needs, HTA practice should accommodate a broader view of policymaking under uncertainty. Approaches from



other disciplines may support this transition, but they will require adaptation, capacity building, and leadership to be successfully implemented. Approaches that broaden the view of policymaking under uncertainty have a different philosophical basis to accepted practice in HTA: system dynamics, for example, determines model structure by surfacing multiple stakeholder perceptions [294, 297], incorporating a social constructivist approach [66], whereas decision analytic models in HTA are based on biological mechanisms and clinical pathways [120], adhering to a positivist view of the world. Implementing these new approaches requires learning around different research philosophies and quality standards, requiring concerted effort and time.

Our work suggests that path dependency in HTA, which has shaped standards around quality and rigour, may impede implementation of approaches that promote a social science lens to policymaking under uncertainty. An example encountered in this work was view that systematic reviews and quantitative decision analytic models represent gold standards, which meant that narrative scenarios and the causal loop diagram mapping were viewed as less rigorous to HTA practitioners, even though they provided crucial insights for the quantitative system dynamics model. To overcome standards of quality and rigour that have developed over many years, policy theory suggests that an incremental approach, accompanied by social learning across stakeholders, may be needed in this context [118].

Adaptation of approaches and implementation strategies may be done at the country level, but this is only likely to be successful in countries like Thailand that have well-established trust in HTA systems, a culture for ongoing learning and improvement within the HTA agency, and capable researchers to implement change. Leadership and development of good practice at the global level could improve the accessibility of new approaches for HTA agencies with fewer resources, as well as providing a level of quality assurance for HTA agencies that are more reluctant to trial new techniques.

For countries with nascent HTA institutions, there is the opportunity to build HTA institutions based on a truly multi-disciplinary approach to policymaking under uncertainty. Approaches facilitating a social science lens may be even more important in these settings, which may have low levels of service coverage, considerable sub-national heterogeneity in demand and supply, fragmented governance, weak regulatory systems, and young institutions for policymaking. It would be challenging, however, to build a foundation for HTA based on a multi-disciplinary approach without

internationally developed and endorsed tools, guidance, and training. This provides another rationale for developing global good practice and capacity to promote a multi-disciplinary approach.

Across settings, building institutions for multi-disciplinary approaches to policymaking under uncertainty will require measures to ensure that any changes to policymaking practice do result in improved policymaking. We demonstrated the benefit of implementation science frameworks applied within an action research approach to structure learning among HTA practitioners, in order to determine the value and opportunity cost of implementing approaches from other disciplines, as well as to adapt approaches and to tailor implementation strategies for their successful integration into practice. Although we applied implementation science frameworks to evaluate specific approaches, they could also be adopted for local teams to develop and iteratively refine their own multi-disciplinary frameworks for improved policymaking under uncertainty.

At the global level, we highlighted directions for future research including mapping unmet policymaking needs and potential approaches to address them, developing tools to navigate and select between multi-disciplinary approaches, and establishing good practice and training materials to build capacity to successfully implement a multi-disciplinary approach. Networks for sharing experience across countries may develop an understanding of how implementation barriers and facilitators differ across approaches and contexts, in order to develop more effective implementation strategies to broaden the view of policymaking under uncertainty. More broadly, the global community could benefit from further research to develop standards for applying implementation science frameworks for improving policymaking, to facilitate its integration into practice.

## **RESEARCHER REFLEXIVITY**

In this section, I discuss the influence of researcher subjectivity and context on the research process, drawing on the four dimensions of reflexivity discussed by Olmos-Vega and colleagues: personal, interpersonal, methodological, and contextual reflexivity [390]. Although the thesis has been written using “our” and “we” to reflect the contributions from all researchers in this work, the following section will be written in the singular.

## Personal reflexivity

Following a degree in natural sciences, I spent five years working in international organisations on government healthcare policy, primarily in stakeholder management and technical assistance roles, before spending the last four years working for an HTA agency in Thailand, during which I also conducted HTA research studies to inform Thai government policy. Throughout the course of my PhD, I was working at the HTA agency.

My experience has predominantly been in developing generalisable tools and principles that are applicable across country contexts, which is reflected in this PhD: despite recognition of socio-contextual environment for policymaking, this work has attempted to develop a generalisable framework across settings. This is likely to align with accepted practice in HTA, but it may miss a fundamental principle underpinning many of the new approaches identified in this research: learning by doing among HTA practitioners will be essential in transitioning to a multi-disciplinary approach. Potentially, locally generated innovation, as opposed to applying the framework from this research, would yield greater learning.

I observed that my prior experience also shaped how I integrated new knowledge. Reviewing the literature on uncertainty and policymaking frameworks expanded my view of policymaking to accommodate the idea that multiple problem frames exist and that institutions are shaped by informal rules too. Initially I mapped this knowledge onto well-established ways of thinking around HTA and policymaking from the World Health Organization. Having a supervisory team from different disciplines was instructive in providing alternative frameworks to accommodate this knowledge (such as Renn's interdisciplinary framework). I did, however, notice that approaches present in business and operations featured heavily in the final framework, which may represent our business school affiliation.

During the first year of my PhD, I completed qualitative research training, with a particular focus on the case study method. I applied learnings from this training in two studies completed alongside my thesis, during which I saw the power of qualitative methods for drawing insight and findings beyond traditional HTA methods. Within the context of the study, it is possible that this experience shaped the value that I saw in the new approaches, whereas other HTA stakeholders may not see the value in the same way, limiting the validity of the evaluation. Involving team members without qualitative research training to regularly discuss and review the new methods helped in this respect.

### Interpersonal reflexivity

Having only spent four years in Thailand, I do not have in-depth knowledge of the language or socio-political and cultural context that is needed when working with policy bodies. As a result, even with considerable support from Thai team members, I may not have captured the dynamics of the policymaking process or only captured them at a superficial level. Moreover, I had initially assumed that people would question the quality or relevance of my work for KRT policymaking, since it was known to the full secretariat and policy working group that it was being undertaken as part of my PhD. However, from the interviews and informal discussions with team members, it seems that completing the work under the PhD may have given a sense that it is good practice that should be accepted and not questioned, which may have given a rose-tinted view of the acceptability and feasibility of introducing the new approaches in the evaluation. As discussed in previous chapters, an action research approach supported joint learning, but it also meant that my colleagues and I were interviewing others about the research we had conducted. Again, this may have painted an overly positive view of the new approaches, as the 6-month timeline for the project is unlikely to have built a sufficient level of trust for everyone to voice concerns, and the only people to openly critique the new methods were the people with whom I had the closest working relationships. In future, incorporating a greater degree of interpersonal reflexivity throughout the course of the study may support modification of the study design to better account for interpersonal dynamics (for example, anonymous feedback forms).

### Methodological reflexivity

This research is founded on the argument that HTA is transitioning from positivism to critical realism, warranting a new set of approaches. From previous work implementing standardised tools across varied settings, I have myself shifted from a positivist to a critical realist perspective, and I cannot discount the possibility that this has shaped how I see the field of HTA. Similarly, my supervisors work in a business school that promotes multi-disciplinary collaboration and learning. The methodological choice to frame this body of work around an interdisciplinary review, while coherent with the research question, was likely shaped by our shared background.

Similarly, undertaking this research whilst working at an HTA agency meant that methodological choices throughout the thesis emphasised the practical elements of policymaking as opposed to

theoretical rigour. Whilst alternative methods could have been used to evaluate the framework, such as eliciting expert opinion or conducting retrospective analysis of past policies, we opted for an action research learning by doing approach, to understand how the approaches would be implemented, whether they worked, and what would be needed to integrate them with existing practice. In this way, we gave preference (both explicitly and implicitly) to methodologies that would prioritise policy and practice over contribution to theory.

### Contextual reflexivity

Most researchers involved in this work also wholly or partly work in HTA. This has the benefit of understanding current HTA practice and how HTA practitioners will interpret the new approaches. It does, however, create a risk that our interpretation of the new approaches was framed by prevailing views in HTA. Involving researchers who are cross-disciplinary or not involved in HTA on the supervisory team helped to overcome this.

The reputation of HTA in Thailand as a trusted institution supported the conduct of this research, as there was trust in the research team and secretariat. It did, however, introduce an important ethical consideration to the research. Institutions for evidence-based decision making are strong and well-established, placing a responsibility and duty on us as a research team to conduct the new approaches to the highest standards possible. It also represented a significant risk for leadership of the HTA agency to trial the new approaches. Other settings with the capacity to adopt new approaches may not have the same openness to learning and attitude to risk that supported this study.

Finally, policymaking in Thailand, particularly in the health sector, does value research and evidence-based policy. The fact that this work was conducted as a research study may have influenced the perceived credibility of the approaches, in itself representing part of the implementation strategy that led to the decision to integrate system dynamics as a core capability of our HTA agency.

## **LIMITATIONS, VALIDITY OF CONCLUSIONS, AND AREAS FOR FUTURE RESEARCH**

Beyond the limitations of individual studies, which have already been discussed in each chapter, this body of work has a number of limitations related to the overarching methodology. In this section, we draw on the discussion in the reflexivity section above, highlight key limitations in the overall thesis study design, and discuss the generalisability of this work, in order to assess the extent to which we were able to address the three research questions set out in the introduction. Based on this assessment, we propose an agenda for future research.

### **Research question 1**

Our first research question concerned the extent to which HTA takes a multi-disciplinary approach to policymaking under uncertainty, for which we concluded that there was insufficient consideration of social science conceptualisations. We believe that our findings for this research question are broadly generalisable, as they are based on a philosophical argument that applies across HTA systems. Yet there are three main limitations to this conclusion. Firstly, our premise that standard HTA practice does not take a sufficiently multi-disciplinary view of uncertainty is based on global standards, and it is possible that individual jurisdictions have already developed good practice for policymaking under uncertainty that does incorporate a social science lens. However, agencies such as the Canada's Drug Agency have undertaken considerable work to promote a multi-disciplinary approach to HTA [366, 391], but are still grappling with questions around how to ensure that multi-disciplinary evidence and different stakeholder views are incorporated in policy [51], suggesting that the conclusions from our review of current HTA practice are globally relevant. Secondly, we relied solely on Renn's interdisciplinary risk framework as the reference for our analysis, due to lack of an appropriate framework within HTA or policy analysis literature. Finally, we made a subjective judgement around the relevance of the missing social science conceptualisations of uncertainty, which may have been influenced by our individual and collective backgrounds that emphasise cross-disciplinary research and HTA policy questions in Thailand and the UK.

Further research could strengthen our conclusions. Consultation with multi-disciplinary or social science HTA practitioners could validate use of the Renn framework or propose alternatives. Interviews or focus group discussions with members of HTA agencies across different settings could identify whether gaps identified by our analysis are, in fact, addressed at the country level even

though they are absent from global HTA good practice, and provide a variety of perspectives around whether identified gaps are relevant for improved policymaking in HTA.

## Research question 2

Our second research question concerned the extent to which approaches from other disciplines could address the gaps identified under research question 1, which we addressed by conducting an interdisciplinary review (**Chapter 2**), illustrating how the findings could be applied to three example policy questions in HTA (**Chapter 2**), and developing a framework to guide HTA practitioners to select suitable approaches for their policy question or context (**Chapter 3**). Although the interdisciplinary review methodology supports generalisability of our findings, there are a number of limitations for this research question related to comprehensiveness, interpretation of results, and the suitability of a generalisable tool. Firstly, although we developed a framework of alternative approaches, these approaches only represent a subset of potential approaches that could encourage a broader view of policymaking under uncertainty, since it was not practical to conduct a detailed review across disciplines. Secondly, most of the researchers in the team were HTA practitioners, which could have influenced how we interpreted the new approaches, potentially leading to misinterpretation of the purpose of each approach, when it should be applied, and how it addresses policymaking under uncertainty. We had selected three examples which were relevant for the Thai HTA context to illustrate applicability of our findings, but it is possible that this limits the generalisability of results outside of Thailand. Finally, as discussed in the reflexivity section, we made an assumption that policymaking could be improved through applying a generalisable tool, even though social learning is known to be an essential part of institutional change [25, 31, 34].

To address these limitations, an interdisciplinary review with the same objectives could be conducted by HTA researchers in another setting and by researchers from other disciplines. This would not only increase comprehensiveness of the results but would also highlight the implications of discipline and country-specific interpretation. Research studies at the country level to co-create local frameworks for policymaking under uncertainty between HTA practitioners and social scientists could also advance knowledge by highlighting how the same objective may be conceptualised differently across settings, potentially resulting in very different frameworks. Case studies comparing countries that have adopted global level frameworks to inform HTA practice with those that have emphasised local learning could also suggest whether a global framework is

appropriate: an unpublished study of HTA guidelines suggests that it is actually the social learning, and not access to global guidelines or international peer-review, that is successful in changing policymaking practice across different country contexts [392]. Perhaps the biggest contribution of this work, in that case, is highlighting the need for locally developed and evaluated solutions for multi-disciplinary policymaking under uncertainty.

### Research question 3

Our third research question investigated whether approaches from other disciplines were transferrable to HTA, which we addressed through an action research design to evaluate the framework and identify an appropriate implementation strategy in Thailand. Limitations include use of a single case study, short timeframe for evaluation, and generalisability to other settings. Since we only operationalised the framework for a single case study, we can only draw preliminary conclusions that the framework successfully identified the need for scenario thinking and system dynamics within the context of the KRT case study. We have limited evidence to generalise our conclusions to other policy questions in Thailand, other settings, or other approaches listed in the framework, as discussed in **Chapter 7**. It is also important to note that the two approaches selected for the case study are methodological in nature and our evaluation methods would likely require modification to address approaches concerned with governance or process.

Due to time constraints, we only assessed short-term indicators and we therefore have no evidence of framework impact in terms of improving the efficiency, quality, and equity of policies (which represent the goals of HTA [2]). As highlighted in the reflexivity section, the timelines were also insufficient for building relationships that facilitated the frank and open discussion needed for action research learning, potentially limiting the usefulness of our findings. It is also possible that, as a research team, we sub-consciously wanted to justify the time we had spent on the new studies, and therefore tended to view the benefits, as opposed to drawbacks, of the new approaches.

More broadly, even if we had tested the framework for more interventions, action research develops context-specific learnings that are not necessarily generalisable across settings. As highlighted previously, without a structured cross-country comparison of the impact of context on policy practice, we cannot articulate the extent to which successful implementation of the framework may depend on transferrable skills and training of staff, existing HTA infrastructure and culture in the



country, flexibility of policy institutions, or local attitudes towards research, learning, and risk, all of which may affect the effectiveness and uptake of the framework. We have also not validated the revised framework from **Chapter 8** in any way.

Despite these limitations, we do believe that certain elements of our findings are generalisable. Insights from the case study around the need for capacity building, alignment with existing practice, and repetitive use for successful implementation have a theoretical basis and are supported by studies in other settings, as discussed in **Chapter 7**. Moreover, it is unlikely to be feasible to define a one-size-fits-all approach to improve multi-disciplinary policymaking under uncertainty in HTA. Any framework or principles will require contextualisation alongside local learning and ongoing adaptation for successful implementation. Although we have not been able to empirically test the framework for multiple policy questions or country settings, we do believe that a number of features of the revised framework set out in **Chapter 8** support generalisability. The framework has a modular design of four steps, each of which intend to account for local context. Adopting CFIR within the framework provides a systematic way in which to adapt to local context and priorities, with action research incorporated as one of the steps to facilitate ongoing learning. Although the framework itself requires further testing, we have been successful in highlighting the potential benefit of adopting approaches from other disciplines in HTA and the revised framework reflects principles that are consistent with the policy institution literature.

Further evidence is needed on the relevance to other HTA contexts and policy questions, as well as the long-term impact or sustainability of a multi-disciplinary approach to policymaking under uncertainty. We recommend that future research build on **Chapter 7** to further develop methods to evaluate whether multi-disciplinary approaches are effective and relevant, including the extent to which improvement to policymaking depends on the HTA system in a country and development of study designs that can assess innovations in process and governance. For Thailand, validation of the framework will require its application to more policy questions alongside evaluation of long-term impact and sustainability. More studies evaluating the impact of multi-disciplinary approaches to policymaking under uncertainty are needed to understand the similarities and differences between countries, in terms of the need for multi-disciplinary approaches, impact on policymaking, sustainability of capacity building efforts (especially given high staff turnover rates in many HTA agencies), and factors for successful implementation.

## **CONCLUDING REMARKS**

Through this work, we have demonstrated a need to expand our toolkit of HTA approaches to better address the questions from today's policymakers. This transition from established practice will likely require incremental change, alongside methods to evaluate modifications to policymaking practice that are both rigorous and feasible to implement within the constraints of policy environments. We have shown how approaches from other disciplines and frameworks from implementation science may support this transition, but further work is required to develop a more detailed map of policy needs, to define standards and tools for applying the new approaches in HTA, and to strengthen our capacity for improved policymaking under uncertainty.

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## Supplement 1

The purpose of this review was to understand how uncertainty is defined in the policy analysis literature and the typologies of uncertainty (i.e. classifications of different types of uncertainty) described. We partly followed methods set out in a protocol for a scoping review of uncertainty characterisation in policy analysis (the scoping review was not conducted, as we identified similar reviews that already existed) [393].

We had the following two research questions:

1. Which types of uncertainty are described in the policy analysis literature?
2. Which classification systems for uncertainty are described in the policy analysis literature?

We conducted an unstructured review from an initial set of textbooks and research articles describing how uncertainty is defined and classified in quantitative risk and policy analysis [10], the water sector [9], operational research [18], health technology assessment [19], and science communication [20, 21]. We reviewed the cited and citing articles using a snowballing approach according to the following selection criteria.

- The primary aim of the article was to classify different types of uncertainty or to describe approaches to analyse, communicate, or appraise different types of uncertainty. Articles were excluded if they failed to provide a definition of uncertainty, or if they did not describe one or more distinct types of uncertainty with a clear description of each.
- The article was published in a peer-reviewed journal or in a book.
- The article or book was published since 1990 (to cover literature published since a key publication on uncertainty in policy analysis [10]).

Additionally, when conducting the screening of articles for the interdisciplinary review in **Chapter 2**, we noted any articles that were also relevant for this literature review and included them in our analysis. A single reviewer conducted screening and extracted data without a structured template in two rounds, in order to allow for learning during the first round of data extraction.

The final analysis included structured reviews of uncertainty definitions and typologies [4–6], proposed frameworks to classify uncertainty [7, 12, 36], policy institution literature [24–26, 31, 34, 35], expert reviews or opinion articles [13, 29, 33, 37], a case study [17], and a methodological paper [23], as well as three articles for policymaking under uncertainty from the review in

**Chapter 2** [27, 28, 165]. As discussed in the main text, thematic analysis was conducted according to the World Health Organization 3-D framework [14].

## Supplement 2.1 Search strategy

As a first step, we identified two groups of benchmark articles for selecting databases and developing search terms. The first set of papers (referred to as “Set 1”) was chosen to cover a range of disciplines and stages of the policy process: policy analysis or decision analysis [4, 9, 22], evidence assessment and reporting [8, 19, 394], or uncertainty communication [20, 21]. A second set of papers (referred to as “Set 2”) was selected to cover gaps in the content of Set 1 papers, namely decision problem formulation [44], evidence synthesis [45] and structural uncertainty [47], and implementation of decisions [198, 395–397]. Both Set 1 and Set 2 papers were used to identify appropriate databases and to validate the search terms, whereas only Set 1 was used to develop search terms.

To identify appropriate databases, Web of Science, ProQuest, Scopus, PubMed, EBSCOhost and Embase were searched for benchmark papers. These databases were selected to cover medical, scientific, and business disciplines. Web of Science indexed 14 of the 15 reference papers (93%) followed by ProQuest (13 papers, 87%) and Scopus (12 papers, 80%). None of the databases contained one of the reference papers, which was published in a journal that ended in 2005 [4]. Although this article was identified in Google Scholar, it was considered that influential articles from journals not indexed in Web of Science would be identified through citation searching. Web of Science was therefore selected as an appropriate database for the review.

Key words were extracted from the title, abstract, and Web of Science Keywords Plus for each article in Set 1 to develop an initial search strategy. The draft search strategy was run in Web of Science and resulting articles were screened for additional key words until no new key words were identified. Since the updated search yielded 44,486 results in Web of Science, a stepwise review of the additional papers identified by each search term refined the key words. For example, it was found that no additional relevant results were identified by the term “risk analysis” and that the key word “framework” only gave relevant results in papers with terms related to uncertainty assessment or uncertainty management in the title/abstract. Citation searching of included papers was conducted for two iterations (i.e. for the papers identified in the Web of Science search and for those identified in the initial round of citation searching).

## Supplement 2.2 Hierarchy of factors from grounded theory analysis

The following hierarchy of factors influencing approaches to decision-making under uncertainty were identified:

1. Nature of the decision problem
  - a. Purpose (e.g. resource allocation, risk management)
  - b. Type of question, as defined by Fischhoff [20]: signal detection, option selection, or creation of options
  - c. Opportunity for policy revision: one-off event (e.g. terrorist attack, pandemic), one-off decision due to policy constraints (e.g. infrastructure, large-scale policy transition), or iterative
  - d. Policy jurisdiction: within a single policy jurisdiction or across multiple jurisdictions
  - e. Time horizon: timeframe for policy to take effect, to measure policy impact, and to implement change
2. Characterisation of uncertainty
  - a. Research philosophy (whether uncertainty is perceived to be an element of nature, the mind, or a societal construction)
  - b. Attitude towards uncertainty (whether uncertainty is perceived as an opportunity, an element to be managed in the policy process, or a factor to reduce as far as possible)
  - c. Goal of approaches to manage policymaking under uncertainty (complete understanding, knowledge of outcomes, sufficient knowledge for decision-making, or confidence in knowledge)
  - d. Types of uncertainty recognised and addressed by the framework (e.g. procedural, institutional, aleatoric, epistemic)
  - e. Steps of the policy process addressed (e.g. problem formulation, assessment, appraisal, implementation)
3. Level of social learning of approaches [31]
  - a. Single loop learning – approaches addressing uncertainty during a single decision cycle
  - b. Double loop learning – approaches addressing the process by which decisions are made (e.g. criteria for decision-making)

- c. Triple loop learning – approaches addressing the governance of decisions (e.g. actor networks, decision rules, responsibilities of actors)



## Supplement 2.3 Appraisal of included studies

Since no established methods for appraisal of frameworks for policymaking were identified, we developed a set of appraisal indicators based on studies evaluating frameworks in management science [136], problem structuring techniques [203], HTA agencies [273], and risk governance [398], incorporating other points from policy institution literature [12, 13, 25, 34, 35, 118] and prior inter-disciplinary reviews related to uncertainty [5, 7]. The resulting appraisal framework is presented in Table S2.1.

**Table S2.1** Indicators used to appraise frameworks included in the review.

1	Internal validity	a) Goals, definition and typologies of uncertainty, and approach are philosophically coherent [5] b) Approach is consistent with articulated goals [398]
2	Construct validity	a) Aims are defined and consistent with current or future problems of decision-makers [136] b) Theoretical basis to components of the framework [136, 203] c) Developed in consultation with framework users and implicated stakeholders [136, 398]
3	Applicability	a) Sufficient generalisability to a range of problem spaces [136]. b) Either: <ul style="list-style-type: none"> <li>• Concepts have shared meaning across stakeholders, align with discipline, and confirm and systematise existing mental models for decision-making [7, 136].</li> </ul> OR <ul style="list-style-type: none"> <li>• Framework takes sufficient account of constraints imposed by existing institutions, including cultural differences and organisational constraints, as well as implicit or explicit rules for decision-making [12, 13, 25, 34, 118].</li> </ul> c) Pilot experience has shown the framework to be parsimonious, useable for target users, and matched to the needs of decision-makers [136, 399]. Demonstrated impact should be due to use of the

		specific framework in question (since use of any framework may overcome procedural uncertainty by reducing complexity of the problem [35]).
4	Effective use in policy formulation	<ul style="list-style-type: none"> <li>a) Framework adds new concepts/actions beyond existing literature and practice [136]</li> <li>b) Following initial use, framework is institutionalised in decision making [136, 273]</li> <li>c) Outputs from applying the framework are implemented (change in practice) and achieve the stated objectives [273, 398]</li> </ul>

## Supplement 2.4 Summary of approaches for policymaking under uncertainty

### Data: managing uncertainty through methodological approaches

Evidence generation methods were influenced by three types of complexity: data complexity (uncertain cause-effect relationships), system complexity (feedback loops and adaptation within the system), and environmental uncertainty (external uncontrollable factors). In this context, “system” refers to social interactions and policy institutions as well as the natural system.

#### *Handling complex and incomplete data*

In the included frameworks, lack of knowledge about cause-effect relationships or incomplete data was addressed through qualitative uncertainty matrices, Bayesian networks, or value of information analysis. These approaches were applied either before, during, or after model development depending on the policy context.

Bayesian networks were employed when facing complex cause-effect relationships, disagreement about causal relationships, or missing data [143, 144]. The method represents probabilistic relationships between variables, allowing for inference about missing relationships and updating conditional probabilities between them as new knowledge emerges [400].

Value of information analyses, which shares a Bayesian foundation, focus more narrowly on quantifying the expected value of collecting additional information before making decisions [154, 155]. Rather than attempting to model all relationships, the method prioritises research efforts toward uncertainties that most affect decision outcomes [395].

To address resource and time constraints, certain frameworks employed techniques to tailor analytical complexity to the decision needs. Qualitative value of information analysis was used to identify influential uncertainties by having stakeholders estimate each parameter’s uncertainty magnitude, influence on the outcomes, and reducibility through further research [401, 402]. Similarly, consequence tables helped to identify key uncertainties requiring further investigation across multiple criteria [148].

### *Approaches to address complex systems*

Complex systems are those in which the sum of the whole is greater than its parts, there is feedback within the system that can reinforce or balance future change, and the system reacts to intervention [102, 103]. Frameworks in this review addressed system complexity through systems thinking, optimisation algorithms, and adaptive management.

Adaptive management approaches are applied when cause-effect relationships are poorly understood, too complex to forecast, and expected to change over time [214, 403]. Adaptive management frameworks are characterised by a learning objective in the decision-making process and are most suitable for policies in which impact can be evaluated over short time horizons and used to inform iterative revisions to the policy [155]. Alongside a formal mandate to monitor compliance, effects, capacity building, or stakeholder trust, this was achieved through formal mechanisms for review and an organisational culture to encourage reflexivity [148, 151, 153].

Systems thinking was applied for frameworks that incorporated learning as part of the evidence generation process (in contrast to adaptive management, in which learning predominantly occurs after action). Systems thinking is an approach from operational and business research that aims to analyse and communicate the complex behaviour of systems, in order to facilitate system change [294]. Among included frameworks, cognitive maps surfaced causal relationships from the perspective of different stakeholders [143–146, 148, 156, 176], which could be merged into causal loop diagrams forming the basis system dynamic models [154, 156] or Bayesian networks [143, 144].

Frameworks applying optimisation algorithms assumed stakeholder views and preferences to be fixed and either identified uncertainty spaces that cause policy failure [147] or optimal strategies for a defined set of stakeholder world views [27].

### *Approaches for robust decision-making under future uncertainty*

Future uncertainty relates to external, uncontrollable factors and potential stakeholder responses that may shape policy impact [209]. In this review, frameworks addressing future uncertainty were consistently applied to policies with long lead times and limited flexibility [145–147, 149, 156, 162, 172, 176, 178]. The frameworks employed futures research and robust decision-making methods to navigate uncertainty.

Futures research constructs images of the future, either to explore paths to achieve a desired future or to better understand the environment for policy action [207, 244, 245]. Among frameworks, scenarios were used to inform the development of alternative policies [146, 149, 172, 178], or developed based on the most influential uncertainties to test outcomes under different potential futures [147, 156, 176].

Robust decision rules were used to select an option that performed well over multiple futures [146, 147, 176, 178], to identify vulnerabilities in existing options (“stress testing”) [145, 156], or to define contingency actions that improve the success likelihood of a policy [172]. Robust decision rules prioritise policies that consistently perform well over multiple plausible futures [209, 212]. They are an alternative to decision rules based on expected utility (i.e. prioritisation of the best performing option), which are only appropriate if cause-effect relationships and uncertainty are well characterised [212].

#### Dialogue: managing uncertainty through stakeholder participation

Within HTA, dialogue traditionally involves stakeholders appraising evidence to form recommendations. Based on our review findings, we have expanded this concept to include additional forms of dialogue: social learning between researchers and policy body secretariats during evidence generation, and engagement between stakeholders during policy implementation. These expanded modes of dialogue address uncertainty by creating shared understanding across diverse perspectives. Our analysis identified two key characteristics of policies that influenced approaches to dialogue: whether the policy process required ongoing learning, and whether the decision needed flexible engagement strategies based on the perceived level of public scrutiny or stakeholder disagreement. These approaches to dialogue complement the methodological approaches in the previous section by addressing how different stakeholders perceive and interpret evidence, which is particularly important when data is ambiguous or incomplete.

#### *Learning agenda of the policy process*

Social learning was a prominent feature of policy frameworks in which there was either ongoing learning and update of a policy (e.g. adaptive management) [144, 148–153], presence of cross-disciplinary teams [150], and/or collaboration across different policy jurisdictions [144, 156]. These frameworks either explicitly or implicitly applied structured decision-making (SDM), which

supports groups to organise complex information in a way that builds a common understanding [148]. SDM promotes social learning, in which actors learn from each other to come to a shared frame of the decision problem [33, 404].

SDM-type approaches were characterised by extensive iteration, allowing stakeholder reflection between group interactions and the opportunity to revise problem frames with learning [144, 148–153]. At the level of the team coordinating the decision process, this iterative learning took place through a decision sketch outlining key elements of the decision problem and process [148] or workshops with the core team before each step [144, 149]. For the broader stakeholder group, individual reflection was cycled with group learning and revisions to the problem frame [144, 148], to promote learning and build stakeholder confidence [153]. Frameworks proposed to address the high cognitive demands of SDM through narrative descriptions that allowed participants to “live in” assumptions [153], using different visualisations to convey the same information [148], and assessing participant understanding to continuously improve communication techniques [144, 148].

#### *Legitimacy of the decision*

Policy literature distinguishes between values-based approaches, which focus on a fair and legitimate process, and outcomes-based approaches, which emphasise technically sound solutions [228, 405]. Empirical tests and case studies suggest that values-focussed frameworks are able to improve the process but have little influence on outcomes [228, 405, 406]. Frameworks in this section aimed to distinguish between routine internal decisions that would benefit from a more outcomes-based approach, and those with high public scrutiny or stakeholder dissensus that would benefit from a more process-based approach [145, 163, 164].

The emphasis of frameworks was transparency and matching the level of stakeholder inclusivity with the specific decision problem, in order to come to a defensible decision. Instead of focussing on learning, these frameworks considered the decision stakes and anticipated level of disagreement, in order to either elaborate a stakeholder engagement plan [163, 164, 229], or to identify mechanisms to effectively engage stakeholders within existing governance structures [145, 164].

## Decision: managing uncertainty through institutions

Decision describes the institutions and governance that determine and regulate how decisions are made. Institutions define funding sources and decision jurisdictions, constrain communication channels, and shape how individuals conceptualise problems [28, 152, 161]. The absence of established institutions, or institutions that are not fit for purpose, can therefore negatively affect policymaking under uncertainty. Conversely, turnover of institutions and conflicting goals between institutions can introduce uncertainty about the future environment in which a policy will operate [12, 25, 34]. In this review we identified the following features that influenced frameworks for policymaking under uncertainty: absence of established institutions for the policy question and existing institutions that are not fit for purpose.

### *Navigating uncertainty in weak institutional contexts*

In weak institutional contexts, appointed bodies may not yet be established as institutions, or no policy body may exist with the mandate to address a specific policy issue. Two frameworks included in the review addressed governance weaknesses that could negatively affect the financing or implementation of policies [145, 164]. In these frameworks, an integrated project management and stakeholder engagement plan included explicit steps to align with governance, regulation, and financing mechanisms [164] or steps of the analysis stress-tested the chosen option for governance constraints [145].

Beyond specific frameworks addressing governance weaknesses, several approaches identified in the data and dialogue sections are also able to address the uncertainty introduced by lack of established institutions for policymaking: structured decision-making has been developed to facilitate collaboration between authorities with different mandates, perceptions, and procedures [407]; system dynamics aims to characterise and evaluate policy impact across institutional boundaries [293]; and scenario thinking accounts for the uncontrollable, external uncertainty that arises in the absence of defined institutional mandates [158].

### *Learning to affect change when institutions are not fit for purpose*

Policymaking under uncertainty may require organisational change or shifts in beliefs that are embedded in laws, policies, educational systems, or professional codes of practice [28, 161]. Four of the included frameworks addressed policymaking under uncertainty through institutional change, all within the context of adaptive management [28, 152, 161, 165]. Frameworks followed

Pahl-Wostl's classification of social learning, in which single loop learning brings about incremental changes to established routines, double loop learning changes the framing or priorities, and triple loop learning represents transformative change to values, norms, and power structures [31].

Two broad approaches were proposed by included frameworks: introducing reflexivity into the policy cycle [28, 161] or development of a roadmap to overcome institutional constraints [152, 165]. Reflection was triggered in these frameworks when existing strategies were insufficient to address uncertainties [28], or reflection was integrated into the policy process to promote revisions to alternatives, models, or stakeholder engagement procedures [161]. For roadmap development, if the required institutional change was known, a diagnostic framework was proposed to identify the temporal jurisdiction of the problem (i.e. the extent to which the problem is influenced by legacy of past decisions and path dependence) and the spatial jurisdiction of the problem (i.e. the ability to influence governance), in order to define an initial roadmap that was updated with ongoing reflexivity and social learning [152]. If the required change was unknown, one of the frameworks proposed four sequential analytical steps to develop a transition pathway plan articulating a set of interventions and level of leadership required [165].



## Supplement 2.5 Application of approaches from the review in HTA

### Managing uncertainty through methodological approaches

Quantitative value of information analysis is a well-established technique in HTA that is often conducted alongside economic evaluation [408, 409]. However, there are rarely appropriate governance mechanisms in place to use the findings for subsequent research and policy revision [410, 411]. Bayesian networks have the potential to inform clinical pathways in decision analysis model structure development [412], but are more frequently used for risk prediction in clinical support systems [413], or integrated with real-world data systems, such as electronic health records [160]. Regression is a more common technique in HTA, even though it does not show the causal relationships of Bayesian networks [160]. We did not identify approaches to determine influential sources of uncertainty prior to model development.

Causal loop diagrams, system dynamics, agent-based models, and discrete event simulation have all been applied for decision analysis and health systems policy questions [120, 414]. They have, however, been underutilised within policy processes, particularly for policy questions outside of infectious disease [102, 296, 414, 415].

Studies applying adaptive management in health included a retrospective analysis of the benefit and cost savings of using an adaptive management approach for disease outbreaks [416], the USAID adaptive management framework for social and behavioural change strategies [417], and the most significant change technique from international development that regularly collects stakeholder narratives across a set of broad domains of change to inform project changes [418, 419]. Application of adaptive management has highlighted the importance of allocating funds to monitoring and learning, as well as fostering a culture that is open to discussing failures and recognising the need to change approach [417]. However, in many settings, mechanisms to revise policies may not exist [420] and there has been poor use of value of information analysis in coverage with evidence development decisions [225, 411], which were put in place to facilitate patient access whilst collecting high value information for decision-making.

Within health, forecasting and horizon planning are commonly used to identify future healthcare needs and new technologies [96, 240]. There is, however, limited uptake of techniques able to account for a higher degree of future uncertainty, with greatest application of scenario planning for health workforce planning [243]. Similarly, expected utility is the dominant decision rule in health, with very limited application of alternative decision rules [131, 421].

## Managing uncertainty through stakeholder participation

Social learning and reflexive governance may be especially relevant in health to hold private service providers accountable to democratic principles [422] and for health issues requiring cross-sector collaboration: a comparison of joined-up governance for child health in two Canadian provinces found social learning across formal and informal institutions to be an important factor for success [127]. Yet although stakeholder engagement is a prominent feature of many HTA guidelines, there is limited (if any) discussion of techniques to enhance learning in cross-disciplinary teams [423], decision-makers seldom have the capacity to interrogate evidence [196], and current participation mechanisms are largely based on consensus-building as opposed to social learning [100, 130].

Within health, there is generic discussion of what constitutes a legitimate process, as opposed to tailoring stakeholder participation to the policy question [79, 424, 425], although it has been raised that a fixed process may lead to lack of depth in certain cases and waste unnecessary time and resources in others [130]. Frameworks in the review came from high-income settings, and a more nuanced approach to stakeholder engagement mechanisms may not be appropriate in settings without strong regulation and governance. This may be particularly acute for health policy, as pharmaceutical manufacturers often sponsor patient groups and channels for patient and public engagement tend to favour privileged members of society [128, 424].

