The role of health information technology in the management of clinical data in kidney transplantation

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Abstract

Kidney transplantation is a complex speciality where care pathways involve multi-speciality coordination and administration of clinical data across organisational boundaries. This PhD aimed to better understand clinical processes and workflows, data management challenges and the role of health information technology (IT) to support kidney transplant services.

The first manuscript in this thesis is a systematic review of the existing evidence on the use of health IT in kidney transplantation. I identified studies that demonstrated that technology has been implemented to manage clinical data, improve efficiency and allow patient-led care. However, there was an overall scarcity of robust evidence on effectiveness in this field, as studies were largely descriptive and did not provide quantifiable evidence of intended benefits. This highlighted a need for further scientific research to better understand workflows, clinical requirements and service needs.

In the second manuscript I presented a data journey model of the kidney transplant network in the North West of England. Applying the data journey modelling methodology allowed me to gain an indepth understanding of the health IT infrastructure pertinent to kidney transplant workflows as well as highlight potential socio-technical barriers to digital transformation. I identified that human actors, rather than IT systems formed the central focus of data movement. The lack of interoperability within the IT landscape impacted the workflow and exerted a significant administrative burden on clinical teams. Based on this study, I suggested that future solutions must consider regional interoperability and transplant-specific views of data to support the service.

I subsequently conducted a national interview study evaluating the current state of digital transformation of kidney transplant services across the United Kingdom. The results of this study are reported in the third manuscript. Analysis revealed that the key challenge revolved around an inability to access clinical data across organisational boundaries. This resulted in dependence on post or e-mail to transfer clinical data, such as blood results or medication lists. Though most centres had hospital-wide electronic health records, these were unable to support workflow requirements. This was primarily because implemented systems were unable to provide a single unified view of transplant-related data. As a result, transplant coordinators reported several manual workarounds to manage clinical data, such as paper folders, Microsoft© Excel sheets and scanned files on hospital shared drives.

In the fourth manuscript I presented a prototype user interface of a conceptual solution based on the needs and requirements gathered through the preceding chapters of this thesis. I applied a usercentred codesign methodology to receive continuous input from clinical stakeholders during the design process. Together with the digital health software team, I used the NHS design toolkit as well as international web accessibility standards to design a user interface that met clinical workflow requirements, but also adhered to best practice. I aimed to demonstrate that rapid prototyping and realworld feedback adds significant value in the development of clinical IT solutions.

Reflecting on the results from the first four manuscripts, I recognised a need for standardised data models to drive the development of interoperable health IT systems. To realise this, I explored the openEHR approach in the final manuscript and created an open information model for living kidney donor assessment. This created the potential of standardisation at the level of data storage and achieve semantic interoperability allowing the future development of transplant-specific clinical applications.

Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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I am indebted to the **patients** I spoke to along the course of this PhD. Your valuable lived experiences of illness and treatment helped ground my thinking. My work ultimately aims to improve the quality of care we deliver and it is critical we keep patients at the heart of digital transformation in the NHS. I will therefore always involve patients throughout project lifecycles to achieve the anticipated potential of technology-enabled healthcare.

I would like to thank the **transplant coordinators, transplant laboratory scientists and clinical colleagues** at the Manchester University NHS Foundation Trust who helped provide feedback and data for the studies in this thesis. I would also like to extend this gratitude to **transplant coordinators at all UK transplant centres** who contributed to the interview study. This also holds true for **lliada** – thank you for teaching me about data journey modelling. I have presented our work on several occasions receiving fantastic feedback on the approach and am already looking for new use cases to apply it!

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Thank you to all the **co-authors** that have contributed to the manuscripts in this PhD. I am grateful for your contributions to my learning and to the quality of our academic output. Through our manuscripts and presentations, we have explored new methodologies, added to the academic literature and provoked thoughtful discussions amongst clinical, informatics and policy-making stakeholders. I hope to continue to work with you in the future and contribute to health informatics research and teaching at the University of Manchester.

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Videha 28/03/2022 Manchester, UK

About the author

I am an aspiring clinical academic with interests in health information technology, digital transformation and user-centred design. During this PhD I have successfully led my own digital health projects and consulted on wider academic and quality improvements activities at the university and regional NHS trusts. I have built a professional network in Manchester and also nationally through the Topol Digital Health Fellowship. During my PhD I have relished working with and learning from professionals across disciplines. This has allowed me to develop new skills and gain independence as a researcher. I look forward to maintaining my relationships with colleagues at the University and I am excited to take up an honorary position at the Division of Informatics, Imaging and Data Science. Most recently, I have been awarded the National Medical Directors' Fellowship by the Faculty of Medical Leadership and Management and will be taking up a clinical fellow post at NHSx in September 2022. This will build on my experiences so far and contribute to my long-term ambition to establish a portfolio career combining clinical, academic and leadership roles.

I am originally from the Netherlands and now settled in Manchester with my wife Zerin and our oneyear old daughter Anaya. I am of Indian heritage and fortunate to have had a diverse upbringing. Beyond the workplace, I enjoy spending time with my family and together we like to explore new cultures and cuisines by travelling within and outside of the UK.

Publications related to this PhD

<u>The use of health information technology in renal transplantation: A systematic review.</u> Sharma V, Piscoran O, Summers A, Woywodt A, van der Veer SN, Ainsworth J, Augustine T *Transplantation Reviews*, 2021

<u>Modelling data journeys to inform the digital transformation of kidney transplant services</u> Sharma V, Eleftheriou I, van der Veer SN, Brass A, Augustine T. Ainsworth J *Journal of Medical Internet Research*, 2022

KidneyCloud: a clinically-codesigned solution to support kidney services with assessing patients for transplantation

V Sharma, S Foster, P Whelan, S Antrobus, T Augustine, J Ainsworth, SN van der Veer *Studies in Health Technology and Informatics*, 2022

The evaluation of digital transformation in renal transplantation in the United Kingdom: a national interview study

V Sharma, T Augustine, J Ainsworth, SN van der Veer International Journal of Medical Informatics, 2022

A full list of Videha's publications can be found here.

Awards/fellowships

Research grant, Kidneys for Life Data-driven healthcare funding call, Manchester University NHS Foundation Trust Topol Digital Health Fellowship, Health Education England National Medical Director's Fellowship, Faculty of Medical Leadership and Management

Conference presentations

Clinical data management at UK kidney transplant centres: complex. chaotic, creative (oral) V Sharma *Digital Health Rewired* (2022), London, UK

Data sharing in multi-centre clinical services – a patient-centric approach (oral) V Sharma *The Covenzis NHS data conference* (2022), virtual

Data ecosystems across integrated care systems (Panel discussion) V Sharma *Healthcare Excellence Through Technology* (2021), London, UK

Digital maturity of UK renal transplant centres (poster) V Sharma, Sharma V, Augustine T, Ainsworth J, van der Veer S *European Society of Transplantation* (2021), Milan, Italy

Health information technology and kidney transplantation (oral) V Sharma *AIMED Clinician Series* (2019), Miami, USA

Chapter 1: introduction

1.1 Chronic kidney disease and transplantation

The kidneys normally serve several critical functions in the human body. They filter waste products and toxins from the bloodstream and also maintain the amount of circulating fluid. They produce hormones, which help regulate blood pressure and salt levels as well as hormones that promote the production of red blood cells. Finally, the kidneys play an important role in the conversion of vitamin D into its active form, which helps to maintain the health of our bone (Fig. 1).¹



Figure 1: the key functions of the kidneys in the human body

Chronic kidney disease (CKD) is the term used to describe the long-term condition characterised by an inability of the kidneys to function as normal. The severity of CKD is staged based on the level of remaining kidney function, which is measured by the residual ability to filter waste products from the bloodstream.² This is represented by the glomerular filtration rate (GFR) and is expressed in ml/min, with a lower GFR corresponding to a more advanced stage of CKD (Table 1). When the GFR reaches below 15 ml/min, the patient is described to have end stage kidney disease, which is also known as end stage renal failure, or sometimes simply as 'kidney failure'.³ In the introduction and discussion of this thesis, we will refer to this as kidney failure for consistency.

| CKD stage | GFR |
|---------------|--------------|
| 1 (normal) | >90 ml/min |
| 2 (mild) | 60-89 ml/min |
| 3 (moderate) | 30-59 ml/min |
| 4 (severe) | 15-29 ml/min |
| 5 (end stage) | <15 ml/min |

Table 1: stages of chronic kidney disease are represented by the residual ability of the kidneys to filter blood of waste products

Kidney failure is an increasing global health issue, affecting over 5 million patients worldwide.⁴ Patients with kidney failure require medical treatment to compensate for the loss of function from their own kidneys. This treatment is known as renal replacement therapy (RRT) and can take the form of dialysis or transplantation.⁵ In the United Kingdom (UK), nearly 70,000 patients were actively receiving RRT in 2019 according to the latest UK Renal Registry report.⁶ Most of these patients had a functioning transplant as their current form of treatment with a mean GFR of 53 ml/min for patients transplanted in the preceding year. Just under 8,000 new patients started RRT in 2019 and haemodialysis was the most common new treatment form. Based on UK data, the life expectancy of patients treated with a transplant is longer compared to those treated with dialysis. This difference is particularly noticeable in younger patients with an expected life span being twice as long.⁷

This is because transplantation is the only form of treatment that provides a sustained cure for kidney failure. It should therefore be the treatment of choice for all eligible patients.⁸ Dialysis, the alternative form of RRT has a significant impact on patients' lives as they need to connected to a dialysis machine three or four times a week for several hours for haemodialysis or connect a bag of fluid to a tube placed in the abdomen for peritoneal dialysis.^{9, 10} Dialysis is further more costly than transplantation, with the costs of a transplant typically equivalent to one year of dialysis treatment.¹¹⁻¹³ A transplant therefore provides significant survival benefit and improved health quality parameters, as well as wider advantages to health systems and society.¹⁴

However, out of the nearly 8,000 new patients who started RRT in 2019, only 8.3% received a transplant as their primary treatment. A significant proportion of patients with kidney failure will not be suitable for a transplant due to other health conditions, such as heart disease. Nonetheless, barriers to transplantation for patients that are eligible remain complex. These include patient and healthcare professional education and the ready availability of organs for transplantation.^{15, 16} Furthermore, American and British data demonstrate disparities in the access to transplantation based on socio-economic and ethnic backgrounds.^{17, 18} Therefore, the prevalence of CKD and kidney failure mandates increased focus on strategies to improve uptake of transplantation, increase equity of access and reduce both the overall burden of disease and associated costs.

