

Challenges in the clinical use of digital tools in healthcare: barriers and blueprint for Kidney Failure Risk Equation implementation

Rupert W Major, Javeria Peracha, Ziva Frangez, Anne Dreyer, Patrick Rueegger, Chaohui Guo, Paul Cockwell, Kristin Veighey

Submitted to: JMIR Formative Research
on: September 22, 2025

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Abstract

Background: Chronic kidney disease (CKD) affects approximately 10% of the global population and is a major contributor to morbidity and the need for kidney replacement therapy. The Kidney Failure Risk Equation (KFRE) is a validated risk prediction tool, yet its implementation remains limited.

Objective: To identify barriers to KFRE implementation and propose a blueprint for integrating digital risk tools into healthcare systems.

Methods: Narrative synthesis of barriers across domains (data infrastructure, clinician engagement, technology integration, and policy), informed by UK NHS case study experience.

Results: Key barriers include low rates of urine albumin-creatinine ratio testing, assay and formula variability for eGFR, limited clinician awareness, fragmented IT systems, and insufficient policy alignment. Solutions include standardisation, embedding KFRE into LIMS/EHRs, automated calculation, and alignment with national strategies.

Conclusions: Embedding KFRE into clinical workflows offers a model for digital risk tool integration. Addressing barriers across technical, educational, and policy domains is essential, and lessons are transferable to other digital health innovations. Clinical Trial: N/A

(JMIR Preprints 22/09/2025:84577)

DOI: <https://doi.org/10.2196/preprints.84577>

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Abstract

Background: Chronic kidney disease (CKD) affects approximately 10% of the global population and is a major contributor to morbidity and the need for kidney replacement therapy. The Kidney Failure Risk Equation (KFRE) is a validated risk prediction tool, yet its implementation remains limited.

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Keywords: Chronic Kidney Disease; Digital Health; Risk Prediction; Implementation Science; Kidney Failure Risk Equation

Introduction

Chronic kidney disease (CKD) is an increasing global health burden, estimated to affect 9.1-13.1% of the global population (up to one billion people) (1). The vast majority of those affected are not symptomatic from CKD and will not progress to kidney failure requiring kidney replacement therapy. The major burden of CKD is caused by the independent increased cardiovascular disease (CVD) risk that starts at early-stage CKD and increases with the severity of CKD. This necessitates management of the modifiable risk factors, such as hypertension, obesity, and diabetes, with additional interventions for primary prevention of CVD through statins and drugs that slow decline of kidney function such as renin-angiotensin-aldosterone system and sodium-glucose co-transporter-2 inhibitors (2). In addition, CKD is often under-diagnosed; a recent international study found that only a third of patients with CKD as defined by diagnostic criteria were coded or documented in their medical records (3). UK national audit data has shown that emergency hospital admission is higher in those who do not have a CKD diagnostic code in primary care (4).

Those who progress to kidney failure may not experience symptoms attributable to CKD until they have advanced CKD, and consequently experience not only a change in physical function but also the psychological impact of counselling that they have a condition that may progress to a requirement for KRT. The impact of CKD on healthcare systems is also significant, with the costs of treating end stage kidney disease and its complications comprising 2-4% of national healthcare budget expenditure in developed countries (3). In Europe this cost is estimated at €140 billion annually (5,6).

There is a lack of effectively implemented early detection methods to assess risk of CKD progression, including identification of those without the condition but at high risk of developing CKD. This paradigm of a common, chronic, frequently asymptomatic condition necessitating early intervention, with variably defined and non-standardised pathways for referral, monitoring, and treatment, with a small number of individuals progressing to significant life and function-limiting illness with a high financial and social burden, makes it an attractive implementation target for digital health solutions: (1) to identify those affected, (2) better risk-stratify those at risk of progression, (3) educate clinicians and patients, (4) implement management strategies, (5) monitor and evaluate outcomes and (6) provide a platform for self-management tools to empower patients and improve adherence.