## Managing uncertainty through institutions

Many HTA agencies consider feasibility as a criterion in decision-making, which encompasses political, strategic, legislative, and regulatory elements [426]. Within HTA, setting up appropriate institutional arrangements for effective policymaking is considered essential and attention is given to establishing institutions as opposed to policymaking in the absence of strong institutions [79, 425]. Yet in practice appointed bodies may be ineffective due to a disconnect with implementing agencies, poor governance arrangements, or weak state capacity to implement and enforce policy (Greer et al., 2019; Nagpal et al., 2023). Even in settings with strong governance systems, the evolving nature of healthcare means that there will always be policy needs that do not yet “belong” to an established institution or that require collaboration across institutions [158].

Institutional learning is not emphasised by the main literature on HTA (for example [79, 96, 425]), but it has been identified as one of the most important success factors in successfully building

towards evidence-informed policy processes that are perceived as fair and legitimate by the population [282]. Most approaches outlined in this review would require double or triple loop learning, by shifting the perception of uncertainty from a property of data and the natural system to a broader view that accommodates social and institutional uncertainty. For such a transformation, structured processes for both institutional learning and evaluation are needed [130].

## Supplement 2.6 Framework characteristics

A total of 25 frameworks for policymaking under uncertainty were used as the basis for this analysis (**Table S2.2**), from the fields of environmental management [27, 28, 143, 145, 146, 148–150, 161–163, 165, 172], water planning [147, 164, 175, 178], conservation [144, 153–155], climate change [151, 152, 176], and clean energy [156]. The majority outlined approaches for a single policy cycle (i.e. from defining the decision problem to recommendation or implementation) [27, 143–156, 162–164, 172, 175, 176, 178] while others outlined approaches to institutionalise policymaking under uncertainty (i.e. how to promote change to the existing policymaking process) [28, 152, 161, 165]. Frameworks covered decision questions concerned with making an irreversible policy choice or investment [27, 156, 162, 164], recurring or revisable choices [28, 148, 152–155, 161, 165], selection of strategies or a portfolio of options [147, 151, 172, 178], resource allocation between programmes [144, 146], defining acceptable limits [145, 150], risk assessment of an investment or policy [149, 155, 163, 176], and system design [175]. Around one third of frameworks were based on the belief that there is an objectively better decision, either considering only the data or from both the data and stakeholder perspectives [143, 146, 147, 154, 155, 175, 176, 178].

**Table S2.2** Summary of included frameworks.

Author, year	Discipline	Type of policy	Objectives (as summarised by the research team)	Philosophy: does a correct policy exist?	Main steps (standardised classification for this review)
Bond, 2015 [149]	Environmental management	Risk/impact assessment	Account for uncertainty in planning and development decisions	No	1) Problem framing (review context, identify stakeholders) 2) Map uncertainties (current and future) 3) Quantitative analysis and deliberation 4) Post-implementation (reflect on uncertainties, scenarios, policies)
Canessa, 2016 [155]	Conservation	Recurring or revisable choice	Reduce uncertainty to improve conservation management outcomes	Yes	1) Problem framing (specify objectives, define alternatives) 2) Map uncertainties (articulate as hypotheses) 3) Decision (using any decision rule) 4) Post-implementation (data collection to update Bayesian priors)
Cardenas, 2016 [143]	Environmental management	Risk/impact assessment	Optimise options and mitigating measures to reduce environmental impact	Yes	1) Problem framing (define alternatives, identify criteria) 2) Map uncertainties 3) Quantitative analysis (Bayesian networks) 4) Decision (using low regret, robust optimisation, or real options analysis) 5) Post-implementation (data collection to update Bayesian priors)
Castrejon-Campos, 2020 [156]	Clean energy	Policy or investment is	Promote a policy transition for structural change	No	1) Problem framing (policy analysis, COPRIEMD framework) 2) Map uncertainties and relevance

Author, year	Discipline	Type of policy	Objectives (as summarised by the research team)	Philosophy: does a correct policy exist?	Main steps (standardised classification for this review)
		difficult to reverse	in energy production		3) Quantitative analysis (systems dynamics modelling, robustness and vulnerability analysis to optimise options, Pareto sets to analyse trade-offs)
Conroy, 2011 [154]	Conservation	Recurring or revisable choice	Improve the selected option over time by reducing uncertainty	Yes	1) Problem framing (define context, objectives, feasible actions) 2) Quantitative analysis (dynamic model) 3) Map uncertainty (quantitative techniques for data and structural uncertainty) 4) Post-implementation (prioritise data collection within available resources)
Dandy, 2019 [175]	Water planning	System design	Optimise facility design	Unclear	1) Problem framing (system analysis, identify end-users and system boundaries, define criteria and alternatives) 2) Quantitative analysis (simulation model to optimise combinations, MCDA)
Furlong, 2016 [164]	Water planning	Policy or investment is difficult to reverse	Make transparent the role of social and political dimensions in policy choice	No	1) Problem framing (context mapping, integrated project management and stakeholder engagement plan, identify options) 2) Quantitative analysis (matched to decisions question needs) 3) Decision (define preferred option(s), account for governance, regulation, and financing)

Author, year	Discipline	Type of policy	Objectives (as summarised by the research team)	Philosophy: does a correct policy exist?	Main steps (standardised classification for this review)
					4) Post-implementation (record outcomes to evaluate policy process)
Giupponi, 2022 [176]	Climate change	Risk/impact assessment	Select the best performing option that is agreeable to stakeholders	Yes (incorporating stakeholder views)	1) Problem framing (identify problem, objectives, develop a shared model of the system with stakeholders, identify plausible solutions) 2) Map uncertainty (exploratory future scenarios, combine MCDA with uncertainty analysis) 3) Decision (robust decision rules)
Gregory, 2012 [148]	Environmental management	Recurring or revisable choice	Joint learning to come to a common view and make better decisions	No	1) Problem framing (decision sketching, set objectives and criteria, represent the system with an influence diagram, select alternatives) 2) Map uncertainties 3) Analysis (consequence table informs depth of analysis required) 4) Decision (MCDA methods, refine alternatives, select option) 5) Post-implementation (establish mechanisms for review)
Haasnoot, 2013 [172]	Environmental management	Selection of strategies / portfolio of options	Make decisions that are robust and able to be updated with learning, keeping preferred	No	1) Problem framing (describe system context and constraints, define objectives and success) 2) Map uncertainties (current and future) 3) Analysis (identify potential actions by comparing objectives with current and

Author, year	Discipline	Type of policy	Objectives (as summarised by the research team)	Philosophy: does a correct policy exist?	Main steps (standardised classification for this review)
			pathways open as long a possible		<p>future scenarios; evaluate and optimise actions; assemble pathways)</p> <p>4) Plan development (add contingency actions for each pathway to assemble dynamic adaptive plan)</p> <p>5) Post-implementation (monitor for triggers to activate subsequent actions)</p>
Halbe, 2019 [165]	Environmental management	Recurring or revisable choice	Bring about transformative change in societal norms and actions	No	<p>1) Problem framing (problem and actor analysis, participatory modelling with causal loop diagrams)</p> <p>2) Analysis (stakeholder interviews and literature review identifies objectives, context, and intervention points; integrated governance system analysis designs transition pathways)</p>
Herman, 2014 [147]	Water planning	Selection of strategies / portfolio of options	Select the portfolio of actions that optimises the balance between cost and robustness	Yes	<p>1) Problem framing (define stakeholder multi-variate performance requirements)</p> <p>2) Map uncertainties (using Monte Carlo simulation and Latin hypercube sampling)</p> <p>3) Quantitative analysis (algorithm selects solutions robust to uncertainties and stakeholder perspectives)</p>
Janssen, 2005 [163]; Petersen, 2013 [177]	Environmental management	Risk/impact assessment	Conduct a legitimate and defensible process	No	<p>1) Problem framing (map the context and role of assessment, consider alternate problem frames, develop stakeholder</p>



Author, year	Discipline	Type of policy	Objectives (as summarised by the research team)	Philosophy: does a correct policy exist?	Main steps (standardised classification for this review)
			to generate evidence for policy		engagement plan, select indicators and criteria to assess quality) 2) Map uncertainty (knowledge and values) 3) Communicate uncertainty (for different stakeholders at each step)
Keller, 2021 [151]	Climate change	Selection of strategies / portfolio of options	Progressively update knowledge to understand the system and consequences of actions	Unclear	1) Problem framing (identify values and mental models of stakeholders, decision-makers, and analysts; specify decision levers, uncertainties, metrics, relationships) 2) Map uncertainties (as part of problem framing) 3) Quantitative analysis (quantify uncertainty, analyse trade-offs, iteratively stress-test proposed strategies to refine the problem framing)
Kingsborough, 2016 [178]	Water planning	Selection of strategies / portfolio of options	Develop flexible strategies to match water supply and demand, which accommodate future uncertainty and time for infrastructural change	Unclear (“better answers”)	1) Problem framing (interviews and literature review to identify organisational priorities, risk management and governance structures; identify planning horizon, decision criteria, risk thresholds, potential actions) 2) Map uncertainties (current and future) 3) Quantitative analysis (cost and risk) 4) Plan development (adaptation canvas visually illustrates actions, timeframes, limits, uncertainties, trade-offs; select

Author, year	Discipline	Type of policy	Objectives (as summarised by the research team)	Philosophy: does a correct policy exist?	Main steps (standardised classification for this review)
					actions appropriate to different futures and assemble into adaptation pathways with stakeholders)
Klauer, 2006 [162]	Environmental management	Policy or investment is difficult to reverse	Make a “good” decision regarding land use under a single government authority	Unclear	<ol style="list-style-type: none"> <li>1) Problem framing (extensive stakeholder interaction to identify fields of action and alternatives, define potential futures, select criteria with stakeholders)</li> <li>2) Map uncertainties (under problem framing)</li> <li>3) Quantitative analysis (modelling for each criterion; MCDA; assess uncertainty in future, data, model structure)</li> </ol>
Lempert, 2021 [27]	Environmental management	Policy or investment is difficult to reverse	Identify a policy that is agreeable to stakeholders with different world views	No	<ol style="list-style-type: none"> <li>1) Problem framing (literature reviews, interviews, and surveys identify worldviews)</li> <li>2) Quantitative analysis (construct XLRM framework of outcomes, policy levers, uncertainties, relationships for each worldview; scenario discovery algorithm identifies options agreeable across different worldviews)</li> </ol>
Lilburne, 2022 [145]	Environmental management	Defining acceptable limits	Facilitate a legal requirement for stakeholder-based policy	No	<ol style="list-style-type: none"> <li>1) Problem framing (stakeholders describe aspirational social, cultural, environmental, economic outcomes; technical team creates concept map; propose indicators as policy options)</li> <li>2) Map uncertainty (current and future)</li> </ol>

Author, year	Discipline	Type of policy	Objectives (as summarised by the research team)	Philosophy: does a correct policy exist?	Main steps (standardised classification for this review)
					3) Quantitative analysis (likelihood of meeting desired outcomes under future scenarios for each indicator; conduct wind tunnel test to stress test options) 4) Decision (select indicators and identify strategies to reduce uncertainty)
Mattsson, 2019 [144]	Conservation	Resource allocation between programmes	Credible, relevant, and legitimate process for transboundary decisions	No	1) Problem framing (clarify roles of core team; outline decision question, objectives, time horizon; identify stakeholder groups; state objectives with stakeholders; identify possible actions and resource allocation scenarios) 2) Map uncertainty (external factors) 3) Quantitative analysis (influence diagrams drawn with stakeholders; Bayesian decision network analysis; EVPI for data and stakeholder inputs)
Miller, 2022 [153]	Conservation	Recurring or revisable choice	Evaluate existing strategies so that stakeholders learn and have confidence in policies	No	1) Problem framing (identify problem; stakeholder discussion and document review maps context, critical uncertainties, conceptual model, and metrics that are useful to the decision-maker) 2) Map uncertainties (define future scenarios)

Author, year	Discipline	Type of policy	Objectives (as summarised by the research team)	Philosophy: does a correct policy exist?	Main steps (standardised classification for this review)
					3) Quantitative analysis (assess strategy performance across future scenarios; identify highly consequential outcomes) 4) Decision (update problem frame or policy)
Moser, 2010 [152]	Climate change	Recurring or revisable choice	<b>Part 1:</b> iterative learning and policy updates in response to actual and expected impacts	No	1) Problem framing (identify issue, frame as a problem, gather information and reframe problem, communicate to relevant jurisdiction; develop criteria; develop options) 2) Map uncertainty (current and future) 3) Assessment 4) Post-implementation (agree on monitoring plan and resourcing, create formal mandate for evaluation, manage vested interests)
			<b>Part 2:</b> overcome barriers to institutional change in how decisions are made		1) Problem framing (diagnostic framework to locate barriers related to temporal and/or spatial jurisdiction) 2) Plan development (roadmap to overcome barriers) 3) Post-implementation (reflect on progress and update roadmap with learnings on a continuous basis)
Ridgley, 2000 [146]	Environmental management	Resource allocation	Allocate resources optimally	Yes	1) Problem framing (define goals, objectives, criterion hierarchies; articulate system structure through

Author, year	Discipline	Type of policy	Objectives (as summarised by the research team)	Philosophy: does a correct policy exist?	Main steps (standardised classification for this review)
		between programmes			<p>cognitive mapping and influence diagrams)</p> <p>2) Map uncertainties (identify plausible futures)</p> <p>3) Quantitative analysis (multi-criterion optimisation algorithm to identify the preferred reallocation across criteria and future scenarios)</p>
Stahl, 2013 [150]	Environmental management	Defining acceptable limits	Create a continuous learning process across stakeholders to progressively identify better options for problems that cannot be clearly defined	No	<p>1) Problem framing (inclusive stakeholder engagement to define the decision question, criteria hierarchy, appropriate data, scope of analysis)</p> <p>2) Analysis (inter-disciplinary team of experts transform data to scores for the criterion hierarchy; stakeholders provide weights for higher level indicators)</p> <p>3) Post-implementation (data collection, iterative learning and policy revisions)</p>
Warmink, 2017 [28]	Environmental management	Recurring or revisable choice	Change established routines and governance structures to better cope with uncertainty	No	<p>1) Map uncertainty (at the start of the decision process)</p> <p>2) Analysis (identify actions, frames, or governance structures that may need to change to better account for uncertainty)</p>

Author, year	Discipline	Type of policy	Objectives (as summarised by the research team)	Philosophy: does a correct policy exist?	Main steps (standardised classification for this review)
Williams, 2018 [161]	Environmental management	Recurring or revisable choice	Implement reflection within the policy cycle to identify when norms and processes need to change	No	<ol style="list-style-type: none"> <li>1) Introduce points for reflection within the decision process itself</li> <li>2) Periodically review stakeholder engagement and monitoring protocols</li> </ol>

EVPI – expected value of perfect information; MCDA – multi-criteria decision analysis

## Supplement 3: Development of the multi-disciplinary framework for policymaking under uncertainty in HTA

The table below lists difference between the results of the interdisciplinary review in **Table 2.3** and the preliminary framework presented in **Table 3.1**. The references (e.g. 3/a/i) locate the element in the tables 2.3 and 3.1.

Element of Table 2.3	Change in Table 3.1	Rationale
Optimisation approaches (3/a/i)	Replaced with cultural prototypes (2/c/i)	Bayesian networks and optimisation approaches only facilitate a social science lens if they search for win-win solutions across defined stakeholder views (already addressed by <b>2/a/i</b> Robust decision rules) or cultural prototypes.
Bayesian networks (3/a/ii)		
Quantitative value of information analysis (3/a/iv)	Removed	Already applied within standard HTA practice and only qualitative value of information analysis was found to facilitate a social science lens.

## Supplement 4.1 Profile of participants involved during scenario development

**Table S4.1a** Profile of the research team.

Profile	Members of research team (n=9)		
	Total	Members of NHSO KRT WG secretariat	Staff at HTA agency
Medical background (dialysis nurse, pharmacist)	2	1/2	2/2
Political scientists (with scenario thinking training)	2	1/2	0/2
Health economics / public health researchers	4	3/4	4/4
Communications expert	1	0/1	1/1

HTA – health technology assessment; NHSO KRT WG – National Health Security Office working group on kidney replacement therapy

**Table S4.1b** Profile of interviewees for secondary interview data.

Profile	Number interviewed (in-depth interview n=20, focus group discussion n=12)
Payer (NHSO)	2
Policymaker	4
Professional associations	3
Dialysis providers	4
Manufacturers	3
Patient representatives	13 (1 interview and 1 focus group with 12 patients)
Academics	3

NHSO – National Health Security Office



**Table S4.1c** Profile of participants attending the stakeholder workshop.

<b>Profile</b>	<b>Number of participants (n=21)</b>
Payer (NHSO, CSMBS)	3
Nephrologists	8
Dialysis nurses	3
Manufacturers/suppliers	3
Patient representatives	4

CSMBS – civil servant medical benefit scheme; NHSO – National Health Security Office

## Supplement 4.2 Development of the evaluation framework

**Table S4.2** Elements of existing HTA evaluation frameworks that were included, adapted, or excluded from the evaluation in this study.

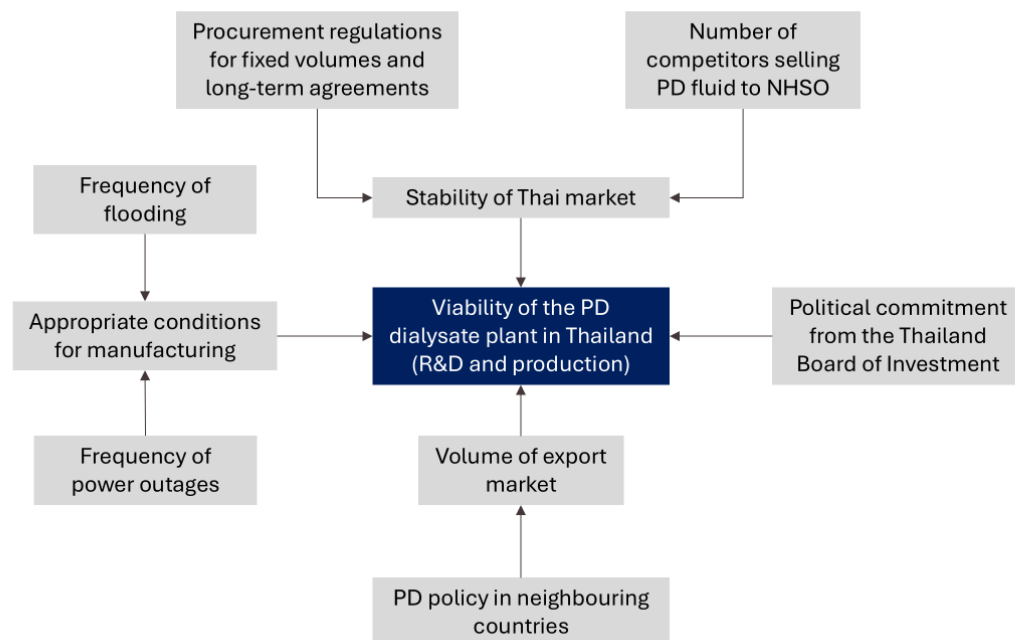
Reference	Framework components	Included/adapted/excluded
Outcome indicators for deliberation in HTA [98]	Sharing and expansion of viewpoints, better understanding of preferences, or the relative weight of preferences	<b>Included</b> (expansion of viewpoints)
	Increased sense of belonging/ ownership	Excluded (research team led study with limited stakeholder engagement)
	Improved capacity for deliberation	<b>Adapted</b> (improved capacity to understand interests of different actors)
	Increase of public trust	Excluded (single study)
	Improvement of the use of evidence including enlarging the range of relevant empirical material admissible as evidence	<b>Adapted</b> (evidence from futures study used in policymaking)
	Strengthening of integrity by limiting the effects of self-interest	Excluded (research team led study with limited stakeholder engagement)
	Reasons provided for decisions	Excluded (not purpose of futures)
	Greater acceptance of decisions (stakeholders and public)	Excluded (single study)
	Efficiency, considering financial resources spent against the deliberative outcomes	<b>Included</b>
Framework to evaluate the impact of HTA systems	Is the HTA agency doing/commissioning HTA studies that are fit for purpose?	<b>Included</b>
	Are HTA studies used in agenda-setting/policy formulation?	<b>Included</b>

[273]	Are HTA studies valued by stakeholders in the healthcare system?	Excluded (single study)
	Do HTA studies inform public debate?	Excluded (single study)
	Do HTA studies support insurers or government in negotiation with manufacturers?	<b>Adapted</b> (used to plan for implementation)
	Do HTA studies result in changes in practice, and did such changes lead to measurable improvements in cost, health impacts, and wider social/economic impacts?	Excluded (beyond timeframe for evaluation)

## Supplement 4.3: Development of future scenarios

**Figure S4.3a.** Summary of driving forces and extreme outcomes identified. Each factor (A-G) represents a cluster of causal links. Two possible extreme outcomes have been identified for each cluster (shown on right-hand side).

### FACTOR A VIABILITY OF THAI PD DIALYSATE PLANT



**A1: the manufacturing plant for PD dialysate in Thailand shuts down due to low and unpredictable volumes in domestic and neighbouring markets**

- PD dialysate must be imported from neighbouring countries, increasing cost.
- Supply disruptions and quality issues with imported products lead to lower confidence in PD across stakeholders.
- Many patients switch to HD, resulting in high out-of-pocket expenditures and low quality of HD care from an over-burdened system.

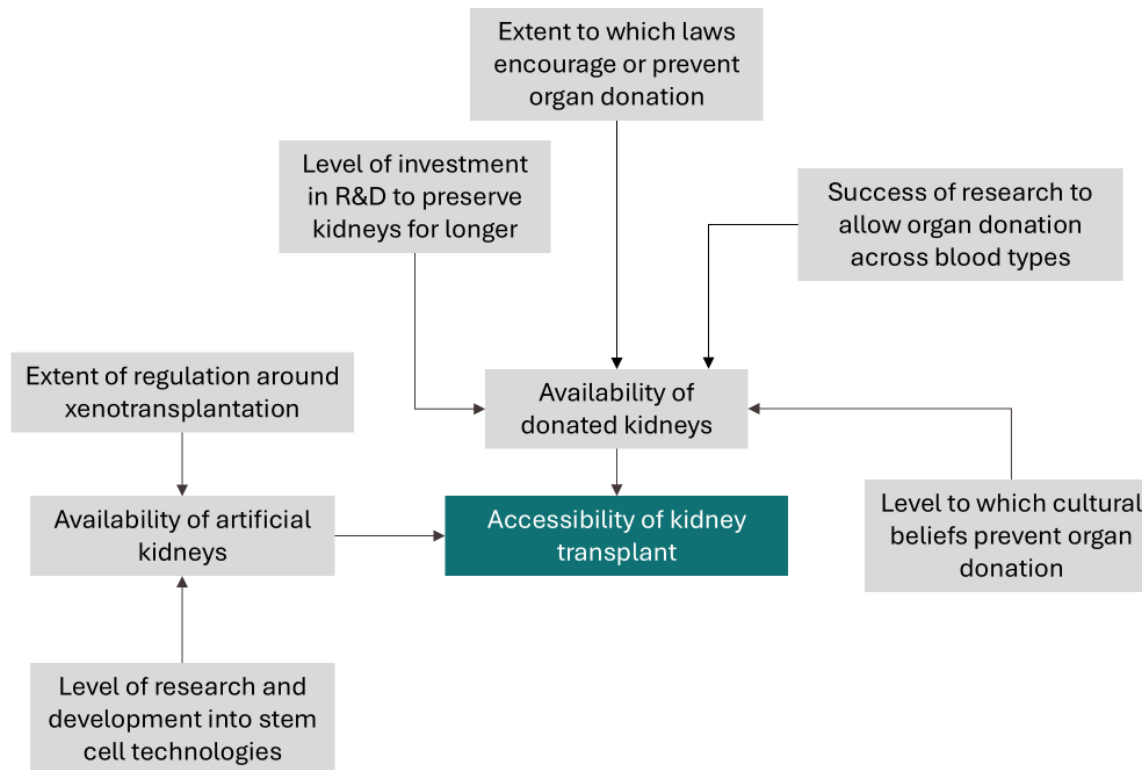
**A2: high investment into R&D in the Thailand plant develops cheaper modes of delivering APD**

- The success attracts further investment, establishing Thailand as a global research hub for dialysis commodities.
- Due to the low cost of APD, NHSO incentivises patients to choose APD, reducing overall NHSO expenditures.
- The budget saved by NHSO is reinvested into quality improvement measures for better PD quality of care.

APD – automated peritoneal dialysis; HD – haemodialysis; NHSO – National Health Security Office; PD – peritoneal dialysis; R&D – research and development

## FACTOR B

### ACCESSIBILITY OF KIDNEY TRANSPLANT



#### **B1: over 80% patients have access to kidney transplantation (via a living or dead donation) within 1 year of kidney failure**

- During the initial period, rate of transplant failure is high as service quality is low.
- Patients with co-morbidities such as HIV and hepatitis B have improved access to transplant.
- Because kidney transplant is free and widely accessible, a higher proportion of transplant patients do not prioritise self-care, increasing rate of transplant failure.
- Number of patients on dialysis decreases significantly, causing HD and PD centres to close, skilled nurses to change profession, and closure of the manufacturing plant in Thailand. Dialysis of patients with transplant failure becomes more expensive and less accessible.

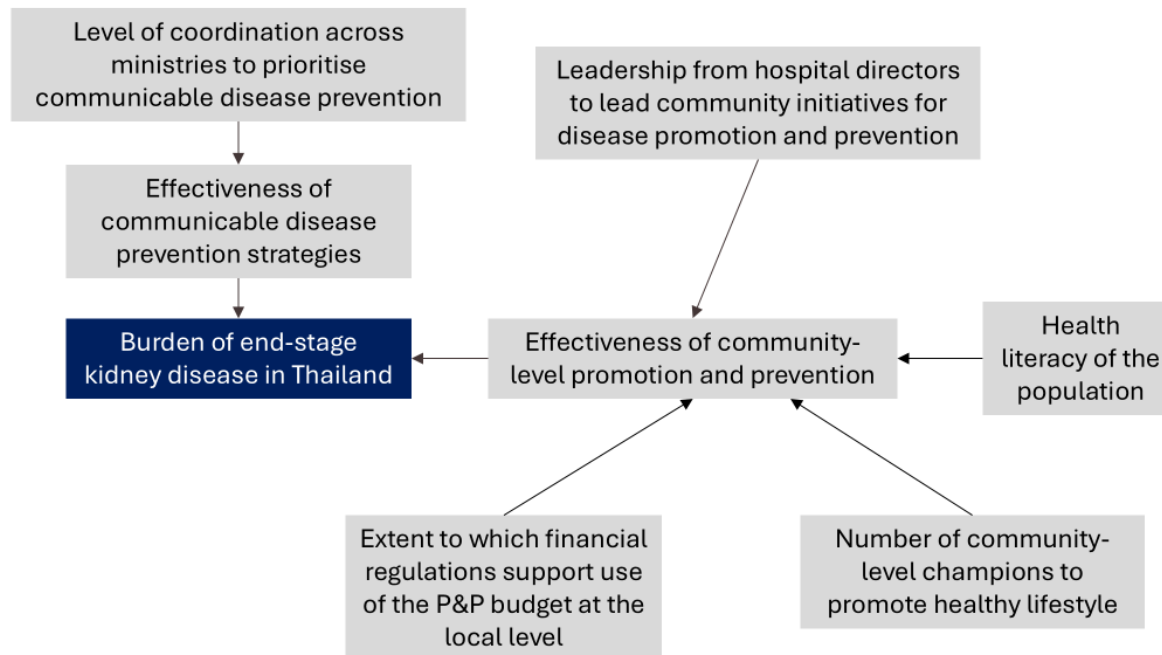
#### **B2: Advancements in stem cell technology allow kidney transplantation without graft failure and without the need for a donor.**

- Inequality in access, as stem cell technology becomes available on the private market and CSMB scheme, but not under NHSO due to high cost.
- Investment in facilities for transplant of donated kidneys decreases, in anticipation of stem cell technology taking over, reducing access.

CSMB – civil servant medical benefits; HD – haemodialysis; HIV – human immunodeficiency virus; NHSO – National Health Security Office; PD – peritoneal dialysis; R&D – research and development

## FACTOR C

### BURDEN OF END-STAGE KIDNEY DISEASE



**C1: Sharp increase in burden of end-stage kidney disease leads NHSO to introduce co-payments for dialysis services.**

- Large increase in number of patients causes significant budget deficit. NHSO introduces dialysis co-payment to increase financial sustainability.

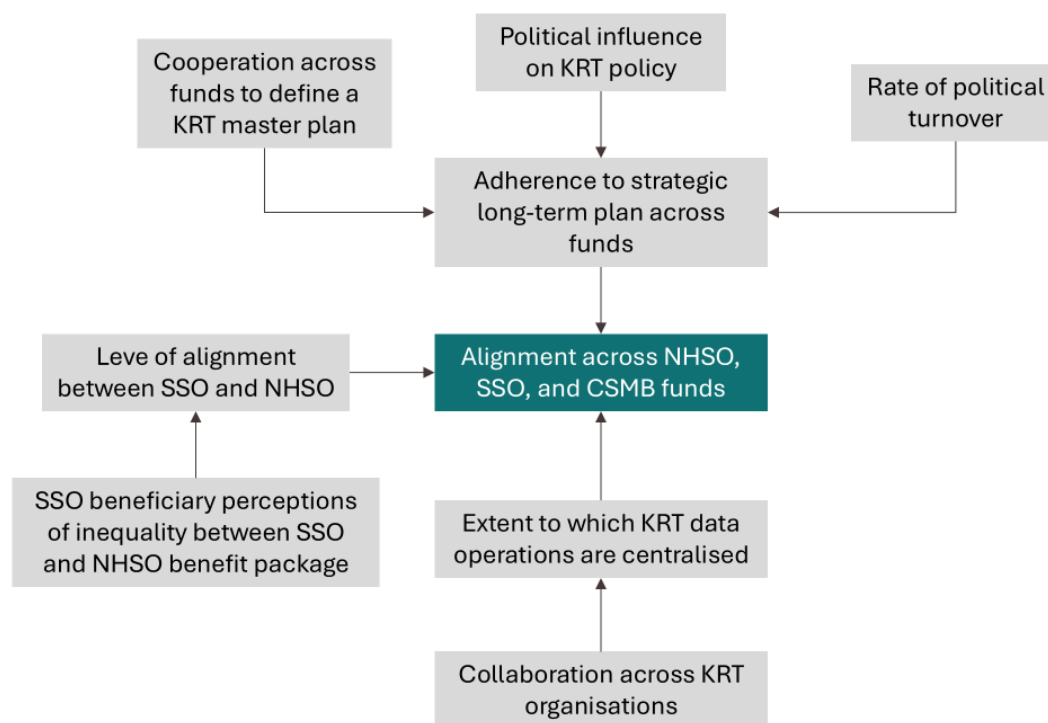
**C2: High burden of end-stage kidney disease, diabetes, and cardiovascular disease causes health service disruption.**

- Large increase in number of chronic disease patients places significant strain on healthcare services, leading to long wait times, burnout of healthcare staff, and long wait times in hospitals.
- Freezes on healthcare staff pay, coupled with high workload, lead to frequent strikes by healthcare staff.

NHSO – National Health Security Office; P&P – health promotion and prevention

## FACTOR D

### ALIGNMENT ACROSS 3 FUNDS



#### **D1: SSO and NHSO schemes are merged into a single health insurance scheme**

- SSO and NHSO beneficiaries are eligible for the same services.
- Improved efficiency as KRT operations and quality assurance mechanisms are coordinated between the two schemes.
- Increased government expenditure for HD from waiving the co-payment for SSO dialysis patients, but cost savings for PD as all dialysate is delivered by GPO.

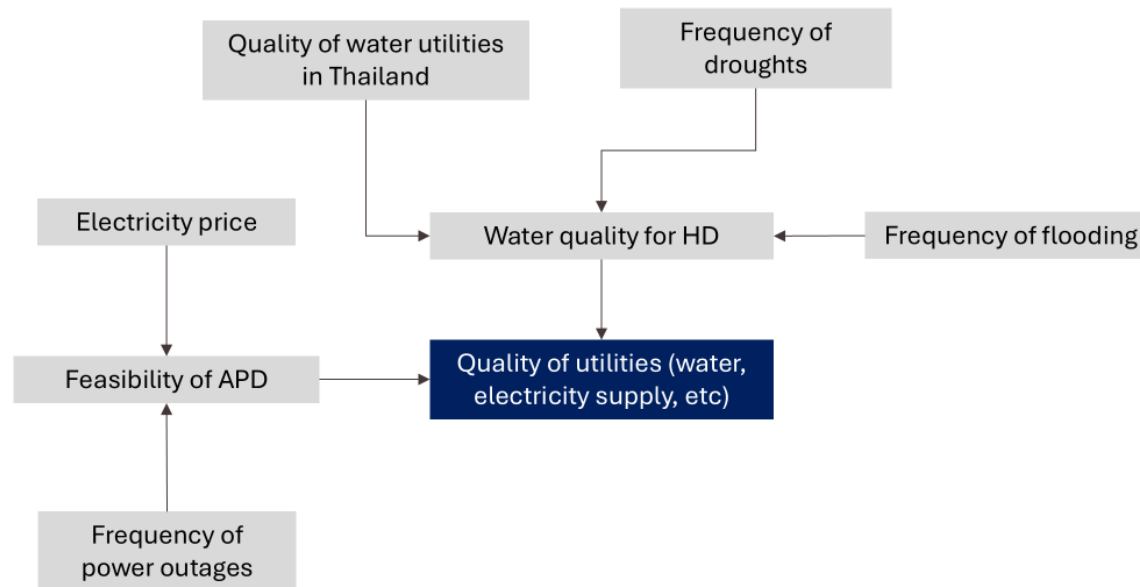
#### **D2: Red tape to access dialysis for SSO patients is reduced and co-payments waived.**

- SSO patients with renal failure tend to stay on SSO and do not “parachute” into NHSO.

CSMB – civil servant medical benefits; GPO – Government Pharmaceutical Organization (state enterprise in Thailand that manufactures and distributes medicines, drugs, and other supplies); HD – haemodialysis; KRT – kidney replacement therapy; NHSO – National Health Security Office; PD – peritoneal dialysis; SSO – social security office (administers the public health insurance scheme for employees in the private sector)

## FACTOR E

### QUALITY OF UTILITIES



#### E1: spikes in electricity prices

- Cost of HD service provision increases: small HD centres are forced to close down, reducing HD accessibility in rural areas, and unofficial patient co-payment becomes more prevalent.
- Cost to the patient of APD increases as NHSO subsidies are insufficient: more patients have catastrophic health expenditure and fewer patients select PD.
- There is a government-wide response due to the widespread cross-sectoral impact, with limited resources to specifically address impact on dialysis.

#### E2: prolonged droughts in the North-East become more prevalent lead to extensive rationing of water

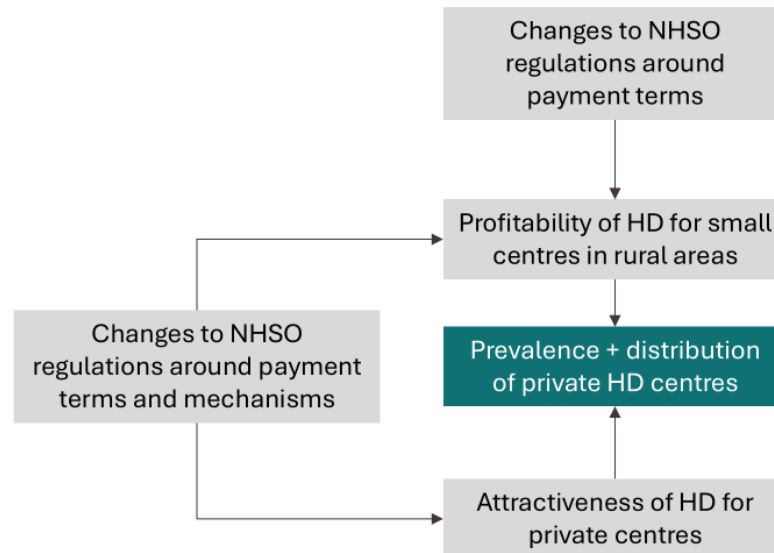
- Water shortage reduces capacity of HD centres. Number of HD sessions provided per centre decrease, waiting times increase, and death rate increases as many patients have insufficient dialysis.

APD – automated peritoneal dialysis; HD – haemodialysis; NHSO – National Health Security Office; PD – peritoneal dialysis



## FACTOR F

### DISTRIBUTION OF PRIVATE HD CENTRES



**F1: Changes in NHSO regulations and payment mechanisms mean that private HD centres become more profitable**

- An increasing number of HD private centres open, improving accessibility of services.
- Insufficient nurses places increasing strain on the HD service system.
- Insufficient staff for quality assurance of centres leads to reduced quality of services.