1.2 The transplant waiting list and patient pathway

There are currently over 5,000 patients on the kidney transplant waiting list in the UK and the median waiting time for a donated kidney is just under three years.¹⁹ This results in patients being established on dialysis while waiting for a kidney transplant, and explains why dialysis is the most common new form of RRT. Pre-emptive transplantation, prior to the requirement for dialysis provides improved outcomes. This makes time on dialysis a potential modifiable risk factor to improve transplant outcomes.²⁰ However, previous studies demonstrate significant variation in practice across the UK, with waiting times, pre-emptive transplant rates and percentage of dialysis patients treated with a living donor kidney transplant differing markedly across the country.²¹ The reasons behind these variations remain poorly understood and early work has suggested that there may be a lack of awareness of the

referral and work-up process amongst non-renal practitioners and junior doctors.²² Similarly, the benefits of transplantation versus dialysis are poorly understood in other medical communities outside of nephrology and transplantation.²³

The evaluation of a potential transplant recipient is a variable process. This is because patients with kidney failure differ considerably in age, aetiology of kidney disease, co-morbidities as well as socioeconomic status and ethnic background.^{24, 25} However, after accounting for case mix, service evaluation studies across Europe, Australia, America and the UK continue to demonstrate marked geographical variation in clinical practices.²⁶⁻²⁸ These studies quote a difference in local protocols, available infrastructure and a differences in clinical risk-acceptance as reasons for variation. The most recently available UK Renal Registry data on transplant wait-listing (up to the end of 2017), showed that the median time from the start of RRT until registration on the waiting list ranged from 0 to 914 days across the 23 transplant centres. This meant that some centres registered all their patients on the waiting list prior to any of them starting dialysis, whereas for other centres the median time from starting dialysis until registration and inequity of access to the transplant waiting list. Due to the imperative of providing early and equitable access to transplantation there is a need to better understand current workflows and investigate novel approaches.

The current transplant patient pathway typically traverses speciality and organisational boundaries. Patients with CKD are under the care of nephrology, where the focus is on limiting the deterioration of kidney function, whilst managing associated complication such as hypertension, anaemia or electrolyte disturbances.²⁹ As with most chronic disease management, care is delivered through a multi-disciplinary team with allied health professionals such as specialist nurses, dieticians and physiotherapist playing critical roles to improve care and outcomes.⁵ For patients who progress towards kidney failure, transplantation should be considered as the primary form of RRT unless not eligible. The conversation around transplantation is typically undertaken by a nephrologist or an advanced CKD nurse and should ideally be initiated prior to the start of dialysis.³⁰ The timing of this conversation varies across renal centres but the aim should be to refer patients for transplant assessment in a timely manner so they can be added to the waiting list before their GFR deteriorates below 15 ml/min.^{22, 31}

When a patient is considered for a transplant, the evaluation process begins. This patient pathway is also referred to as 'transplant listing' and patients are known as 'recipients'. Transplant listing is a complex clinical pathway and the process can be daunting for recipients.³² Typically, this includes multiple hospital visits and the process can take several months.³³ Different clinical team members assess the potential recipient and they undergo a multitude of laboratory and radiological investigations before a decision to add them to the national waiting list can be made. Along the transplant listing pathway, a large volume of data is collected, which needs to be centralised and readily available for clinical decision-making (Fig. 2).



Figure 2: data sources related to kidney transplant listing

From the clinical team's perspective, it can be challenging to maintain a transparent overview of the clinical workflow, as several patients, with varying complexity, are being evaluated at the same time. This, in turn makes it difficult to deliver a timely and standardised service. Patients often have several co-morbidities and additional input from ancillary clinical teams, such as anaesthetics, cardiology or urology, may be required as part of decision-making processes. Once a patient has been reviewed by the referring nephrology team and investigated as a suitable potential recipient, they are referred to the regional transplant centre. Unless the referral is from within the same NHS trust, this requires a transfer of data across organisational boundaries. Anecdotally, this incurs a significant administrative burden upon transplant teams as they manually manage complex clinical data across centres and specialities.

At the transplant centre, the patient is reviewed by the multi-disciplinary transplant team, which includes a surgeon, transplant coordinator or living donor coordinator. The referral data is reviewed and the patient is assessed for surgical suitability for transplantation. Records of previous transplants, previous surgeries and blood-thinning medications are some examples of critical pieces of information that inform decision-making and management plans. Once the assessment is complete, the patient must be registered on the national waiting list. In the UK, this waiting list is maintained by NHS Blood and Transplant (NHSBT), which is based in Bristol. In order for the patient to be listed, details of the patient must be transferred to NHSBT based on a standardised dataset. Only once the patient's name is registered on the waiting list can they be the potential recipient of a donated organ. A balance must therefore be struck to assess and list patients in a timely manner (before they require RRT (GFR<15ml/min)), but not so early that they receive potential organ offers inappropriately.³⁴

1.3 The potential for health information technology to support data management in kidney transplantation

The above summary explains why transplant listing is a complicated process with several actors, services and organisations involved in the patient pathway and wider delivery of the service. The coordination of care requires meticulous management of data and accurate, timely communication to ensure the pathway is safe, efficient and effective. CKD and kidney transplantation, like many other chronic diseases, require life-long follow-up and care. A coherent longitudinal patient record is therefore critical to manage the data of these patients throughout their lifetime. The record must be shared

between the different healthcare providers involved in their care, both in the community and at acute services. It needs to reflect the detailed medical, surgical and immunological treatments the patient has received to inform future clinical decision-making. With this being said, it is apparent that health information technology (IT) could play a significant role in supporting the management of data, and thus benefit both clinicians and patients.

However, little work has been done to establish the current state of clinical data management in transplantation and the potential application of health IT solutions.^{35, 36} It remains unknown where the challenges lie from a socio-technical and organisational perspective. This has made it difficult to inform meaningful solutions.³⁷ Furthermore, transplant-related data has thus far been collected and managed for documentation purposes only, without considering whether more innovative methods may influence decision-making, predictive care and patient experience. With the additional requirement to centralise data nationally for the transplant waiting list, better understanding of current processes may inform improvements in regional and national data sharing and standardisation of workflows.

1.4 Health information technology and electronic health records

Modern clinical care is a venture dependent on data. Healthcare professionals must have access to accurate, up-to-date data to make the best possible decisions in the interest of patients. As our understanding of the human body and associated diseases has expanded, the amount and complexity of clinical data has similarly increased. Combined with an ageing population, multi-morbidity and polypharmacy it has become progressively challenging to manage this data. The application of health IT to support clinical data management stretches as far back as the 1970s when computers were first used to record basic demographic and administrative data. In transplantation, the first scientific report on the use of health IT is from Dallas, Texas, America, where the authors described the use of a computer algorithm to match donor and recipients for transplantation in 1976.³⁸

Historically, the majority of health-related data was collected in paper format. With computing technology becoming increasingly ubiquitous, most records have been or are being rapidly digitised.³⁹ Data pertaining to clinical sciences (laboratory results) have been recorded electronically for several decades. However, most of the systems capturing this data have been developed in isolation, based on local needs and requirements, influenced by clinical leadership and availability of IT vendors at the time of procurement.^{40, 41}

In a bid to better record clinical activity for the purpose of billing and quality assurance, electronic health records (EHRs) were developed.⁴¹ Over time, these systems have evolved to become monolithic enterprise solutions. They are implemented with a view unify clinical data in to a single piece of software within a healthcare organisation and support workflows. Through national policies, such as the American Health Information Technology for Economic and Clinical Health (HITECH) (2009) and England's NHS National Programme for IT (NpfIT) (2005), the adoption of EHRs has accelerated across health systems.^{42, 43} Over time, monolithic EHRs have largely replaced smaller locally developed IT

systems (also known as 'best-of-breed') and digitised paper notes, which has improved the organization, accessibility and communication of medical information.⁴⁴

However, the implementation of EHRs incurs significant technical liability as years of legacy IT systems need to be replaced with new software. It has proven challenging for large healthcare organisations to integrate all their clinical systems into a single solution resulting in persistent data silos.^{45, 46} This challenge is compounded across healthcare organisations as procurement of clinical IT systems or EHRs rarely considers regional multi-centre or multi-service needs and requirements. This results in silos and an inability of EHRs to share data and achieve real-world impact on clinical workflow. Despite ambitious plans, data sharing across organisational boundaries remains a major barrier to the delivery of high-quality integrated clinical care.⁴⁷ Reflections on both HITECH and NpfIT highlight how a lack of focus on interoperability has limited the meaningfulness of EHRs to achieve the intended benefits of IT in healthcare.^{47, 48}

1.5 Interoperability in healthcare

Interoperability describes the ability of different IT systems to work together and exchange data within and across organisations.⁴⁹ The Healthcare Information and Management Systems Society (HIMSS) categorises interoperability into four levels, with the highest level describing an organisational maturity that supports data sharing that is seamless, timely and meaningfully considered to support clinical workflows (Table 2).⁵⁰

| HIMSS interoperability level | Definition |
|------------------------------|---|
| Foundational (level 1) | Establishes the inter-connectivity requirements needed for one |
| | system or application to securely communicate data to and receive |
| | data from another. Also described as technical interoperability. |
| Structural (level 2) | Defines the format, syntax and organization of data exchange |
| | including at the data field level for interpretation. |
| Semantic (level 3) | Provides for common underlying models and codification of the data |
| | including the use of data elements with standardized definitions from |
| | publicly available value sets and coding vocabularies, providing |
| | shared understanding and meaning to the user. Also described as the |
| | data layer. |
| Organizational (level 4) | Includes governance, policy, social, legal and organizational |
| | considerations to facilitate the secure, seamless and timely |
| | communication and use of data both within and between |
| | organizations, entities and individuals. These components enable |
| | shared trust and integrated end-user processes and workflows. |

Table 2: Healthcare Information and Management Systems Society interoperability levels 50

Within the interoperability levels, semantic interoperability describes the state where both sender and receiver of data in an information processing environment are able to share, interpret and understand data without ambiguity.⁵¹ This may be achieved by using common data models and terminologies, which creates standardisation at the level of data storage. This is also referred to as the data 'layer' or data 'platform'.⁵² The emergent outcome is contextually accurate data sharing across health IT solutions. Unfortunately, contemporary EHRs and vendors of health IT solutions rarely conform to data standards and store data in their own proprietary data models.⁵³

Achieving semantic interoperability has been highlighted as a key priority to improve patient care and outcomes. It is part of the recent UK Department of Health and Social care policy paper "*Data saves lives: reshaping health and social care data*".⁵⁴ There is an increasing realisation that healthcare services form part of a wider system that depends on multi-disciplinary and multi-organisational working, making communication between teams and providers critical. This holds true for transplantation as well as other areas of acute and chronic disease management. In reality however, system-wide interoperability in health is yet to be achieved.⁵⁵

1.6 Designing and developing interoperable health IT solutions

To achieve meaningful data sharing across healthcare systems, we must develop health IT solutions that are interoperable by design. NpfIT and HITECH were resource-intensive efforts, and though largely successful at digitizing health records and driving the adoption of EHRs, a lack of interoperability at the core of these strategies created fragmented data siloes. The subsequent Wachter Report (UK, 2016) reflected on both these experiences and concluded how healthcare systems depend on the timely and accurate availability of clinical data (Fig. 3). The report also emphasized how it remains difficult to share electronic data between hospitals and clinics using EHRs built by different vendors, which impacts care and outcomes.⁴⁷ It is therefore critical to establish the existing health IT infrastructure in order to reflect upon interoperability challenges and prevent repeating past mistakes. To achieve this, we applied established and emerging methodologies (described below) to better understand these challenges in the context of transplantation and identify an applicable way forward.