Identification of risk factors that show promise for prediction models have informed the development of risk-stratification tools (7,8). These tools are useful for diagnosis and prognosis, more precisely identifying those who require intervention, and optimising health resource utilisation. International guidelines developed by KDIGO (Kidney Disease: Improving Global Outcomes) use a traffic light system based on estimated glomerular filtration rate (eGFR), derived from measurement of serum creatinine and urine albumin-creatinine ratio (uACR). This is used to diagnose and stage CKD as low, moderate, high, and very high risk (9). KDIGO clinical practice guidelines also recommend (1A recommendation) the use of clinically validated risk prediction equations/models for assessing individual risk, such as the kidney failure risk equation (KFRE) (9). The 4-variable KFRE, first developed in 2011, provides a percentage risk of ESKD within a given time frame (10). It has been validated in over one million patients in over 30 countries, providing an international evidence base (11,12,13,14,15), and its use is recommended by several national and international guideline committees and advocated for as part of a risk based approached instead of categorisation. (9,16,17,18). Despite this, its integration into clinical use has been limited.

In this paper we describe the steps required and barriers to implementation of the KFRE tool for CKD risk prediction in healthcare systems, using the UK National Health Service (NHS) as a case study. Barriers vary, and are identifiable at every stage of the process of

implementation. These include ensuring the correct data is available, clinician awareness and education, technological limitations, security considerations, resource implications, policy challenges, and outstanding research questions. We propose solutions and discuss the role of digital health tools in facilitating these, and suggest an implementation blueprint to be tested in a UK healthcare setting (figure 1). This blueprint provides a template for challenges and potential solutions for implementation of such tools, using the KFRE as an example (figure 2). We also describe proposals for generalisability in other international healthcare settings and disease areas.



Methods

We performed a narrative synthesis of barriers to implementing the KFRE in UK clinical practice. The analysis drew on three complementary sources:

1. Published evidence – peer-reviewed literature on KFRE validation, uptake, and integration, and relevant NICE and KDIGO guidelines.
2. UK NHS experience – insights from service evaluation, quality improvement projects, and ongoing national implementation initiatives in primary and secondary care.
3. Stakeholder perspectives – practical reflections from nephrologists, primary care clinicians, health service managers, and industry collaborators with experience in digital algorithm integration.

Barriers were categorised across four domains:

1. Data infrastructure – accuracy and availability of biochemical tests, assay variability, coding and case-finding practices.
2. Clinician engagement – knowledge of CKD and KFRE, workflow integration, and perceptions of clinical utility.
3. Technology integration – information technology interoperability across NHS laboratory and primary/secondary care systems, and data security requirements.
4. Policy and resources – commissioning arrangements, financial incentives, workforce pressures, and alignment with national CKD strategies.

The synthesis was iterative with discussion among the multidisciplinary author group. The UK NHS was used as the primary case study, with attention to how findings may generalise to other health systems.

Results

Overview of the KFRE

The KFRE has been developed for use in CKD stages 3-5 (eGFR <60ml/min/1.73m²) using four data points; age, gender, eGFR, and uACR, to calculate a percentage risk of progression to require KRT over 2 and 5 years. This allows clinicians to identify those patients at low risk, where the focus is on CV disease prevention, and those at higher risk, who need both CV disease prevention and referral to secondary care for assessment of disease specific causes of CKD (e.g. immune-mediated or genetic disease) and/or advanced kidney care to support an informed choice around treatments for kidney failure.

Risk prediction tools can be used to design monitoring pathways, inform treatment decisions, and support those affected to better understand and make informed decisions about their health. This is particularly true for long term conditions such as CKD, where meaningful patient-centred conversations in early asymptomatic CKD, such as to demonstrate the effect of treatment on KFRE and hence ESKD risk, may have a role improving treatment adherence (19–21).