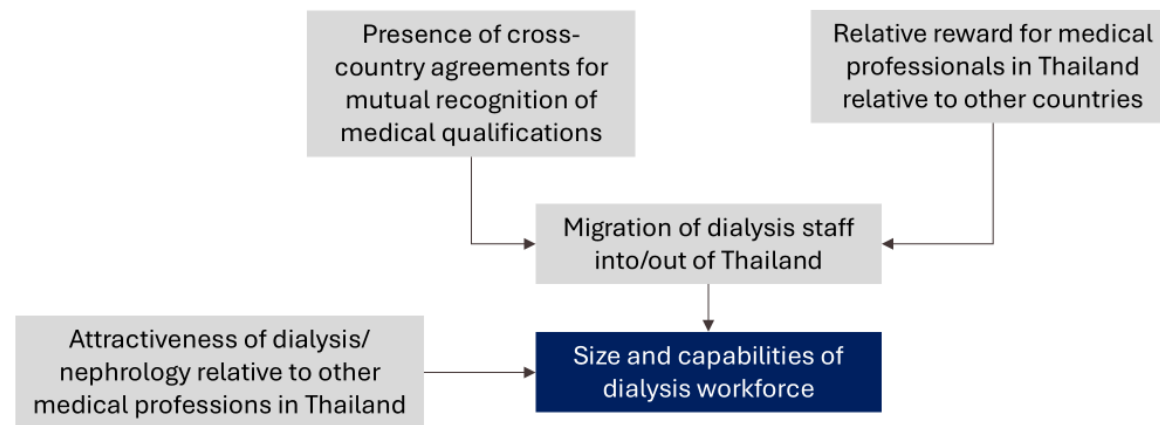
**F2: Changes in NHSO regulations and payment mechanisms mean that private HD centres become less profitable**

- Private HD centres close, especially small centres in rural areas. Accessibility to HD services decreases and out-of-pocket spending increases.

HD – haemodialysis; NHSO – National Health Security Office

## FACTOR G

### SIZE & CAPABILITIES OF DIALYSIS WORKFORCE



#### **G1: Loss of healthcare workforce following pan-ASEAN agreement**

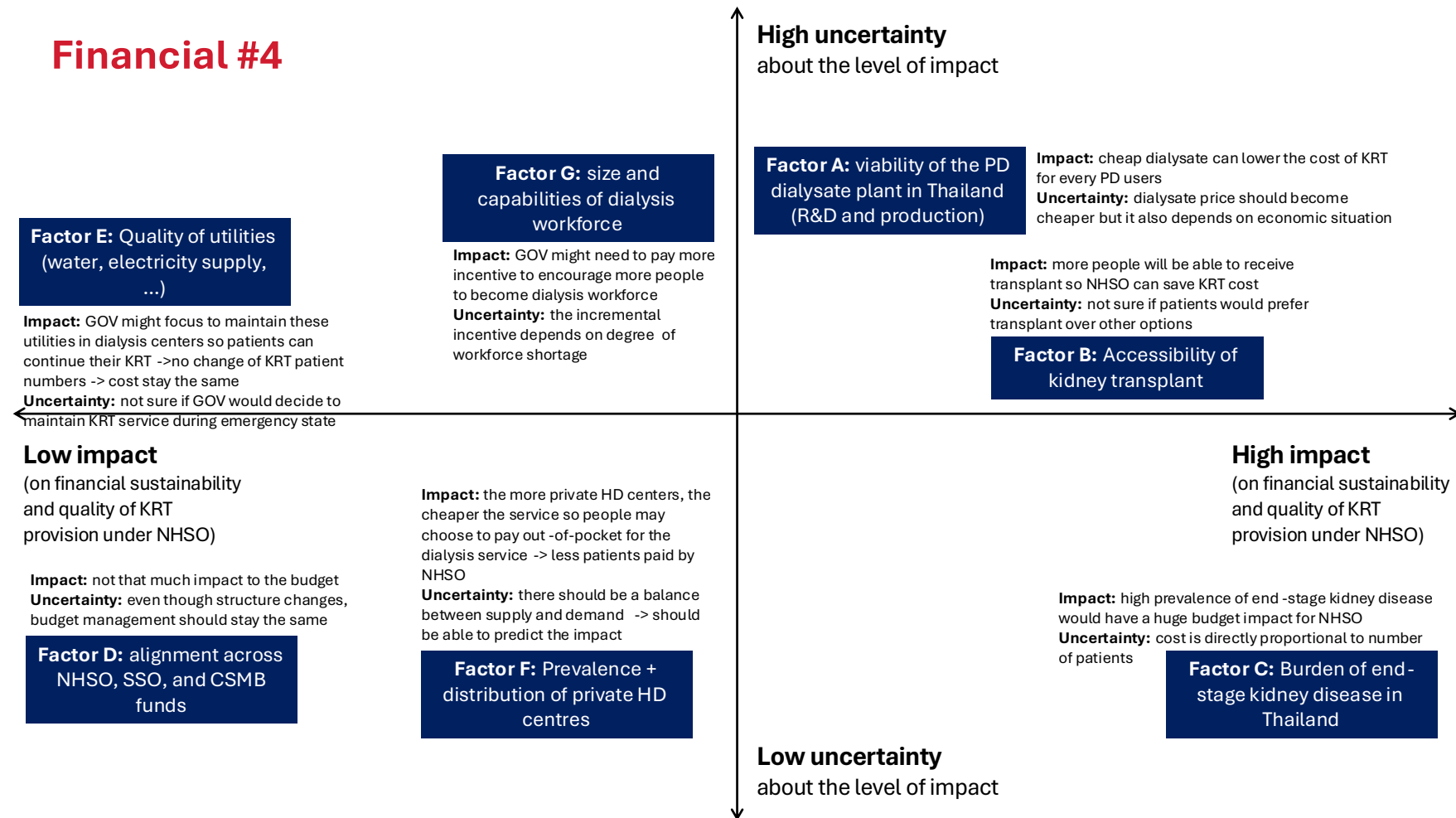
- ASEAN countries sign an agreement to mutually recognise qualifications of healthcare professionals in other countries. Healthcare professionals in Thailand migrate to countries with more favourable remuneration.
- High turnover of staff increases the burden on dialysis services and leads to a reduction in quality of care.

#### **G2: Instability in neighbouring countries leads to an influx of highly trained healthcare professionals**

- Migrant healthcare professionals are employed as dialysis technicians.
- High capability and knowledge among dialysis technicians allows for increased task shifting, improving the efficiency and quality of dialysis services.

ASEAN - Association of Southeast Asian Nations (a political and economic union of 10 states in Southeast Asia)

**Figure S4.3b** Example of participant feedback on the impact-uncertainty matrix during the mini Delphi panel.



CSMB – civil servant medical benefits; GOV – government; HD – haemodialysis; KRT – kidney replacement therapy; NHSO – National Health Security Office; PD – peritoneal dialysis; R&D – research and development; SSO – social security office

**Table S4.3** Narratives for each of the four scenarios.

Scenario	Narrative
<p><b>Scenario 1:</b></p> <p>Thailand as a centre of transplant excellence</p>	<p>In this scenario, predictions of skyrocketing budget requirements for dialysis, due to the rising burden of chronic kidney disease, leads the National Health Security Office (NHSO) and other government stakeholders to place high priority on increasing access to kidney transplant. A collaboration between NHSO, royal colleges, and the Thai Red Cross prompts development and implementation of a multi-pronged strategy including the following components:</p> <ul style="list-style-type: none"> <li>i. improvements to the service system to prevent wastage of donated kidneys,</li> <li>ii. public awareness campaigns and engagement with civil society groups to encourage kidney donation from relatives, and</li> <li>iii. increased financial incentives to service providers for kidney transplantation, in order to expand the number of tertiary hospitals providing transplantation services.</li> </ul> <p>During discussions with stakeholders, two key risks are identified for implementation of this strategy: insufficient upfront financing and decreasing acceptance of transplantation triggered by low-quality services during the initial phase of scaling up transplantation capacity. There have traditionally been negative perceptions around organ donation in Thailand for cultural and religious reasons, hence public acceptance and trust are viewed as critical in successfully increasing rate of kidney transplantation. In order to overcome both the quality and funding challenge, NHSO puts in place an innovative financing mechanism in which service providers are paid through a set of staged payments contingent on quality indicators such as low graft failure rate. In addition, NHSO collaborates closely with civil society organisations, including the Kidney Friends Association of Thailand, to improve training and self-care of kidney recipients to reduce the rate of kidney failure, with multi-disciplinary teams formed for patient follow-up.</p> <p>As a result of these efforts, rate of kidney transplantation over a 5-year period gradually increases in Thailand from around 0.5% of kidney failure patients receiving a transplant per year to over 10%. In the public sector, an increasing</p>

	<p>percentage of dialysis staff are re-trained to work in transplantation units to meet demand. Positive experiences of transplant recipients and advocacy from civil society and NHSO put pressure on the government to change the restrictive laws around organ donation, with draft bills discussed in parliament to move towards an “opt-out” system of organ donation after death.</p> <p>In parallel, at the regional level, increased cooperation and harmonisation across countries through the Association of Southeast Asian Nations (ASEAN) Health Sector culminates in a cross-country agreement between ASEAN states to mutually recognise professional medical qualifications. Although it is anticipated that language barriers may prevent extensive migration of personnel, the Thai government nonetheless anticipates that a small but significant proportion of doctors and nurses may leave the country. In response, the government puts in place two key measures. Firstly, to reduce emigration of trained medical personnel, healthcare worker salaries are raised at a uniform rate across the country. Secondly, the government increases investment to develop “centres of excellence” aiming to retain and attract medical specialists in Thailand and from abroad. Given the growing movement towards organ transplantation, this is selected as one of the domains of expertise. From the perspective of NHSO, this government response further incentivises policies to expand availability and increase uptake of kidney transplant, as the salary increase disproportionately affects budget requirements for HD and the government strategic priority to advance transplantation encourages development of system capacity.</p> <p>After 10 years, Thailand has one of the highest rates of kidney transplantation in Asia, with growing expertise in organ transplantation. Individuals registering for kidney transplant enjoy short wait times and high service quality, while NHSO benefits from economies of scale that lead to lower cost per transplant. However, for patients remaining on dialysis, quality of care and accessibility of services decreases. There is a shortage of staff as the dialysis workforce increasingly re-skills to transplantation or moves to neighbouring countries with better career prospects and fewer dialysis nurses are trained each year. Coupled with higher healthcare worker salaries, the workforce shortage forces</p>
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	<p>many satellite dialysis clinics to close. This disproportionately affects remote areas, in which patients that cannot be treated with PD are forced to travel long distances to receive treatment.</p>
<p><b>Scenario 2:</b> A two-tier system in access to KRT services</p>	<p>In the second scenario, increased pan-ASEAN harmonisation has led to mutual recognition of professional medical qualifications, as in scenario 1, but without concerted effort to increase rates of donation and system capacity for transplantation. Rates of kidney transplantation have therefore remained below 1% of patients with kidney failure per year and patients in all three health insurance schemes predominantly rely on dialysis.</p> <p>Outside of Thailand, a breakthrough in research and development demonstrates the feasibility of stem cell technology for organ replacement. Despite high costs and lack of long-term efficacy data, the technology is rapidly taken up across private clinics worldwide due to the lack of requirement for a matching donor or immunosuppression. Five-years after initial proof-of-concept, many high-income country governments are taking the decision to provide stem cell technology for kidney failure patients due to the considerable improvement in quality of life. Widespread use of the technology brings substantial cost reductions, but the high budget impact and specialist expertise remain bottlenecks to access.</p> <p>In Thailand, large private hospitals in Bangkok invest in stem cell technology for kidney failure, as a lucrative business opportunity allowing hospitals to maintain competitive staff salaries that prevent migration to other ASEAN countries. Dialysis patients with the ability to pay for this expensive technology are able to access life-saving treatment, but the cost is too prohibitive to justify its inclusion under UCS. The resulting situation is one of increasing disparity for kidney failure patients. Following the pan-ASEAN agreement, professional medical bodies are increasingly vocal in voicing dissatisfaction with levels of remuneration for medical professionals. In response, the government increases salary rates, particularly for specialists. While this measure appeases medical professionals, it adds even more burden to the financially strained KRT programme. HD satellite clinics are forced to close due to high personnel costs and the business case for private HD centres becomes weaker, as the NHSO service fee for HD does not fully accommodate the higher staff costs. As a result, accessibility of HD services gets worse, pushing more</p>

	<p>and more HD patients towards catastrophic health expenditures, and eventually availability of HD services becomes insufficient to meet demand, lowering quality of care and forcing many patients to PD or comprehensive conservative care.</p> <p>At the end of the 10 years, a small subset of fortunate kidney failure patients has access to a new life, while the quality of care and availability of services for the rest the kidney failure population gradually deteriorates.</p>
<p><b>Scenario 3:</b> Strict regulation and standards</p>	<p>In scenario 3, NHSO prioritises increased access for kidney transplantation, as in scenario 1, but with a different health workforce dynamic. Instability in neighbouring countries has led to an influx of migrants, including skilled health professionals seeking employment in Thailand. Initially the Thai government fast-tracks licenses for incoming migrants with medical qualifications, particularly for dialysis, as despite the successful expansion of kidney transplantation, number of HD patients remains high and better remuneration for transplantation has led to many dialysis staff to re-train (as in Scenario 1).</p> <p>As a result of fast licensing procedures, a high number of licensed migrant health professionals are subsequently hired in private HD centres as technicians. This increases the practice of task-shifting from dialysis nurses to technicians, as many migrant technicians had originally trained as dialysis nurses. However, there is soon backlash from medical professionals and the public, who are concerned around lack of due diligence in the fast-track licensing procedures and lack of oversight for task-shifting in HD centres. Professional associations additionally protest on the basis that fewer nurses are being trained, arguing that it could be detrimental to the dialysis profession over the long term.</p> <p>In response, the government collaborates with professional associations to tighten regulations, improve quality assurance mechanisms, and employ technology for real-time monitoring. These measures not only re-build trust in the system, but also reduce the prevalence of poor practices in HD centres (which had been common long before the influx of migrants), including overlapping nurse shifts, reduced dialysis sessions, and task-shifting to unqualified</p>

	<p>personnel. As a result, patient satisfaction and HD quality of care improves significantly for patients waiting for kidney transplantation, those with graft failure, and those opting out of transplantation.</p>
<p><b>Scenario 4:</b> Boom and bust of dialysis</p>	<p>In the final scenario, stem cell technology becomes available on the private sector, but remains out of reach for the majority of kidney failure patients. With the ever-increasing burden of kidney failure, there is high demand for dialysis services, which represents an increasing burden on both the NHSO budget and the service system. As with scenario 3, immigration of trained healthcare workers from neighbouring countries is welcomed by the government to fill the shortage in dialysis nurses and technicians, with many short training programmes set-up to re-train incoming migrants and provide licenses for them to seek employment in Thailand.</p> <p>In the short-term, many migrant professionals are hired by private HD centres, due to the shortage of staff and lower labour costs, allowing availability and quality of dialysis services to be maintained. However, the drop in average salary for dialysis nurses and technicians, from fewer opportunities to supplement pay with extra shifts, causes many to either upskill or leave the profession, and number of new nurses trained drops as the profession is seen as less attractive. Over time, NHSO also decreases the service fee paid to healthcare providers for HD, due to budget constraints as the number of dialysis patients continues to rise. After a few years, the capacity of the system to deliver HD is severely weakened: the workforce has reduced considerably and is no longer being “topped-up” by migration, and the lower service fee disincentivises private HD centres.</p> <p>Furthermore, due to the global shift towards stem cell technology, research and innovation in dialysis stagnates. In response to calls for greater equality between health insurance schemes from civil society, and through concern around the dialysis situation, the government engages in bilateral discussions with stem cell technology developers to increase access, but no favourable agreement is reached due to the high level of competition globally and greater purchasing power of high-income nations.</p>



## **Supplement 4.4 Policy analysis (future scenarios)**

### *#1 Restrict payment of the doctor fee*

System dynamic modelling had projected that, if the status quo in 2024 continued, around one quarter of new dialysis patients over the next 5 years would be initiating dialysis prematurely, due to financial incentives for nephrologists to refer patients for HD. The policy proposal to restrict payment of the doctor fee aimed to reduce the number of new HD patients that are either better suited to a different type of care or initiating dialysis prematurely by placing restrictions on when the financial incentive can be paid. The policy was projected to have very high impact in terms of patients receiving the most suitable type of care and reducing expenditures for the government.

Vulnerability of this policy was judged to be low. Currently, payment of the doctor fee is considered to be a grey area. Even if enforcement of the policy is poor, explicit statement that the doctor fee is only allowed under specific circumstances is likely to decrease the prevalence of this practice in itself. However, it was highlighted that private clinics may develop alternative mechanisms to incentivise patient uptake of HD, such as advertisement campaigns or paying for doctor travel to conferences, which may undermine the policy to a limited extent.

In terms of robustness, this policy was considered to have similar benefit to the status quo in most scenarios. However, if competition between private centres increases in future, as illustrated by scenario 4, this policy would guard against increases in financial incentives for inappropriate start of HD.

### *#2 Pre-authorisation of dialysis*

Prior to the 2022 policy change, provincial committees were responsible for approving requests for patients to initiate PD or HD, to ensure that they met the relevant criteria. The pre-authorisation policy was proposed to reinstate these committees, to prevent premature initiation of dialysis and to ensure that the proposed kidney replacement therapy is suitable given the patient profile.

Similar to restrictions on the doctor fee, this policy was considered to have very high impact due to improvements in patient quality of life and budget savings for the government payer. However, the critical scenario method highlighted that this policy may be vulnerable to stakeholder actions and

responses. Without strong support from professional associations, the policy may be perceived as removing decision-making power from doctors, and any inefficiencies in the system that lead to delays in approval could lead to patient dissatisfaction. Since previous policy changes had been motivated by advocacy from patients and clinicians, there is a strong risk that the policy may be overturned or watered down. The pre-authorisation could also have limited impact if viewed as a checkbox exercise.

Robustness assessment of a pre-authorisation system suggests that it may bring even greater benefit in futures requiring prioritisation of patients for services, as the systems for external patient evaluation would already be in place, as well as guarding against perverse financial incentives that may arise to recommend inappropriate treatments to patients. The policy could strengthen the system to better cope with future uncertainty, but its implementation would need to be carefully managed.

### *#3 Patient education by a multi-disciplinary team*

A literature review of successful interventions to increase home-based dialysis had identified patient education by a multi-disciplinary team as a potentially high impact intervention [276]. Modelling had suggested this policy could not override financial incentives in the Thai system but could decrease the number of patients best suited for PD or CCC opting for HD. There could also be broader benefit for patients and their caregivers by providing information around the package of services they have access to: interviews had highlighted, for example, that patients may pay out-of-pocket for free services (such as erythropoietin) or not be aware of the process to sign up for the transplant waiting list.

Although the critical stakeholder method did not highlight any major stakeholder opposition to this policy, its success was considered to depend on the quality of implementation. Without appropriate oversight and resourcing, there may be a risk that the education is seen as a box-checking exercise as opposed to shifting to a culture of shared decision-making. A multi-disciplinary team had been proposed on the basis that it would reduce the influence of the doctor fee, but private providers may develop additional incentives in response. For the robustness assessment, a platform for patient education could be effectively leveraged to inform patients of their options and their entitlements, but could cause greater dissatisfaction if patients are provided

with a false sense of choice in futures with supply constraints. If financial incentives in the system or workforce shortages increase, the success of this policy may be much lower.

#### *#4 Protocols to refer patients to comprehensive conservative care (CCC)*

Research into high death rates among HD patients after the 2022 policy change had suggested that many patients near end of life were initiating dialysis, even though their quality of life would likely be higher with comprehensive conservative care (CCC, elective palliative care). An international literature review suggested that providing doctors with protocols to assess patients for CCC suitability could increase the proportion of CCC-suitable patients selecting CCC [275]. Since HD initiation for patients best suited to CCC was relatively low compared to premature HD initiation and PD-eligible patients selecting HD (and because of financial incentives in the system), this policy was only projected to have modest impact from the government payer perspective in Thailand. It could, however, lead to much higher quality of life for patients and their caregivers near end of life, and potentially strengthen platforms for end-of-life palliative care in Thailand.

It was not anticipated that stakeholders would oppose the policy or take responsive actions. For futures in which the dialysis programme is under severe constraints, this policy could provide greater benefit as CCC service provision in Thailand is likely to improve as a result, improving quality of life for patients unable to access dialysis services.

#### *#5 Systems for continuous quality improvement (CQI) of dialysis service provision*

Qualitative research had suggested that coping mechanisms to deal with increases in HD patients had led, in some instances, led to poor quality of HD service provision (for instance, non-adherence to infection control and prevention measures, reduced length of dialysis sessions, re-use of filters, or patient to nurse ratios exceeding the recommended limits). This policy proposed to put in place a working group to monitor data for both PD and HD, in order to identify and resolve potential issues with quality of dialysis services.

The success of this policy was considered to be highly dependent on implementation, most notably the authority and mandate of the working group (i.e. whether they have the power to implement change), technical quality of data systems, and cooperation of service centres to

provide reliable real-time data. However, if successfully implemented with coordination and support across government and service providers, the CQI system could strengthen the KRT programme, as it provides a platform to uphold quality during periods of strain and during introduction or expansion of new technologies and services.

#### *#6 Global budget for dialysis service provider payments*

Future projections of budget requirements for the KRT programme had indicated that the required budget could exceed 10% of the budget for all within the next 10 years. To manage the financial sustainability of the KRT programme, it was proposed to implement a global budget for dialysis. Under this programme, the total budget for the KRT programme would be capped each year, meaning that service provider payments would inversely depend on number of dialysis patients.

Two major risks were identified for this policy due to the responses of service providers, primarily in the private sector. With greater uncertainty around profits, the business case for many private HD centres is likely to be low, causing centres to close. This would disproportionately affect patients living in rural areas. Dialysis centres that do remain open (for PD and HD) may implement cost-cutting measures that could compromise on service quality, such as higher numbers of patients per nurse or reduced infection control and prevention. This reduction in quality and inequitable access would likely be amplified in futures with system strain or increased numbers of patients transitioning to KT or emerging technologies.

#### *#7 Bundle payments to service providers as “fee per kidney failure patient”*

Qualitative research had suggested that service providers and nephrologists have financial incentives that, in many cases, may lead them to recommend HD to patients who are not yet ready to initiate dialysis or unsuitable for HD due to health reasons. The proposed bundle payment policy would provide a fee for service for dialysis patients, according to the profile of patients, to remove the financial incentive for HD.

The success of the policy is likely to depend on the actions of private HD centres. HD centres that do not diversify their portfolio of services to include comprehensive conservative care and PD would still have a strong incentive to promote HD. Similar to the global budget, accessibility and

quality of services is likely to depend on the business case for private centres and payment mechanisms for complications (i.e. whether the financial burden of complications is borne by the service provider or not). In our analysis, changes in the healthcare workforce or kidney transplant rates were unlikely to change the impact of this policy significantly.

## Supplement 4.5 Data used for evaluation

**Table S5.** Evaluation of the use of futures in the 2024 KRT policy process, according to the framework in Table 2 of the main text.

#	Goal	Indicator	Evidence
1	Fitness for purpose	d) Additional information/insight from the futures study, beyond other research conducted for the policy	<ul style="list-style-type: none"> <li>• Programme-level impact for KRT and palliative care were not identified in other studies or working group discussion.</li> <li>• Potential service provider responses to policies were recognised to a greater extent in the futures analysis than system dynamics modelling. Both futures and system dynamics questioned assumptions around the impact of proposed policies given uncertainty around how actors would respond.</li> </ul>
		e) The research team had an expanded view of future uncertainty	<ul style="list-style-type: none"> <li>• In developing the narratives, there were questions around how a single narrative could be developed given that multiple options were possible at each step of the process (suggesting understanding of multiplicity of futures).</li> <li>• Comments related to the “likelihood” of different scenarios decreased throughout the process. However, this could reflect adherence to, as opposed to acceptance of, the methods, especially as questions around the purpose of the exercise were consistently raised throughout the study.</li> </ul>

		f) The research team had a greater understanding of the interests of different actors and how their responses may shape the future	<ul style="list-style-type: none"> <li>As noted under 1a, assumptions around the impact of proposed policies and the uncertainty in actor responses (especially service providers) was recognised to a greater extent.</li> <li>Some points raised during the analysis were raised separately by members of a learning committee not involved in this study (e.g. patient and medical professional reactions to a pre-authorisation policy). It is possible that other methods, such as structured discussion with experts, could have given similar findings.</li> </ul>
2	Influence	c) The futures study influenced policy	<ul style="list-style-type: none"> <li>The draft recommendations were modified after presentation of the futures results to place greater emphasis on pre-authorisation and CQI. Conversely, the prominence of bundle payments was decreased.</li> <li>Use of the futures results to show uncertainty quantitatively through system dynamic modelling prompted discussion around assumed private service provider behaviour for bundle payment and global budget. There was, however, no explicit discussion of the futures study during the working group or Board meetings.</li> </ul>
		d) The futures study influenced planning and implementation	<ul style="list-style-type: none"> <li>No mention of points raised in futures analysis during Board meeting.</li> </ul>
3	Efficiency	b) The human and financial resources to conduct the futures	<ul style="list-style-type: none"> <li>Only one member of the team completed a time sheet: 5 hours (if representative of all team members, this translates to 45 hours).</li> </ul>

		study were justified given the additional insight	
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## Supplement 5 Causal loop diagram

**Table S5.1** Profile of interviewees.

Profile	Number interviewed (in-depth interview n=20, focus group discussion n=12)
Payer (NHSO)	2
Policymaker	4
Professional associations	3
Dialysis providers	4
Manufacturers	3
Patient representatives	12 (1 focus group with 12 patients and 1 interview with a patient who also took part in the focus group)
Academics	3

**Table S5.2** Profile of workshop participants, facilitators, and observers (responsible for recording observations from group discussions).

	Group 1 (n=8)	Group 2 (n=6)	Group 3 (n=7)
Workshop participants	<ul style="list-style-type: none"> <li>• Senior nephrologist (6)</li> <li>• NHSO (1)</li> <li>• Supplier (1)</li> </ul>	<ul style="list-style-type: none"> <li>• Nephrologist (1)</li> <li>• Nurse (2)</li> <li>• Patient (1)</li> <li>• Supplier (1)</li> <li>• CSMBS (1)</li> </ul>	<ul style="list-style-type: none"> <li>• Nephrologist (1)</li> <li>• Nurse (1)</li> <li>• Patient (3)</li> <li>• Supplier (1)</li> <li>• NHSO (1)</li> </ul>
Facilitator(s)	<ul style="list-style-type: none"> <li>• Political scientist (member of the secretariat for the NHSO working group)</li> </ul>	<ul style="list-style-type: none"> <li>• Communications expert, working at HTA agency</li> <li>• HTA expert (lead of the secretariat for the NHSO working group)</li> </ul>	<ul style="list-style-type: none"> <li>• Pharmacist, working at HTA agency</li> </ul>

Observer	<ul style="list-style-type: none"> <li>Data scientist (member of the secretariat for the NHSO working group)</li> </ul>	<ul style="list-style-type: none"> <li>Dialysis nurse (member of the secretariat for the NHSO working group)</li> </ul>	<ul style="list-style-type: none"> <li>Pharmacist, working at HTA agency</li> </ul>
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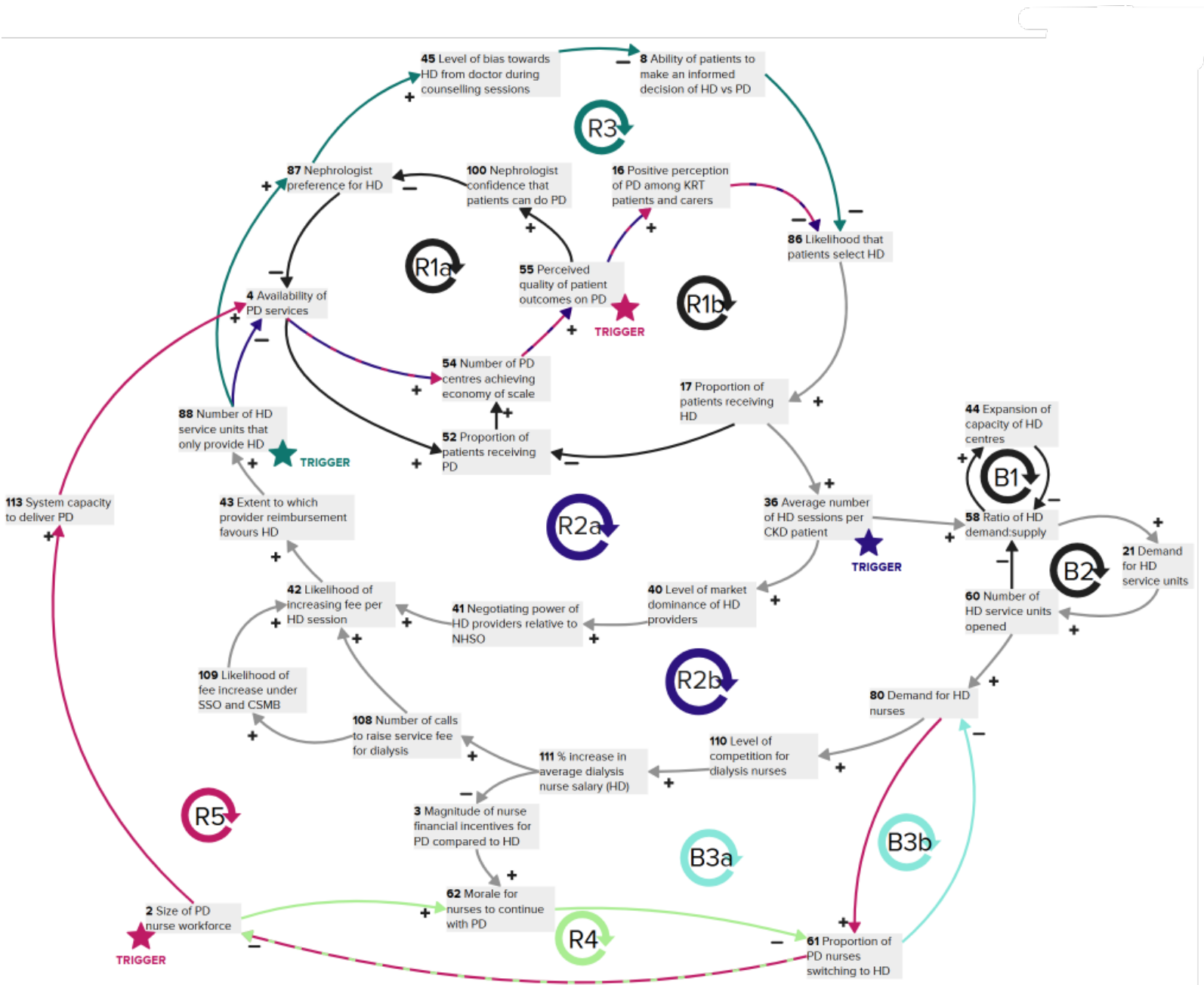
CSMBS – Civil Servant Medical Benefit Scheme; HTA – health technology assessment; NHSO – National Health Security Office (government payer)

**Table S5.3** Questions included in the survey to dialysis centre directors in the private (n=4) or public (n=3) sector. Note: the survey was provided in Thai, the questions below are a translation.

#	Question	Respondents
1	Please indicate the year you became director of this dialysis centre.	All
2	How many HD beds are in operation in your centre?	
3	Is your dialysis centre public or private?	
4	If you pay a fee to doctors referring patients to your centre, how much is the doctor fee?	Private sector only
5	In the past 2 years has there been a change in the amount paid for the doctor fee? If yes, what was the reason for the change?	
6	Was there any change in the amount paid for the doctor fee prior to the 2022 policy change? If yes, what was the reason?	
7	Which factors influence a decision to open a new HD centre?	
8	Would you consider opening a new HD centre if the existing centre is below its maximum capacity? If yes, please explain why.	
9	How long does it take to open a new HD centre (time from the decision to open a new centre to registration and opening)?	
10	Under which circumstances would you consider permanently closing an HD centre?	
11	Is there any threshold, in terms of percentage capacity filled or NHSO reimbursement per patient, that would influence your decision to close an HD centre?	

12	If demand for HD services exceeds current capacity of the centre, which factors influence your decision to expand capacity of the centre?	
13	How long would it take to increase service capacity of the HD centre?	
14	Conversely, what would affect your decision to reduce capacity of the centre (e.g. reducing number of dialysis sessions per day or reducing number of nurses)?	
15	How long would it take to process a reduction in service capacity?	
16	If there is high demand for HD, would your hospital be able to expand service capacity? If yes, how would you increase capacity and how long would this take?	Public sector only
17	If you find that demand for PD has decreased, which actions would you take and what would influence your decision?	
18	In your experience, how long does it take for a centre to gain experience in PD, both in terms of improved clinical outcomes of patients and in terms of staff confidence in PD?	
19	In your hospital, are there PD nurses providing services without PD nurse training? If yes, how many nurses have not been trained yet?	
20	Does your hospital send nurses for PD training? <ul style="list-style-type: none"> <li>• If yes, how many per year and which factors influence the number sent for training?</li> <li>• If not, what is the reason?</li> </ul>	

**Figure S5.1** Interim causal loop diagram presented to workshop participants. The version



presented in the workshop was in Thai.

## Supplement 6.1 Model structure and functions

**Table S6.1a** Tests and modifications to model structure during iterative development of the system dynamics model.

#	Component	Assumption	Finding	Modification to model structure
1	HD supply	Insufficient HD supply causes: (1) expansion of HD supply (2) increased HD death rates	<ul style="list-style-type: none"> <li>Private HD centres open when capacity is around 60-70%.</li> <li>Removing HD supply stocks had negligible impact on model output.</li> </ul>	<ul style="list-style-type: none"> <li>Stocks for number of HD centres and HD centre capacity removed.</li> <li>Change in HD supply is proportional to rate of change in HD patients.</li> </ul>
2	HD nurses	Insufficient HD nurses increases death rate	<ul style="list-style-type: none"> <li>Number of registered HD nurses is sufficient to cope with continued increase in patients beyond the 2022 policy change.</li> <li>Removing HD nurse stocks had negligible impact on model output.</li> </ul>	<ul style="list-style-type: none"> <li>Stocks for HD nurses removed.</li> <li>Burden on nurses is proportional to changes in HD supply (i.e. from turnover between HD centres).</li> <li>A stress factor introduced for sudden peaks in number of HD patients.</li> </ul>
3	PD nurses	Rate of peritonitis is influenced by: (1) ratio of PD patients per nurse (2) rate of PD nurse turnover to HD	<ul style="list-style-type: none"> <li>Renal registry and TRT data show that ratio of PD patients/nurse was above the recommended threshold before <u>and after</u> the 2022 policy change.</li> <li>Changing functional form to linear relationship between PD nurse ratio and peritonitis showed poor fit.</li> </ul>	<ul style="list-style-type: none"> <li>Stocks for PD nurses removed (absolute nurse number not influential).</li> <li>Experienced PD nurses transitioning to HD has been kept and is modelled as proportional to changes in HD supply.</li> </ul>

			<ul style="list-style-type: none"> <li>Removing nurse threshold showed good fit whereas switching off PD nurse “turnover” factor changed shape of model and led to worse fit.</li> </ul>	
4	Vascular access	Death rates from increased temporary vascular access can be modelled as a stressor	<ul style="list-style-type: none"> <li>Total number of dialysis patients is strongly correlated with proportion of patients with temporary access.</li> <li>Model stressor for vascular access did not accurately predict proportion of patients with vascular access.</li> </ul>	<ul style="list-style-type: none"> <li>New stock introduced for HD patients with temporary access.</li> <li>Functional form iteratively defined through model calibration (depends on rate of change).</li> </ul>
5	PD to HD transitions	Only affected by peritonitis risk after 2022 policy	Negligible influence of relaxing this assumption.	None
6	PD death rate	PD death rates are independent of rate of change in number of PD patients	Introducing a change in death rate (immediate or delayed) proportional to rate of change in number of PD patients (relative or absolute) and calibrating for the best fit parameters led to a pre-2022 shape that was “bent” in the wrong direction.	None
7	Policy relaxation	PD-first policy was implemented until 01 February 2022	From the renal registry:	Gradual phasing in of 2022 policy for PD-eligible patients from December 2021. All

			<ul style="list-style-type: none"> <li>• Number of new PD cases is lower in 2022 than other years. However, new HD cases is also lower.</li> <li>• There is a drop in new PD cases and increase in new HD cases in December 2021. This aligns with NHSO Board policy approval.</li> </ul> <p>From changing model structure:</p> <ul style="list-style-type: none"> <li>• Relaxing the PD-first policy in 2021 showed poor fit.</li> <li>• Phased change in PD eligible choice from December 2021 showed a better fit, but phased change of other HD patients did not.</li> </ul>	other 2022 policy changes implemented in February 2022.
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HD – haemodialysis; PD – peritoneal dialysis

**Table S6.1b** Structural analysis of functional forms in the base model. The analysis informed base model structure and alternative structures for model calibration in the structural uncertainty analysis.