"The purpose is to radically improve the chances that **important information** will be **available when and where it is needed**, because **no healthcare system or clinician can perform** at the top of their potential **if it is not**."

Wachter review (2016)

Figure 3: concluding quote from the Wachter review (UK, 2016)

1.6.1 Data journey modelling

Data journey modelling was developed to better understand data movement in healthcare and to systematically identify the technological, organisational and cultural challenges that obstruct the effective movement of health data.⁵⁶ Its overarching aim is to improve decision-making around new health IT solutions procurement by highlighting potential costs and risks to data management in large complex healthcare systems.⁵⁷ Its application to transplantation has not previously been described. Based on the multi-disciplinary and multi-organisational nature of the kidney transplant pathway, it will help understand the relationship between the health IT landscape and the clinical processes. This will identify areas for further investigation and potential future investment to address the current challenges in clinical data management for kidney transplantation.

1.6.2 User-centred design

Technological innovation in health and social care is marred with non-adoption and failed attempts.⁵⁵ New health IT solutions are frequently designed based on assumed benefits, with poor understanding of the processes or outcomes the intervention is trying to improve.⁵⁸ Additionally, a lack of engagement with the people affected by an intervention creates a further barrier for successful implementation. ⁵⁹ The mantra for successful digital transformation is thus described as 'people, process and technology' (Fig. 4).^{60, 61}



Figure 4: successful digital transformation in healthcare combines an understanding of clinical workflow (process), engagement of healthcare professionals and patients (people), and the application of technology to achieve a change

The uncertainty of the healthcare funding model does not lend itself to digital transformation and sustainable change. NHS boards have been shown to wrongly prioritise outputs rather than outcomes in order to secure the next round of funding. We must embed leaders with improved methods of planning and decision-making that focus on long-term goals of investment in health IT within healthcare systems.⁶² One of these methods is user-centred design and was highlighted a key strategy to achieve successful digital transformation in the NHS.⁶³

User-centred design is a development method that seeks input from end-users of a planned solution throughout the design process.⁶⁴ It can be applied to any aspect of service improvement, but is commonly used in the development of IT solutions. Though the most common IT solutions in healthcare, EHRs, allow some customisation, mostly during the implementation phase, they are rarely designed with an understanding of the contemporary user. As a result, current EHRs are unable to meet specific workflow requirements.⁶⁵ This has been shown to be associated with increased physician burnout rates, and recent usability studies highlight how clinician satisfaction with EHRs remains low.^{66, 67} This results in users devising work-arounds or simply not adopting new technologies.⁶⁸ The application of user-centred design in healthcare remains limited, however it is gaining traction.⁶⁹ By readily welcoming feedback and placing part of the responsibility with clinical stakeholders, user-centred design provides an opportunity for understanding usability barriers while nurturing buy-in from end-users. Involving those with lived experience of delivering and receiving healthcare drives shared ideation and can thus significantly add to the development of meaningful solutions.

1.6.3 Knowledge elicitation and clinical information modelling

The foundation for meaningful interoperability in healthcare is derived from a semantic harmonisation of clinical concepts.⁷⁰ For example, most EHRs will store a concept such as 'blood pressure' in their database. However, the contextual metadata associated with this common clinical concept, such as 'cuff size', 'position' or 'device' are all stored in proprietary information models. If EHRs adopted the same standard to store clinical data they would be able to exchange information seamlessly, without the need for additional translation between systems (HIMSS level three and four). Each piece of clinical software typically consists of a database (back-end) and an application (front-end). An information model is a representation of concepts captured in a database and assigns contextual meaning to that data and sits between the front- and back-end (Fig. 5).



Figure 5: the typical structure of a software solution showing the role of the information model that assigns meaning and context to the data being queried by an application from the database

Involving end-users with the development of IT leads to lower barriers to adoption down the line and contributes to organisational buy-in. This is particularly true in healthcare where data is complex and domain-specific expertise are required to develop information models that accurately reflect clinical concepts. Model-driven development is an approach to building software, which focusses on the

accurate abstraction of concepts and aims to ensure coherent and re-usable information models. It demands a committed 'ground-up' strategy, to gather rich requirements and help overcome social and organisational challenges to scalability.⁷¹ Case studies outside of healthcare show that successful model-driven development requires input from domain experts in a progressive and iterative approach. Combined with organisational commitment, integration with existing processes and well-defined patient outcome measures model driven development can bridge the gap between the clinical front-line and technical developers.⁷² Bringing this approach to healthcare has tremendous potential as there is an opportunity to develop health IT systems that share information readily, improve the coordination of care and standardise health data for potential analytic or research purposes.⁷³

However, developing standardised information models in healthcare is not easy.⁷⁴ It strongly relies on clinical domain expertise, which provides the knowledge necessary to create a model that accurately represents a clinical concept and is re-usable across use cases. Despite an increase in the availability of tools that allow clinicians to contribute to the authoring and reviewing of clinical content in information models, barriers remain to their involvement in this work.⁷⁵ This requires further research; however anecdotal reports suggest that barriers may relate to a lack of training on the role of digital and data in healthcare professional undergraduate courses.^{76, 77} This means that the current workforce is unable to recognise the critical role they play as domain experts in driving digital transformation in healthcare. Additionally, allocating time for clinicians to participate in non-direct care related activities is difficult with a potential to impact on front-line services, which are already under marked pressure.

1.7 Overall aim and objectives

The overall aim of this thesis is to better understand the clinical workflows and data management processes in kidney transplantation, with an investigation of the current and potential role of IT to support the service. Each chapter addresses an aspect of this overall aim informing the social, technical and organisational challenges (objectives – Table 3).

This included establishing the current evidence base by undertaking a systematic review in chapter 2; in particular I hoped to identify examples of transplant-specific EHRs or evidence-based solutions that addressed the challenge of data management across transplant and referral centres. This work identified a gap in the literature and the EHR market for IT solutions that meet the needs and requirements of transplant services. This led to exploring the transplant recipient journey and clinical workflows in chapters 3 and 4 with a view to informing future solutions. Having gained a better understanding of the challenges, chapter 5 explored what a potential transplant-specific EHR would look like by codesigning a prototype user interface with front-line healthcare professionals. The emerging key requirement from this established that access to a representation of data across organisational boundaries was critical for any solution to meaningfully support the workflow. The final chapter thus investigated the development of an open data model for the assessment of a potential transplant patient. As a first use case with selected a living donor assessment for the data model development, due to the reduced complexity of these patients. This allowed us to understand the

modelling tools and challenges associated with these methods in the context of transplant-related clinical data.

Chapter seven (discussion) aggregates the results from all manuscripts and draws an overall summary of the findings. It further highlights implications for clinical practice and identifies areas for future research.

| Objective: | Addressed in: |
|--|------------------|
| Understand current use of health IT in kidney transplantation | Chapter 2 |
| Understand workflows and data management challenges | Chapters 3 and 4 |
| Explore the feasibility of a transplant-specific EHR | Chapter 5 |
| Investigate the use of open data modelling to support interoperability | Chapter 6 |

objectives of this PhD thesis and the chapters each objective is addressed in

1.8 Rationale for journal format of thesis

I chose to present this thesis in 'journal format'. There are two main reasons for this. Firstly, the natural progression of the research followed a comprehensible narrative, which could be divided in to five academic exercises, each summarised as a research paper. Secondly, by publishing my research in academic journals, I aim to reach a wider academic, clinical and patient audience. Though specific to kidney transplantation, I recognise how findings from my research may translate to other (specialist) clinical areas and may further be of interest to health informaticians, clinical leadership and policymakers. Presenting the chapters in journal format will therefore facilitate publication and dissemination.



Figure 6: comprehensible progression of the work conducted in this PhD presented as five research manuscripts each building on progress of the previous

All manuscripts are presented as they are published or submitted. However, referencing styles, fonts and layout have been standardised.

1.9 Minute lecture

I created a 'minute lecture' together with an illustrator from the Faculty of Biology, Medicine and Health at the University of Manchester introducing my research at the start of my PhD. You can watch it by clicking <u>here</u>.

1.10 Author contributions

As per the recommendation by the University of Manchester guidance on journal format thesis presentations, the contributions made by each author to the herein presented manuscripts are as follows:

Chapter 2: The use of health information technology in renal transplantation: a systematic review

 VS, SNVDV and JA designed the study. VS and SNVDVD proposed the search strategy and inclusion criteria. VS and OA collected and curated the data. VS undertook formal analysis and wrote the original draft of the manuscript. OA, AS, AW, SNVDV, JA and TA reviewed and edited the final manuscript.

Chapter 3: Modelling data journeys to inform the digital transformation of kidney transplant services

• VS, IE, SNVDV and JA designed the study. VS undertook field interviews and collected data, VS and IE analysed the data. VS wrote the original draft of the manuscript. IE, SNVDV, AB, TA and JA reviewed and edited the final manuscript.

Chapter 4: The evaluation of digital transformation in renal transplantation in the United Kingdom: a national interview study

• VS, SNVDV, TA and JA designed the study. VS undertook the interviews, summarised data, analysed results and wrote the original draft of the manuscript. SNVDV, TA and JA reviewed and edited the final manuscript.

Chapter 5: KidneyCloud: a clinically-codesigned solution to support kidney services with assessing patients for transplantation

 VS, SF and JA designed the study. VS collected data. VS and SF analysed the data and designed the prototype. VS, SF, PW and SA reviewed and iterated the prototype. VS wrote the original draft of the manuscript. SF, PW, SA, TA, JA and SNVDV reviewed and edited the final manuscript.

Chapter 6: Co-development of an openEHR-based information model for kidney transplant services in the United Kingdom

 VS, JA and IM designed the study. VS and DJ undertook the business process mapping. VS, IM, NDB, HK and DJ undertook the clinical information modelling. VS, IM and HK undertook the validation of the models. VS wrote the original draft of the manuscript. IM, NDB, HK, DJ, PW, SA, TA, JA and SNVDV reviewed and edited the final manuscript.

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Chapter 2

Manuscript title

The use of health information technology in renal transplantation: a systematic review

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Abstract

Renal transplantation is a complex, multi-disciplinary and cross-centre service. Clinical pathways naturally traverse specialty and organizational boundaries as patients transition from chronic kidney disease to renal failure and ultimately transplantation. Health information technology (IT) has the potential to support transplant care by improving access to data, information sharing and communication. This novel review aimed to identify and characterize health IT solutions in renal transplantation, and where possible evaluate any intended benefits. A systematic literature review was conducted of studies covering any part of the clinical pathway, with end-users being clinical staff or patients. Interventions were characterized and evaluated for achieved benefits using the World Health Organization (WHO) Classification of Digital Health Interventions and the mixed methods assessment tool (MMAT) was used to determine the quality of experimental studies. Of 4,498 articles, 12 descriptive and 6 experimental studies met the inclusion criteria. Median MMAT percentage score of experimental studies was 64 (i.q.r. 57 to 74.8). The most frequent functionality of technology involved overcoming communication roadblocks and improving access to data. Intended benefits included improving information management and supporting workflow, however only one study reported evaluated results. Six patient-facing applications that primarily addressed adherence-to-treatment were identified, five of which were evaluated for intended benefits, showing overall positive results. Overall, despite transplantation being well suited to health IT interventions, this review demonstrates a scarcity of literature in this field. A small number of clinician- and patient-facing IT solutions have been reported, albeit mostly in non-experimental studies. Due to this lack of formal evaluation, the effectiveness of solutions remains unclear. High-quality evaluative studies are required to develop effective IT solutions that improve clinical care.