Validation of the KFRE in clinical practice has been conducted in over 30 countries (22). In the UK validation has led to recalibration of baseline risk for a contemporary UK primary care population, and adoption of hybrid criteria in guidance for referral to secondary care (12). This evidence has informed guideline development on the use of KFRE by the National Institute of Health and Clinical Excellence (NICE) and the UK Kidney Association (17).

Despite its impact on health, awareness of CKD remains variable amongst both clinicians and those living with CKD (23,24). This is particularly true in primary care, where the majority of CKD identification and management takes place (25,26). The KFRE is available as an online tool, which necessitates manual transcription of variables into data fields to generate a percentage risk score. The measurement of eGFR is common in national health systems, and in the UK may form part of the NHS health check for those aged over 40 if indicated by preliminary screening (27). However, there is a significant gap in screening of potentially high-risk patients, such as those with hypertension, for CKD (28). In addition, urine uACR measurement is poor; in a recent analysis only 40% of patients with an abnormal eGFR had had their uACR checked (29). The large majority of these had diabetes, therefore other at high risk of and from CKD were not being identified and/or monitored.

Consequently, many patients with progressive CKD are not identified in a timely fashion and not able to access care that is outcome modifying. At a population level, inaccurate and incomplete case-finding has resource implications for health systems such as the NHS, including shortfalls in management of the increased cardiovascular risk in the population, increasing health inequalities, adding to the costs of treating end stage kidney, and contributing to economic inactivity.

Primary care practitioners are familiar with accessing risk prediction tools such as those used for cardiovascular disease, but the additional time taken and impracticalities of doing so in tools that are not integrated into existing IT systems present a barrier to widespread adoption, even when clinicians are aware of the existence of such a tool. Manual transcription also risks use of an incorrectly calibrated version of the KFRE, error, and consequently inaccurate results. An automated result provided via a digital platform would negate the need for additional clinician time, and increase accuracy, efficiency and safety. Integration of the KFRE into existing electronic health record (EHR) or laboratory systems, where existing data can automatically be used to generate a result, would enable monitoring of trends in KFRE, and potentially improve uACR measurement by raising awareness about its use and significance. This would lead to improved coding, increased

case-finding, triage, and improve risk-prediction, enabling more timely diagnosis and treatment of CKD.

Data accuracy and availability

Measurement of kidney function in routine clinical practice in many countries is via serum creatinine measurement in patient blood samples. However, heterogeneity in the assays produced by different manufacturers to measure creatinine exists mostly notably in relation to assay methodology of Jaffe and enzymatic. Laboratories in the UK use both; the Jaffe assay is less accurate at or around eGFR 60ml/min/1.73m²; Despite this only 50% of UK laboratories currently use an enzymatic assay to measure creatinine. External validation via NEQAS is used for quality assurance, but this cannot make up for the variation between laboratories. Validation studies have therefore standardised measured serum creatinine to that used by the original study laboratory.

The serum creatinine value is then used to calculate estimated GFR (eGFR) using the CKD-EPI and NICE has been recommending the use of this formula since 2014, having previously recommended the Modified Diet in Renal Disease (MDRD) formula. However, approximately 20% of laboratories in the UK are still using MDRD formula to calculate eGFR, despite the recommendation for NICE. CKD-EPI has greater specificity and sensitivity in estimating actual GFR than MDRD (30), this has practical implications as the MDRD formula to overdiagnosis of CKD in some people. Furthermore, CKD-EPI 2009 is the method used in the original KFRE study (10).

Another important issue is Digital health solutions can provide/facilitate standardised calculation at laboratory level, or through use of a single standardised reference lab for measurement. However, a review at the time of implementation is essential to ensure that these challenges are considered before they are embedded into new systems.