#	Component	Function	Alternative functions tested	Structural analysis for policy projections
1	Patient choice	<p>S-shaped curve between 0 and 1 to scale importance of doctor fee (and peritonitis for PD)</p> <p>e.g. <math>(1/(\exp(-sDF \cdot aDF\_PD\_k)) - 1)</math> where sDF is the doctor fee and aDF_PD_k is a scaling factor</p>	<p>Linear, exponential, plateau, switching off:</p> <ul style="list-style-type: none"> <li>Value of k (parameter scaling rate of change) had greater influence than function for PD-eligible and CCC-suitable choice</li> <li>For premature DF initiation, S-shaped showed the closest fit to the data (even when varying other parameters)</li> <li>Switching off doctor fee with extreme values of other parameters could represent shape for premature HD initiation</li> </ul>	<ul style="list-style-type: none"> <li>No change to functional form.</li> <li>Conduct structural uncertainty analysis to “switch off” the doctor fee for premature HD initiation.</li> <li>Conduct structural uncertainty analysis to “switch off” risk of peritonitis in PD-eligible patient choice.</li> </ul>



<b>2</b>	Temporary VA	VA required is sum of new HD patients, PD to HD transitions, and HD patients with temporary access divided by average lifespan of catheter	Time lag for number of patients, with or without adjustment for death rate (no improvement in fit)	No change in functional form.
<b>3</b>	Proportion temporary VA	<ul style="list-style-type: none"> <li>• A baseline proportion of patients will require temporary access (e.g. urgent start HD)</li> <li>• Rate of change in new temporary access patients scales the proportion of patients with temporary access, with a power term and multiplicative term</li> <li>• Above a threshold rate of change, a maximum proportion is applied</li> </ul>	<ul style="list-style-type: none"> <li>• Fixed capacity (absolute or percentage) for VA</li> <li>• Setting the baseline constant, power and multiplicative terms to zero</li> <li>• Proportional to new HD cases or rate of change in total HD cases</li> <li>• No maximum threshold rate of change</li> </ul>	No change in functional form (no parameter sets in calibration showed a good fit to any of the other functions).

CCC – comprehensive conservative care; DF – doctor fee; HD – haemodialysis; PD – peritoneal dialysis; VA – vascular access

**Table S6.1c** Functions in the base model.

Component	Type	Function	Description
<i>HD supply</i>			
aHD_ref1	Aux	$\text{ifelse}(\text{time} < \text{aHDsupply\_lag}, 1, \text{lagvalue}(\text{time} - \text{aHDsupply\_lag}, 1))$	Number of HD patients when the decision to increase HD supply was taken
aHD_ref2	Aux	$\text{ifelse}(\text{time} < (\text{aHDsupply\_lag} + \text{aHDinfo\_lag}), 1, \text{lagvalue}(\text{time} - (\text{aHDsupply\_lag} + \text{aHDinfo\_lag}), 1))$	Number of HD patients at the point in the past used to inform decisions to increase HD supply
aHDsupply	Aux	$\text{max}((\text{aHD\_ref1} - \text{aHD\_ref2})/\text{aHD\_ref1}, 0)$	Increase in HD supply depends on the rate of increase in HD patients in the past (due to the delay in constructing and registering new centres)
<i>CCC-suitable choice</i>			
aRRTbase	Aux	$\text{aRRT\_t} * \text{time} + \text{aRRT\_i}$	Base rate of dialysis incidence (according to the 2008 policy), which increases over time due to increasing chronic kidney disease burden
aCCC_i	Aux	$\text{aCCCmax} * \text{aRRTbase}/(1 - \text{aCCCmax})$	Incidence of CCC-suitable patients (based on proportion of kidney failure patients suitable for CCC)
aCCC_DF	Aux	$\text{min}((1/(\exp(-\text{sDF} * \text{aDF\_CCC\_k})) - 1), 1)$	Scales between 0 (when doctor fee is zero) to 1 (high values of the doctor fee) according to an S-shaped curve
aCCC_DF_influence	Aux	$\text{max}(1 - \text{aCCCpref} - \text{aCCCprefHD}, 0)$	Proportion of CCC-suitable patients whose choice is modified by the doctor fee

aHD_CCC_new	Aux	$aCCC_i * (aCCC_{prefHD} + aCCC_{DF\_influence} * aCCC_{DF})$	CCC-suitable patients selecting HD depends on inherent preference for HD and the amount of the doctor fee
fHD_CCC_new	Flow	$aPolicy_{2022} * aHD\_CCC\_new$	Number of new CCC-suitable patients per month – CCC-suitable patients can only choose HD after the 2022 policy change ( $aPolicy_{2022}$ is a function of time with value 0 prior to the policy change and 1 after)
<i>PD to HD transitions</i>			
aRRperitonitis	Aux	$1 + aRR_{nurse\_scaler} * aHDsupply$	Relative risk of peritonitis, which increases above baseline proportional to rate of increase in HD supply
aPDtoHD_DF	Aux	$\min((1/(\exp(-sDF * aDF_{PDtoHD\_k}))), 3)$	S-shaped curve from 0 (no doctor fee) to 3 (high doctor fee)
aPDtoHD_peritonitis	Aux	$\max(aRR_{peritonitis} * aPDtoHD\_peritonitis\_k, 1)$	Influence of relative risk of peritonitis on rate of switch from PD to HD
aPDtoHD	Aux	$aPDtoHD\_base * (aPDtoHD\_DF * aPDtoHD\_peritonitis * aPD_{2022} + 1 - aPD_{2022})$	Base rate of PD to HD transitions increases after the 2022 policy change relative to risk of peritonitis and amount of the doctor fee
fPDtoHD	Flow	$aPDtoHD * sPD$	Number of patients transitioning from PD to HD (rate multiplied by number of PD patients)
<i>PD-eligible choice</i>			
aPD_i	Aux	$aRRT_{base} * aPD_{max}$	Incidence of PD-eligible patients
aHD_always_i	Aux	$aRRT_{base} * (1 - aPD_{max})$	Incidence of dialysis patients who are not PD-eligible (HD always)
aPD_DF	Aux	$\min((1/(\exp(-sDF * aDF_{PD\_k})) - 1), 1)$	S shaped curve from 0 (no doctor fee) to 1 (high doctor fee)

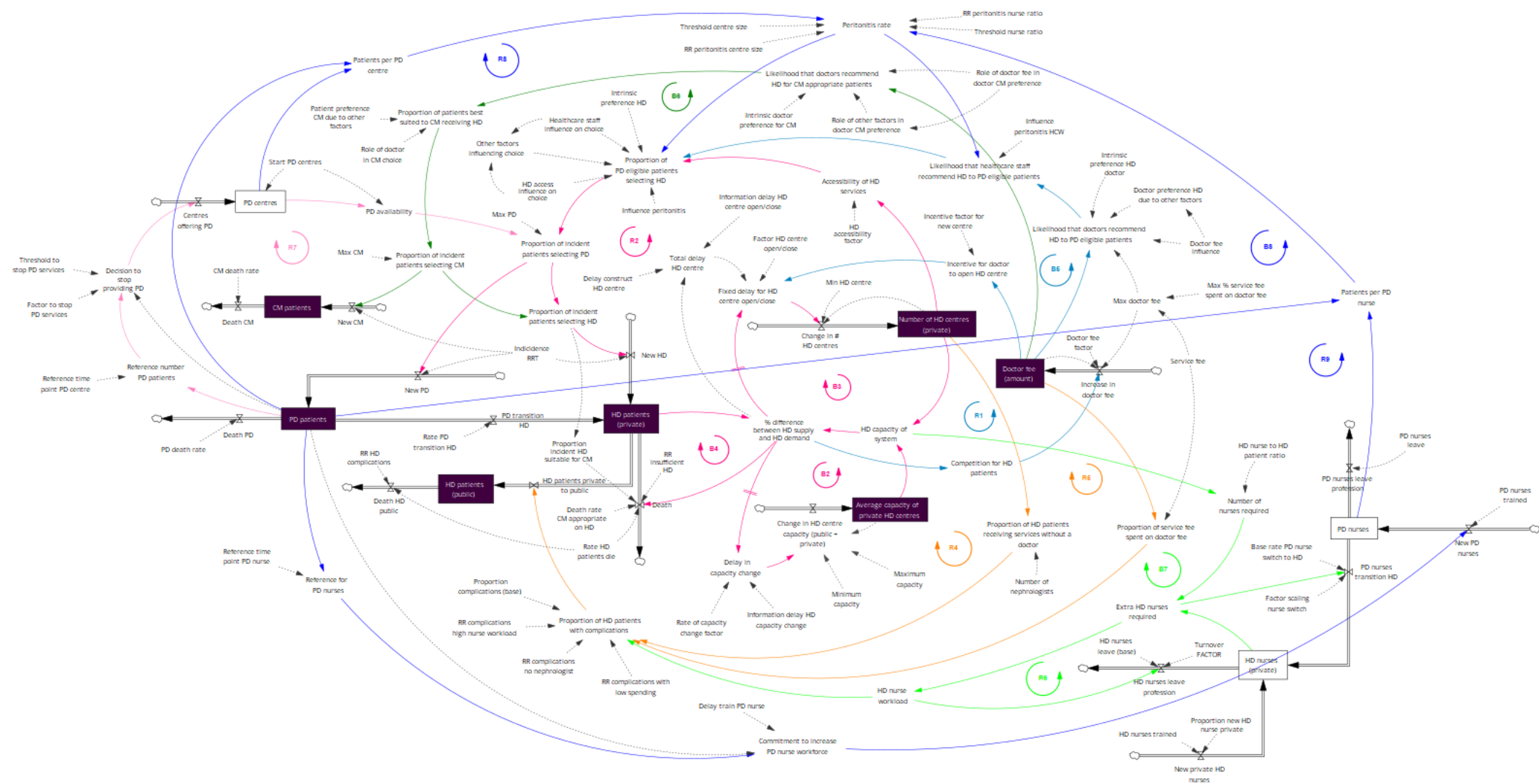
aPD_peritonitis	Aux	$\min((1/(\exp(-aRR_{\text{peritonitis}} * aPD_{\text{peritonitis\_k}}) - 1), 1)$	S shaped curve from 0 (low relative risk of peritonitis) to 1 (high risk of peritonitis)
aPD_changeable	Aux	$\max(1 - aPD_{\text{pref}} - aPD_{\text{prefHD}}, 0)$	Proportion of PD patients whose choice is modified by relative risk of peritonitis and the doctor fee
aPD_chooseHD	Aux	$aPD_{\text{prefHD}} + aPD_{\text{changeable}} * \min((aPD_{\text{DF}} + aPD_{\text{peritonitis}}), 1)$	Proportion of PD-eligible patients selecting HD, which depends on inherent HD preference and the scale of peritonitis risk and the doctor fee (additive)
aPD_choosePD	Aux	$1 - aPD_{\text{chooseHD}}$	Proportion of PD-eligible patients selecting PD
aHD_PD_new	Aux	$aPD_i * aPD_{\text{chooseHD}}$	Number of incident PD-eligible patients selecting HD
aPD_new	Aux	$aPD_i * aPD_{\text{choosePD}}$	Number of incident PD-eligible patients selecting PD
fHD_PD_new	Flow	$aHD_{\text{PD\_new}} * aPD_{2022}$	PD-eligible patients can only select HD after the 2022 policy change
fPDnew	Flow	$aPD_{2022} * aPD_{\text{new}} + (1 - aPD_{2022}) * aPD_i$	Prior to the 2022 policy change, all PD-eligible patients select PD
<i>Premature HD initiation</i>			
aHDprem_i	Aux	$\min((1/(\exp(-sDF * aDF_{\text{prem\_k}}) - 1), 1) * aRRT_{\text{base}}$	Premature HD initiation is scaled between 0 and 1 as a proportion of dialysis incidence, dependent on the average amount of the doctor fee
fHDprem_i	Flow	$aHD_{\text{prem\_i}} * aPolicy_{2022}$	Only premature HD initiation after the 2022 policy change
<i>Other HD incidence</i>			

aSSO_i	Aux	SSO_PDrefuse * aRRTbase	Number of new HD cases that would not have been registered under NHSO prior to the 2022 policy change (fixed proportion of base dialysis incidence)
fSSO_i	Flow	aSSO_i * aPolicy_2022	Only applicable after the 2022 policy change
<i>Temporary vascular access</i>			
aVA_ref1	Aux	ifelse(time < aVALag1, sHD_temp, lagvalue(time - aVALag1, 3))	Number of HD patients with temporary access at a reference point in the past
aVA_ref2	Aux	ifelse(time < aVALag2, sHD_temp, lagvalue(time - aVALag2, 3))	Number of HD patients with temporary access at a reference point in the past
aVArate1	Aux	(sHD_temp - aVA_ref1)/max(sHD_temp,1)	Rate of change in number of HD patients at the current point in time
aVArate2	Aux	(aVA_ref1 - aVA_ref2)/max(aVA_ref1,1)	Rate of change in number of HD patients with temporary access in the past
aVAreq	Aux	fHDnew + fPDtoHD + sHD_temp / aVAtemp_redo	Number of vascular access operations required per month depends on number of new HD patients, number of PD to HD transitions, and number of HD patients with temporary access requiring another vascular access operation
aVAtemp_p	Aux	aVAconstant + max(aVArate1 - aVArate2, 0) ^ aVA_k1 * aVA_k2	Proportion of patients receiving temporary vascular access depends on a constant rate and the rate of change of number of temporary access patients
aVAtemp_new	Aux	ifelse(aVArate1 > aVA_max_rate, aVAreq * aVA_p_max, aVAtemp_p * aVAreq)	Above a certain rate of change, a maximum proportion of HD patients receiving temporary access is applied

fVAtemp_new	Flow	aVAtemp_new	Number of HD patients receiving temporary vascular access per month
<i>PD death rate</i>			
aPD_death	Aux	$aPDdeath\_base * (1 + (aRRperitonitis-1) * aRRdeath\_peritonitis)$	PD death rates increase as peritonitis increases
fPD_death	Flow	$aPD\_death * SPD$	Number of PD patients dying per month
<i>HD death rate</i>			
aHDdeath_nurse	Aux	$1 + \min(aHDsupply * aHDnurse\_death\_k, 2)$	Relative risk of HD death from higher rate of HD nurse turnover as HD supply increases
aHDpatient_ref3	Aux	$ifelse(time < aHDstrain\_lag, 1, lagvalue(time - aHDstrain\_lag, 1))$	Reference number of HD patients at a point in the past
aHDchange	Aux	$\max((sHD - aHDpatient\_ref3)/sHD, 0)$	Percentage change in number of new HD patients compared to reference time point in the past
aHDstrain	Aux	$\max(aHDchange - aHDsupply, 0)$	Increase in rate of change of number of HD patients compared to in the past
aHDdeath_strain	Aux	$1 + \min(aHDstrain * aHDstrain\_death\_k, 2)$	Additional risk of death due to strain on the HD system due to above-average increase in number of patients
aHD_adjust	Aux	$aHDdeath\_base * aHDdeath\_nurse * aHDdeath\_strain$	HD death rate, adjusted for strain on the HD system from increases in patients and increases in HD supply
pHDtemp	Aux	$sHD\_temp/sHD$	Proportion of HD patients with temporary access
pCCC	Aux	$sHD\_CCC/sHD$	Proportion of HD patients who are CCC-suitable

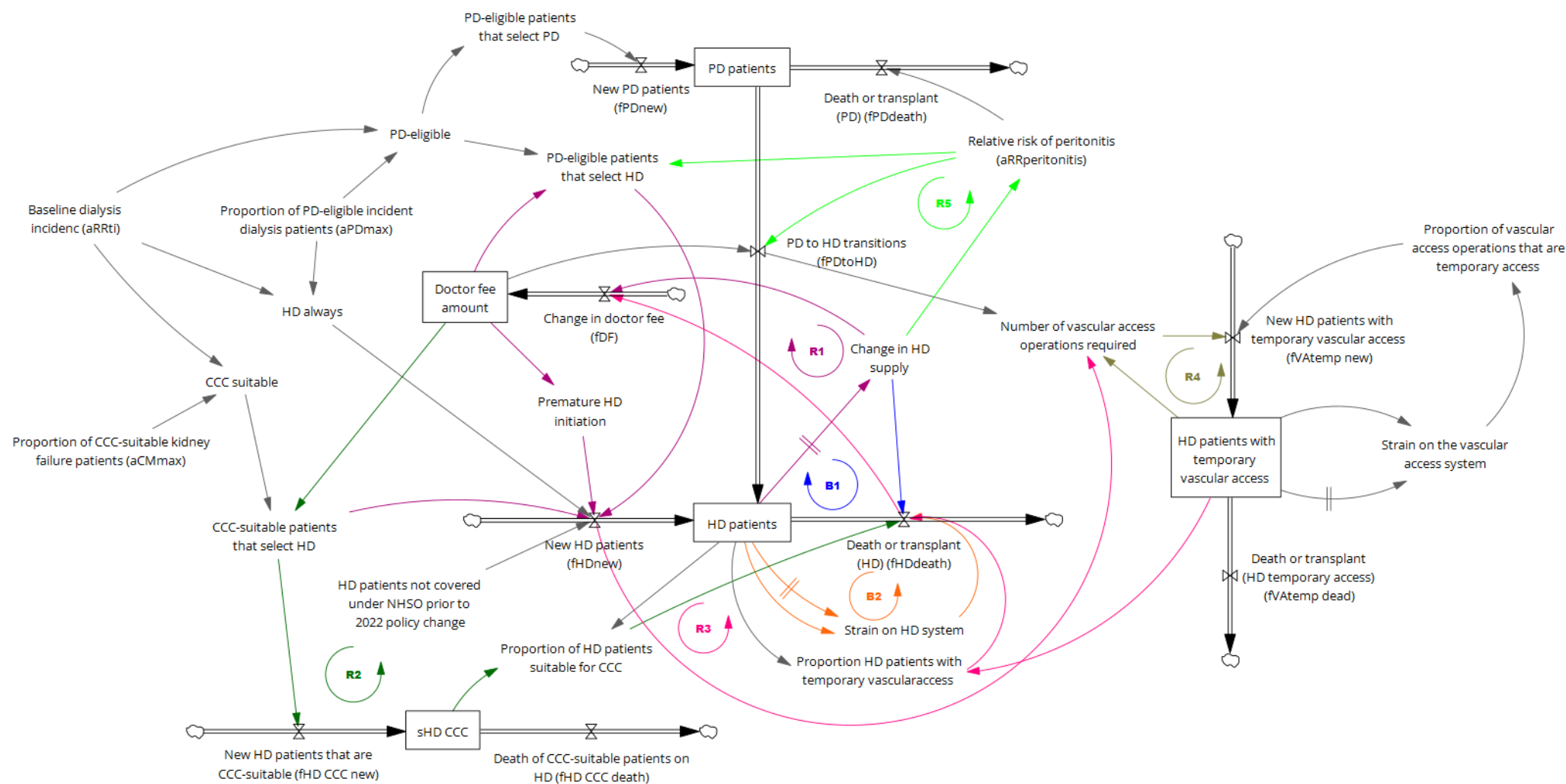
aHD_CCC_death	Aux	$aHD\_adjust * aRRdeath\_CCC * (1 - pHDTemp + pHDTemp * aRR\_VATemp)$	Death rate among CCC-suitable HD patients
aVATemp_death	Aux	$aHD\_adjust * aRR\_VATemp * (1 - pCCC + pCCC * aRRdeath\_CCC)$	Death rate among HD patients with vascular access
fHD_CCC_death	Flow	$aHD\_CCC\_death * sHD\_CCC$	Number of CCC-suitable HD patients dying per month
fVATemp_death	Flow	$aVATemp\_death * sHD\_temp$	Number of HD patients with temporary vascular access dying per month
<i>Doctor fee</i>			
aDFsupply	Aux	$aDFsupply\_factor * aHDsupply$	Increase in the average doctor fee due to increased competition from changes in HD supply
aDFdeath	Aux	$(aHDdeath - aHDdeath\_base) * aDFdeath\_factor$	Increase in average doctor fee due to increased competition from increased HD death rates
fDF	Flow	$aDFsupply + aDFdeath$	Overall change per month of average doctor fee per patient per session

**FigS6.1a** Structure of the preliminary model developed from the causal loop diagram.





**FigS6.1b** Revised model structure, after the iterative process of model testing, showing the main reinforcing and balancing feedback loops.



**CCC-** comprehensive conservative care; **HD** – haemodialysis; **PD** – peritoneal dialysis

## Supplement 6.2 Parameters of the system dynamics model

**Table S6.2a** Parameters in the model that are taken directly from national databases, published literature, or expert opinion.

Parameter	Description	Unit	Value (lower – upper)	Source
aHD_start	Starting number of HD patients in the model (January 2018)	People	19,725 (19,579 - 19,801)	Renal registry
aPD_start	Starting number of PD patients in the model (January 2018)	People	20,546 (20,465 – 20,766)	Renal registry
aHD_topup	Self-funded patients that switched to NHSO following the 2022 policy change	People	1,600 (1,300 – 2,500)	Renal registry
aPDtoHD_topup	PD patients that switched to HD on 1 February 2022	People	350 (350-400)	Renal registry
aCCCmax	Percentage of incident patients with kidney failure that are best suited to CCC	%	12.5 (10-15)	Expert opinion (single nephrologist specialised in palliative care)
aCCCpref	Percentage of patients best suited to CCC who choose CCC regardless of doctor fee	%	5 (0-20)	Expert opinion (nephrologist and working group member)
aCCCprefHD	Percentage of patients best suited to CCC who choose HD regardless of doctor fee	%	70 (30-90)	Expert opinion (nephrologist and working group member)

aRRdeath_CCC	Relative risk of death among HD patients that are best suited to CCC, as compared to other HD patients	RR	1.88 (1.2-3.1)	Longitudinal study of US patients from 1998-2014 [427]
aPDmax	Percentage of baseline incident dialysis cases that are PD-eligible	%	68 (60-75)	Renal registry data 2016-2020
aPDpref	Percentage of PD-eligible patients that choose PD regardless of peritonitis rates or doctor fee	%	11 (0-20)	Expert opinion (nephrologist and working group member)
aPDprefHD	Proportion of PD-eligible patients with a preference for HD that is not moderated by the doctor fee or relative risk of peritonitis	%	50 (0-80)	Expert opinion (nephrologist and working group member)
aRRdeath_peritonitis	Relative risk of death for PD patients with peritonitis, as compared to other PD patients without peritonitis	RR	2.08 (1.59-4.88)	Retrospective cohort in Spanish registry from 1993-2005 [428]
aVAtemp_redo	Average duration of temporary vascular access operation (after which the patient requires another vascular access operation)	Months	14 (5-23)	Observational multi-centre study from Iran [344]
aRR_VAtemp	Relative risk of death for HD patients with temporary vascular access, as compared to HD patients with permanent access	RR	1.85 (1.13-3.03)	Prospective cohort study from Palestine [429] (similar to registry studies from Indonesia [430] and the US [431] and a prospective cohort study in Iran [344], but higher use of

				non-tunnelled catheters than Thailand
aHDstrain_lag	Time delay to calculate strain on the system from increase in HD patients	Months	1 (0.5-3)	Assumption

CCC – comprehensive conservative care; HD – haemodialysis; PD – peritoneal dialysis; RR – relative risk

**Table S6.2b** Parameters in the model that have been estimated from one or more data sources.

Parameter	Description	Unit	Value (lower – upper)	Parameter estimation methods
aHD_temp_start	Number of HD patients with temporary vascular access at the start of the model (January 2018)	People	2,762 (1,972 – 2,958)	No data on catheter use in 2018. Assumed 14% temporary access in 2018, based on increase in catheter use 2020-2023 in TRT database [268].
aDF_start	Average doctor fee paid to nephrologists per session per HD patient (accounts for public and private centres without doctor fee)	THB	100 (10 – 150)	Assumption informed by survey responses on the doctor fee from 4 directors of private HD centres (September 2024).
aRRT_i	Intercept to calculate baseline dialysis incidence by time	People/ month	902 (881-923)	Linear regression of number of dialysis patients per month from 2016-2021, in renal registry.
aRRT_t	Coefficient to calculate baseline dialysis incidence by time	People/ month	2.88 (0 – 3)	
aHDsupply_lag	Average time to increase HD supply (expand capacity and/or open a new centre)	Months	3 (1-9)	Optimisation of fit between HD patients and HD centres from TRT data (2018-2024) [268]; ranges based on survey to 7 HD centre directors.
aHDinfo_lag	Reference point in the past that is used for judgements to increase HD supply	Months	3 (0-4)	

aDF_CCC_k	Factor scaling the relationship between the doctor fee and proportion of CCC-suitable patients selecting HD	None	0.001 (0 – 0.004)	Assumption (not calibrated as little impact on results). Range determined to vary between 0 and 1 for doctor fee range between 0 and 350.
aPDtoHD_base	Base rate (net) of PD patients switching to HD	People/month	0.004 (0.003 – 0.006)	Estimated from the average rate of transitions (PD to HD and HD to PD) in renal registry from 2016-2017.
SSO_PDrefuse	Incident HD patients who would have refused PD under the 2008 policy or from SSO, as a proportion of baseline dialysis patients	%	0.1 (0-0.2)	Estimated from NHSO database: 5,186 self-pay patients, equivalent to 10% reimbursed patients, on 1 <sup>st</sup> February [363]. The upper bound (20%) is based on 12% refusal and an additional 25-30% SSO patients switching to NHSO (equivalent to 8% NHSO patients).

HD – haemodialysis; PD – peritoneal dialysis; THB – Thai Baht (currency)

**Table S6.2c** Parameters estimated by calibration. The calibration range represents the upper and lower bounds for calibration, the calibrated value is the parameter value with the best fit to the data, and the calibration dataset is the data used for calibration.

Parameter	Description	Unit	Calibration range	Calibrated value	Calibration dataset
<b>Vascular access</b>					
aVAconstant	Baseline percentage of VA patients receiving temporary access (due to urgent start dialysis, etc).	%	0-10	5	Q1 2020 to Q1 2023: proportion of HD patients with temporary access (TRT data) [268]
aVALag1	Reference time point to calculate current rate of change in number of temporary access patients	Months	0-3	1	
aVALag2	Reference time point to calculate past rate of change in number of temporary access patients	Months	1-4	2.5	
aVA_k1	Constant to scale rate of change in number of temporary access patients to proportion of patients receiving temporary access (power term)	None	0.3 – 0.5	0.41	
aVA_k2	Constant to scale rate of change in number of temporary access patients to proportion of patients receiving temporary access (multiplication term)	None	1 – 1.5	1.2	

aVA_max_rate	Rate of change in number of HD patients with temporary access at which the system limit for AV access is reached	None	0-1	0.12	
aVA_p_max	Maximum proportion of VA patients receiving temporary access	%	50 - 100	62	
Calibrated to data <u>before</u> the 2022 policy change					
aHDdeath_base	Baseline death rate of HD patients, with optimal quality of care	% per month	0.8-1.5	1.0	2019-2021: HD patients (renal registry)
aHDnurse_death_k	Factor to scale HD death rate relative to changes in HD supply	None	0 - 10	4.5	
aHDstrain_death_k	Factor to scale HD death rate due to surges in number of HD patients	None	0 - 20	1	
aPDdeath_base	Baseline death rate of PD patients	% per month	1.2 – 2.0	1.75	2019-2021: PD patients (renal registry)
aRRnurse_scaler	Factor to scale relative risk of peritonitis to changes in HD supply (due to PD nurse turnover)	None	0 - 2	0.8	
Calibrated to data <u>after</u> the 2022 policy change					
aDF_PDtoHD_k	Factor to scale rate of PD to HD transitions according to doctor fee	None	0.008	0 – 0.02	2022: PD to HD transitions (renal registry)
aPDtoHD_peritonitis_k	Factor to scale rate of PD to HD transitions according to peritonitis rate	None	0.1	0-2	



aDFdeath_factor	Factor to scale rate of change of the doctor fee according to HD death rate	None	50	0 – 150	2022: Total dialysis patients (renal registry)
aDFsupply_factor	Factor to scale rate of change of the doctor fee according to change in HD supply	None	7	0 – 20	
aDF_prem_k	Factor scaling rate of premature HD initiation according to the doctor fee	None	0.0025	0-0.004	
aDF_PD_k	Factor to scale proportion of PD-eligible patients selecting HD according to the doctor fee	None	0.002	0-0.005	2022: proportion of incident dialysis patients on PD (renal registry)
aPD_peritonitis_k	Factor to scale proportion of PD-eligible patients selecting HD according to relative risk of peritonitis	None	0.03	0-0.1	

AV – arteriovascular; HD – haemodialysis; PD – peritoneal dialysis; VA – vascular access

**Table S6.2d** Calibration sets for structural analysis.

#	Description	Parameter set
1	<b>Lower bound of PD-refusers:</b> calibrated according to the lower bound for SSO_PDrefuse	aDFsupply_factor: 8 SSO_PDrefuse: 0.02 aDF_prem_k: 0.0028
2	<b>No premature HD initiation:</b> to achieve a good fit to the data, an equivalent of 50% pre-2022 policy dialysis patients would have to be joining from other health insurance schemes or have previously refused PD, which is not consistent with the data (we estimate an upper bound of 20%, see Table S2b). We therefore re-calibrated the model with the upper bound for patients who would have self-paid or accessed care under other health insurance schemes prior to the 2022 policy.	SSO_PDrefuse: 0.2 aDF_prem_k: 0.002
3	<b>PD-eligible choice is influenced by perceived and not actual peritonitis risk</b>	aPD_peritonitis_k: 0 aDF_PD_k: 0.0022

## Supplement 6.3 Policy analysis (system dynamics model)

**Table S6.3** List of policies proposed for consideration and rationale for their inclusion/exclusion from the system dynamics model projections. Policies were either identified directly from other research informing the policy process or proposed by policy working group members to address specific challenges associated with the 2022 policy change in Thailand. Further details are available in other publications describing policies identified from the causal loop diagram (CLD) [345], literature review [275, 276], or National Health Security Office (NHSO) policy working group (WG) [238].

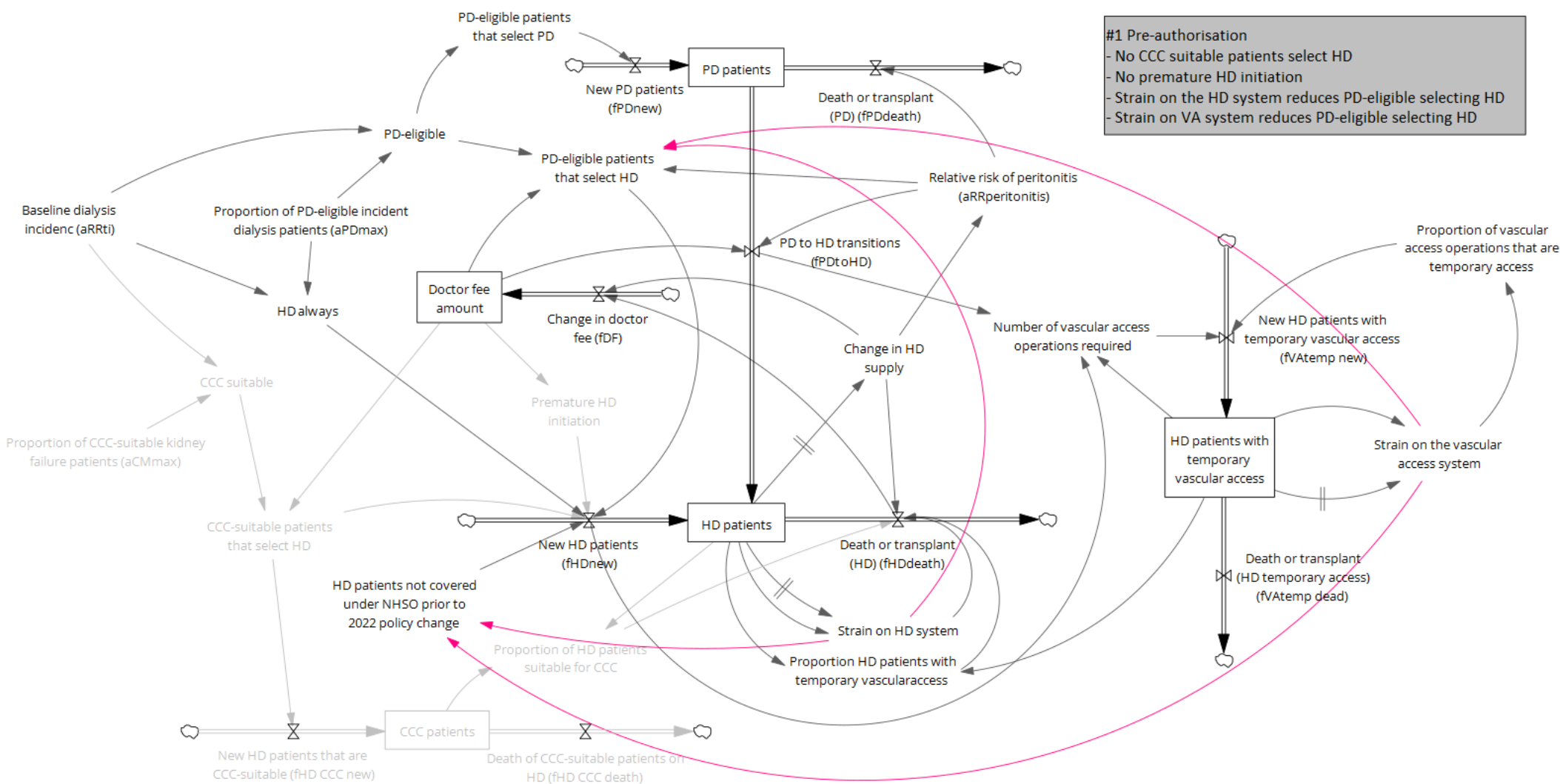
#	Policy	Description	Source	SD model	Rationale
1	Pre-authorisation	HD patients require pre-authorisation prior to initiating dialysis, to ensure that: (1) timing of HD initiation is appropriate, (2) patient quality of life is best on HD, and (3) there is available HD supply.	WG + CLD	Yes	Prevents premature HD initiation
2	KPI for regulatory capacity	Key performance indicator that measures quality assurance staff for regulation of dialysis services relative to supply.	CLD	No	Impact relates to HD death rate only
3	Quality-based payment for HD	HD service provider payments are provided per patient, contingent upon performance against a set of quality indicators.	CLD	Yes	Potential to reduce the doctor fee (and therefore PD-eligible, CCC-suitable, and premature HD)

4	KPI for HD nurse to patient ratio	Key performance indicator that measures number of registered HD nurses in service relative to registered number of HD patients.	CLD	No	Affects loops removed from model structure (as there are sufficient HD nurses according to the data)
5	HD nurse regulations	Enforceable regulations determining maximum number and length of shifts for HD nurses.	CLD	No	Impact relates to HD death rate only
6	PD investment planning	Demand projections for PD determine investment in PD nurse training and PD centres.	CLD	No	Only modified PD-eligible patients selecting HD
7	Doctor fee restrictions	Regulation to allow payment of the doctor fee only when the nephrologist attends the full dialysis session of the patient.	WG	<b>Yes</b>	Decreases the doctor fee (and therefore PD-eligible, CCC-suitable, and premature HD)
8	Education by multi-disciplinary team	Patients with stage 4 chronic kidney disease are provided with multiple education sessions from multi-disciplinary teams of healthcare professionals prior to making a choice between HD, PD, and CCC.	Literature review	<b>Yes</b>	Potential to reduce HD initiation among PD-eligible, CCC-suitable, and premature initiation
9	CCC protocols	Prior to dialysis initiation, doctors are provided with prompting questions and/or protocols to identify patients with short life expectancy who may have better quality of life on CCC.	Literature review	No	Only changes CCC-suitable HD incident patients
10	CQI for dialysis services	Establishment of a working group to monitor and resolve issues with dialysis quality of care.	WG	No	Only changes HD and PD complications and death rates

11	Global budget for dialysis	Service provider payments are allocated according to a fixed budget per year (therefore payments per patient are lower with more patients).	Literature review	<b>Yes</b>	Changes across all categories of HD incident patients
12	Bundle payments for dialysis	Service provider payments are provided per kidney failure patient, with adjustment to make CCC, PD, and HD equally profitable, with adjustment for case mix of patients.	Literature review	No	Changes only affect CCC-suitable and PD-eligible patients

**CCC** – comprehensive conservative care; **CLD** – causal loop diagram; **HD** – haemodialysis; **KPI** – key performance indicator; **PD** – peritoneal dialysis; **SD** – system dynamics; **WG** – ad-hoc working group on kidney replacement therapy under the National Health Security Office (NHSO) Board

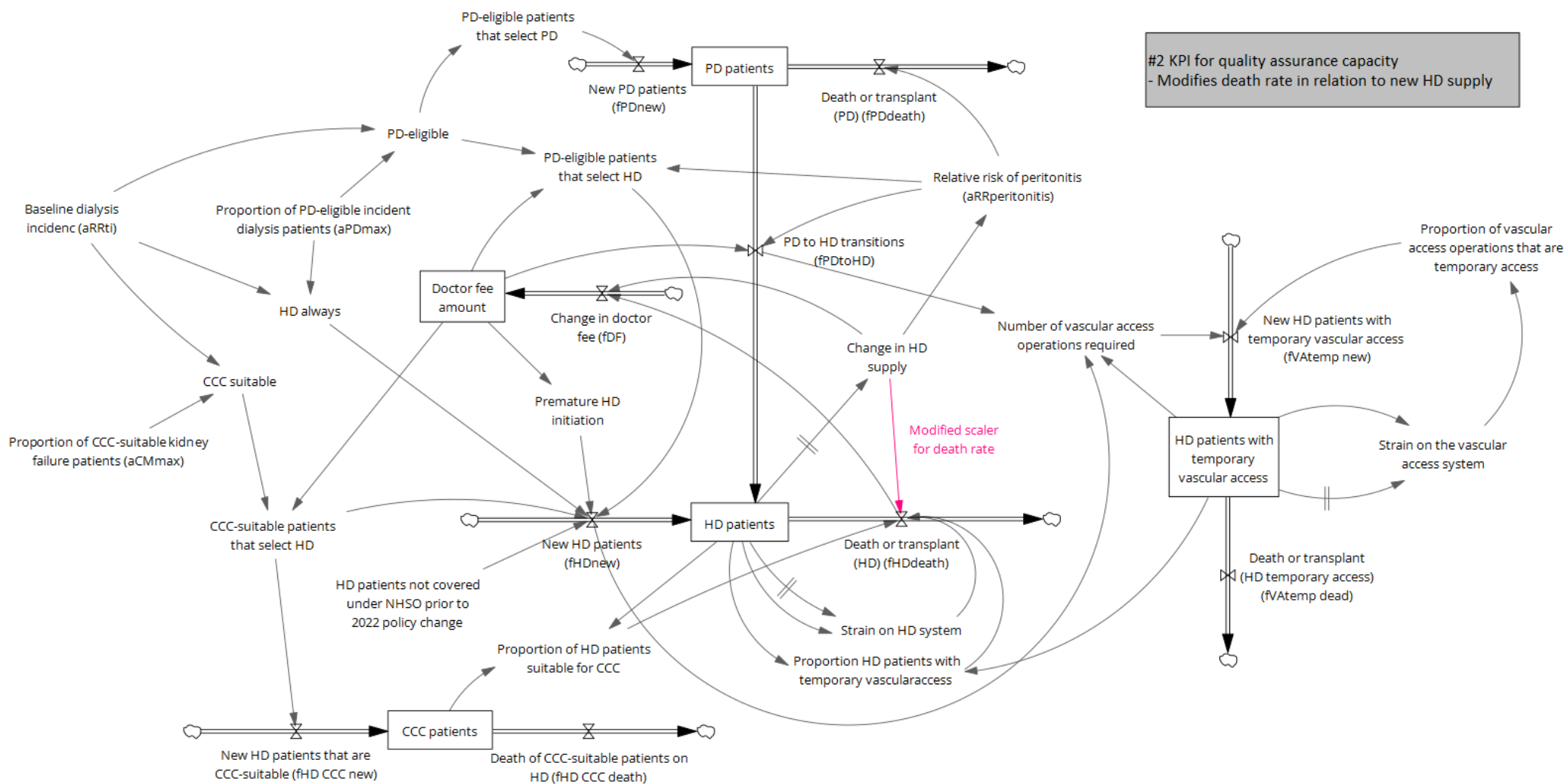
**FigS6.3a** Model diagram for the pre-authorisation policy. Following policy implementation, the light grey lines represent parts of the model structure that are switched off and the pink lines those that are switched on.