Key words

Kidney transplantation, health IT, medical informatics, electronic health records, digital health, patientfacing apps

Abbreviations

IT – Information Technology, WHO – World Health Organization, MMAT – mixed methods assessment tool, EHR – electronic health record, UK – United Kingdom, PRISMA – preferred reporting items for systematic reviews and meta-analyses, MeSH – medical subject headings, EUNETHTA – European Network for Health Technology Assessment





41. Introduction

Across healthcare, information technology (IT) has the potential to enhance the organization and delivery of care by redesigning processes, improving efficiency and ultimately quality of care.^{1, 2} Specifically, the use of computer systems has been shown to directly improve clinical outcomes,³ reduce the incidence of serious medical incidents⁴ and improve utilization of health resources.^{5, 6} Quantum advances in processing capability, data storage capacity and the rapidly growing volume of digital clinical data, make the need to better understand how technology can support clinical practice more critical than ever.⁷

Transplantation is a complex multi-disciplinary service spanning medicine and surgery. Patients traverse clinicians, specialties and organizations as the transition from chronic kidney disease to end-stage renal disease and ultimately surgical transplantation.⁸ The pre-transplant work-up process includes multiple reviews to optimize health parameters and assess fitness for surgery. This is aggregated with a long wait for a donated kidney during which health must be maintained. Similarly, post-transplant care is centred around immunosuppression and graft monitoring as well as prevention and treatment of common complications such as infection, rejection and recurrent disease (*Fig 2*).



Figure 2: transplant patient journey

A prerequisite for providing high quality and timely care for the transplant patient is access to and transfer of rich and reliable clinical data to help clinical teams make crucial decisions. The clinical area of transplantation is thus dependent on efficient use of IT to support administrative and workflow processes.⁹ Transplant services are delivered at regional tertiary centres receiving referrals from affiliated renal units. There is thus a requirement for information flow and data transfer across organizational boundaries. System analyses in transplantation have previously suggested the potential of IT to improve data management and quality of health records.¹⁰ A report in the *American Journal of Transplantation* (2012) highlighted the lack of integration of hospital-wide electronic health record (EHR) systems within kidney transplant care.¹¹

Efforts to improve electronic data management have been made across other clinical specialties, particularly in cancer care. In the United Kingdom (UK), the Somerset Cancer Register is a software application developed by the National Health Service (NHS), which provides a bespoke IT solution to support the multi-disciplinary nature of cancer treatment.¹² Also in general surgery, studies have demonstrated positive impacts of digital health implementation on the quality of clinical documentation and even length of post-operative stay.¹³ Specific example include the introduction of a personalized e-health program for patients undergoing elective surgery reducing the recovery time in the Netherlands ¹⁴ or an integrated software solution to seamlessly analyse healthcare data and provide real-time personalised risk profiles for cardiovascular disease in patients attending primary care in New Zealand.¹⁵ Thus, digital solutions can support clinical processes, but also provide data capture for registry and audit purposes as well as a repository for research. Within transplantation it is unclear whether any similar developments exist even though it is imperative for contemporary and future clinical practice.

The overarching aim of this review was to gain insights into the use of IT for data management, information sharing and communication in kidney transplantation. We anticipated to highlight how IT had been used to enrich the quality of and access to data, save clinical time, reduce cost or improve the quality of care. Specific objectives were to (1) identify and characterize health information technologies; (2) describe the intended use and role of the technology; and (3) summarize any intended and evaluated benefits.

2. Materials and methods

This review was reported in accordance with PRISMA guidelines.¹⁶ Research meetings with all coauthors guided the development of the search strategy, inclusion/exclusion criteria and fields of extraction. All data were recorded electronically in tabular form.

2.1 Search strategy

We executed a comprehensive literature search on the 15th of November, 2019 using OVID® for Medline and SCOPUS for all published journal articles, combining search terms relating to health IT and kidney transplantation. Medical subject headings (MeSH) terms were used when available. An experienced librarian at the University of Manchester reviewed the search strategy, and iterations were made based on their feedback (*supplement I*).

2.2 Selection of relevant studies

The inclusion criteria for this review related to five areas:

• *Type of technology:* we defined health IT as any method or application that deals with the recording, storing, processing, exchanging or displaying of digital healthcare data to facilitate patient pathways, assessment, monitoring, communication or clinical decision-making.¹⁷ We selected studies using solutions that would directly impact clinical care and pathways, such as clinical decision support systems. We excluded technology that affected a single point of care in the pathway (e.g. robotic surgery, 3D printing for pre-operative planning), as well as digital data management solely for research purposes.

• *Clinical area:* we included studies applied to any care area within kidney transplantation. This included the pre-transplant assessment phase, surgical transplantation and post-transplant follow-up. As transplantation is a multi-facetted discipline we included health IT that supports clinical processes, patient communication and supporting medicines management. We excluded studies pertaining to other solid organ transplantation, blood donation or the use of technology in research settings such as animal studies.

• Users of the systems: we included articles describing the use of health IT by patients or any member of the multi-disciplinary team including nephrologists, transplant surgeons, nurses, pharmacists, transplant coordinators, etc. We excluded studies targeting the general public, such as the use of social media to raise awareness for donor registration.

• Study types and design: we included all original study types, including descriptive studies pertaining to proof-of-concept, feasibility, or development of health IT solutions, even if not evaluated or implemented. We excluded reviews.

• *Publication types:* we included papers published in peer-reviewed journals and conference proceedings. Conference abstracts, reviews, editorials, commentaries, and grey literature were excluded. Non-English reports were excluded.

Two reviewers (VS and OP) independently screened all citations by title and abstract, followed by fulltext review to reach a final decision on inclusion. *Supplement II* details the selection criteria with examples.

2.3 Data extraction and thematic analysis

Both reviewers (VS and OP) independently extracted, summarised and categorised the following basic study characteristics from each included manuscript using a pilot-tested proforma: country of origin, year of publication, study design and summary.

Informed by the World Health Organization's (WHO) *Classification of Digital Health Interventions* v1.0¹⁸ and the *European Network for Health Technology Assessment (EUNETHTA) Core Model (2016)* ®,¹⁹ we extracted the following information to characterize each health IT intervention: (i) positional role in pathway, (ii) health system challenge addressed, (iii) targeted primary user, (iv) details of the health IT – functionality and type of system, (v) intended benefits, i.e. the aspect(s) of healthcare quality the technology intended to impact and (vi) evaluated benefits (if any). We used the Institute of Medicine domains of health care quality to categorize intended and evaluated benefits in each study.²⁰ To achieve an effective qualitative analysis, we used the WHO classification to identify common themes that emerged from the results and classified studies based on healthcare challenges addressed. A summary of these steps is summarised in the appendix.

2.4 Quality assessment

The quality of all experimental studies was evaluated using the Mixed Methods Appraisal Tool (MMAT), which allows concomitant appraisal of quantitative, qualitative, and mixed-methods studies.²¹

3. Results

Our search yielded a total of 4,498 unique citations. Following screening, 62 titles were identified for full-text review (*Fig 3*). Eight titles could not be retrieved. Following full-text review, data was extracted and thematically analysed from 18 papers, which are summarized in detail in tabular form *supplement III*, including types of systems and a narrative summary of intended and achieved benefits.²²⁻³⁹

3.1 Study characteristics

There were six experimental and 12 descriptive studies. Of the experimental studies, there were two randomized control studies, two retrospective observational studies, and two prospective observational studies. The majority of the studies (n=9) originated in the USA and most studies were recent (13/18 since 2013). Three studies were pre-2000 (1991, 1988 and 1987) (*Supplementary table 2*).



Figure 3: PRISMA flow diagram of screening and selection of relevant studies

3.2 Health IT characteristics

Extracted data from each study was thematically analysed and summarized based on the WHO classification as demonstrated in *Fig 4*. All health IT had either healthcare professionals (n=12) or patients (n=6) as the intended end-users. Most studies described systems that fulfilled a role in the donor identification process (n=7), followed by across the entire transplant pathway (n=6), pre-transplant care (n=3) and post-transplant follow-up (n=2). The health system challenges which the technology aimed to address were: 1) 'information' (lack of quality/reliable data, lack of access, n=16), 2) 'efficiency' (inadequate workflow management, poor planning and coordination, n=11) and 3) 'quality' (insufficient continuity of care, poor adherence to guidelines, n=7). In four out of six studies with patients as end-users the health system challenge revolved around adherence to treatment.



Figure 4: example of data extraction (Development of a Clinical Decision Support System for living kidney donor assessment based on national guideline, Knight et al)

The most frequent type of technology used was health information management systems (n=10), fulfilling functions such as data collection and management, providing checklists according to protocol and transmitting workflow notifications to healthcare professionals. Six studies described the use of patient applications, which served functions as self-monitoring of health or diagnostic data, active data capture/documentation and patient-to-patient communication. Three studies included any qualitative assessment of end-user needs during the development phase of their technology.

3.3 Analysis of intended and evaluated benefits

All studies described intended benefits in the introduction of their manuscripts. All six domains of healthcare quality were included across studies. Intended benefits were generally non-specific such as 'digitize clinical workflow processes in donor data management'²⁶ or 'increase operational efficiency'.²⁵ Most studies did not include any evaluation of the intended benefits and reported anecdotal impact of technology. Six experimental studies evaluated whether technology achieved the intended benefits. These included benefits such as 'reduction in time taken to identify donors' (quantitative)³⁵ or 'acceptance of an mHealth solution' (qualitative).²⁷ We grouped recurring intended benefits in themes and summarized them in greater detail, including illustrative examples where available:

3.3.1 Information management

The most common intended benefit related to data and information management. A number of studies reported on technologies to collect, store and communicate healthcare data. For example, to improve the quality of data collected for performance evaluation in living donor kidney transplantation³⁷; increase the utilization of data by developing a digital organ donor registry²²; and to overcome information communication roadblocks through a web-based referral system for newly identified donors in intensive care units.³⁵
3.3.2 Improving efficiency

A second recurring theme was efficiency, with 11 studies intending to address delays, poor planning and inadequate workflow management. Even though most studies discussed the importance of the reliability of data management solutions, the impact this may have on efficiency was not consistently highlighted. Clinical efficiency was addressed through the application of clinical decision support systems to help identify potential donors earlier,³⁶ a web-based database to access donor and recipient data through a single system²⁶, and integration of multiple databases in to a new electronic system for transplantation.³⁹

3.3.3 Improving effectiveness

A number of studies aimed to improve the effectiveness of healthcare processes. Most frequently these technology involved the use of patient-facing applications to increase immunosuppressive therapy adherence,²⁷ reduce loss to follow-up³⁷ and promote enrolment in transplant programs through digital education.³⁴ In particular, Moore et al developed a web-based screening tool for potential living donor candidates.²⁸ This was evaluated in a retrospective cohort study, which demonstrated that the transplant team increased the number of donors assessed, without utilizing additional resources.