The lack of uACR measurement is a further barrier. The reasons for this are myriad but may relate to; a lack of reimbursement for uACR in primary care, poor clinician awareness of indications for testing, the perception that it is a high-volume test with a low yield beyond diabetes, limited patient engagement and education, and the move to remote consultations, particularly in secondary care, where an additional step may be required on the part of patient and clinician. In addition, remote consultations may encourage the use of semi-quantifiable home digital solutions for uACR testing, which evidence has shown to be of limited value, and may result in overdiagnosis, increased cost and workload (31). Adoption of the KFRE, and the use of digital health solution (DHS) to do so, may mitigate these barriers, by educating patients and clinicians and highlighting the need for uACR measurement.

Where there has been research into implementation of the KFRE, consideration has been given to the optimum place to introduce its use; within laboratory information systems or in electronic health records. Standardised national guidance on its use, combined with engagement of biochemists, primary and secondary care clinicians, can identify the strengths and weaknesses of each approach to implementation, and allow testing at scale.

Patient and clinician knowledge

In the UK, as in most countries, the vast majority of people living with CKD are managed in primary care settings by generalists who also manage other conditions, where CKD comprises only a small but significant aspect of workload. The prospect of tools that can identify those who need specialist care, and those who can safely be managed in primary care, therefore is an attractive one.

Knowledge amongst patients is also limited. The vast majority of CKD is asymptomatic and studies suggest significant variation in awareness of the condition and its implications

amongst people living with CKD (32). Raising awareness and increasing patient activation has the potential to increase adherence to treatment (33). Much of the advice for early CKD relates to improvement in related co-morbidities, such as hypertension and diabetes including lifestyle and cardiovascular risk management to improve outcomes, therefore patient education and self-care is critical to improving outcomes.

Implementation needs to therefore be conducted in conjunction with a comprehensive programme of education and dissemination of information, using existing patient-facing tools where available. This needs to be conducted at multiple levels; policy and national strategy to incentivise healthcare providers to increase measurement, standardised national guideline development, local educational resources, tools for primary and secondary care clinicians, and engagement with integrated care boards to highlight the impact of CKD and the demand for services.

Data integration and technological limitations

UK laboratories, primary care providers and secondary care trusts use a heterogeneity of IT providers and systems, with limited integration and functionality, within and between healthcare providers and laboratory systems. This fragmentation also means IT systems may vary, and each health provider may need a bespoke approach to integration of the KFRE paying attention to internal IT timescales and pressures. This also limits the access to readily available data, despite being in similar geographies, resulting in delayed care for patients.

An automated calculation such as that developed by Roche can be integrated with either LIMS or EHR as determined by local systems and preferences. These platforms can also provide data insights and tracking of results. Where KFRE is integrated at a laboratory level, it can be ordered as a simple laboratory test. This gives it an advantage over other risk prediction tools that use super learner processes to calculate risk; these cannot be integrated into existing primary care systems such as SystmOne and EMIS in the UK, and their results are not transparent due to the nature of the algorithm used to calculate risk (34). Integration allows the development of actionable insights for clinicians and policymakers within a system that can also provide testing and feedback on pathway and service changes. Rolling evaluation, involving all stakeholders and a robust health economic analysis, ensures performance is assessed in an iterative way to prioritise delivery of high-quality care for all.

Patient-level data, accessible to patients and clinicians alike, needs to be maintained in a secure framework that can be managed and monitored. In the UK individuals can access information about their health via the NHS app and Patients Know Best, a secure online portal which integrates with the NHS app. There needs to be increased attention towards data security and a better understanding of cybersecurity risks. There is an increased risk of cyberattacks and cyber-breaches and clear evidence of their risk to patient safety making the need for secure data systems urgent (35). Pre-existing digital tools which have already received regulatory approval ensure quality and compliance and enable safe and effective use, whilst secure environments as provided by tools such as Roche's Algosuite ensure security of patient-level data.

Outstanding research questions

The KFRE provides a snapshot in time of risk, and work continues on questions about its longitudinal use, and use in earlier CKD stages. Important questions remain about how risk prediction equations, such as KFRE, can support patient understanding and shared decision-making, and how their use across different populations can reduce inequalities in access to care and disparities in outcomes.