**CCC** – comprehensive conservative care; **HD** – haemodialysis; **PD** – peritoneal dialysis; **NHSO** – National Health Security Office (NHSO) Board

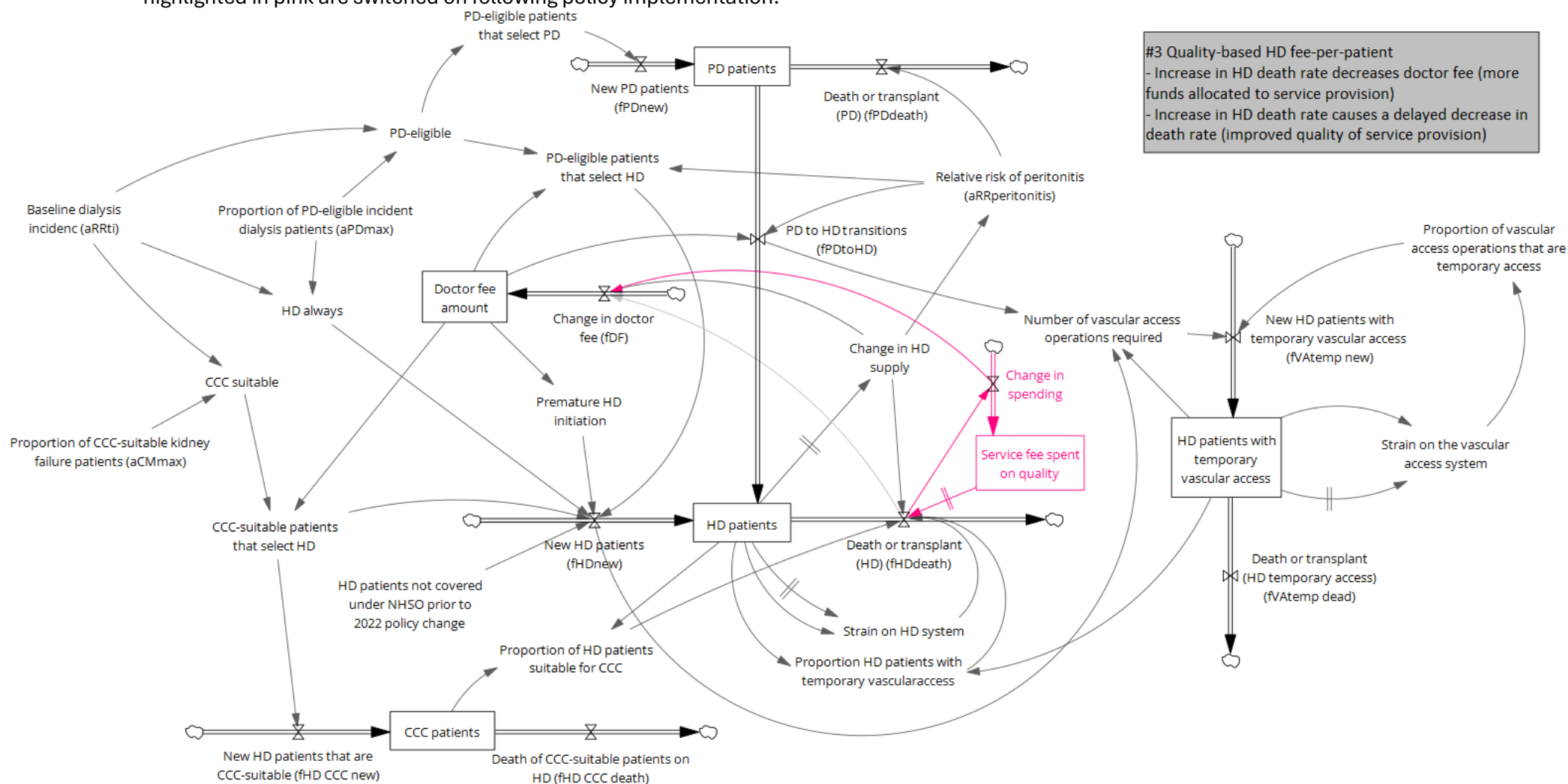
**FigS6.3b** Model diagram for a key performance indicator (KPI) to ensure adequate quality assurance capacity to open new centres.

Following policy implementation, the pink lines are switched on.



**CCC** – comprehensive conservative care; **HD** – haemodialysis; **PD** – peritoneal dialysis; **NHSO** – National Health Security Office (NHSO) Board

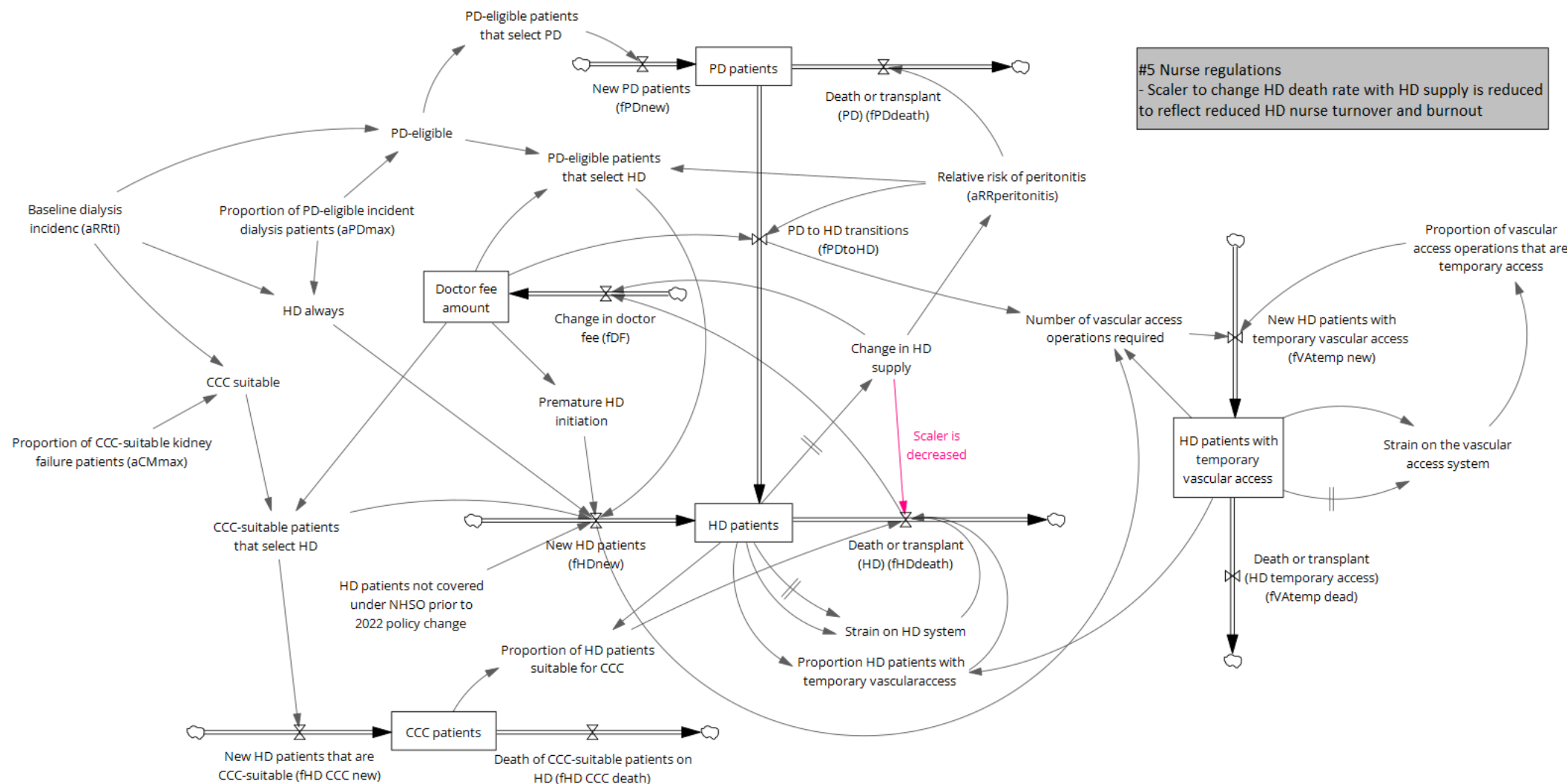
**FigS6.3c** Model diagram for changing service provider payments from fee-for-service to quality-based fee-per-patient. The structures highlighted in pink are switched on following policy implementation.



**CCC** – comprehensive conservative care; **HD** – haemodialysis; **PD** – peritoneal dialysis; **NHSO** – National Health Security Office (NHSO) Board

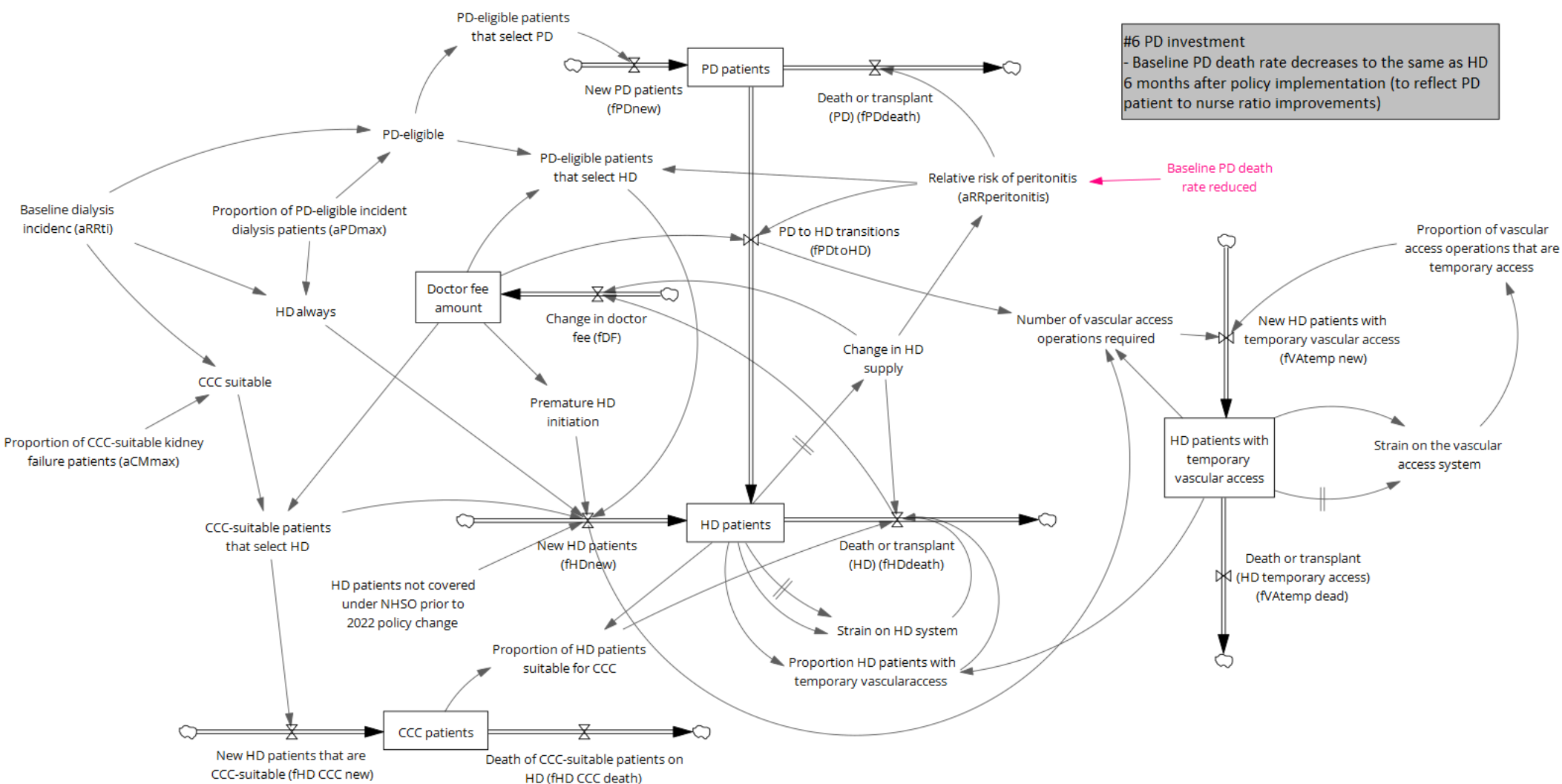


**FigS6.3d** Model diagram for regulations around HD nurse shifts. The pink line is modified after policy implementation.



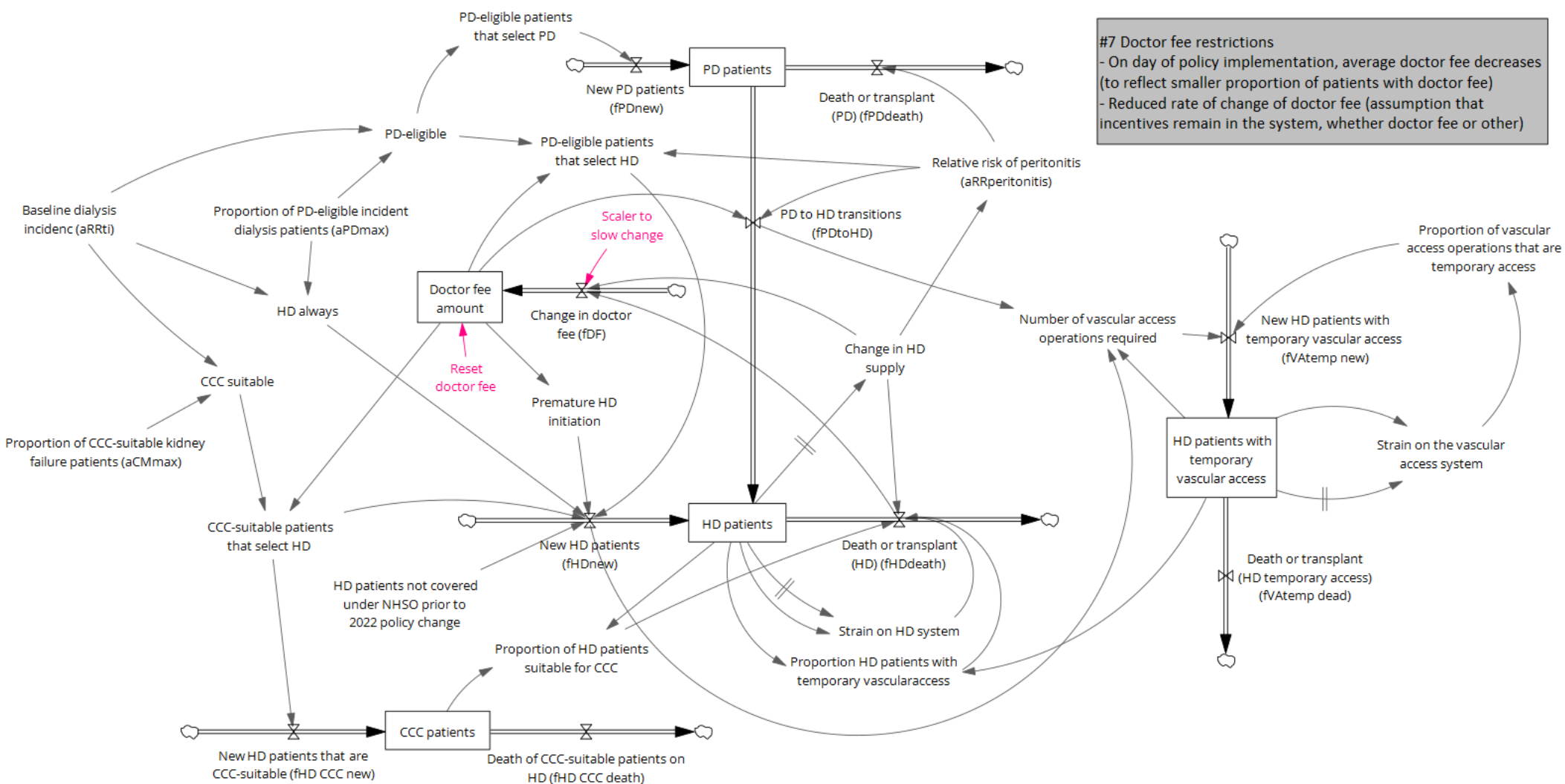
**CCC** – comprehensive conservative care; **HD** – haemodialysis; **PD** – peritoneal dialysis; **NHSO** – National Health Security Office (NHSO) Board

**FigS6.3e** Model diagram for PD demand forecasting to determine investment in capacity. Pink text represents changes to the model following policy implementation.



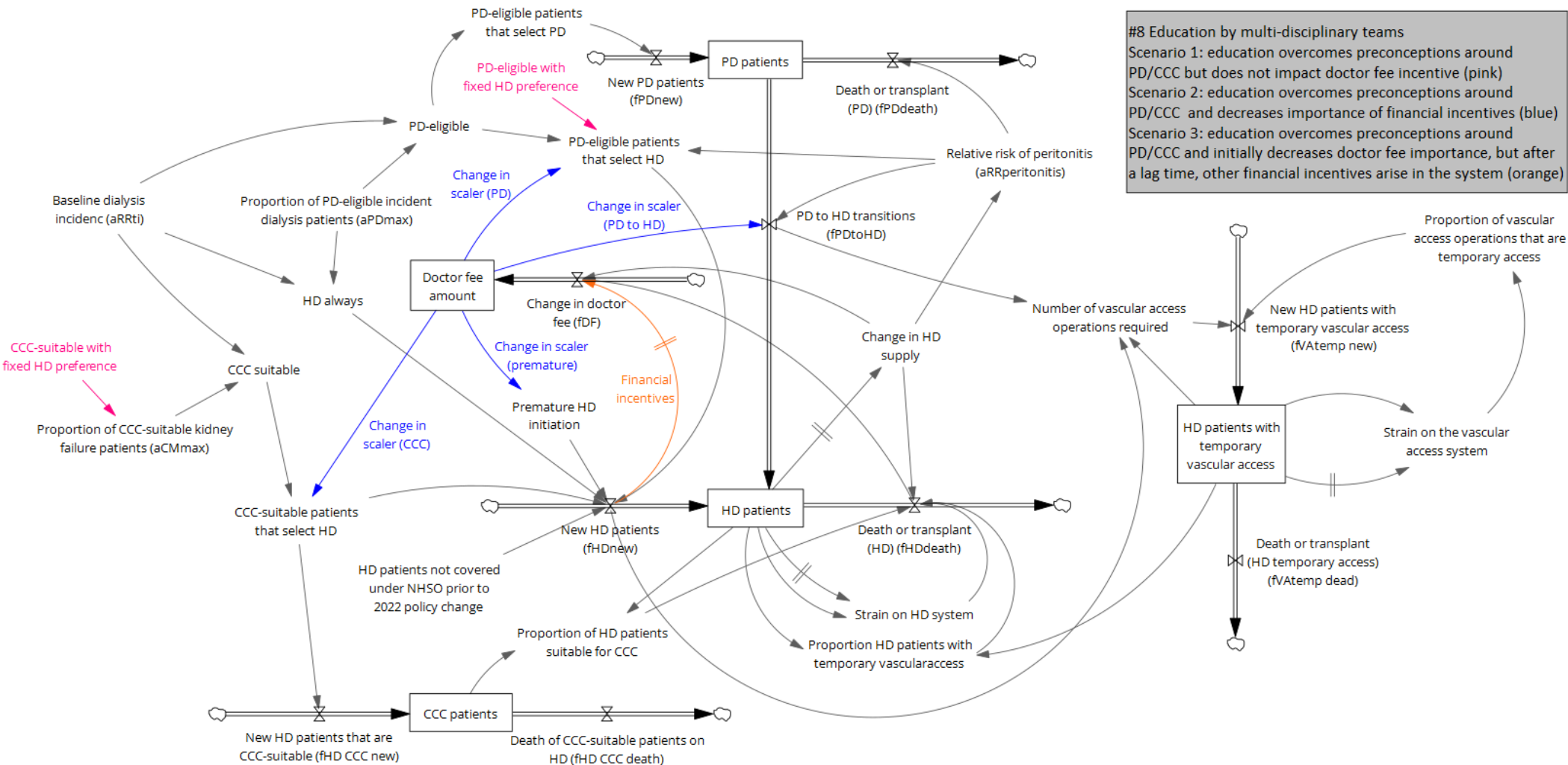
**CCC** – comprehensive conservative care; **HD** – haemodialysis; **PD** – peritoneal dialysis; **NHSO** – National Health Security Office (NHSO) Board

**FigS6.3f** Model diagram for a policy to restrict payment of the doctor fee. Parts in pink are switched on following policy change.



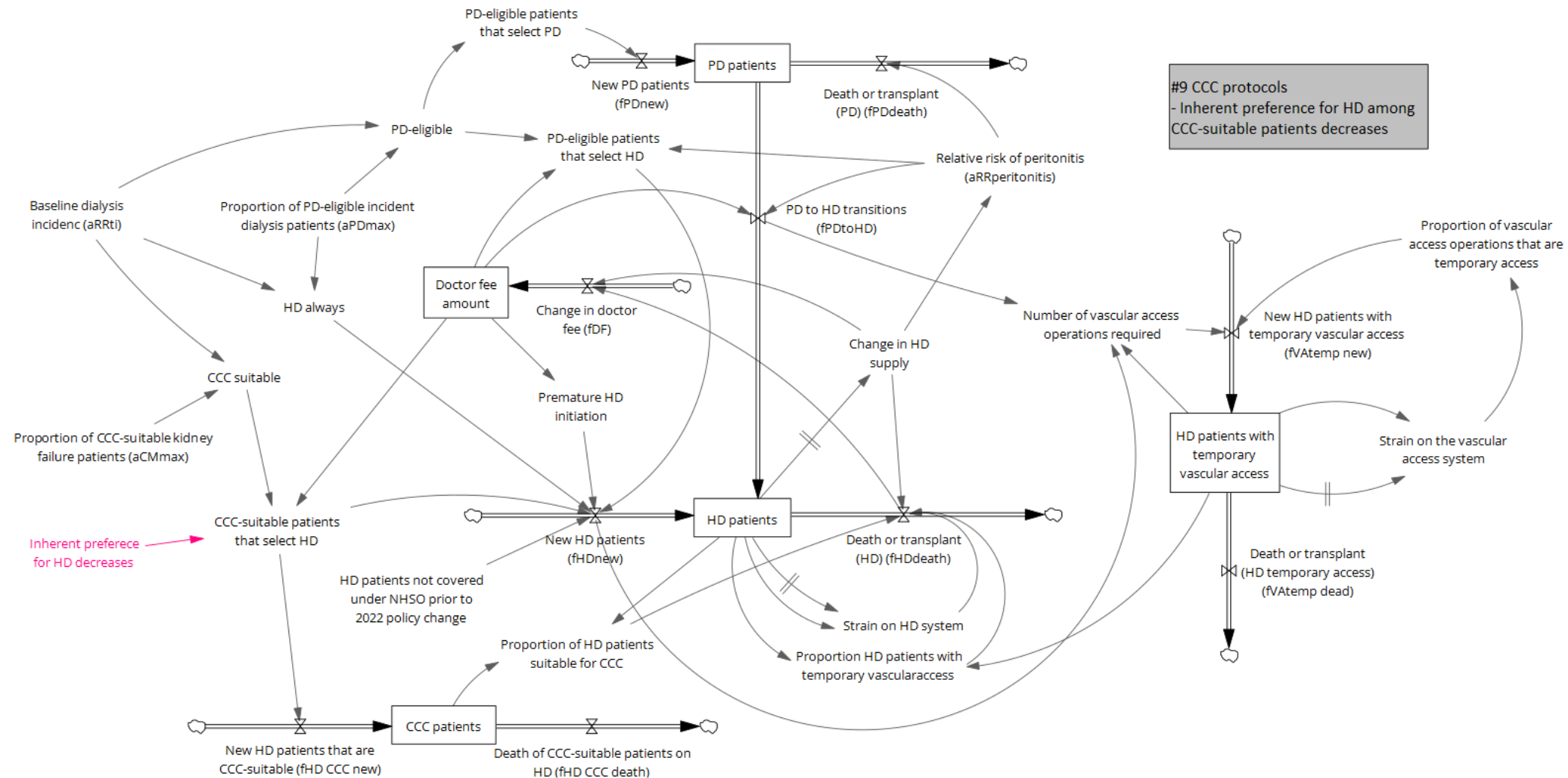
**CCC** – comprehensive conservative care; **HD** – haemodialysis; **PD** – peritoneal dialysis; **NHSO** – National Health Security Office (NHSO) Board

**FigS6.3g** Model diagram for patient education by a multi-disciplinary team. Parts of the model in pink are changed following implementation of the base policy, the parts in blue and orange are changed in sensitivity analysis (see grey box for details).



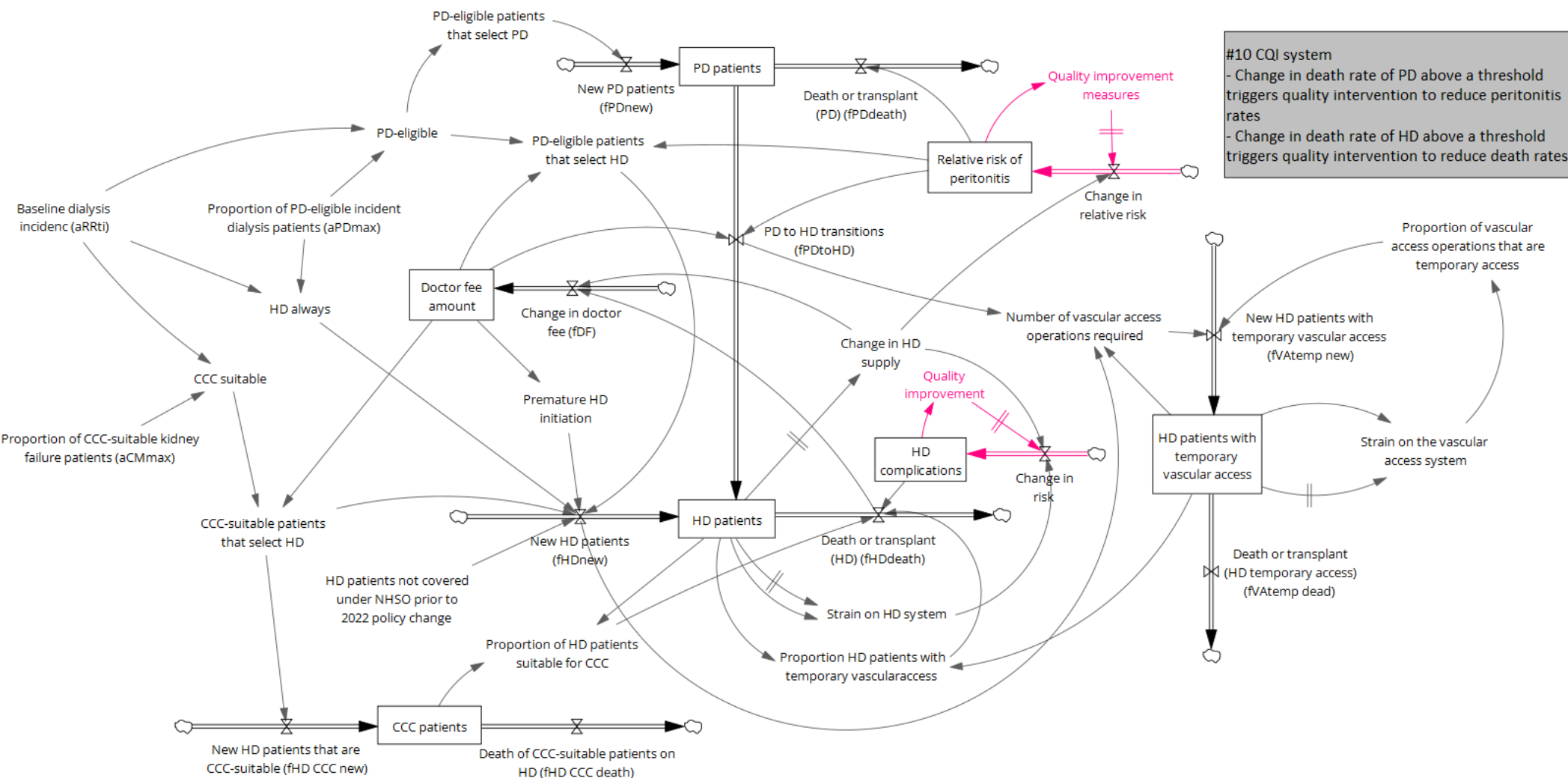
**CCC** – comprehensive conservative care; **HD** – haemodialysis; **PD** – peritoneal dialysis; **NHSO** – National Health Security Office (NHSO) Board

**FigS6.3h** Model diagram for comprehensive conservative care (CCC) protocols. Changes to the base model structure following policy implementation are highlighted in pink.



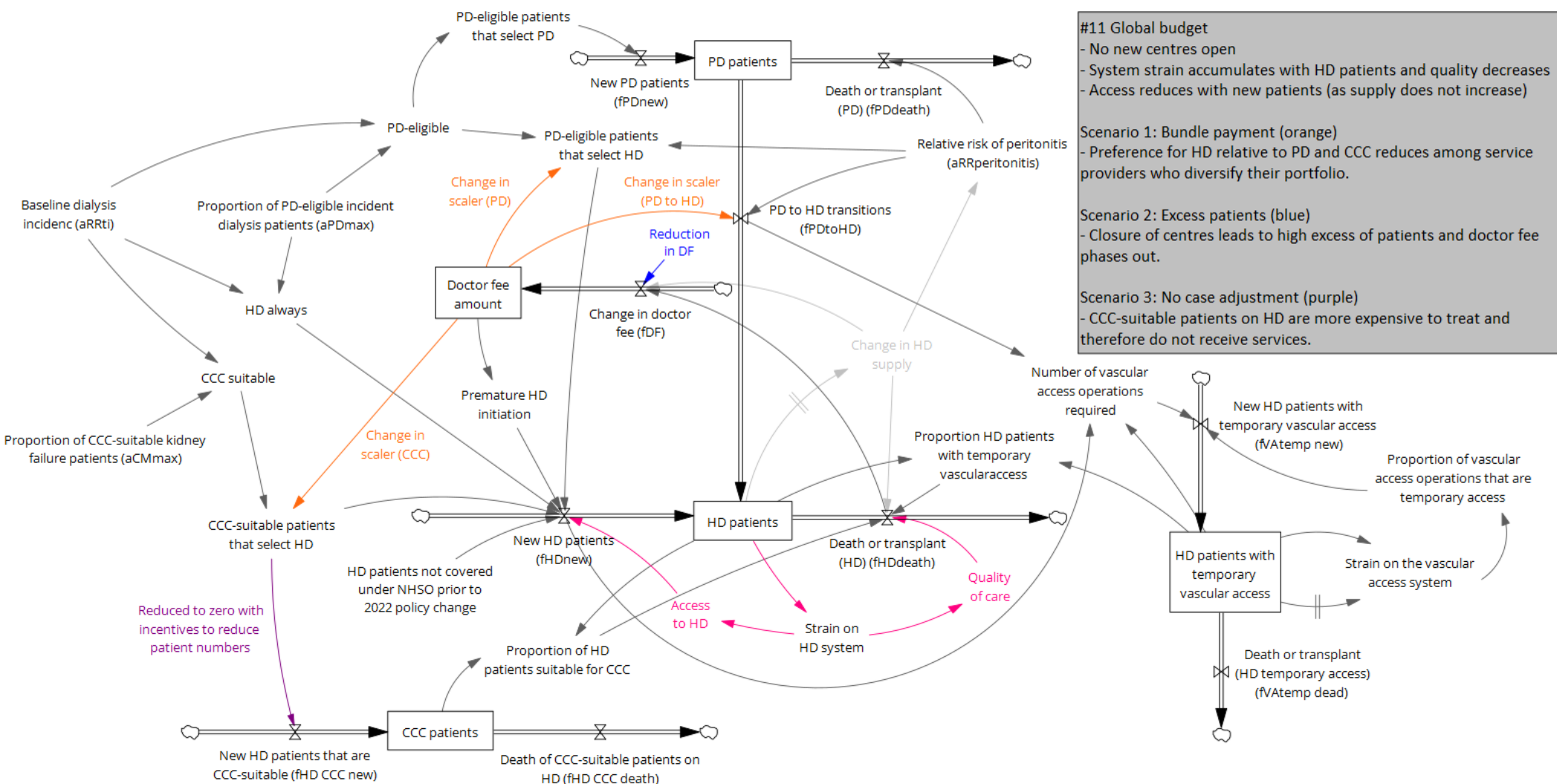
**CCC** – comprehensive conservative care; **HD** – haemodialysis; **PD** – peritoneal dialysis; **NHSO** – National Health Security Office (NHSO) Board

**FigS6.3i** Model diagram for a continuous quality improvement (CQI) scheme. Changes to model structure following policy implementation are shown in pink.