3.4 Study quality appraisal

We appraised the quality of all experimental studies that reported evaluated benefits using the MMAT tool (n=6). These included three observational cohort studies^{28, 31, 35}, two randomized control trials^{27, 34} and one qualitative study³⁸ (see *supplement IV*). None of the cohort studies reported how they chose study samples and all had risk of reporting bias. They were all three graded as 'moderate' quality (MMAT score 50-70%). The randomized control trials investigated the use of patient-facing technology and aimed to improve adherence to treatment and improve patients' understanding of treatment. Both were of 'good' quality (MMAT score >70%), even though blinding was not possible due to the nature of technology interventions. The single qualitative study explored patients' immunosuppression adherence and was also of 'good' quality, with the authors reporting appropriate qualitative methodology and interpretation of results.

4. Discussion

4.1 Summary of main findings

This systematic review identified 18 articles on the use of health IT to support kidney transplant clinicians and patients. Most were descriptive and published within the last seven years. IT has been used to address healthcare challenges in access to data, adherence to treatments and to overcome communication roadblocks. Intended benefits revolved around information management, and improving

the efficiency or effectiveness of clinical care. Functionality of technology included providing prompts or alerts, transmit workflow notifications and active data capture/documentation (*Fig 5*). A total of six moderate to good quality experimental studies evaluated whether the intended benefits were achieved, reporting overall positive impact of the technology.



Figure 5: summary of main findings

4.2 Relations to other studies

Despite widespread use of IT across healthcare we only identified a limited body of literature pertaining to its role in renal transplantation. In other fields of medicine, such as primary care, a larger body of evidence exists, with several systematic reviews reporting quantitative benefits of technology in general practice.^{40, 41} These reports highlight the meaningful use of clinical decision support systems and computerized order entry. However, similar to our review they identify insufficient reporting of contextual details and evaluative results, making it difficult to fully establish the benefits of reported interventions.

A previous review on the impact of health IT on organ transplant care reported an overall positive impact.⁴² However, this review was across all solid-organ transplantation and excluded descriptive studies. By including descriptive studies on interventions at an early stage of development in our report we were able to identify common healthcare challenges and intended benefits. There are no scientific reports on the use transplant-specific EHR systems, even though a number of commercially available products exist (OTTR CareDX and Epic Phoenix – both USA). In bone marrow transplantation, individual centres have reported the use of health IT to support pathways, manage data and clinical workflow, though these have been locally developed and not commercialized as yet.⁴³ In current practice, transplant-related data is stored in different formats across multiple electronic data management solutions.⁴⁴ This makes it difficult for clinical teams to efficiently exchange, analyse or interpret digital clinical information for decision-making. However, based on the findings of our study investigating novel solutions, evaluating them rigorously and reporting them to scientific standards is likely to improve care outcomes and benefit patients.

4.3 Implications for practice and future research

Digital health research is rapidly enhancing with improved methodologies and means of evaluation being readily available. This review identifies a number of pertinent avenues for future research for kidney transplantation. The use of an established computer modelling tool to better understand care processes in paediatric kidney transplantation by Andellini et al (included in our review) showed potential for improved efficiency and saving valuable clinical time.³³ Such an intervention may have a lasting impact on services.

Transplant programs are provided at specialist centres covering wide geographical areas, which requires regional coordination and data management.¹¹ Due to the complexity and longevity of care for transplant patients it is probable that standard hospital-wide EHR systems may not fulfil the functionality required for the management of these patients. This may be translated to other surgical services that deal with multi-morbidity and deliver multi-specialty patient care, such as vascular surgery or orthopaedic surgery. The Topol Review (UK, 2019) highlights the opportunities for digital transformation in healthcare, if accompanied by a thorough understanding of the context of change and developing a learning environment to innovate and evaluate new technologies.⁴⁵ A recent review published in the *Journal of the American Medical Association* however highlights how the increasing complexity of contemporary medical care requires IT to allow clinicians to deliver the human side of care which cannot be substituted by technology.⁴⁶ This was echoed in a recent debate in the *Annals of Surgery* where it is argued that the EHRs in their current form negatively impact the clinician-patient relationship.⁴⁷ It is therefore paramount that future research takes a user-centric approach, with an understanding of clinical workflow and full understanding of the healthcare challenge being addressed.

As is evidenced by a lack of experimental studies in this review, impact of health IT is often difficult to evaluate due to challenges in experimental design and uncertainty of appropriate outcome measures.⁴⁸ Also, the experimental studies rated moderate or good quality using MMAT were unable to truly capture the relevance of research, and thus the rating may not reflect the actual value of those studies. Alternative quality assessment methodologies, specific to health IT research may be more suited to evaluate the impact of studies.⁴⁹ A challenge for health IT research is the development-to-implementation gap; by the time evaluative data is available the workflow challenge, or indeed the technology itself may have evolved, thus not realizing intended benefits. Recognised validating bodies may help overcome this challenge by using standardized and reproducible evaluative frameworks to speed up this process.⁵⁰ A further solution to this may be change the focus of evaluation from solutions, to principles or concepts. Using common classification systems, such as the WHO *Classification of Digital Health Interventions* may thus allow learning to be shared across specialties and disciplines minimizing duplication and increasing impact.

A number of studies included in our review reported the use of patient-facing applications to raise awareness, educate, and to improve medication adherence. When evaluated, these received positive feedback from patient users. In life-long conditions such as renal failure, such technologies have the potential to give patients a greater role in their treatments and promote personalised care.⁵¹ Previous qualitative studies exploring the views and perspectives of transplant patients in using technology for health monitoring or treatment adherence showed positive results.^{52, 53} An established web-based application in use amongst kidney transplant patient is Renal PatientView, which allows remote access of laboratory results to patients on smartphones, tablets or computers.⁵⁴ A single-centre survey-based study by Woywodt et al of 295 patients showed that 92% of patients found the system easy to use and 93% felt that it helped them taking control of their condition.⁵⁵ This positive end-user engagement strengthens the case for developing solutions to support transplant patients.

41.5 Limitations of this study

A limitation of this study is that it was designed to identify published scientific literature reporting the use of health IT in kidney transplantation, which may result in missing initiatives reported outside of the academic context. IT is integral to healthcare delivery, and frequently updated – however implementation of novel solutions frequently occurs without peer-reviewed reporting of intended and evaluated benefits.⁵⁶ The aforementioned Somerset Care Record (cancer MDT data management) is widely used and implemented across NHS trusts, however there is no associated scientific reporting on development, evaluation or achieved benefits.¹² We focused specifically on the field of kidney transplantation due to its unique requirements, being a multi-specialty and cross centre surgical service. We recognize there may be health IT in other fields, which may translate to the transplant sphere, or provide useful lessons and insights. At the same time, the thematic analysis of this review may also be useful for investigators in other fields of medicine.

This review included any form of health IT and any study type, leading to a heterogeneity in intended benefit, study design, and types of technology. We were thus unable to summarize effect sizes across studies. The studies were largely descriptive in nature making it difficult to draw meaningful conclusions. However, this explicitly highlights the lack of work in this relevant and pertinent field. Future reviews may select a particular health system challenge or type of technology with the aim to conduct a meta-analysis, thereby strengthening the quantitative evidence base. We found the relatively highest quality studies were conducted in patient-facing technology and this may be the first area of future interest.

4.5 Conclusion

This review has demonstrated that technology has been implemented to manage clinical data, improve efficiency and allow patient-led care. However, there is an overall scarcity of robust evidence on effectiveness in this field, as studies were largely descriptive and did not provide quantifiable evidence of intended benefits. The complex regional nature of kidney transplantation relies on data sharing and

information flow, which is likely to benefit from IT innovation. There is thus merit in further scientific work in this field. Future studies to better understand patient pathways, clinician requirements and service needs will inform development and implementation of new health information technologies. Novel interventions must then be evaluated for their intended benefits using established frameworks to allow best practice to be established and improve outcomes for patients.

Declaration of interests

The authors of this manuscript have no conflict of interest to disclose. The authors of this manuscript confirm this work is original and how not previously been presented/reported.

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Supporting information statement

Additional supporting information may be found online in the Supporting Information section at the end of this article.

Supplementary materials

- I Search strategy
- II Inclusion criteria
- III Data extraction and thematic analysis
- IV MMAT quality assessment

Appendix

Data extraction and thematic analysis steps

To replicate this systematic review, follow these steps:

- 1. Independently extract basic study characteristics from each included manuscript capturing the country of origin, year of publication, study design and summary.
- 2. Use the World Health Organization's (WHO) Classification of Digital Health Interventions and the European Network for Health Technology Assessment (EUNETHTA) Core Model (2016) to extract information characterizing each health IT intervention, including positional role in pathway, health system challenge addressed, targeted primary user, details of the health IT (functionality and type of system), intended benefits, and evaluated benefits (if any).
- 3. Categorise intended and evaluated benefits in each study based on the Institute of Medicine domains of health care quality
- 4. Use the WHO classification to identify common themes that emerge from the results.
- 5. Classify studies based on healthcare challenges addressed such as lack of access to information or data, low adherence to treatment or communication roadblock
- 6. Present the results in a thematic narrative based on the common themes of intended benefits

Concordance statement:

A high level of concordance was observed between the two reviewers of this systematic review, indicating a strong agreement in their assessments of the included studies. The evaluations suggest that the reviewers applied the inclusion and exclusion criteria consistently and reached similar conclusions about the quality of the evidence.

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SUPPLEMENT I: SEARCH STRATEGY

Database: Ovid MEDLINEI and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and VersionsI <1946 to November 15, 2019>

Search Strategy:

41 kidney transplantation/ (93329)

2 tissue donors/ or living donors/ or unrelated donors/ or transplant recipients/ or kidney donor*.tw. or kidney donation*.tw. (55329)

3 ((kidney or renal) adj5 transplant*).tw. (84528)

4 (transplant* adj5 (assessment* or waiting list* or listing process* or pathway* or access*)).tw. (6827)

5 1 or 2 or 3 or 4 (155725)

6 ((data or information or communication or knowledge) adj5 (manag* or captur* or exchang*)).tw. (78201)

7 exp medical informatics/ or clinical decision support systems/ or information centers/ or exp information management/ or information services/ or data curation/ or exp "information storage and retrieval"/ or information technology/ or exp systems analysis/ or exp systems integration/ or exp workflow/ (705440)

8 exp Medical Records Systems, Computerized/ or exp algorithms/ or fuzzy logic/ or exp database management systems/ or electronic data processing/ or cloud computing/ or computer systems/ or exp software/ or data science/ or data warehousing/ or health information interoperability/ (468181)
9 exp Internet/ or exp Smartphone/ or exp Computers, Handheld/ or exp computers/ or talewarehousing or electronic data warehousing/ or health information interoperability/ (468181)

telemedicine/ or ehealth.tw. or mhealth.tw. (169791) 10 (((data or information or communication or knowledge) adj5 (manag* or captur* or exchang*)) or

((cell or mobile) adj2 (application or app*))).tw. (107253)

11 7 or 8 or 9 or 10 (1189904)

12 5 and 11 (4503)