Integration and implementation of the KFRE may enable other questions to be answered, such as the clinical and health economic impacts of monitoring early CKD, and the role of risk prediction in this group. The use of automated systems, as well as increasing awareness of KFRE and measurement of uACR would allow further refinement of treatment pathways, by better stratifying frequency of testing in different groups. UK guidance currently recommends at least annual repetition of the test, with more frequent measurement in advanced disease, however research continues into this.

Resource implications and policy challenges

All new innovations in healthcare come with a question of cost, benefit, and resource implications. In the UK QALYs are used to determine the cost/benefit of specific interventions, and early detection of CKD has been shown to prove cost effective on health economic analyses (36). Internationally the notion of value-based healthcare is well-established as a tool to improve outcomes (37). CKD is a high-cost condition; it accounts for 1.3% of the total annual NHS budget (38), of which £1.05 billion, or 0.53% is spent on dialysis every year. Early detection and intervention may prove to be cost-effective in delaying or preventing progression to ESKD. Health economic evaluation therefore is an essential component of implementation of the KFRE in clinical practice, and should be integrated into evaluation of the process.

Greater and earlier identification of CKD will necessarily require additional resources and/or transformation of the delivery of services for healthcare systems. However, digital health tools that can automate and remove some of the manual work in this process have the potential to streamline and improve efficiency from a provider perspective, whilst also improving patient experience and outcomes. Platforms such as Algosuite can work with local clinicians to integrate digital health tools and change management into a clinical workflow. Improved risk assessment also optimises allocation of resources in health systems, by improving timely referral for high-risk patients, and ensuring those at lower risk are managed appropriately in primary care.

As an algorithmic risk prediction tool, the KFRE requires regulatory approval by medical device health authorities. In the UK it has been approved by the MHRA, and incorporated into recommendations by national guideline bodies. The next step therefore is in implementing this guidance widely.

Implementation in other settings

There is evidence for the implementation of a staging system to identify acute kidney injury in laboratory systems in the UK (39). With awareness and education, it is now widely used as a screening tool by non-specialists. Despite the evidence base and recommendations by guideline committees, there has been limited adoption of the KFRE in health systems. Where it has been used, there is evidence that a risk-based approach improves targeting of the highest risk patients in CKD clinics, whilst a US health provider reported that adoption was limited by provider knowledge about its use in clinical decision-making (40). Our implementation blueprint considers the challenges described in the literature to date, and suggests solutions that address these. Identification of the steps and challenges at each stage of the process allows it to be adapted and refined for use in different health systems worldwide.

The general principles described mean it can also be used as a template for implementation of digital solutions in other disease areas, such as those included in Algosuite and in development in other disease areas including cancer, cardiovascular, and lung disease.

Discussion

The development of eGFR reporting from creatinine presented a major step forward in patient and clinician understanding of kidney disease and its management. The implementation of the KFRE is the next iteration from eGFR reporting, and has the potential to cause a similar shift, moving towards a new understanding of CKD and a paradigm of personalised medicine. The most exciting potential for the use of risk management tools such as the KFRE is in moving towards a more holistic and collaborative model of healthcare.

Using a digital health tool such as Algosuite can provide standardised eGFR calculation for use in KFRE, or allow integration of the KFRE into existing electronic health record or laboratory systems. It is easy to scale, and can provide further data insights to improve efficiency, reduce error, and improve clinical decision-making. Its tools can leverage patient data to facilitate generation of new knowledge, to inform redesign of clinical systems. A key goal of chronic disease management is patient activation and self-management. Algosuite can support improved communication between patients and clinicians, allowing for more meaningful discussions about care and better decision-making. We propose using the blueprint described above to test implementation of Algosuite into a UK provider network in Leicester, and a primary care network in Southampton, with evaluation and reporting of outcomes in two different settings and population cohorts. Successful use of digital health solutions in CKD could be used as a template for the role of digital health solutions in other long-term conditions in the future.