**CCC** – comprehensive conservative care; **HD** – haemodialysis; **PD** – peritoneal dialysis; **NHSO** – National Health Security Office (NHSO) Board

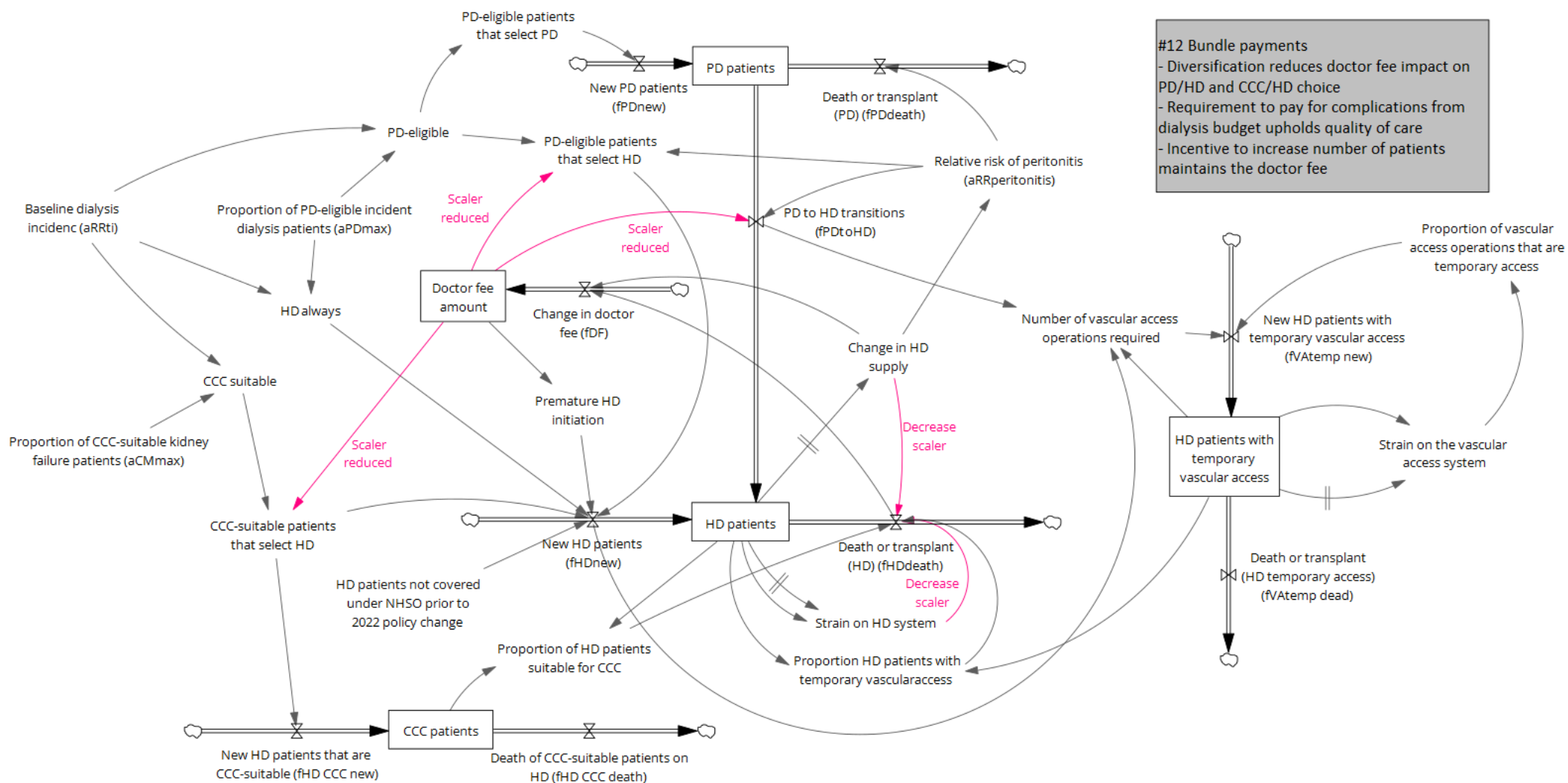
**FigS6.3j** Model diagram for the global budget policy. Following policy implementation, the light grey lines represent parts of the model structure that are switched off, parts of the model that are switched on are shown in pink, and parts in orange, blue, or purple are switched on/off dependent on the scenario (details in the grey box).



**CCC** – comprehensive conservative care; **HD** – haemodialysis; **PD** – peritoneal dialysis; **NHSO** – National Health Security Office (NHSO) Board



**FigS6.3k** Model diagram for bundle payments. Following policy implementation, the scalars associated with the parts of the model highlighted in pink are modified.

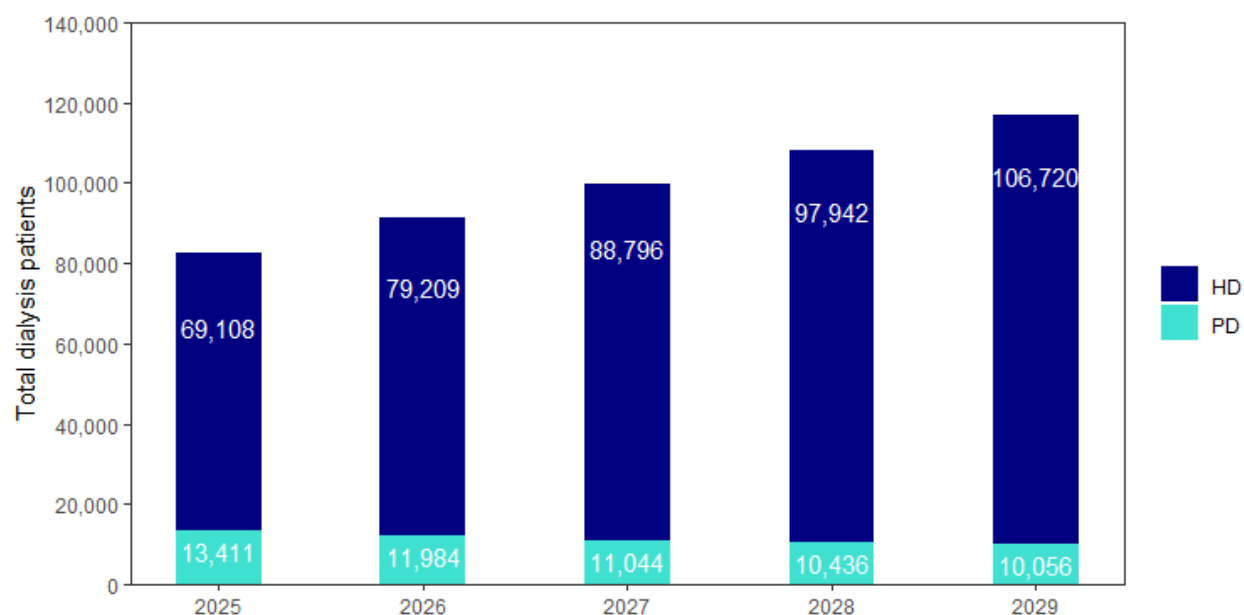


**CCC** – comprehensive conservative care; **HD** – haemodialysis; **PD** – peritoneal dialysis; **NHSO** – National Health Security Office (NHSO) Board



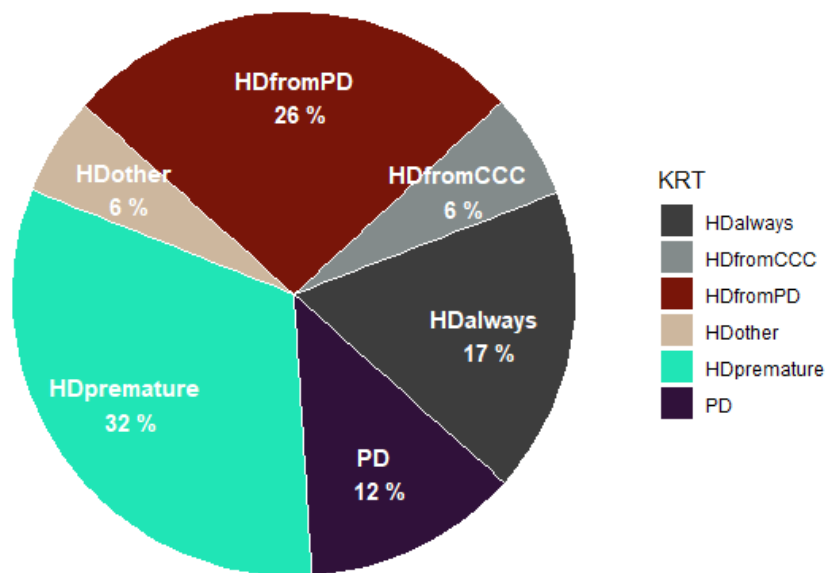
## Supplement 6.4 Base case analysis (2022 policy)

**Figure S6.4a** Base case projection of number of dialysis patients registered under the Universal Coverage Scheme (UCS) per year, from 2025-2029, showing a decreasing proportion of patients on peritoneal dialysis (PD) and an increasing proportion of patients on haemodialysis (HD) over time.



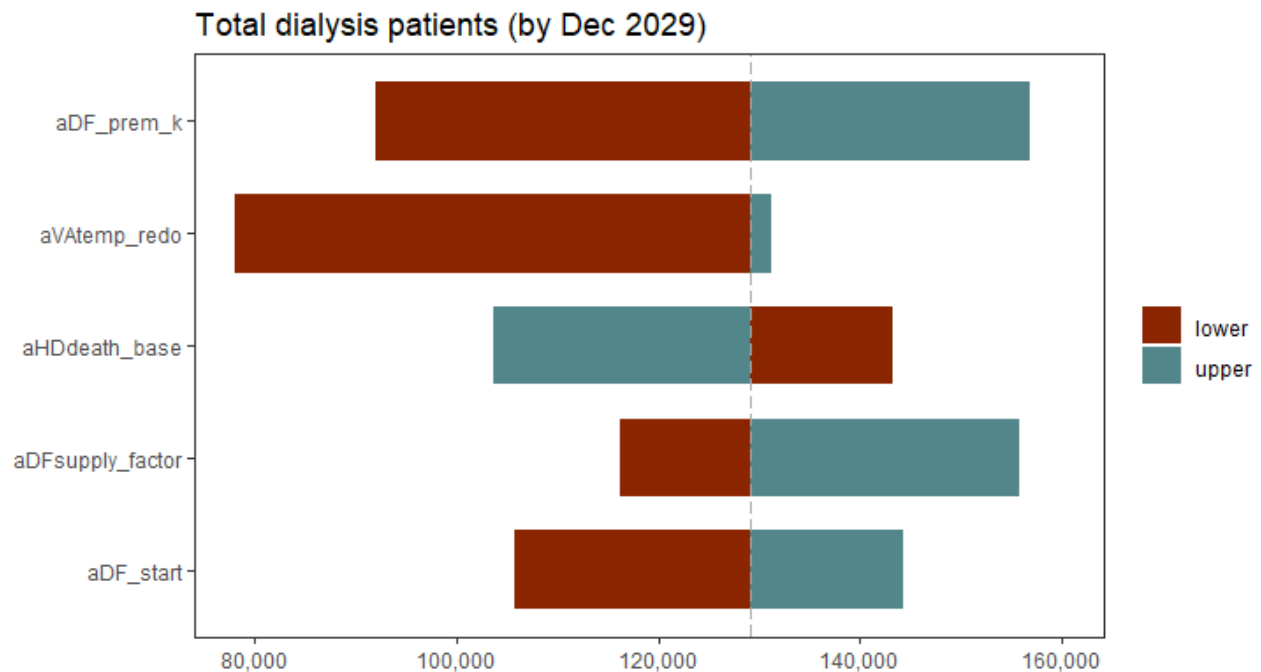
HD – haemodialysis; PD – peritoneal dialysis

**Figure S6.4b** Profile of new dialysis patients under the base case scenario, from 2025-2029.



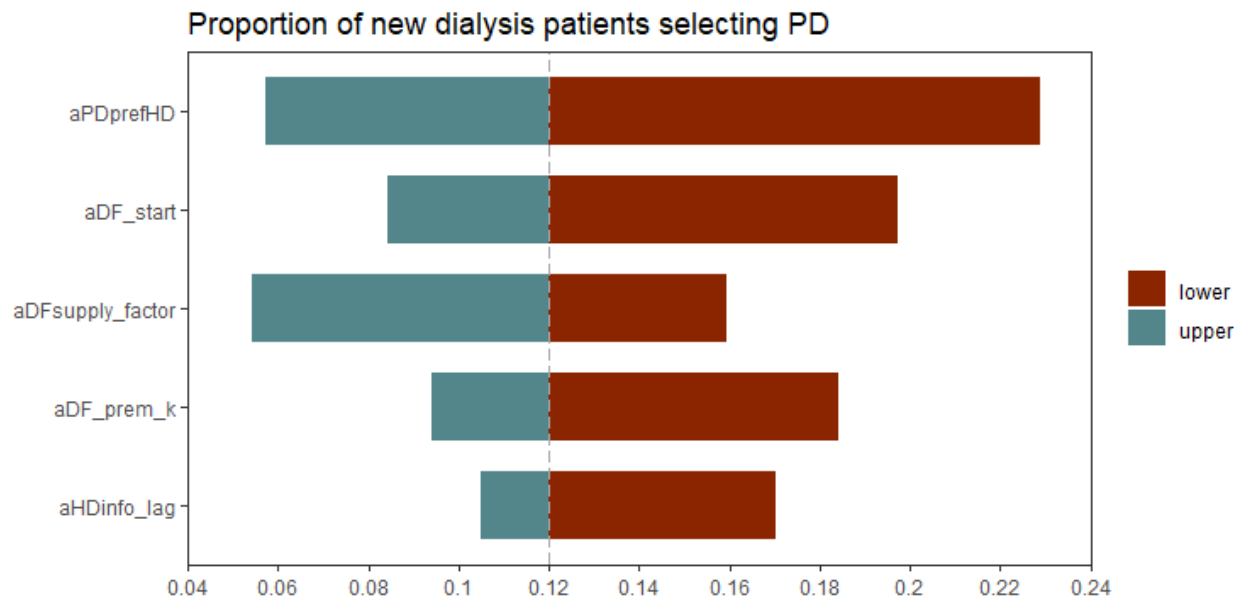
**HDalways** – haemodialysis (HD) patients that are best suited to HD; **HDfromCCC** – haemodialysis (HD) patients that would be best suited to comprehensive conservative care; **HDfromPD** – haemodialysis (HD) patients that are eligible for peritoneal dialysis (PD); **HDother** – haemodialysis (HD) patients that would not have registered for dialysis services under NHSO prior to the 2022 policy change, either because they preferred to self-pay for HD under the PD-first policy or because they were registered under another health insurance scheme (administered by the Social Security Office, SSO) prior to initiating dialysis; **HD premature** – haemodialysis (HD) patients that have residual kidney function and have initiated HD prematurely; **KRT** – kidney replacement therapy; **PD** – peritoneal dialysis.

**Figure S6.4c** Deterministic sensitivity analysis of parameters in the base case model projection. The chart shows the five parameters with the greatest influence on total dialysis patients. The grey dotted line shows the total dialysis patients at the end of the projection period (December 2029) under the base case. For each of the five parameters listed on the left-hand side, the red bar shows the difference in number of dialysis patients using the parameter lower bound and the blue-grey bar shows the difference using the parameter upper bound.



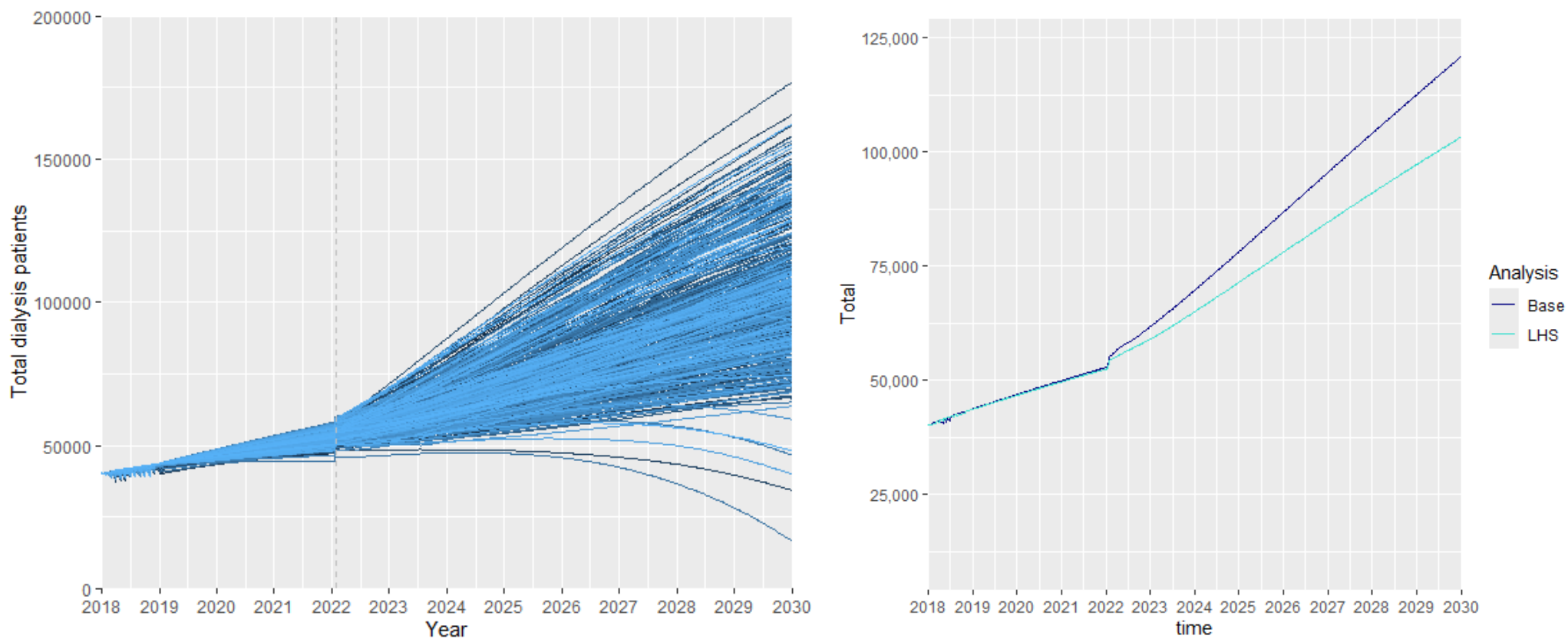
**aDF\_prem\_k** – factor scaling the doctor fee to number of new patients initiating HD prematurely;  
**aVAtemp\_redo** – average length of time before an HD patient with temporary access requires a subsequent vascular access operation; **aHDdeath\_base** – base death rate among HD patients (i.e. with optimal standard of care); **aDFsupply\_factor** – factor scaling the rate of increase in the doctor fee to the rate of change in HD supply; **aDF\_start** – average doctor fee paid by private HD centres to doctors for patient referrals, per patient per session, at the start of model projections (January 2018).

**Figure S6.4d** Deterministic sensitivity analysis of parameters in the base case model projection. The chart shows the five parameters with the greatest influence on proportion of new patients selecting PD. The grey dotted line shows the average proportion of new dialysis patients selecting PD over the projection period (2025-2029) under the base case. For each of the five parameters listed on the left-hand side, the red bar shows the difference using the lower bound and the blue-grey bar shows the difference using the upper bound.

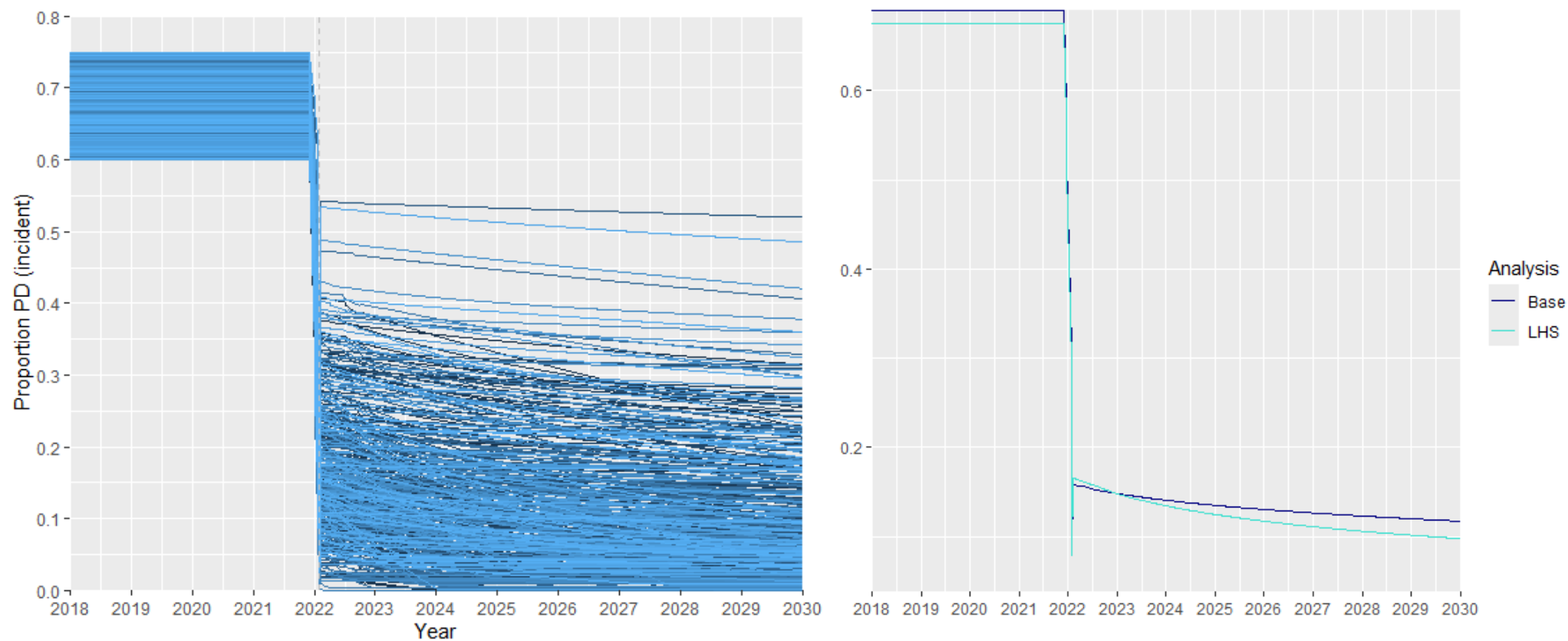


**aPDprefHD** – proportion of PD patients with a preference for HD that is not modified by peritonitis rates or the doctor fee (for example, patient education, healthcare worker training, etc); **aDF\_start** – starting value of the doctor fee in the model (January 2018); **aDFsupply\_factor** – factor scaling the rate of increase in the doctor fee to the rate of change in HD supply; **aDF\_prem\_k** – factor scaling the doctor fee to number of new patients initiating HD prematurely; **aHDinfo\_lag** – reference time point in the past used to make decisions around opening new HD centres (affects HD supply).

**Figure S6.4e** Latin hypercube sampling to show uncertainty across parameter inputs, for total dialysis patients. The top figure shows the results from all runs, whereas the bottom figure shows the average from all runs (green line) plotted against the base case deterministic result (navy line).

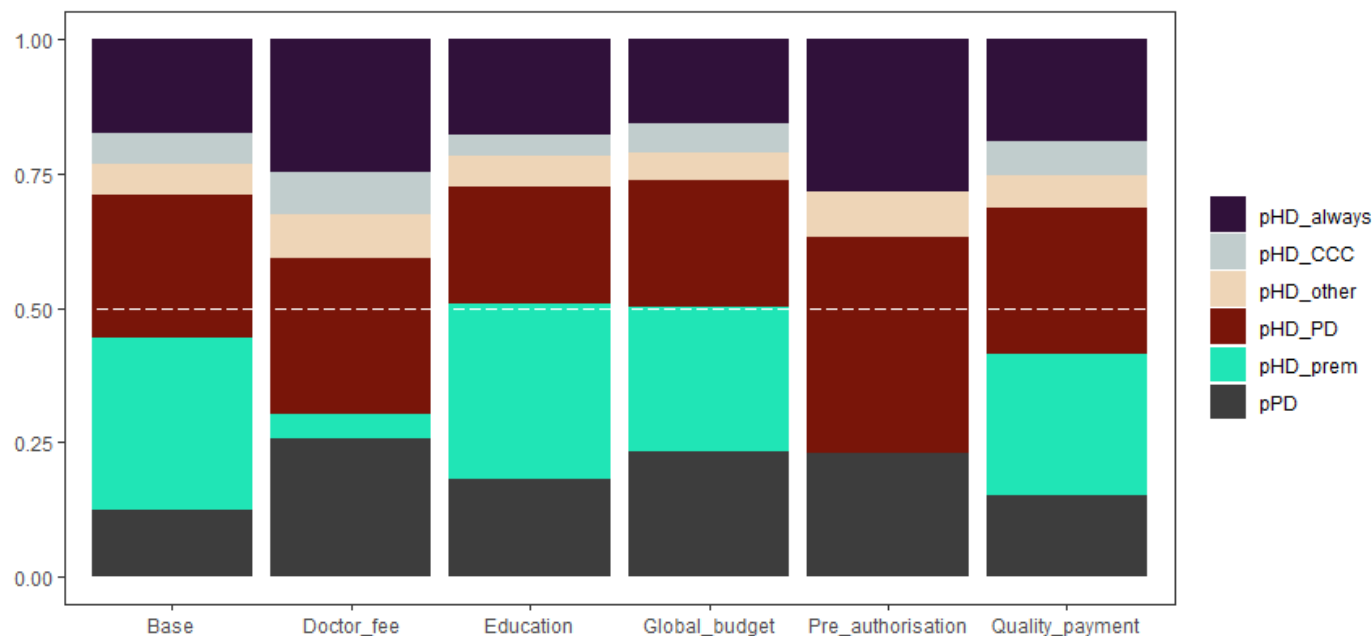


**Figure S6.4f** Latin hypercube sampling to show uncertainty across parameter inputs, for proportion of incident patients initiating dialysis on PD. The top figure shows the results from all runs, whereas the bottom figure shows the average from all runs (green line) plotted against the base case deterministic result (navy line).

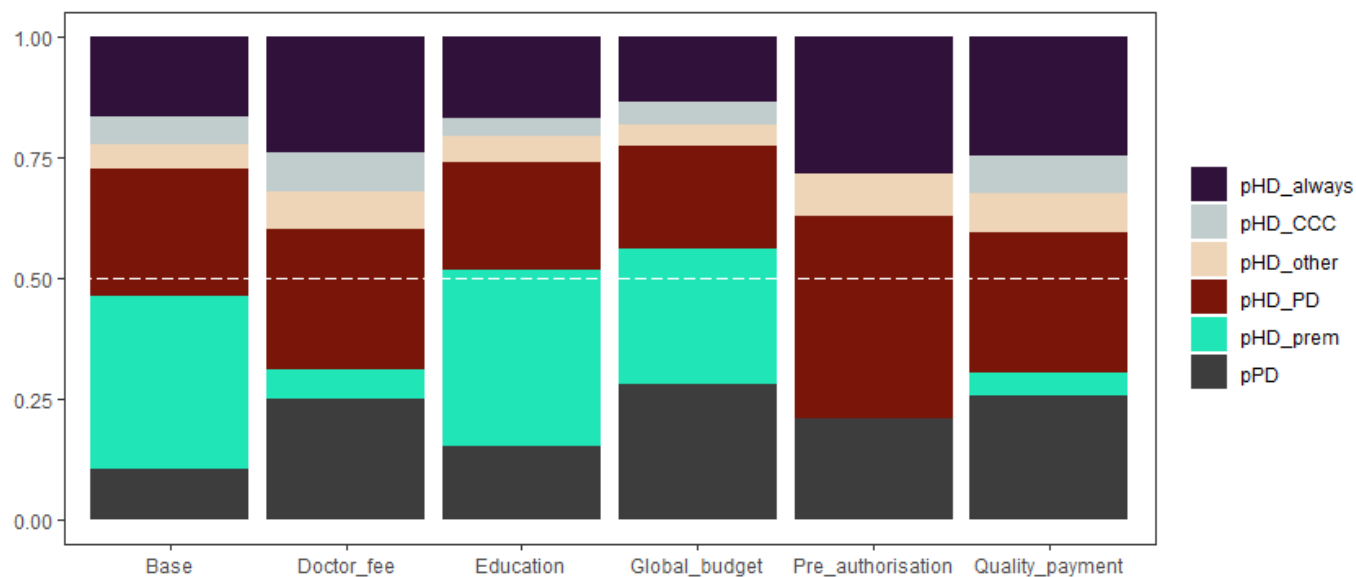


## Supplement 6.5 Policy performance projections

**Figure S6.5a** Profile of new dialysis patients after 3 years of policy implementation (end of 2027).



**Figure S6.5b** Profile of new dialysis patients after 10 years of policy implementation (end of 2034).



**pHD\_always** – patients initiating haemodialysis (HD) who would also have initiated HD under the PD-first policy; **pHD\_CCC** – patients initiating HD who are best suited to CCC (comprehensive conservative care); **pHD\_other** – patients initiating HD who would not have registered under UCS (universal coverage scheme)

under the PD-first policy; **pHD\_PD** – patients initiating HD who are PD-eligible; **pHD\_prem** – patients initiating HD prematurely; **pPD** – patients initiating peritoneal dialysis (PD)

**Table S6.5a** Summary of proportion of dialysis patients initiating dialysis on PD (pPD) by end of 2027, total dialysis patients by end of 2029, and death rate of dialysis patients by end of 2029 across the base case and each policy option.

Policy	Proportion new dialysis on PD (end 2027)	Total dialysis cases (end 2029)	Excess death rate above base line (end 2029)
<b>Base case (2022 policy)</b>	<b>0.12</b>	<b>121,000</b>	<b>0.0037</b>
Single policy options			
Doctor fee regulation	0.26	96,000	0.0034
Education	0.18	119,000	0.0035
Global budget	0.23	106,000	0.0063
Pre-authorisation	0.23	90,000	0.0028
Quality payment	0.15	118,000	0.0026
Combining two policy options (combinations with highest impact on PD)			
Doctor fee + education	0.40	94,000	0.0031
Doctor fee + pre-authorisation	0.31	89,000	0.0028
Education + pre-authorisation	0.31	89,000	0.0028
Combining multiple policy options (combinations with highest impact on PD)			
Doctor fee + education + pre-authorisation	0.44	89,000	0.0027
Doctor fee + education + pre-authorisation + quality-based payment	0.45	90,000	0.0025
All options	0.45	90,000	0.0025



**Table S6.5b** Analysis of structural uncertainty. In structure 1, a higher proportion of new HD patients are premature initiation; under structure 2, the lower limit for premature HD initiation is used; under structure 3, actual peritonitis rates have no influence on PD-eligible patient choice (details in Table S6.2d).

Policy	Proportion of new dialysis on PD (end of 2027)			
	Base structure	Structure 1	Structure 2	Structure 3
Base case	0.123	0.117	0.126	0.120
Doctor fee	<b>0.259</b>	<b>0.274</b>	<b>0.241</b>	<b>0.264</b>
Education	0.181	0.171	0.185	0.175
Global budget	0.233	0.233	0.231	0.231
Pre-authorisation	0.231	0.238	0.218	0.226
Quality payment	0.151	0.147	0.151	0.149

**Table S6.5c** Deterministic sensitivity analysis results for which proportion of incident dialysis patients selecting HD was greater than 30%.

Policy	Parameter	Value	Proportion incident dialysis on PD
Pre-authorisation	HD preference among PD-eligible patients that is not modified by peritonitis risk or the doctor fee	0	0.40
Doctor fee	HD preference among PD-eligible patients that is not modified by peritonitis risk or the doctor fee	0	0.52
Education	Starting value of the average doctor fee per patient per session in the model	10	0.31

**Table S6.5d** Time-dependent outcomes for combining the policies: doctor fee regulation, education, pre-authorisation, and quality-based payment.

Time	Proportion of new dialysis on PD	Total dialysis patients	Death rate of HD patients (% per month)
<b>Dec 2027</b> (3 years)	0.45	85,000	0.013
<b>Jan 2030</b> (5 years)	0.45	89,000	0.012
<b>Jan 2035</b> (10 years)	0.46	102,000	0.012

**Table S6.5e** Performance of the combination of doctor fee regulation, education, pre-authorisation, and quality-based payments under different mode structures and parameter values.

One-way parameter sensitivity analysis		Proportion of new dialysis on PD (end of 2027)			
		Base structure	Structure 1	Structure 2	Structure 3
No change		0.45	0.48	0.42	0.46
HD preference among PD-eligible	Low	0.59	0.64	0.55	0.61
	<b>High</b>	<b>0.37</b>	<b>0.39</b>	<b>0.34</b>	<b>0.38</b>
Doctor fee starting value	Low	0.46	0.49	0.43	0.47
	High	0.45	0.48	0.41	0.46
Influence of doctor fee on premature HD	Low	0.46	0.48	0.42	0.47
	High	0.45	0.48	0.42	0.46
Doctor fee scaling to supply change	Low	0.45	0.48	0.42	0.47
	High	0.44	0.48	0.41	0.45

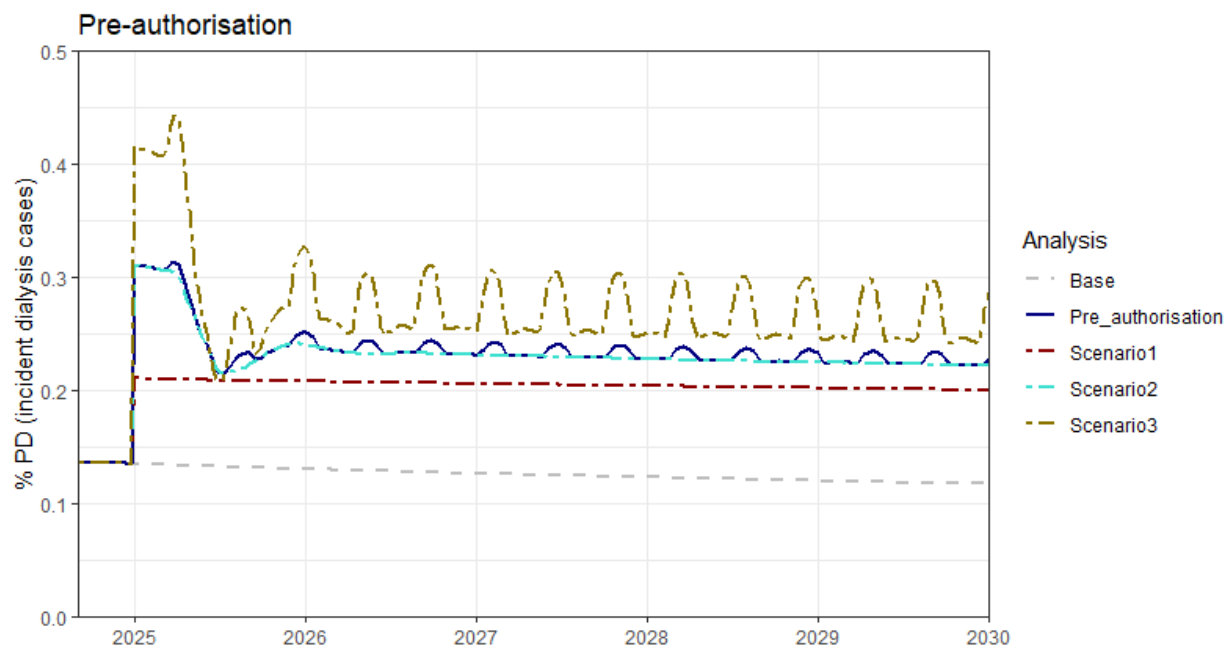
## Supplement 6.6 Scenario analysis of policy options

### PRE-AUTHORISATION POLICY

The projected impact of the pre-authorisation policy assumes that no CCC-suitable patients will initiate dialysis and that there will be no premature initiation of dialysis. Additionally, the proportion of PD-eligible and HD other patients that select HD is moderated by level of strain on haemodialysis (HD) and vascular access services.

Under **scenario 1** we consider the impact if the provincial committees did not account for supply and instead only considered patient profile in their approval of dialysis initiation. Under **scenario 2**, the model only incorporates HD supply constraints and not constraints in vascular access supply. **Scenario 3** considers the impact if the provincial committees are very conservative in their estimates of available supply.

**Figure S6.6a** Scenario analysis for the pre-authorisation policy, showing the projected proportion of incident dialysis patients selecting peritoneal dialysis (PD) under different scenarios.