SUPPLEMENT II: INCLUSION CRITERIA

Table 1: inclusion criteria for study selection with examples

| Category | Criterion | Examples included | Examples excluded |
|--|--|---|--|
| Type of health information technology | Information Technology (hardware and/or software) or methods/applications | Electronic data management systems to monitor patient pathways | Robotic technology to support surgical procedures |
| | that deal with the recording, storing, | Smartphone | 3D printing for pre- operative planning |
| | processing, exchanging or displaying of digital | applications to communicate with patients | Paper-based data management solutions |
| | facilitate monitoring, patient management, communication clinical workflow or decision- making | Computerised Clinical Decision Support to evaluate renal function post transplantation | Medical technology used for diagnostic or therapeutic purposes e.g. USS probe, digital fluoroscopy |
| шалшу | Solutions integrating data sources for clinical workflow | Laboratory based technology such as HLA-matching | |
| | | | Use of IT as part of methodology e.g. online survey |
| | | | Development and evaluation studies of AI based prediction models |
| | | | Telehealth interventions |
| | | | Qualitative studies assessing end-user needs |
| Clinical area | Any aspect of clinical care, including structures, processes | Pre-transplantation workup | Research data collecting systems Other solid organ transplantation |
| | and outcomes, of adult or paediatric kidney | In-patient care | Blood donation |
| | transplantation along the entire pathway | Post-transplantation follow-up care | Animal studies |
| Users of the HIT/setting of the HIT | Clinical and non- clinical individuals involved in delivering | Doctor, nurse, pharmacist, etc | Other (solid organ) transplant patients General public |
| | organising or commissioning kidney transplant care | Hospital managers, health policy decision makers, government departments, etc | |
| | Patients receiving kidney transplant care | Patients on the transplant waiting list | |

| Study types and design | Original studies | Patients living with a transplanted kidney Randomised and non- randomised studies, observational studies, engineering studies describing HIT solution development, feasibility studies, usability studies, implementation | Systematic, narrative or scoping reviews, case reports |
|------------------------|---|---|---|
| Publication types | Articles in peer reviewed journals Conference papers Grey literature | studies Full-text articles, technical reports | Conference abstracts Editorials Perspectives Letters Opinion papers |
| Language | English | | Commentaries Non- English literature |

SUPPLEMENT III: DATA EXTRACTION AND THEMATIC ANALYSIS

Table 2: studies on the use of health information technology in kidney transplantation and their main findings

a In chronological order of publication year

b Whenever a p-value is not provided, it was not referenced in the article

| Reference ^a | Summary | Health system challenge | Intended end-users | Functionality of system | Positional role in pathway | Type of system | Intended benefit | Evaluated benefits and study quality (if applicable) ^b |
|------------------------|---|---|-----------------------------|---|-------------------------------|---|--|---|
| Dewhurst 19 | Develop a computerised database containing patients expressing their wish to donate organs after death across 8 regional hospitals | Lack of access to information or data Insufficient utilisation of information or data Poor planning and coordination | Healthcare professionals | Enrol patient for health service/clinical care plan Manage patients' structured clinical records | Donor identification | Census, population information & data warehouse | Increase healthcare professionals' access to information regarding patients' wishes to become an organ donor after death | n/a |
| Markus 20 | Development and design of a centre-oriented computerised kidney transplant information management system (TIMY) | Lack of quality/reliable data Communication roadblock Lack of access to information or data Insufficient continuity of care Loss to follow up Inadequate workflow management Poor planning and coordination | Healthcare professionals | Enrol patient for health services/clinical care plan Longitudinal tracking of clients' health status and services Manage patients' structured clinical records Manage referrals between points of service within health sector | Entire transplant pathway | Health Management Information System | Develop a user-friendly transplant database to store all patient data | n/a |
| Kurtz 21 | Developed a computerised management information system capable of supporting clinical requirements of a multifaceted transplant. For the following reasons: 1) to comply with reporting requirements, 2) for reporting government agencies and insurances, 3) to obtain updates operative experience, 4) to integrate the Histocompatibility and Immunogenetics Laboratory for online test result reporting, and 5) to facilitate clinical investigation. | Lack of quality/reliable data Communication roadblock Lack of access to information or data Insufficient continuity of care Inadequate workflow management Poor planning and coordination | Healthcare professionals | Longitudinal tracking of patients' health status and services Manage patients structured clinical records Routine health indicator data collection and management Transmit diagnostic result to healthcare provider | Entire transplant pathway | Health Management Information System | Support entire transplant pathway from assessment to matching to post- operative care | n/a |
| Zhao 22 | Analysis of bottlenecks in current deceased donor kidney distribution process and how agent technology may improve this process. Propose a distributed multi-agent system operating in a mobile communication environment to assist transplant coordinators in coordinating with multi-parties in this time- critical distribution process. A prototype system has been developed to demonstrate the feasibility of such system. | Communication roadblocks Inadequate workflow management Poor planning and coordination Delayed provision of care Lack of effective resource allocation | Healthcare professionals | Provide prompts and alerts based according to protocol Transmit routine news and workflow notifications to healthcare provider(s) Manage referrals between points of service within health sector | Pre-transplant care | Health Management Information System | Increase operational efficiency of deceased donor organ donation process | n/a |
| Van Hees 23 | Designed an online donor database, that was created for donor registration and quality data reporting. A 24h accessible website was created and was linked with clinical pathways and reports. | Lack of quality/reliable data Communication roadblock Lack of access to information or data Insufficient continuity of care Loss to follow up Inadequate workflow management Poor planning and coordination | Healthcare professionals | Enrol patient for health services/clinical care plan Longitudinal tracking of clients' health status and services Manage patients' structured clinical records Manage referrals between points of service within health sector | Entire transplant pathway | Health Management Information System | Digitise clinical workflow processes in donor data management | n/a |

| McGillicuddy 24 | A mobile phone-based application to improve adherence to antihypertensive medication through automated notifications and a medication box, which communicated to the mobile app once the medication had been taken with home-based BP monitoring via a Bluetooth BP cuff. | Low adherence to treatments | Patients | Self-monitoring of health or diagnostic data by patients | Post-transplant care | Patient applications | 1) acceptance of intervention 2) adherence to BP medication 3) resting BP | 75% of patients approached for the study agreed to participate; high satisfaction with mHealth intervention (ease of learning 4.7/5, ease of use 4.8/5, usefulness for health management 4.3/5) 2) mHealth intervention group had significantly higher medication adherence rates compared to control group 3) statistically significant reduction in clinic BP at 3 months Study quality: good |
|--------------------|--|---|-----------------------------|--|-------------------------|---|--|---|
| Moore 25 | Interactive web-based application for live donor candidates to complete pre-referral assessment survey via internet rather than telephone survey. | Lack of access to information or data Inadequate workflow management Poor planning and coordination High cost of manual processes | Patients | Transmit targeted health information to patients based on health status or demographics Active data capture/documentation by patients | Donor identification | Patient applications | the time of usage of the web-based application; the temporal course of usage of the web-based application in comparison to phone contacts; the impact of the web- based application on the numbers of persons over time who self-referred to be a potential living donor | 801 vs 399 used the web-based application vs telephone survey (p<0.05) 24% of web-screened donors excluded based on survey results. Web-based application saved coordinators 10-12 min per patient number of referrals increased from 186 to 249 and LD transplants increased from 54 to 76 (not significant) Study quality: moderate |
| Cavallin 26 | Developed an application for iOS devices to facilitate approach to relatives and procedures for organ donation. The application, which includes algorithms, tutorials, and simple calculators, has been designed by transplant coordinators to speed up the process of organ donation. | Insufficient utilisation of information or data Insufficient health worker competence Poor adherence to guidelines Inadequate workflow management | Healthcare professionals | Enrol patient for health services/clinical care plan Provide checklist according to protocol | Donor identification | Health Management Information System | Improve workflow and management of potential deceased donor assessment through clinical decision support application | n/a |
| Danek 27 | A web-based ICU reporting system for all deaths (www.koordynator.net) in 209 hospitals for transplant coordinators to increases the number of identified potential and effective actual donors due to self-assessment analysis. | Delayed reporting of events lack of access to information or data Insufficient utilisation of information or data Poor planning and coordination | Healthcare professionals | Enrol patient for health service/clinical care plan Manage patients' structured clinical records Manage referrals between points of service within health sector | Donor identification | Census, population information & data warehouse | improved management of ICU patients who may be potential organ donors earlier identification of potential donors Increase in organ donor number | n/a |
| Kumar 28 | Developed a mobile application that enables waitlisted candidates to create a Facebook post about their experience with organ failure and their need for a live donor. Conducted a single- centre prospective cohort study of 54 adult kidney- only and liver-only waitlisted candidates using the intervention. | Communication roadblocks Low adherence to treatments | Patients | Patient to patient communication | Donor identification | Patient applications Community- based Information system | easy to use Facebook application allowing participants to post about their transplant journey increase number of potential donors; | the Facebook app was "good" or "excellent" with regard to the installation process (82.9%), readability (88.6%), simplicity (70.6%), clarity (87.5%), and the information provided (85.3%) intervention group was 6.6 (Cl 2.43 – 17.98) times more likely to have a donor come forward Study quality: moderate |
| Patzer 29 | Developed a mobile clinical decision aid that provides estimates of risks of death and survival on dialysis compared with kidney transplantation Used these risk prediction models to develop an electronic, user-friendly, mobile (iPad, iPhone, and website) clinical decision aid called iChoose Kidney. | Lack of quality/reliable data Communication roadblock Lack of access to information or data | Patients | Transmit targeted health information to client(s) based on health status or demographics | Pre-transplant care | Patient applications Civil registration and vital statistics | Allow improved decision making for ESRD patient to understand dialysis versus transplantation mortality risks at the time of RRT decision | n/a |