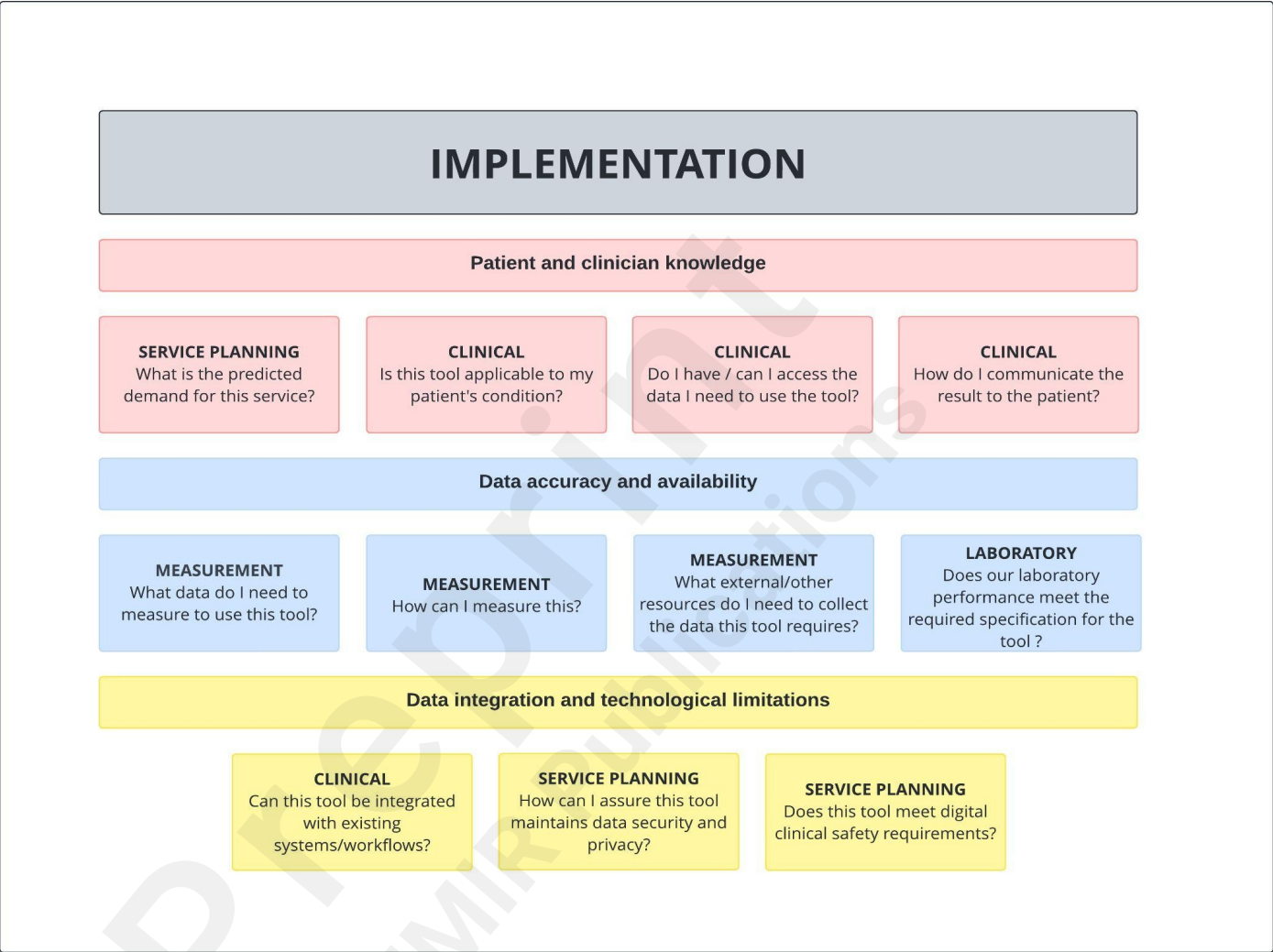


Figure 1. Template for implementation of digital health tools in a healthcare setting