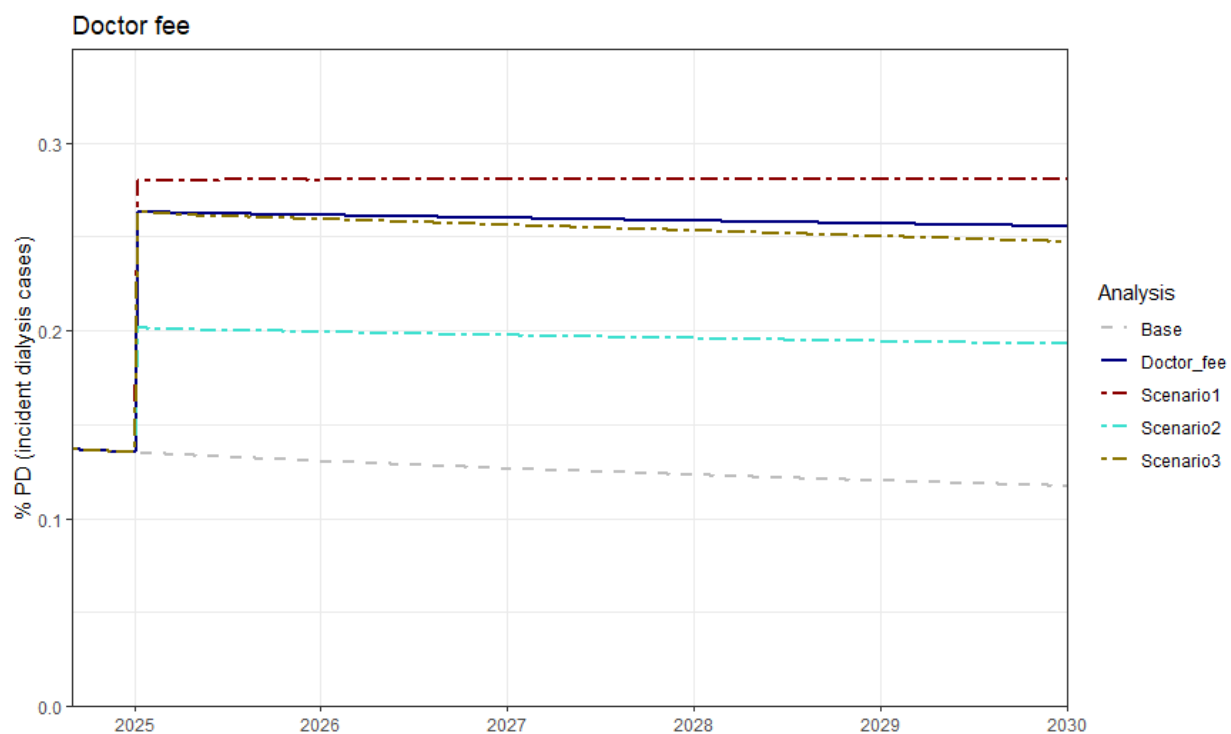


## DOCTOR FEE POLICY

The projected impact of the doctor fee policy assumes that the average doctor fee per patient per session will decrease immediately following the policy change, as each doctor can receive the doctor fee for fewer patients. It also assumes a slower rate of increase of the doctor fee, since there is a constraint in number of patients per nephrologist.

**Scenario 1** considers a scenario in which restrictions on the doctor fee reduce it to 0.1% of its prior amount and prevent further increases in financial incentives for healthcare staff to recommend haemodialysis (HD) to patients. **Scenario 2** considers the impact if the average value of the doctor fee only decreases to 50% of its pre-policy value (in this scenario the doctor fee may be considered in a broader sense to incorporate the impact of speaker and consultation fees to nephrologists, which has also been correlated with pharmaceutical prescribing in the US [361]). **Scenario 3** explores the impact if there is no change in the scaler determining rate of change of the doctor fee, meaning that the doctor fee continues to increase at the same rate as the base case.

**Figure S6.6b** Scenario analysis for the doctor fee policy, showing the projected proportion of incident dialysis patients selecting peritoneal dialysis (PD) under different scenarios.

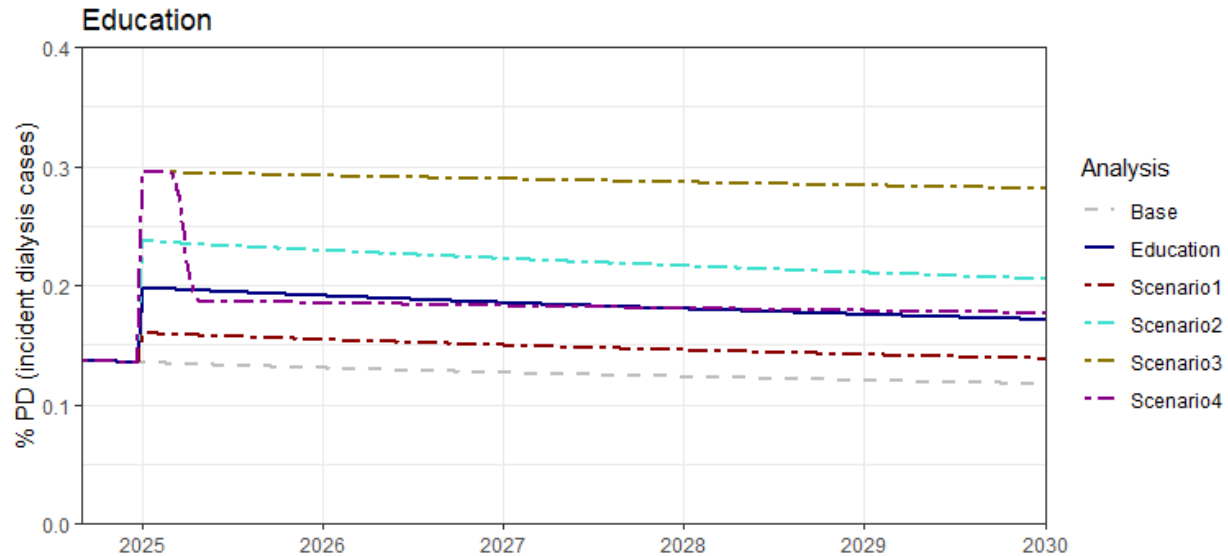


## EDUCATION POLICY

The projected impact of the education policy assumes that it will reduce by 50% the number of PD-eligible and CCC-suitable patients who will always have a preference for HD (i.e. even with low rates of peritonitis and no doctor fee).

**Scenarios 1 and 2** show the impact with lower or higher effectiveness in influencing patient preference towards a more suitable dialysis option, respectively. Under **scenario 3**, education by a multi-disciplinary team is also modelled to reduce the impact of the doctor fee on patient decisions, as other healthcare professionals aside from the nephrologist are involved in decision-making, thereby addressing the information asymmetry between private providers and consumers [129]. **Scenario 4** considers what would happen if, in response to scenario 1, private service providers develop incentives for other healthcare professionals to recommend HD.

**Figure S6.6c** Scenario analysis for the education policy, showing the projected proportion of incident dialysis patients selecting peritoneal dialysis (PD) under different scenarios.



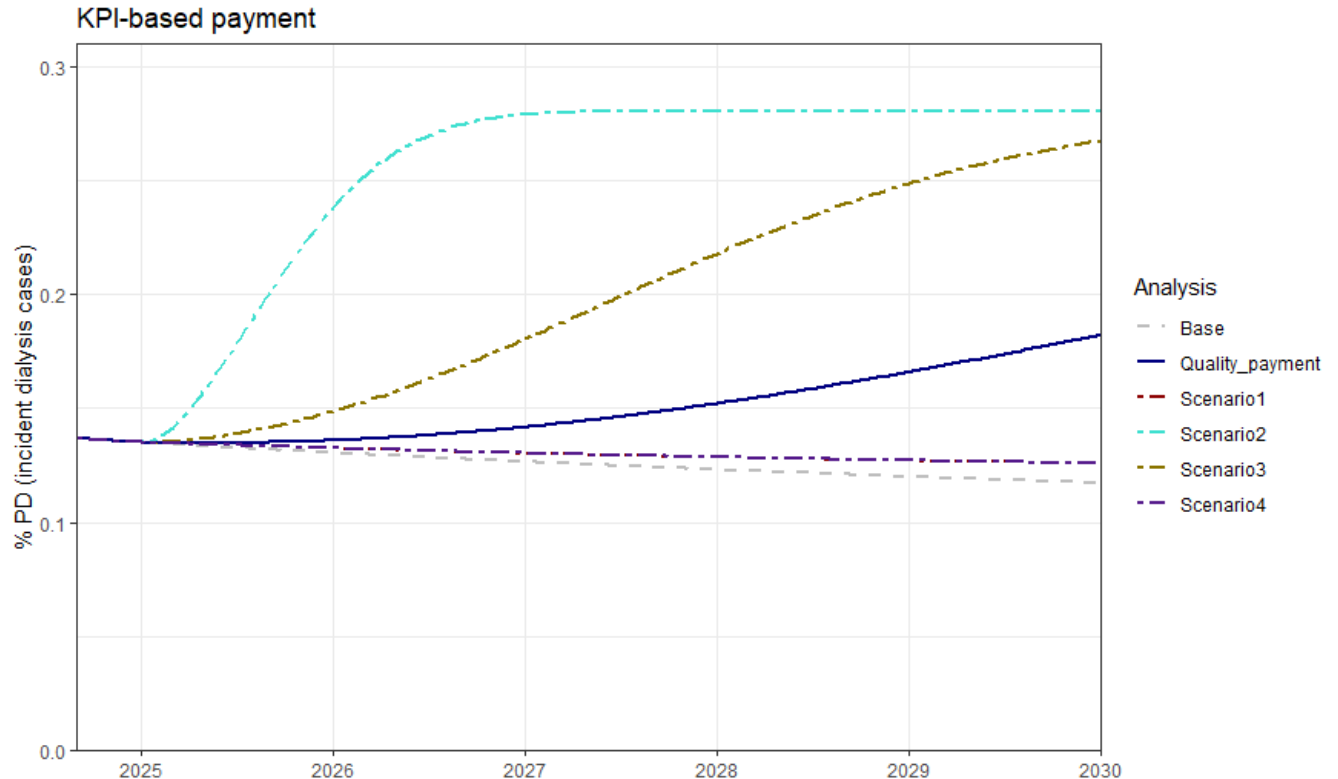
## QUALITY-BASED PAYMENT POLICY

Under the quality-based payment policy, the projection assumes that increases in death rate above baseline lead to an improvement in quality of services (which is measured as a stock, or accumulation), which in turn reduces average amount of the doctor fee (as more money is spent on service provision).

Under **scenario 1**, we consider the impact if the policy has no effect on the average doctor fee.

**Scenario 2** shows a scenario with greater impact on both reduction in excess death rates and impact on the doctor fee, whereas **scenario 3** models a greater impact in reducing death rates but a lower impact on the doctor fee. **Scenario 4** considers a scenario in which pay-for-performance targets are not adjusted by case mix, leading to private centres improving outcomes through cherry picking patients [333], with patients with many co-morbidities referred to public hospitals.

**Figure S6.6d** Scenario analysis for the quality-based payment policy, showing the projected proportion of incident dialysis patients selecting peritoneal dialysis (PD) under different scenarios.

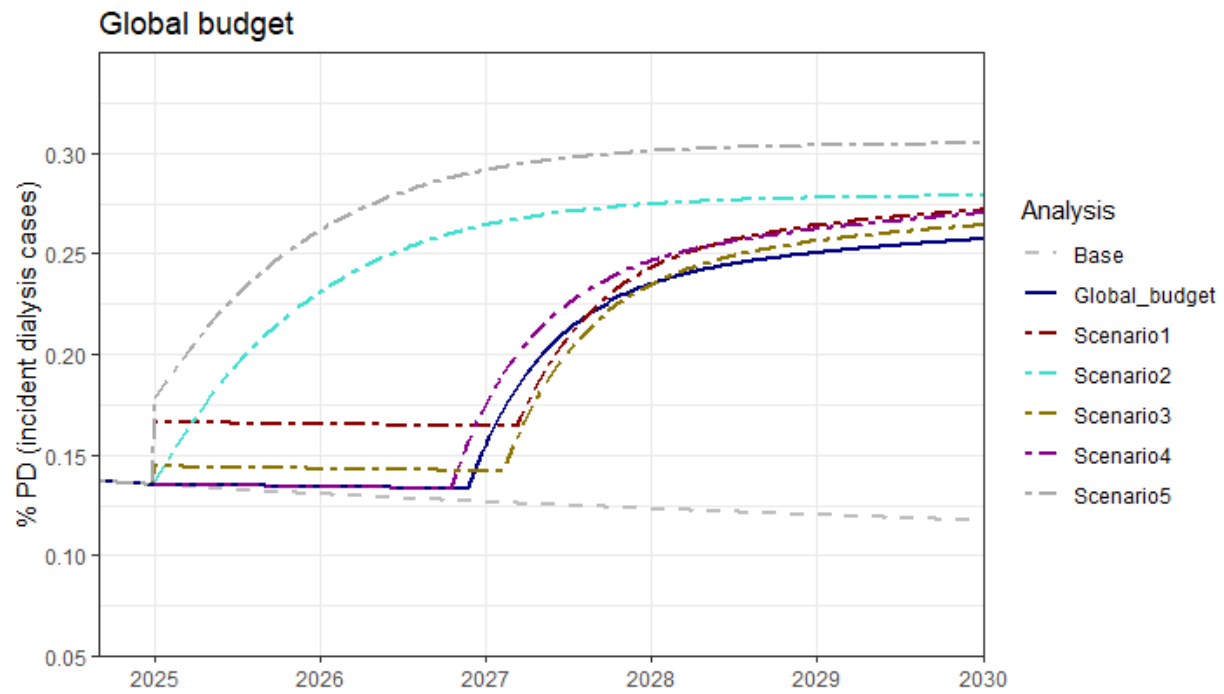


## GLOBAL BUDGET POLICY

The global budget policy is modelled to affect HD supply and quality of care, as has been documented in the literature [331, 332]. stop increases in HD supply (due to the poor business case) and strain on the HD system is therefore modelled in terms of absolute difference in number of patients relative to system capacity, with an assumption that 75% capacity would be filled at the time of policy implementation and no centres would close. Increased strain on the system decreases quality of care, as before, but also affects access to HD, as supply is modelled not to increase with number of patients.

**Scenario 1** explores the impact if global budget were coupled with bundle payments that make PD and CCC just as profitable as HD. **Scenario 2** considers a scenario in which the excess of HD patients relative to supply leads to a reduction in payment of the doctor fee over time. **Scenario 3** explores the effect if the global budget does not include case adjustment (and therefore it is not favourable for providers to enrol HD patients with a short life expectancy [331], such as CCC-suitable). **Scenario 4** assumes that HD centres close following the policy change or that providers restrict their services to self-pay patients or those from other health insurance schemes [332, 432]. **Scenario 5** shows the cumulative effects of scenarios 1-3.

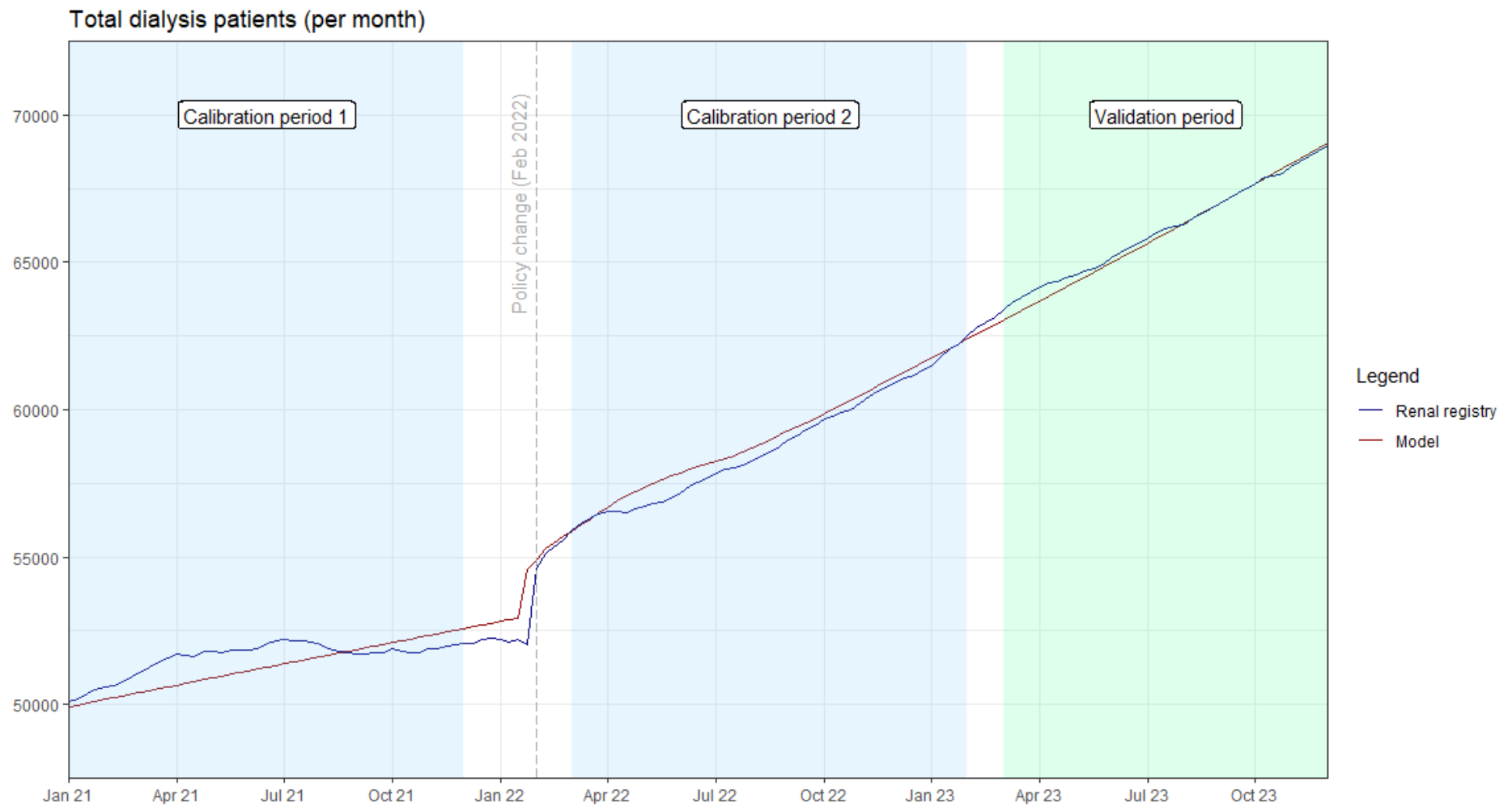
**Figure S6.6e** Scenario analysis for the global budget policy, showing the projected proportion of incident dialysis patients selecting peritoneal dialysis (PD) under different scenarios.



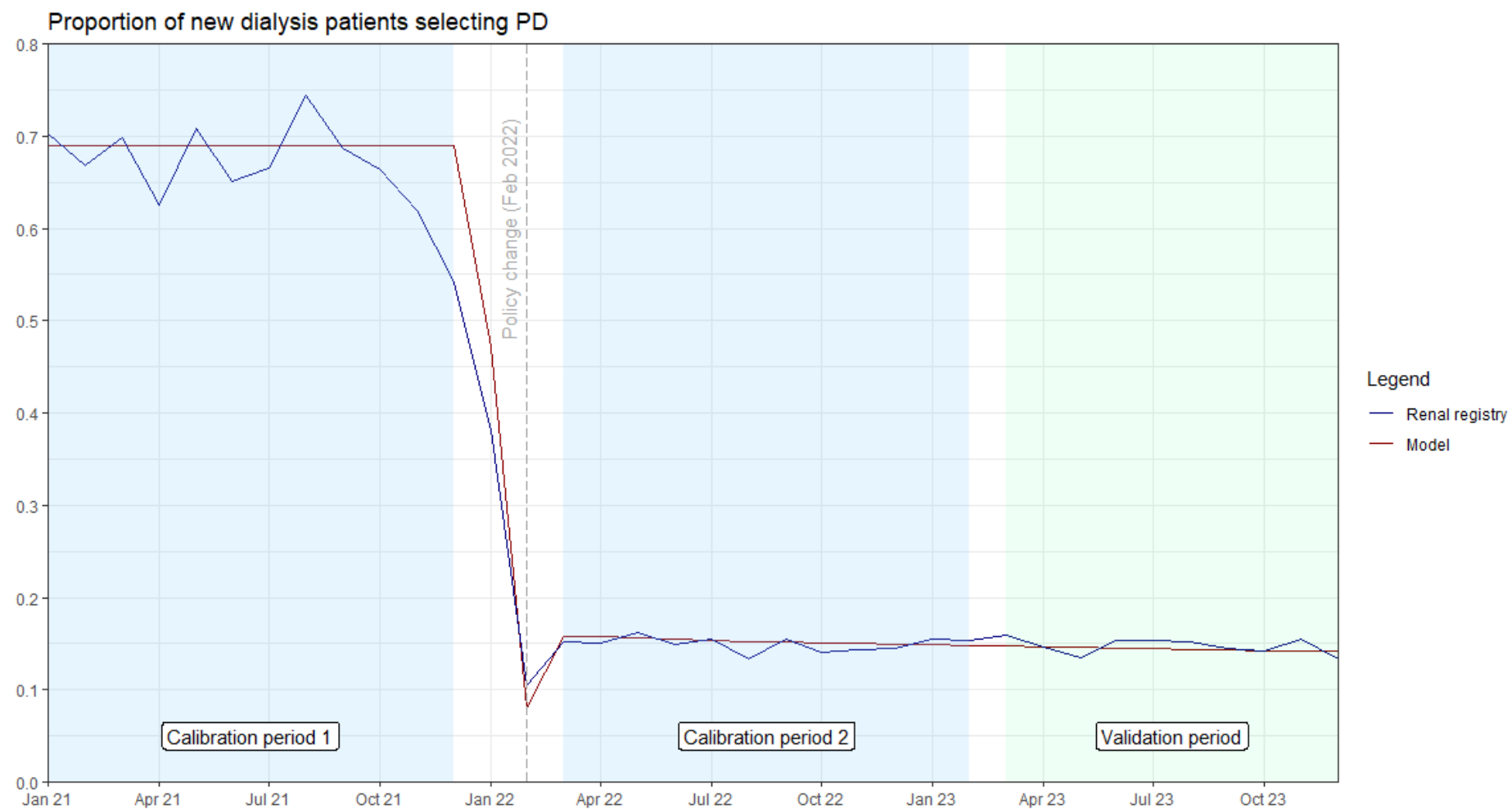


## Supplement 6.7 Model validation (system dynamics)

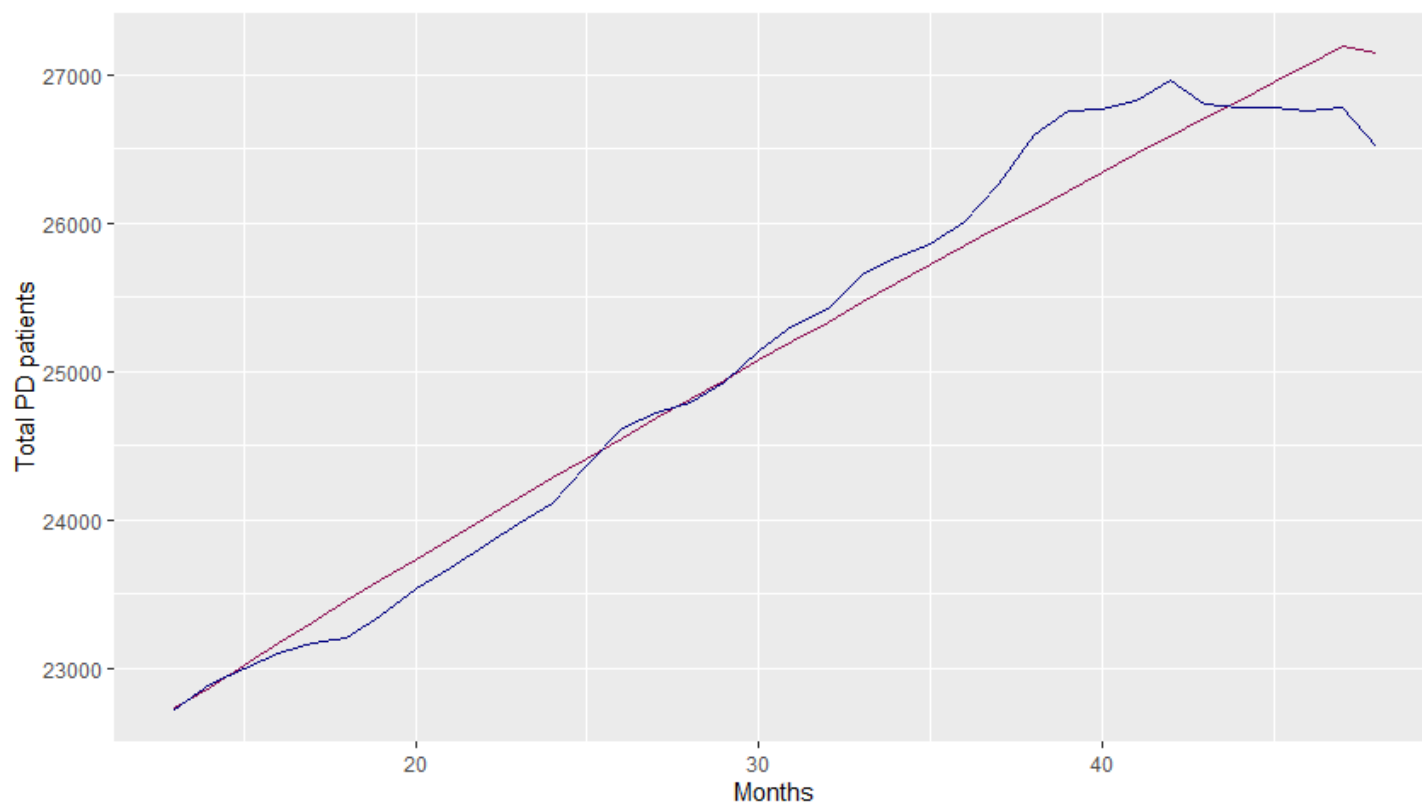
**Figure S6.7a** Validation of model behaviour against renal registry data for total dialysis patients.



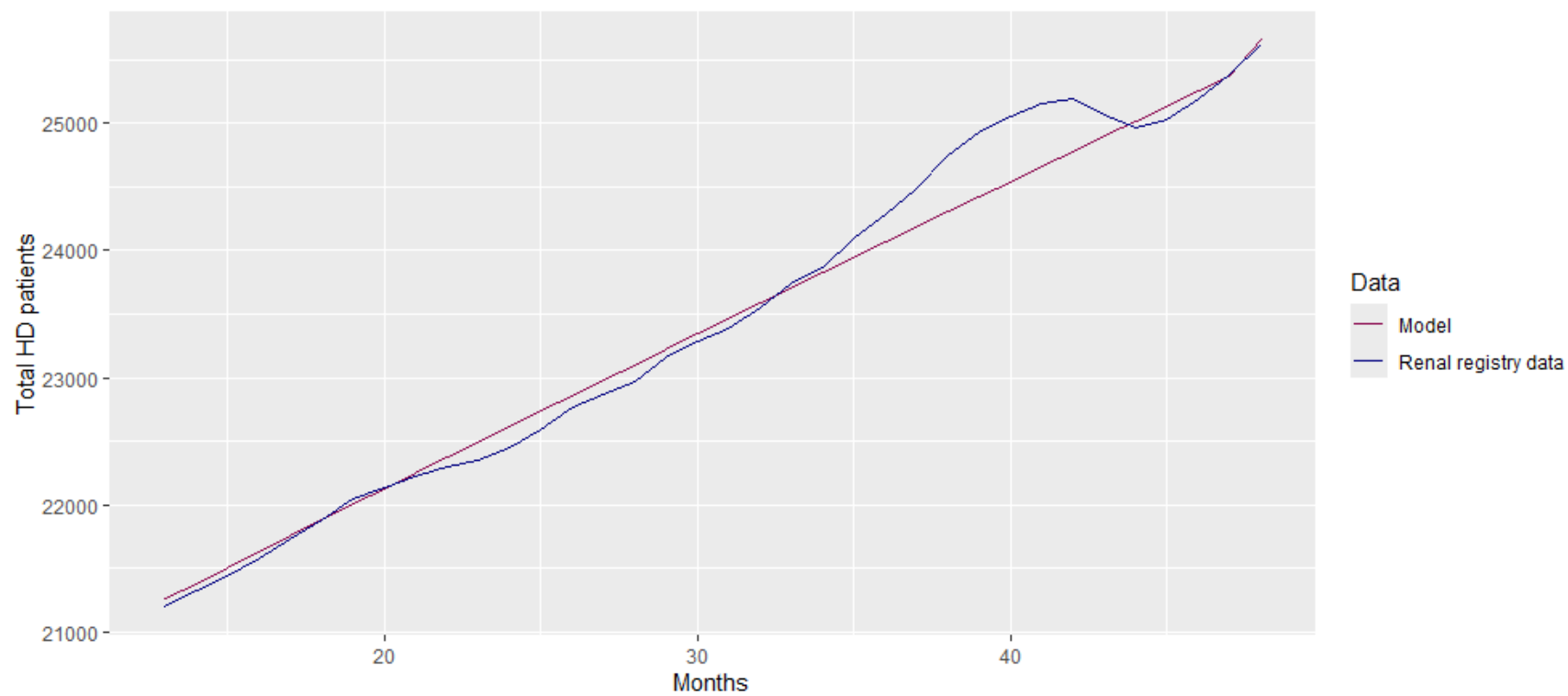
**Figure S6.7b** Validation of model behaviour against renal registry data for proportion of incident dialysis patients on PD.



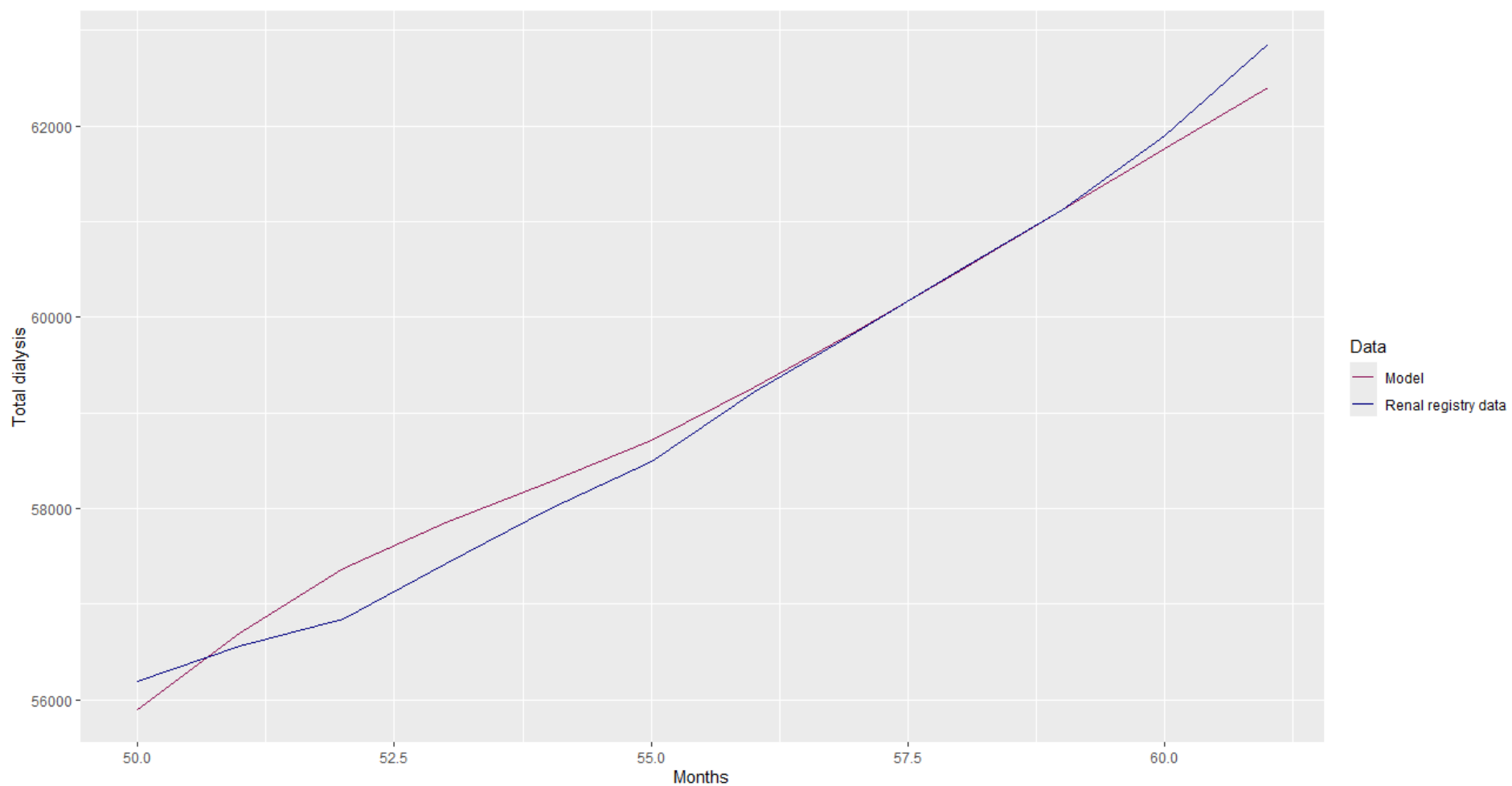
**Figure S6.7c** Calibration of parameters associated with PD death against total PD cases, prior to 2022 policy change. Purple line – renal registry data; pink-red line – model projection.



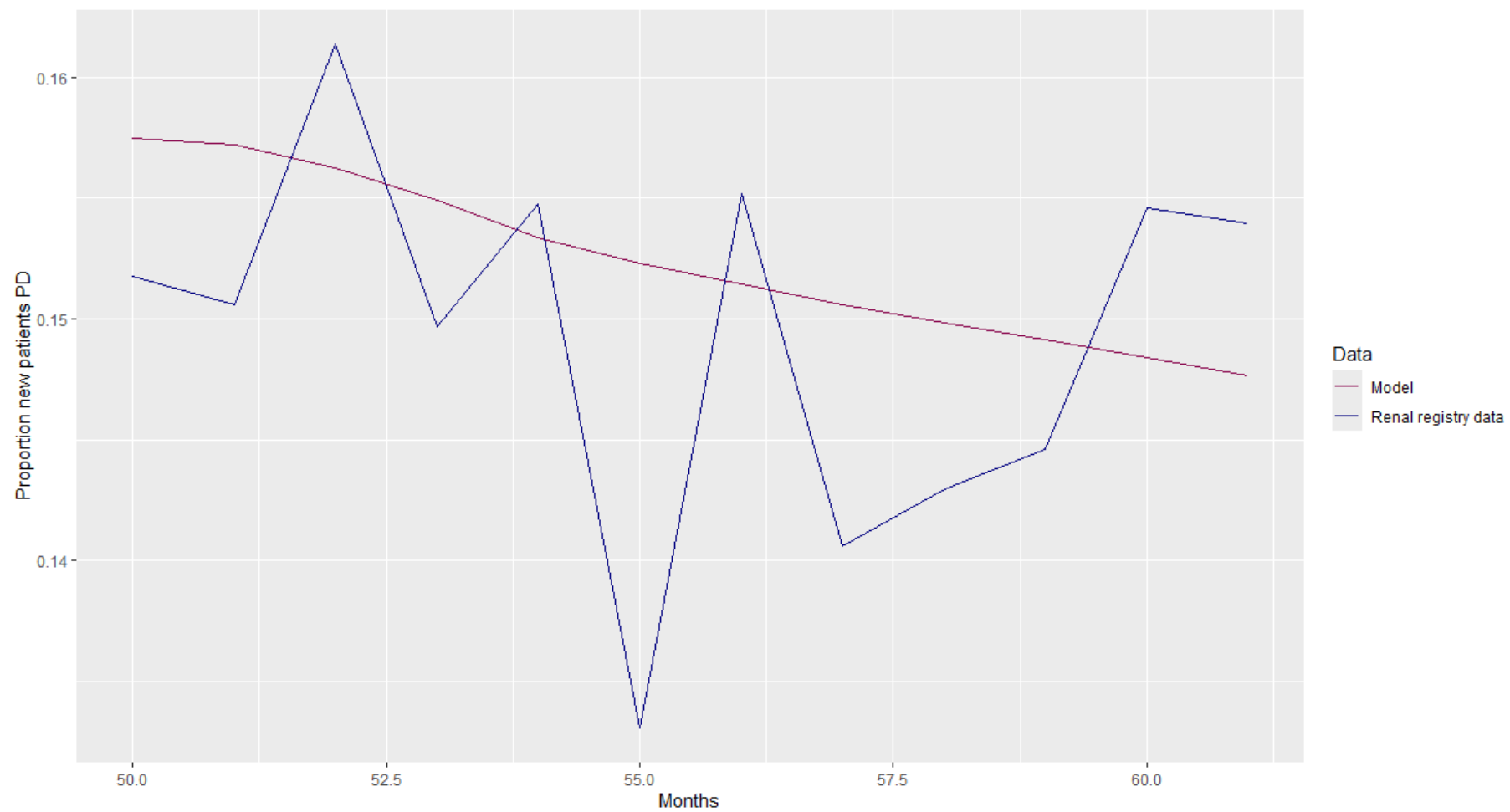
**Figure S6.7d** Calibration of parameters associated with HD death against total HD cases, prior to 2022 policy change.