| Andellini 30 | Used a Business Process Management platform to implement a specific application to manage the clinical pathway of paediatric patients, and monitored the activities of the coordinator in charge of the case. | Lack of access to information or data Insufficient utilisation of information or data Insufficient continuity of care Poor planning and coordination; | Healthcare professionals | Longitudinal tracking of patients' health status and services Manage patients' structured clinical records Transmit routine news and workflow notifications to healthcare provider(s) | Entire transplant pathway | Health Management Information System | optimize the amount of time and resources devoted to management purposes improve the quality of care | n/a |
|--------------|--|--|-----------------------------|--|------------------------------|--|---|--|
| Gordon 31 | Mobile web application (Inform Me), which aims to educate transplant recipients about increased risk donors to help decision- making at time of organ offer | Lack of quality/reliable data Insufficient utilisation of information or data Low adherence to treatments High cost of manual processes | Patients | Transmit targeted health information to patient(s) based on health status or demographics Patient look-up of health information | Pre-transplant care | Patient applications Community- based Information system | increase knowledge and understanding of kidney transplantation from increased risk donors 2) increase willingness to accept kidney from increased risk donors | candidate's knowledge increased by 44% compared to control group (score difference 6.6 (95% CI 5.37 – 7.86)) no difference in willingness to accept increased risk donor kidney Study quality: good |
| Zier 32 | Implemented an electronic clinic decision support system in ICU to automatically notify transplant coordinators of children meeting clinical triggers indicating impending brain death in order to reduce time to notification of potential organ donors | Delayed reporting of events Communication roadblock Poor adherence to guidelines Inadequate workflow management Poor planning and coordination Delayed provision of care | Healthcare professionals | Healthcare Provider Decision Support Transmit routine news and workflow notifications to healthcare provider(s) Manage referrals between points of service within health sector | Donor identification | Health Management Information System | reduction in time to notify transplant coordinator of potential donors; increase the number of donors | 1) Time to notification significantly reduced from 30.2h to 1.7h (p <0.05) 2) total number of donors post intervention was significantly greater (11/24 deaths vs 7/57 deaths (p <0.05)) Study quality: moderate |
| Knight 33 | Developed a clinical decision support system, based on national living donor guidelines, to facilitate the identification of contra-indications, additional investigations, special considerations, and the decision as to nephrectomy side in potential living donors. | Insufficient utilisation of information or data Low adherence to treatments | Healthcare professionals | Provide prompts and alerts based according to protocol Provide checklist according to protocol | Donor identification | Health Management Information System | Improve adherence to national donor guidelines | n/a |
| Famure 34 | Manually completed digital database (in Microsoft Access) of demographic, medical, psychosocial, and evaluation data on living kidney donor candidates abstracted from multiple health information sources. | Lack of quality/reliable data Insufficient utilisation of information or data | Healthcare professionals | Routine health indicator data collection and management Transmit routine news and workflow notifications to healthcare provider(s) | Entire transplant pathway | Health Management Information System | Integrate data sources to create central data repository of living donor data | n/a |
| Levine 35 | Mobile app (Transplant Hero) and a smartwatch were used to help immunosuppression adherence. | Low adherence to treatments | Patients | Self-monitoring of health or diagnostic data by patients | Post-transplant care | Patient applications | Adherence (coefficient of variability – marker or chronic rejection) | 41) No significant difference between the intervention group and control group Study quality: good |
| Savikko 36 | Implementation of Phoenix (transplant module by Epic Systems) for the new electronic medical record in transplantation. Forms the basis of transforming digital patient care process in kidney transplantation. | Lack of quality/ reliable data Communication roadblock Lack of access to information or data Insufficient continuity of care Loss to follow up Inadequate workflow management Poor planning and coordination | Healthcare professionals | Longitudinal tracking of patients' health status and services Manage patients structured clinical records Routine health indicator data collection and management Transmit routine news and workflow notifications to healthcare provider(s) Transmit diagnostic result to healthcare provider | Entire transplant pathway | Health Management Information System | Digitise clinical workflow processes in kidney transplantation | n/a |

SUPPLEMENT IV: MMAT QUALITY ASSESMENT

Table 3: mixed-methods appraisal tool quality assessment of evaluative studies

| Domain | Criterion | McGillicuddy ³² | Moore ³³ | Kumar ³⁶ | Gorden ³⁹ | Zier ⁴⁰ | Levine ⁴³ |
|-----------------------------|--|----------------------------|---------------------|---------------------|----------------------|--------------------|----------------------|
| Screening question | Clear research question | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| | Data adequate to address research questions | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark | \checkmark |
| Qualitative | Appropriate qualitative approach | | | | | | \checkmark |
| | Adequate data collection methods | | | | | | \checkmark |
| | Findings adequately derived from data | | | | | | Х |
| | Interpretation substantiated by data | | | | | | Х |
| | Coherence: data sources, collection, analysis and interpretation | | | | | | \checkmark |
| Quantitative descriptive | Relevance of sampling strategy | | Х | Х | | Х | |
| | Representative sample | | \checkmark | Х | | Х | |
| | Appropriate measures | | \checkmark | \checkmark | | \checkmark | |
| | Low risk of non-response bias | | Х | Х | | Х | |
| | Appropriate statistical analysis | | Х | \checkmark | | \checkmark | |
| Randomised control | Appropriate randomisation | \checkmark | | | \checkmark | | |
| trials | Comparable groups at baseline | Х | | | \checkmark | | |
| | Complete outcome data | \checkmark | | | \checkmark | | |
| | Blinding | Х | | | Х | | |
| | Low drop-out rate | \checkmark | | | \checkmark | | |
| | Total scores | 5/7 | 4/7 | 4/7 | 6/7 | 4/7 | 5/7 |
| | Percentages | 71% | 57% | 57% | 86% | 57% | 71% |

Chapter 3

Manuscript title

Modelling data journeys to inform the digital transformation of kidney transplant services

Authors list

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Abstract

Background:

Data journey modelling is a methodology used to establish a high-level overview of information technology (IT) infrastructure in healthcare systems. It allows a better understanding of socio-technical barriers and thus informs meaningful digital transformation. Kidney transplantation is a complex clinical service involving multiple specialists and providers. The referral pathway for a transplant requires the centralisation of patient data across multiple IT solutions and healthcare organisations. At present, there is a poor understanding of the role of IT in this process, specifically around the management of patient data, clinical communication and workflow support.

Objective:

To apply data journey modelling to better understand interoperability, data access and workflow requirements of a regional multi-centre kidney transplant service.

Methods:

An incremental methodology was used to develop the data journey model. This included review of service documents, domain expert interviews and iterative modelling sessions. Results were analysed based on the LOAD (landscape, organisations, actors and data) framework to provide a meaningful assessment of current data management challenges and inform the role for IT to overcome these.

Results:

Results were presented as a diagram of the organisations (n=4), IT systems (n>9), actors (n>4) and data journeys (n=0) involved in the transplant referral pathway. The diagram revealed that all movement of data was dependent on actor interaction with IT systems and manual transcription of data on to Microsoft© Word documents. Each actor had between two and five interactions with IT systems to capture all relevant data, which was reported to be time-consuming and error-prone. There was no interoperability within and across organisations, which led to delays as clinical teams manually transferred data such as medical history and test results via post or email.

Conclusions:

Overall, data journey modelling demonstrated that human actors, rather than IT systems formed the central focus of data movement. The IT landscape did not complement the workflow and exerted a significant administrative burden on clinical teams. Based on this study, future solutions must consider regional interoperability and speciality-specific views of data to support multi-organisational clinical services, such as transplantation.

Key words

digital transformation; health information exchange; interoperability; medical informatics; data journey modelling; kidney transplantation

1. Introduction

Data journey modelling is an emerging methodology, developed to help establish the socio-technical challenges and boundaries to data movement as part of digital transformation.^{1, 2} It has been used successfully to identify risks and costs of information technology (IT) projects within healthcare systems, such as the United Kingdom (UK) National Health Service (NHS).³ Specifically, data journey modelling provides a high-level overview of data entities, IT systems, manual processes and organisations associated with a clinical service. It is a cross-collaborative methodology between health informaticians and clinical domain experts with the aim of producing a conceptual overview of the IT infrastructure pertinent to a clinical service. This allows a better understanding of how services are delivered from a data-centric perspective and helps inform meaningful solutions. As such, data journey modelling has been shown to identify opportunities for improving operational efficiency, data management and patient safety, amongst other potential benefits.³ The purpose of this study is to apply data journey modelling to a specific clinical use case, that is planning to undergo digital transformation.

Kidney transplantation is a regional multi-organisational clinical service.⁴ It is delivered at large university hospitals (transplant centres), which receive patients from neighbouring renal referral units. This hub-and-spoke model allows a wide geographical area to be covered and is similar to other specialist services, such as cancer, genetics or vascular services. The patient journey in transplantation is complex and requires the capture of large volumes of heterogeneous clinical data. Multiple clinical teams are involved, and patients naturally cross organisational boundaries as they transition from declining kidney function to kidney failure and ultimately transplantation. The data capture during the patient journey requires meticulous administration to prevent delays and bottlenecks.⁵ However, managing high-volume complex clinical data across organisations is time-consuming and error prone, and incurs significant administrative costs. The 2014 UK *Transplant First* initiative recognised this, quoting "inefficient use of technology and administrative support" as one of the key barriers to timely transplantation.⁶ The *American Journal of Transplantation* further highlighted the impact of the lack of integration of hospital-wide electronic patient records (EPRs) on kidney transplant care.⁷

Owing to the aforementioned reasons, transplantation is a clinical area that will benefit from digital solutions to improve the management and flow of data. Health IT has been shown to successfully achieve these intended benefits, however, novel interventions are often marred with non-adoption and failure.⁸ A lack of understanding of the technical and organisational context for change is one of the key factors limiting success.^{9, 10} Further barriers exist due to a lack of consideration of the social aspect of the intervention, such as relying on human input, resistance to change, and failure to share perceived benefits with end-users.¹¹ New interventions may be developed without including the end-users in the requirement gathering process, and as a result solutions are unsuccessful at achieving intended benefits.^{1, 12} In an effort to successfully overcome these challenges, data journey modelling was identified as a methodology to establish the current IT infrastructure and involve domain experts in developing potential solutions.

The transplant referral process is an integral part of the overall transplant patient journey. It depends on the capture of data from various internal and external sources at the transplant centre, concluding with the patient being registered on the national organ waiting list. This study aims to understand this process from a data journey perspective. Specific objectives are to: 1) map the data management processes including the role of IT to support in a regional transplant network, 2) identify challenges and categorise them based on established frameworks, and 3) use the findings to suggest potential solutions.

2. Materials and Methods

We followed an iterative and incremental approach to build the data journey model with input from clinical and administrative domain experts. We used the modelling process to identify potential challenges to data management and validated the final version with domain experts not involved in the original modelling.

2.1 Context

The context for our study was the transplant centre at the Manchester University NHS Foundation Trust (Manchester, UK). It is the largest kidney transplant centre in the UK,¹³ receiving patients from two further regional renal referral units (Royal Salford NHS Foundation Trust and Lancashire Teaching Hospitals NHS Foundation Trust). The transplant centre registers around 300 new patients on the national transplant waiting list every year. Patients are also under the care of a local general practice (GP), which maintains long-term wellbeing through community-based medical care.

Each referral includes several hospital visits, medical tests and clinical assessments. Multiple healthcare professionals are involved at different stages of the pathway. Data capture along the pathway is undertaken on a Microsoft[©] Word document titled '*listing form*'. Various sections of the listing form are populated by members of the clinical team with patient data at multiple clinical time points. Data captured includes routine healthcare data such as medical history, test results and examination findings. A complete and accurate listing form is required to assess patients' fitness for transplantation and registration on the national waiting list. Once the form is completed and the patient is deemed suitable for transplantation, it is sent to the transplantation laboratory for registration (*Fig. 1*).



Figure 1: the transplant referral pathway data management is based on the transplant 'listing form'.

2.2 Data journey modelling

Data journey modelling was conducted over three steps summarised in *Fig. 2*. The aim was to establish the IT systems containing transplant-related data, organisations involved in delivering the service, individuals delivering direct care or administration (actors) and interactions of actors with systems. This would provide a comprehensive overview of the IT infrastructure, processes undertaken to extract/store data and the data journeys as part of the referral pathway. We then analysed the results using an established framework, which was developed alongside data journey modelling, to help characterise our findings and draw meaningful conclusions.¹ Finally, we evaluated the final version of the model and our findings from the modelling process with domain experts not originally involved in the development methodology. A step-by-step summary of steps is provided in the appendix.