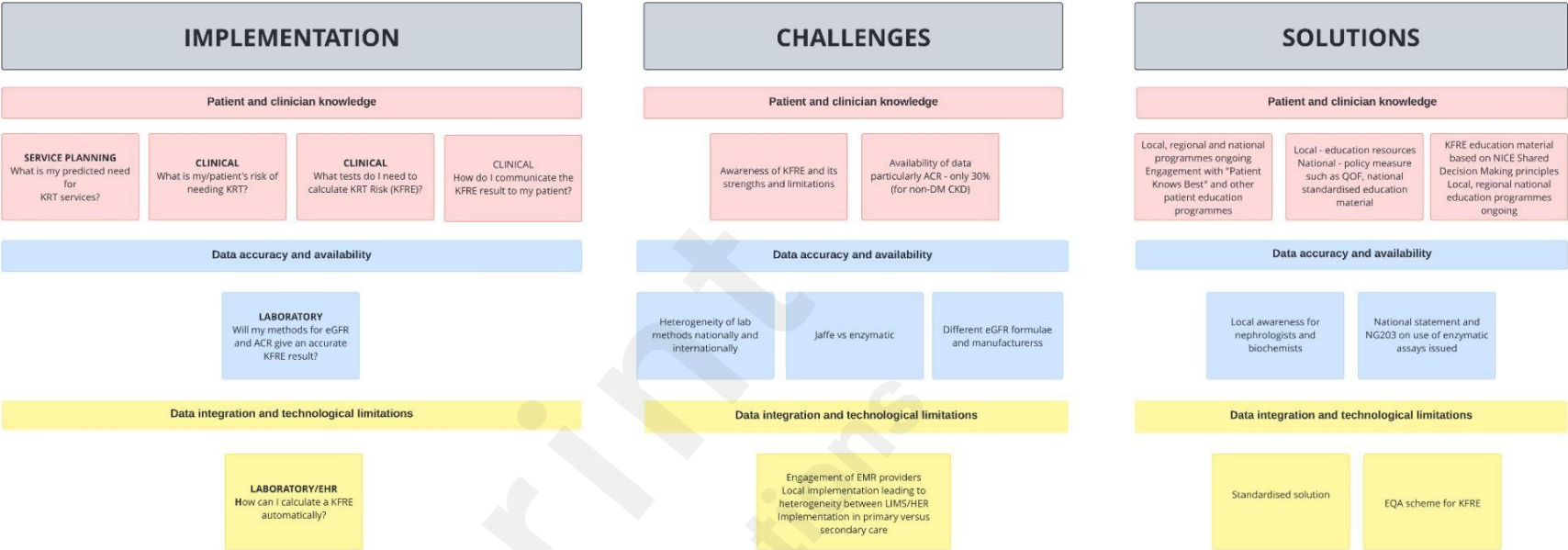


Figure 2. Example of how to implement the KfRE in a healthcare system, identifying challenges and solutions at each stage.

Conflicts of Interest and Funding: Roche Diagnostics own the intellectual property for Algosuite (“navify® Algorithm Suite”) and funded a medical writer to draft the manuscript.

Ethics, Consent to Participate, and Consent to Publish declarations: not applicable.

Data Availability: not applicable, no data to share.

Registration: not a clinical trial and no registration of study.

Author Contributions Statement: Roche Diagnostics funded a medical writer to draft the first draft of the manuscript. Major RW and Guo C coordinated the re-drafting of the manuscript. CG prepared the figures in the manuscript. Major RW, Peracha J, Frangez Z, Dreyer A, Rueegger P, Guo C, Cockwell P and Veighey K reviewed the manuscript and agreed to submission.

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