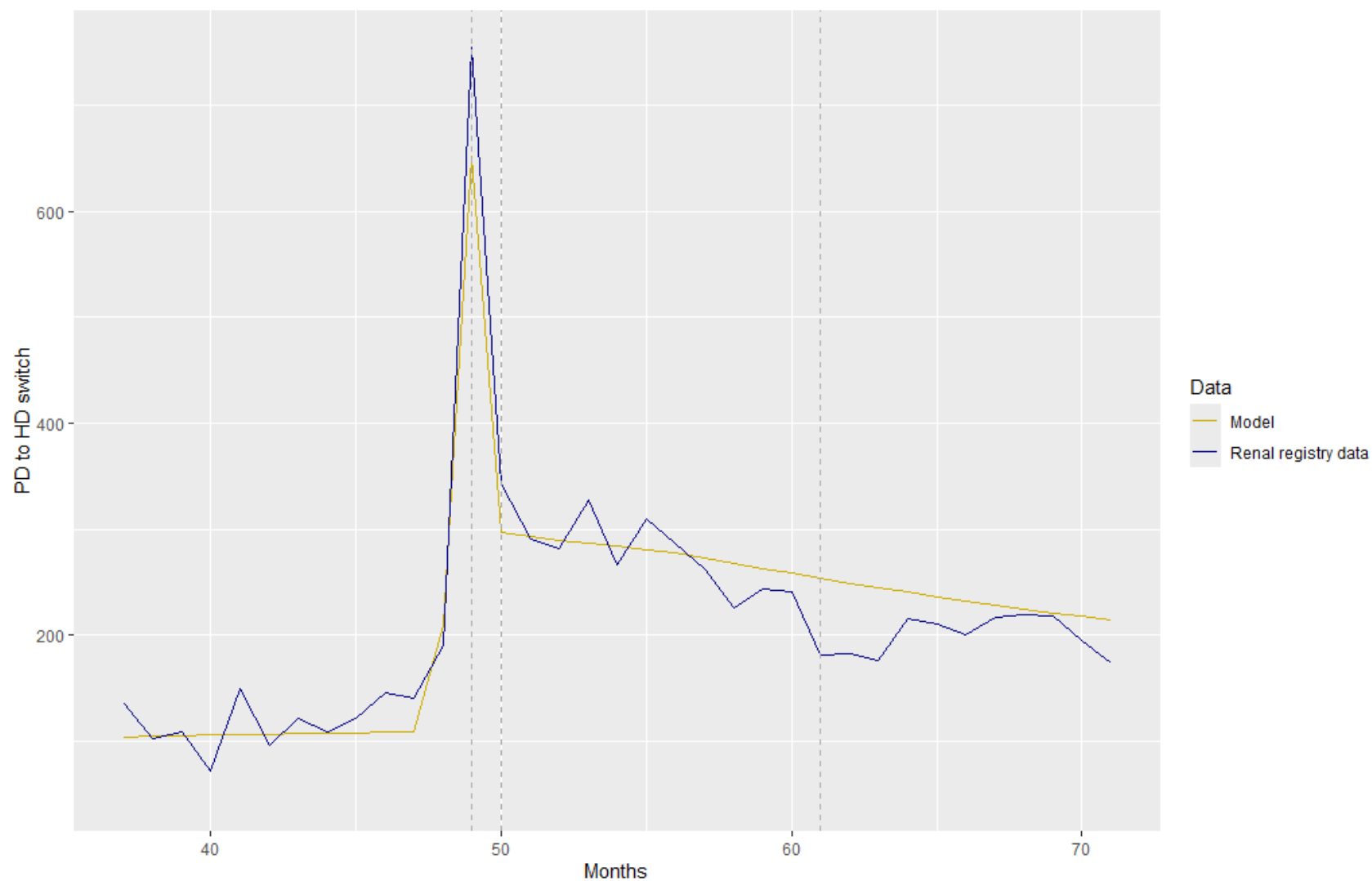
**Figure S6.7e** Calibration of parameters associated with new HD cases against total dialysis cases, for 1-year after the 2022 policy change.



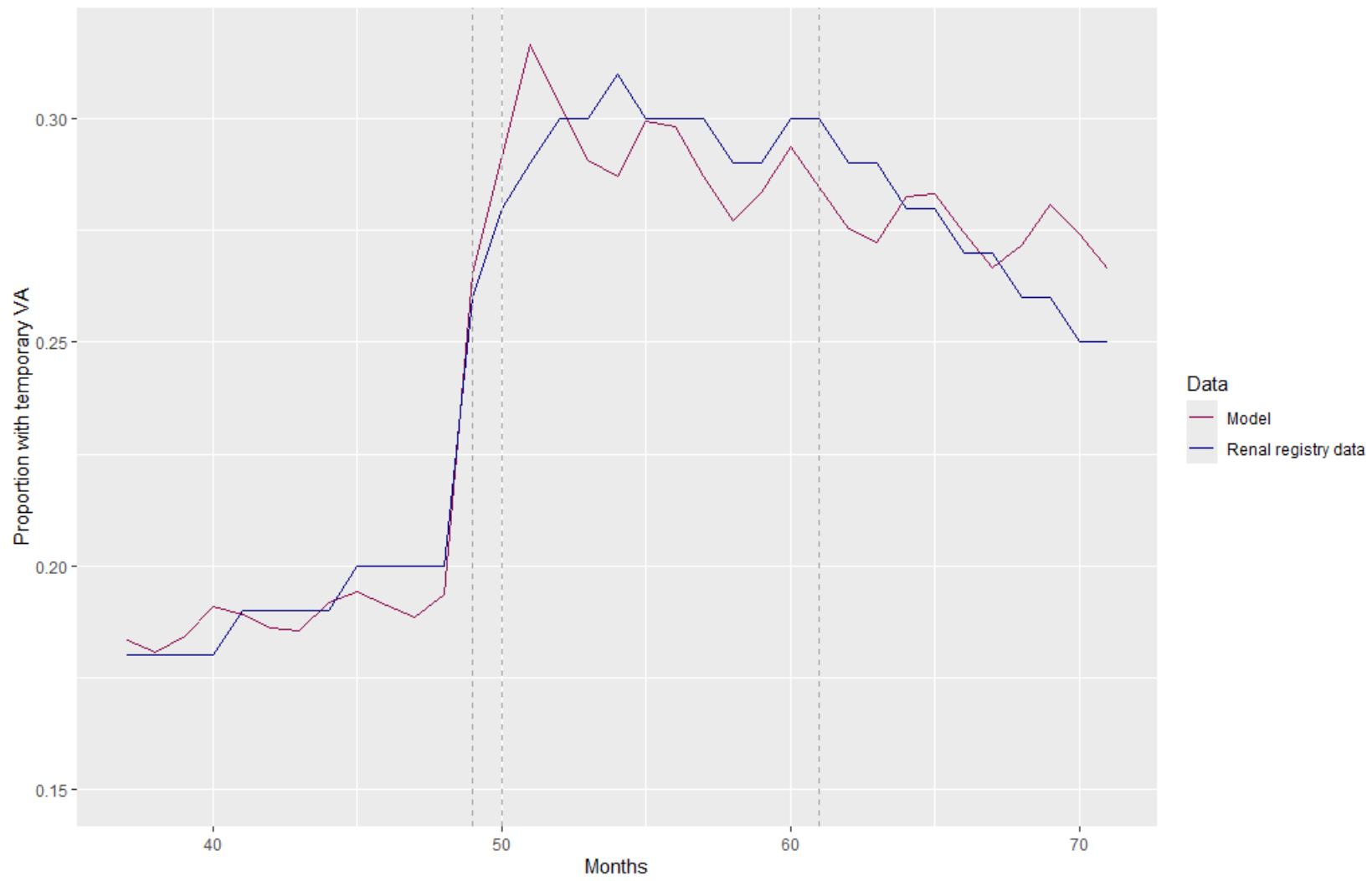
**Figure S6.7f** Calibration of parameters associated with proportion of new cases selecting PD, for 1-year after the 2022 policy change.



**Figure S6.7g** PD patients switching to HD per month, as estimated by the model and renal registry data for the model validation period. The dashed lines at months 49, 50, and 61 represent the 2022 policy change, start and end of the calibration period, respectively.



**Figure S6.7h** Proportion of total HD patients with temporary vascular access (catheter), as estimated by the model and renal registry data for the model validation period. The dashed lines at months 49 and 61 represent the 2022 policy change and end of the calibration period, respectively.





## Supplement 7.1 COREQ (Consolidated criteria for reporting qualitative research) Checklist

Topic	Item	Guide Questions/Description	Reported on Page No.
<b>Domain 1: Research team and reflexivity</b>			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	Methods 3b
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	N/A
Occupation	3	What was their occupation at the time of the study?	Methods (Intervention)
Gender	4	Was the researcher male or female?	N/A
Experience and training	5	What experience or training did the researcher have?	Methods (Intervention)
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	Methods 3b
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Methods 3b
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Methods 3b
<b>Domain 2: Study design</b>			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Methods (study design)
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Methods 3b

Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	Methods 3b
Sample size	12	How many participants were in the study?	Methods 3b
Non-participation	13	How many people refused to participate or dropped out? Reasons?	Methods 3b
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	Methods 3b
Presence of nonparticipants	15	Was anyone else present besides the participants and researchers?	Methods 3b
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	Methods 3b
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Supplement 7.4
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	N/A
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	Methods 3b
Field notes	20	Were field notes made during and/or after the inter view or focus group?	Methods 2
Duration	21	What was the duration of the inter views or focus group?	Methods 3b
Data saturation	22	Was data saturation discussed?	Methods 3b
Transcripts returned	23	Were transcripts returned to participants for comment and/or correction?	Methods 3b
<b>Domain 3: analysis and findings</b>			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	Methods 3b
Description of the coding tree	25	Did authors provide a description of the coding tree?	Supplement 7.3
Derivation of themes	26	Were themes identified in advance or derived from the data?	Methods 3b
Software	27	What software, if applicable, was used to manage the data?	Methods 3b
Participant checking	28	Did participants provide feedback on the findings?	Methods 3b

<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/ findings? Was each quotation identified? e.g. participant number	Supplement 7.7
Data and findings consistent	30	Was there consistency between the data presented and the findings?	Results
Clarity of major themes	31	Were major themes clearly presented in the findings?	Results
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	N/A

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

## Supplement 7.2 Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)

Title and Abstract		
<b>1. Title</b>	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	Title
<b>2. Abstract</b>	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	Abstract
<b>Introduction</b>	<i>Why did you start?</i>	
<b>3. Problem Description</b>	Nature and significance of the local problem	Introduction
<b>4. Available knowledge</b>	Summary of what is currently known about the problem, including relevant previous studies	Introduction
<b>5. Rationale</b>	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	Introduction and Methods- Intervention
<b>6. Specific aims</b>	Purpose of the project and of this report	Introduction
<b>Methods</b>	<i>What did you do?</i>	
<b>7. Context</b>	Contextual elements considered important at the outset of introducing the intervention(s)	Methods: Context
<b>8. Intervention(s)</b>	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	Methods: Intervention + Supplement 3
<b>9. Study of the Intervention(s)</b>	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	Methods: Study design + Outcomes and analysis

<b>10. Measures</b>	<ul style="list-style-type: none"> <li>a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability</li> <li>b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost</li> <li>c. Methods employed for assessing completeness and accuracy of data</li> </ul>	Methods - Outcomes and analysis + Supplement 4
<b>11. Analysis</b>	<ul style="list-style-type: none"> <li>a. Qualitative and quantitative methods used to draw inferences from the data</li> <li>b. Methods for understanding variation within the data, including the effects of time as a variable</li> </ul>	Methods - Outcomes + analysis
<b>12. Ethical Considerations</b>	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	Methods - Ethics
<b>Results</b>	<i>What did you find?</i>	
<b>13. Results</b>	<ul style="list-style-type: none"> <li>a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project</li> <li>b. Details of the process measures and outcome</li> <li>c. Contextual elements that interacted with the intervention(s)</li> <li>d. Observed associations between outcomes, interventions, and relevant contextual elements</li> <li>e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).</li> <li>f. Details about missing data</li> </ul>	<ul style="list-style-type: none"> <li>a) Results Part 2 + Supplement 6</li> <li>b) Results - Part 3</li> <li>c) Results - Part 3</li> <li>d) Results - Part 3</li> <li>e) Results - Part 3</li> <li>f) Results - Part 3</li> </ul>
<b>Discussion</b>	<i>What does it mean?</i>	
<b>14. Summary</b>	<ul style="list-style-type: none"> <li>a. Key findings, including relevance to the rationale and specific aims</li> <li>b. Particular strengths of the project</li> </ul>	Discussion
<b>15. Interpretation</b>	<ul style="list-style-type: none"> <li>a. Nature of the association between the intervention(s) and the outcomes</li> <li>b. Comparison of results with findings from other publications</li> <li>c. Impact of the project on people and systems Reasons for any differences between observed and anticipated outcomes, including the influence of context</li> </ul>	Discussion

	d. Costs and strategic trade-offs, including opportunity costs	
<b>16. Limitations</b>	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations	Discussion
<b>17. Conclusions</b>	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps	Discussion
<b>Other information</b>		
<b>18. Funding</b>	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	[Provided in manuscript]

## Supplement 7.3 Indicators in this study mapped against the updated Consolidated Framework for Implementation Research.

Adapted from: Damschroder LJ, Reardon CM, Widerquist MAO, Lowery J. The updated Consolidated Framework for Implementation Research based on user feedback. *Implementation Science*. 2022;17:75.

In our study, we applied constructs from the Consolidated Framework for Implementation Research (CFIR) at four points: (1) case study selection, (2) adaptation of the approaches during implementation, (3) evaluation of the effectiveness of the new approaches, and/or (4) as codes for analysis of facilitators/barriers to implementation. In the table below, we document each construct and how it was included in the study. We document any constructs for which we used a modified definition and the exclusion reason for any constructs that were not included in our study.

Construct name	Construct definition <i>The degree to which:</i>	Nature of inclusion in this study (including measurement and modified definitions, if relevant)
<b>I. Innovation domain</b>		
A. Innovation Source	The group that developed and/or visibly sponsored use of the innovation is reputable, credible, and/or trustable	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
B. Innovation Evidence Base	The innovation has robust evidence supporting its effectiveness	<b>Outcome evaluation (effectiveness):</b> comparison against information for policymaking from conventional HTA approach; use of outputs across steps of the policy process

C. Innovation Relative Advantage	The innovation is better than other available innovations or current practice	<b>Outcome evaluation (effectiveness):</b> comparison against information for policymaking from conventional HTA approach
D. Innovation Adaptability	The innovation can be modified, tailored, or refined to fit local context or needs	Not included (the pilot was only conducted in one setting, with adaptation as part of the study)
E. Innovation Trialability	The innovation can be tested or piloted on a small scale and undone	<b>Case study selection:</b> framework was initially implemented for a policy question that fell outside of the mandate of established institutions for policymaking
F. Innovation Complexity	The innovation is complicated, which may be reflected by its scope and/or the nature and number of connections and steps	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
G. Innovation Design	The innovation is well designed and packaged, including how it is assembled, bundled, and presented	Not included (due to focus on barriers/facilitators to implementation of approaches rather than design quality)
H. Innovation Cost	The innovation purchase and operating costs are affordable	<b>Outcome evaluation (barriers/facilitators):</b> measured through timesheets of staff implementing approaches from the framework
<b>II. Outer Setting domain</b>		
A. Critical Incidents	Large-scale and/or unanticipated events disrupt implementation and/or delivery of the innovation	Not included (due to short study time frame)



B. Local Attitudes	Sociocultural values (e.g., shared responsibility in helping recipients) and beliefs (e.g., convictions about the worthiness of recipients) encourage the Outer Setting to support implementation and/or delivery of the innovation	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
C. Local Conditions	Economic, environmental, political, and/or technological conditions enable the Outer Setting to support implementation and/or delivery of the innovation	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
D. Partnerships & Connections	The Inner Setting is networked with external entities, including referral networks, academic affiliations, and professional organization networks	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
E. Policies & Laws	Legislation, regulations, professional group guidelines and recommendations, or accreditation standards support implementation and/or delivery of the innovation	<b>Case study selection:</b> framework was initially implemented for a policy question that was not governed by existing guidelines or regulations
F. Financing	Funding from external entities (e.g., grants, reimbursement) is available to implement and/or deliver the innovation	Not included (as funding for HTA system improvements was already secured in the study setting in Thailand)
G. External Pressure	External pressures drive implementation and/or delivery of the innovation	Not included (as funding for HTA system improvements was already secured in the study setting in Thailand)

1. Societal Pressure	Mass media campaigns, advocacy groups, or social movements or protests drive implementation and/or delivery of the innovation	Not included (since it is more relevant for technology-focused interventions)
2. Market Pressure	Competing with and/or imitating peer entities drives implementation and/or delivery of the innovation	Not included (since it is more relevant for technology-focused interventions)
3. Performance Measurement Pressure	Quality or benchmarking metrics or established service goals drive implementation and/or delivery of the innovation	Not included (as there were no performance measures for policymaking in Thailand at time of study)
<b>III. Inner Setting domain</b>		
A. Structural Characteristics	Infrastructure components support functional performance of the Inner Setting	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
1. Physical Infrastructure	Layout and configuration of space and other tangible material features support functional performance of the Inner Setting	Not included (since it is more relevant for technologies)
2. Information Technology Infrastructure	Technological systems for tele-communication, electronic documentation, and data storage, management, reporting, and analysis support functional performance of the Inner Setting	Not included (since it is more relevant for technologies)

3. Work Infrastructure	Organization of tasks and responsibilities within and between individuals and teams, and general staffing levels, support functional performance of the Inner Setting	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
B. Relational Connections	There are high quality formal and informal relationships, networks, and teams within and across Inner Setting boundaries (e.g., structural, professional)	<p><b>Case study selection:</b> framework was first implemented in a setting with formalised relationships and high-quality informal relationships between the research team and policymakers. This was to ensure support for the additional research activities and use of outputs in policy.</p> <p><b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis</p>
C. Communications	There are high quality formal and informal information sharing practices within and across Inner Setting boundaries (e.g., structural, professional)	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
D. Culture	There are shared values, beliefs, and norms across the Inner Setting	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
1. Human Equality-Centeredness	There are shared values, beliefs, and norms about the inherent equal worth and value of all human beings	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis

2. Recipient-Centeredness	There are shared values, beliefs, and norms around caring, supporting, and addressing the needs and welfare of recipients	Not included (since it is more relevant for technologies)
3. Deliverer-Centeredness	There are shared values, beliefs, and norms around caring, supporting, and addressing the needs and welfare of deliverers	Not included (since it is more relevant for technologies)
4. Learning-Centeredness	There are shared values, beliefs, and norms around psychological safety, continual improvement, and using data to inform practice	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis. <i>Modified definition used:</i> shared values around evidence-informed policies and continual improvement of policymaking processes
E. Tension for Change	The current situation is intolerable and needs to change	<b>Case study selection:</b> framework was first implemented for a policy question in which it was recognised that existing HTA approaches are insufficient
F. Compatibility	The innovation fits with workflows, systems, and processes	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
G. Relative Priority	Implementing and delivering the innovation is important compared to other initiatives	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis

H. Incentive Systems	Tangible and/or intangible incentives and rewards and/or disincentives and punishments support implementation and delivery of the innovation	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
I. Mission Alignment	Implementing and delivering the innovation is in line with the overarching commitment, purpose, or goals in the Inner Setting	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
J. Available Resources	Resources are available to implement and deliver the innovation	<b>Outcome evaluation (barriers/facilitators):</b> measured through timesheets of staff implementing approaches from the framework. <i>Note: measured alongside 1H Innovation cost.</i>
1. Funding	Funding is available to implement and deliver the innovation	<b>Case study selection:</b> framework was first implemented for a policy question with funding secured for research activities
2. Space	Physical space is available to implement and deliver the innovation	Not included (since it is more relevant for technologies)
3. Materials & Equipment	Supplies are available to implement and deliver the innovation	Not included (since it is more relevant for technologies)
K. Access to Knowledge & Information	Guidance and/or training is accessible to implement and deliver the innovation	<b>Case study selection:</b> given limited time and resources for implementation, approaches highlighted by the framework were prioritised for implementation according to expertise of technical partners at the University of Strathclyde

IV. Individuals domain		
Roles subdomain		
A. High-level Leaders	Individuals with a high level of authority, including key decision-makers, executive leaders, or directors	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
B. Mid-level Leaders	Individuals with a moderate level of authority, including leaders supervised by a high-level leader and who supervise others	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis; selected for interview (working group chair)
C. Opinion Leaders	Individuals with informal influence on the attitudes and behaviours of others	<b>Case study selection:</b> framework was first implemented for a policy question in which a member of the research team was a key opinion leader  <b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis; selected for interview
D. Implementation Facilitators	Individuals with subject matter expertise who assist, coach, or support implementation	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
E. Implementation Leads	Individuals who lead efforts to implement the innovation	Not included (due to overlap with researchers leading evaluation process in our study)

F. Implementation Team Members	Individuals who collaborate with and support the Implementation Leads to implement the innovation, ideally including Innovation Deliverers and Recipients	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis; selected for interview (members of the research team)
G. Other Implementation Support	Individuals who support the Implementation Leads and/or Implementation Team Members to implement the innovation	Not applicable
H. Innovation Deliverers	Individuals who are directly or indirectly delivering the innovation	Same as <i>F. Implementation team members</i>
I. Innovation Recipients	Individuals who are directly or indirectly receiving the innovation	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis; selected for interview (members of the policy working group)
<b>Characteristics subdomain</b>		
A. Need	The individual(s) has deficits related to survival, well-being, or personal fulfilment, which will be addressed by implementation and/or delivery of the innovation	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis <i>Modified definition: the individual perceives that the existing HTA approach is insufficient for policymaking</i>
B. Capability	The individual(s) has interpersonal competence, knowledge, and skills to fulfil Role	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis

C. Opportunity	The individual(s) has availability, scope, and power to fulfil Role	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
D. Motivation	The individual(s) is committed to fulfilling Role	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
<b>V. Implementation Process domain</b>		
A. Teaming	Join together, intentionally coordinating and collaborating on interdependent tasks, to implement the innovation	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
B. Assessing Needs	Collect information about priorities, preferences, and needs of people	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis <i>(using data collected for B1 and B2)</i>
1. Innovation Deliverers	Collect information about the priorities, preferences, and needs of deliverers to guide implementation and delivery of the innovation	<b>Adaptation:</b> reflection and revisions in the process modified the approaches to account for research team / secretariat needs
2. Innovation Recipients	Collect information about the priorities, preferences, and needs of recipients to guide implementation and delivery of the innovation	<b>Adaptation:</b> reflection and revisions in the process modified the approaches to account for policymaker needs
C. Assessing Context	Collect information to identify and appraise barriers and facilitators to implementation and delivery of the innovation	Not included (as it was addressed under 5E Tailoring strategies and Case study selection)



D. Planning	Identify roles and responsibilities, outline specific steps and milestones, and define goals and measures for implementation success in advance	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
E. Tailoring Strategies	Choose and operationalize implementation strategies to address barriers, leverage facilitators, and fit context	<b>Adaptation:</b> reflection and revisions in the process modified the approaches in response to barriers / facilitators  <b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis ( <i>using data from adaptation phase</i> )
F. Engaging	Attract and encourage participation in implementation and/or the innovation	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
1. Innovation Deliverers	Attract and encourage deliverers to serve on the implementation team and/or to deliver the innovation	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
2. Innovation Recipients	Attract and encourage recipients to serve on the implementation team and/or participate in the innovation	<b>Outcome evaluation (barriers/facilitators):</b> code in qualitative analysis
G. Doing	Implement in small steps, tests, or cycles of change to trial and cumulatively optimize delivery of the innovation	Not included (since the study was a preliminary test in itself)
H. Reflecting & Evaluating	Collect and discuss quantitative and qualitative information about the success of implementation and/or the innovation	Included within <b>Adaptation</b> and <b>Outcome evaluation</b> , applying other indicators in the framework
1. Implementation	Collect and discuss quantitative and qualitative information about the success of implementation	Included within <b>Adaptation</b> and <b>Outcome evaluation</b> , applying other indicators in the framework

2. Innovation	Collect and discuss quantitative and qualitative information about the success of the innovation	Included within <b>Adaptation</b> and <b>Outcome evaluation</b> , applying other indicators in the framework
I. Adapting	Modify the innovation and/or the Inner Setting for optimal fit and integration into work processes	Not included (as no changes were made to the framework itself, since the focus was on approaches incorporated under the framework)

## Supplement 7.4 Interview guide.

**READ:** We are conducting these interviews to learn about your perspectives on the process and evidence used to inform the NHSO WG recommendation, with a broader goal of identifying good practice to take forward. We would appreciate your honesty and candour, as we are most interested in which elements of the policy process were of greatest benefit and which may not have been worth the opportunity cost of committee time and resources. Do you have any questions?

**READ:** Before we begin, please confirm that you have been informed about this study, your questions have been answered, you understand that if you wish to avoid a question or stop at any point you may do so, and that you are participating willingly.

**READ:** Can you please confirm without stating your name that you consent to this interview being audio recorded?

#	Questions	Prompts/follow-up
WARM-UP		
1a	What do you see the role of this working group in terms of the broader policymaking structure?	N/A
1b	How do you see your role within the working group?	
PROCESS		
2	Can you walk through the policy process that led to the WG recommendation? Please share your impressions, reflections, and personal view of the process	Follow-up on points raised as important, positive, or influential
3	Can you walk me through how your own perceptions and understanding evolved through each step of the policy process?	Prompt for timing, specific change, what would have happened otherwise

4	Were there meetings or informal discussions outside of the official working group meetings that shaped your understanding? This could be side discussions with other WG members, the research team, external teams, or any other forums.	Prompt for timing, specific change, what would have happened otherwise
5	Then thinking up to the level of the committee (or research team), did you observe any shifts in thinking through the process, again thinking through from the start to the end?	i) Prompt for timing, specific change, counterfactual ii) Were there differences in perspective? How did they come about? Were they resolved?
6	Do you think final recommendation is different given the process that was followed?	Why? Which specific elements caused the change? What would have happened otherwise?
EVIDENCE		
7	Can you talk me through the different evidence that was presented to the working group and at which stages?	<ul style="list-style-type: none"> <li>Which evidence was new?</li> <li>What was less familiar but aligned with your current way of thinking?</li> <li>What was very different?</li> </ul>
8	So going through each of these, can you tell me your views on the extent to which each piece of evidence shaped how you think about the problem?	Prompt for the reason (redundant, hard to understand, etc) and what would have happened without a specific piece of evidence
FINAL RECOMMENDATION		
9	Can you share your perspectives on the final set of recommendations?	- Do they agree with the final recommendation? Why (not)?

		- What is their sense of the level of agreement across the committee?
10	How do you see the WG recommendation being taken forward in the broader context of policymaking?	Ask for the reason
11	If you were involved in a similar WG in future, what would you replicate? What would you differently?	

**READ:** Thank you for participating in this interview. If we use any quotes in the evaluation, we will first contact you to ensure that you feel comfortable that you cannot be identified. If you think that any quote could breach your anonymity, we will remove the quote. You are free to withdraw your consent at any time.

## Supplement 7.5 Adaptations made to **system dynamics** methods during the policy process.

The table below outlines the challenges encountered during the integration of system dynamics methods into the policy process, their implications, and the corresponding strategies employed to facilitate effective use of systems approaches.

Issue encountered	Implications	Adaptations made
Timelines for policy	Limited time for stakeholder engagement for iterations of the causal loop diagram and system dynamics model.	The policy secretariat, who oversaw the research and policy process, provided review and input at each stage.
	Short timelines with large number of policy options to model.	<p>The working group and secretariat were asked to describe the expected mechanism of action for each policy to inform modelling.</p> <p><b>Learning:</b> This led to optimistic projections of policy performance. In future, we would propose using causal loop diagram and base case analysis to shortlist policies targeting the most influential parts of the model.</p>
Familiarity with system dynamics	Low understanding of system dynamics tools limited the input from the working group and workshop participants.	<ul style="list-style-type: none"><li>Initially, the implementation team developed training slides, but this quick training was insufficient for participants to understand model diagrams.</li><li>Instead, facilitators requested input on key messages, narratives of how the system works, and assumptions.</li></ul>

	Legitimacy: lack of knowledge and trust in the new method, without institutional processes to oversee research quality.	<ul style="list-style-type: none"> <li>• Showed empirical validation graphically before presenting the results.</li> <li>• Provided the logical reasoning in the model structure to explain the findings, distinguishing between model assumptions and the data.</li> </ul>
	Sustainability: although the model would ideally be updated with new knowledge, there is not the capacity to support this.	To enhance the agency's ability to integrate system dynamics into future policy development, targeted capacity-building activities—including cross-unit training workshops, development of guidance materials, and ongoing mentorship programs—are planned to strengthen staff expertise and foster a culture of systems-based analysis.
Stakeholder dynamics	Professional hierarchies and power dynamics prevented certain stakeholders from speaking up during discussions.	During the stakeholder workshop, groups were arranged to separate different job grades in the same profession and to separate senior physicians from nurses and patients.
	Strong disagreement around the amount and importance of the doctor fee, which was a key component of the model.	An anonymous survey was circulated to hospital directors to collect evidence on the doctor fee.

## Supplement 7.6 Comparison of the standard HTA approach and new approaches from the framework.

The table shows the results from the evidence assessment following the standard HTA approach and the new approach. Since the analysis using scenario thinking and system dynamics was not finalised before the official working group recommendation, the table shows preliminary results from the analysis presented to the working group (“New approaches: preliminary results”), as well as the final results (“New approaches: final results”).

	Standard HTA approach	New approaches: preliminary results	New approaches: final results	Key difference with new approaches
Projected dialysis patients by 2033 (base case)	300,000 (95% CI 160,000-430,000)	N/A (only new patients modelled)	145,000 (11% PD)	<ul style="list-style-type: none"> <li>• Able to estimate % patients on PD</li> <li>• Projected significantly fewer dialysis patients</li> </ul>
Proposed policies*	<ol style="list-style-type: none"> <li>1. Pre-authorisation</li> <li>2. Global budget</li> <li>3. Doctor fee restriction</li> <li>4. Bundled payment</li> <li>5. CQI</li> <li>6. Education</li> <li>7. CCC protocol</li> </ol>	N/A (only modelled policies proposed by the working group through the standard HTA approach)	<ol style="list-style-type: none"> <li>1. Pre-authorisation</li> <li>2. KPI for regulatory capacity</li> <li>3. KPI for number of nurses</li> <li>4. Quality-based payment</li> <li>5. Regulations of HD nurse hours</li> <li>6. PD investment plan</li> </ol>	<ul style="list-style-type: none"> <li>• Cross-boundary solutions (e.g. regulation and investment)</li> <li>• Proposed approaches may be outside of policy jurisdiction</li> </ul>



Effective policies (able to reach 50% target)	All policies	Global budget	None (including interventions from standard approach)	<ul style="list-style-type: none"> <li>Lower projected impact</li> </ul>
Effectiveness over time	N/A	N/A	Performance of all policies decreases except for strict regulation of financial incentives or reduced access	<ul style="list-style-type: none"> <li>Able to project time- dependent dynamics</li> </ul>
Socio-economic or feasibility considerations	<ul style="list-style-type: none"> <li>Feasibility</li> </ul>	<ul style="list-style-type: none"> <li>Accessibility</li> <li>System strength</li> <li>Vulnerability</li> </ul>	<ul style="list-style-type: none"> <li>Equity</li> <li>System strength</li> <li>Vulnerability</li> <li>Uncertainty</li> </ul>	<ul style="list-style-type: none"> <li>Multi-dimensional impact (more measures of impact)</li> </ul>
Recommendation from the secretariat	All 7 policies	5 out of 7 policies; recommend against global budget	PD-first policy; recommend against global budget	<ul style="list-style-type: none"> <li>Change in recommended policy (highlights risks)</li> </ul>

\* The new approaches leveraged policies nominated by the working group where it aligned with problem solutions, otherwise alternative policy solutions were developed.

## Supplement 8

**Table S8.1** Prioritisation of multi-disciplinary approaches for policymaking under uncertainty for the HTA agency in Thailand. We applied the criteria for prioritisation in a funnel approach, so that only highly relevant techniques were assessed for compatibility with standard HTA practice, and only compatible approaches were evaluated for the HTA agency's ability to influence whether the approach is used.

Element	Feature	Approach	Relevance (3 = high, 1 = low)	Compatibility with HTA (3 = high, 1 = low)	Ability to influence (3 = high, 1 = low)
<i>For individual policy questions</i>					
<b>5. Decision question</b>	d) Nature of the problem	iv) The policy problem, goals, or process is unclear or contested	Soft problem structuring	<b>2</b> (policy questions that do not arrive through established channels)	
		v) Crosses system boundaries, feedback, and/or unintended consequences	System dynamics	<b>3</b> (questions cannot be addressed with HTA e.g. C-section, AMR, cancer delivery)	<b>2</b> (similar cause-effect principles, ability to model, more reliance on qualitative data)
		vi) Cross-jurisdictional decision-making or implementation	SDM	<b>1</b> (normally NHSO or MOPH has authority)	<b>3</b> (ability to influence methodologies used to generate evidence for policy)
	e) Policy	iii) Change attitudes or behaviour	Futures	<b>3</b> (strategic emphasis on health promotion policies)	<b>1</b> (multiple futures and quality standards are not aligned)

Element		Feature	Approach	Relevance (3 = high, 1= low)	Compatibility with HTA (3 = high, 1 = low)	Ability to influence (3 = high, 1 = low)
6. Decision context	f) Time	iv)Account for high impact, low probability events	Futures	<b>1</b> (not within mandate)		
		ii) Long timeline for policy implementation and/or reversal	Futures	<b>1</b> (most policies relate to health technologies with rapid turnover)		
	d) Stakeholders	iii)High level of disagreement on important criteria, reliable evidence, or future	Robust decision rules	<b>2</b> (uncommon but current HTA methods do not address)		
		iv)Strong vested interests across multiple stakeholder groups	Scenario thinking	<b>1</b> (frequent, but already addressed to a certain extent)		
	e) Policy institutions	iii)The policy question does not fall under the mandate of existing institutions	Futures	<b>3</b> (policy analysis not related to specific technologies, e.g. health care organisation)	<b>1</b> (multiple futures and quality standards are not aligned with HTA)	
		iv)Past decisions or institutional mandates	Roadmap	<b>2</b> (policies such as low value care, but there is		

Element		Feature	Approach	Relevance (3 = high, 1= low)	Compatibility with HTA (3 = high, 1 = low)	Ability to influence (3 = high, 1 = low)
7. Evidence	f) Urgency	impede policymaking or implementation		openness to address from policymakers)		
		iv)Emergency context with insufficient time for stakeholder engagement	Prototypes	<b>2</b> (infrequent but HTA practice is insufficient)		
	c) Type of evidence	iii)Multi-disciplinary	SDM	<b>3</b> (increasing multi-disciplinary evidence without expertise for social sciences)	<b>2</b> (existing forums for engagement but no reflexivity)	<b>1</b> (low in established processes, mixed for other policies)
		iv)Complex causal relationships, that cannot be understood ex-ante	Adaptive management	<b>3</b> (policies with unintended impact may show sub-national variation)	<b>2</b> (builds on value of information concepts, but limited ability to revise policy)	<b>2</b> (limited ability to influence policy agenda; could be implemented in research)
	d) Resources	iii)Across multiple criteria	Consequence table	<b>3</b> (inherent to HTA)	<b>3</b> (structured mechanisms for full or rapid HTA)	<b>1</b> (existing policy bodies prioritise evidence)
		iv)For a decision-analytic model	Qualitative value of information	<b>3</b> (inherent to HTA)	<b>3</b> (quantitative value of information is well-established)	<b>3</b> (HITAP responsible for guidelines and studies)

Element		Feature	Approach	Relevance (3 = high, 1= low)	Compatibility with HTA (3 = high, 1 = low)	Ability to influence (3 = high, 1 = low)
<b>For governance</b>						
<b>8. Institution</b>	c) Variation	ii) Dissensus, decision stakes, and/or available knowledge vary across policies	Stakeholder analysis	<b>3</b> (wide variation in NLEM and NHSO)	<b>2</b> (informal channels to vary engagement, even though participation is standardised in current practice)	<b>1</b> (stakeholder engagement defined by operational guidelines)
	d) Unfit governance	iii) Governance can be modified on an ongoing basis	Adaptive governance	<b>3</b> (no institutions to address system organisation or health system problems)	<b>2</b> (informal learning and revision to governance)	<b>1</b> (can only influence if secretariat)
		iv) Governance cannot be changed on an ongoing basis	Transformation	<b>1</b> (main policy questions are addressed within HTA)		

AMR: antimicrobial resistance; C-section: caesarean section; MOPH: Ministry of Public Health; R&D: research and development

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