2.2.1 Document review

We reviewed local written protocols pertaining to deceased donor, living donor and transplant recipient pathways at the transplant centre. We extracted all data entities routinely expected to be captured on the 'listing form' and cross-referenced in which IT systems these items were stored. We identified which other healthcare organisations were involved in delivering the service and drew their boundaries. Finally, we established which actors play a role in the referral pathway within the transplant centre. With this information we designed a baseline iteration of the data journey model demonstrating the technical and organisational infrastructure, but still missing the actors and data journeys. We used Lucidchart© (Lucid Software, Inc), a web-based diagram and visual design application to draw our model iterations.

2.2.2 Domain expert interviews

We conducted informal interviews and held small group meetings with domain experts working at the transplant centre to gather information needed to further develop the model. Based on a pre-defined topic guide, we defined domain experts as any member of the clinical or administrative team that was involved in direct patient care or back office management of transplant-related data. We ensured this

covered all the necessary actors identified through document review and baseline iteration of the model. We spoke with four transplant coordinators, two nephrologist, two surgeon, one transplant assessment nurse, two secretaries and a laboratory administrator. Domain expert interviews provided the processes to extract/store data and the data journeys between IT systems and across organisational boundaries. Meetings lasted between 15 and 60 minutes and we kept minutes to increase accuracy and recall.

2.2.3 Iterative modelling

We followed an Agile-inspired method to develop the model, based on an incremental approach. Agile is an adaptive project methodology, which relies on continuous collaboration with stakeholders to change the output based on feedback and repeated cycles of review.^{14, 15} It has been shown to successfully accomplish goals in healthcare projects and is well suited to the development of a model, which depends on embedding feedback from domain experts to iterate a final version.¹⁶

We modelled the processes that the various actors undertake in their work that deal with the key data entities to either capture and store or move data from one system to another. A total of five iteration sessions were held with the data journey modeller (IE) and domain experts to create the final model for analysis.



Figure 2: summary of data journey modelling steps with associated output of each step.

2.3 Analysis and external evaluation

We used the LOAD framework to analyse the final version of the data journey model and categorise our findings. LOAD stands for landscape, organisation, actors and data, each denoting a dimension of IT as part of a clinical service (*Fig. 3*).¹ Using the LOAD framework ensured we comprehensively analysed the model and associated data journeys, allowing us to identify technical barriers, such as lack of systems interoperability and social challenges, such as manual workarounds.



We then externally evaluated the final model by conducting semi-structured interviews with domain experts not directly involved with model development. Interviewees included two transplant coordinators, one transplant surgeon and one nephrologist. We presented them with the model and asked them if it accurately reflected the clinical workflow and data management processes at the transplant centre. We prompted them to consider elements of the LOAD framework and think about how time spent on data management impacted delivery of the service and patient experience. The meetings lasted typically 30 minutes and were recorded as researcher notes.

3. Results

3.1 Baseline iteration of the data journey model

Based on the document review we established the basic elements of our model. There were four organisations contributing patient data pertinent to delivering the service: one transplant centre, two referring centres and GP surgeries. Within the transplant centre, we identified six IT systems that held data related to the transplant referral pathway (*Table 1*). There were also several external IT systems outside of the organisational boundary of the transplant centre that contained pertinent data. These were GP systems containing medical history and medications, and systems of other trusts containing local medical history and results. As we did not map IT systems at other organisations in detail we denoted them as a single IT system, though each organisation may have had multiple systems in use. Finally, once data collection along the clinical pathway is complete, it is transferred through a webbased system called Organ Donation and Transplantation Online (in-house developed by NHS Blood and Transplant) to register the patient on the national waiting list.

We identified a total of four actors that played a role to manage clinical data: clinicians, transplant coordinators, secretaries, and administrators. The term 'clinician' referred to multiple specialists including nephrologists, surgeons and transplant assessment nurses. However, as their roles were similar from a data perspective and we denoted them as 'transplant clinician' for the purposes of our model. *Fig. 4* demonstrates the output of document review and first iteration of data journey model.

Table 1: summary of all IT systems at the Manchester University NHS Foundation Trust, their suppliers and clinical data management purposes

| System | Supplier | Purpose |
|--|-----------------------------|--------------------------------|
| | | |
| Chameleon EPR | In-house | Correspondence/results |
| Integrated Clinical Environment | CliniSys© | Ordering tests |
| Picture Archiving and Communication System | General Electric Company© | General radiology |
| ClinicalVision 5 | Constellation Kidney Group© | Renal history/dialysis details |
| xCELERA | Philips© | cardiovascular imaging |
| Shared drive | Microsoft© Windows | Transplant listing form |





Figure 4: baseline iteration of data journey model demonstrating IT systems, organisational boundaries and actors.

IT = information technology NHSBT = NHS Blood and Transplant

3.2 Final data journey model

The baseline model and domain expert interviews iteratively informed actor interactions and data journeys, which were added to the model to create the final version. The organisations were rearranged, placing the transplant centre at the centre of the model and the other organisations around it. There were no direct data journeys between IT systems within the transplant centre, or between systems across organisational boundaries. It became clear that the shared drive was the centre focus of data management, which was an in-house solution resulting from the need to centrally capture and view clinical data that was not being met by existing systems. To complete the workflow, a minimum of twelve separate actor interactions with IT systems were necessary. Actors had the following minimal number of interactions with the IT systems: clinicians – five; coordinators – three; secretaries – two; administrators – two. The final data journey model is shown in *Fig. 5.*



Figure 5: final data journey model, demonstrating the IT landscape and data journeys in kidney transplant referral.

3.3 LOAD analysis

The final data journey model and feedback from external evaluation with domain experts allowed us to analyse findings based on the LOAD dimensions.

3.3.1 Landscape

The overall landscape demonstrated the complexity of the transplant referral pathway from a data perspective. The IT systems were not developed for the needs of the transplant service and have not been updated as the requirements have changed over time. A lack of interoperability across organisational boundaries raises data governance issues, and it was unclear whether data sharing agreements between the organisations was formally agreed. There was no IT system that provided a unified view of transplant data, which resulted in a workaround solution in the form of Microsoft© Word documents and shared drives. This has led to a landscape where human actors, rather than IT systems form the central focus of data movement.

3.3.2 Organisations

Key data was mainly stored internally within the transplant centre's organisational boundary. Patient data, such as results of investigations not undertaken at the centre, were stored externally at referral units and general practices. There were no direct data journeys from IT systems at external organisations in to the transplant centre and this data was typically transferred via post, email or fax to the transplant coordinators. They then manually scanned paper-based data and saved it to the shared drive alongside other electronic data. We identified that two-thirds of the patients going through the pathway were from external referral units. This meant that for majority of patients registered on the waiting list, there was no up-to-date clinical data at the transplant centre. All interviewees reported that this posed a significant challenge to clinical workflow. Time was spent to chase-up data from referral units, there were frequent delays and need for repeated requests. An additional social challenge raised was the lack of accountability, with clinical staff being unclear who was responsible for data being updated and accurate; the transplant centre or the referral units.

3.3.3 Actors

Data journeys were wholly dependent on actor interaction with IT systems and manual transcription of data. Key data was stored across multiple IT systems, which lead to loss of efficiency as clinicians must log in multiple times to view and extract data. Only two actor groups were able to interact with the shared drive, which meant that in their absence a patient would not be able to progress along the listing pathway. Domain experts reported that this created a bottleneck for the overall data journey and resulted in patient delays. Due to the impracticality of switching between multiple applications to access and transcribe data, actors reported using heuristic work-arounds, such as the use of two devices (laptop and desktop). However, from interviews it emerged that there was a variation in digital aptitude and actors reported a range of experiences of interacting with the systems.

3.3.4 Data

We identified that the listing form included a total of 247 data fields that needed to be populated. All required data was stored in the five IT systems of the transplant centre and in the systems of the GP or referral centres. There were no data journeys between IT systems or from systems to the transplant shared drive. To move data to the shared drive, clinicians had to access the different systems and transcribe (i.e. type) clinical data in the relevant fields and save the form in the designated shared folder. The file name was saved as the patient's first and last name. All data required to populate the form was in electronic format. Data was directly transcribed without any clinical expertise required to transform or manipulate it. Domain expert interviews revealed that transcription errors and incomplete data fields were a source of both patient risk as well as delays in the listing pathway. There was also currently no way of confirming data accuracy or obligating data completion. Interviewees further expressed their frustration of the time-consuming nature of the task, which detracted from time spent with patients.

3.3.5 Risk mitigating strategies

Based on the above findings, a regional solution with an agreed data sharing and governance contract will help mitigate the risks of the current fragmented landscape. A need has emerged for a central clinical data repository, with a user interface accessible at the transplant centre and referral units. Considering the range of multi-disciplinary actors involved in the transplant referral pathway the user interface will have to be adaptable and easy to operate in order to lower barriers to adoption. Technically, such a solution will benefit from being web-based and apply cloud storage to provide security and safe access across organisational boundaries. Underpinning this integration of data across IT systems will be the use of interoperability or open data standards. Critically, a deep understanding of needs and requirements, as provided through the results of this study, will drive the development of solutions that achieve intended benefits. This holds true for health IT projects in other clinical domains, demonstrating the value of this methodology.

4. Discussion

This study applied data journey modelling to evaluate the kidney transplant referral pathway and successfully identified the data, IT systems, actors and organisations and the relationship between them. This has provided an overview of the data landscape and highlighted the complexity of data administration, as well as a lack of data flow. We identified that clinical staff must undertake significant manual processes to summarise and visualise data from multiple IT systems. Work-arounds have been created in the absence of a meaningful solution that addresses the needs and requirements of the clinical workflow. The lack of interoperability and central access to relevant data increases the effort and time required to complete transplant referral, which can delay patients' registration on the transplant list.

4.1 Relation to other studies

This is the first study to apply data journey modelling to transplant services. Previous studies have highlighted the complexity of kidney transplantation from a clinical management perspective. These recommended the use of IT solutions, such as business process management technology to lower management costs.¹⁷ Our study has established the dependence on manual processes to administer data, which is likely to incur management costs. The current data landscape strictly serves a documentation process, and does not provide any process support. Experience across the European Union advocates that contemporary IT systems and EPRs must provide functionality beyond data capture to better support the needs of clinical services.¹⁸

This study identified that data journeys in the transplant pathway naturally crossed speciality and organisational boundaries. However, with the absence of interoperability there was a dependence actor interaction to share data. In other clinical areas, access to data across organisational boundaries continues to be a significant challenge.¹⁹ The introduction of a national EPR in Finland has facilitated implementation of digital pathways across nephrology and transplantation.²⁰ However, larger nations with more heterogenous populations and geographical variations, face challenges to harmonise fragmented healthcare data.²¹ Data journey modelling in this study, however, confirms that meaningful interoperability remains one of the key barriers to meaningful digital transformation.

4.2 Implications for practice and future concepts

Data journey modelling identified that during the referral pathway, clinicians are not required to transform or manipulate any data in order to complete the form – thus the IT challenge is one of summarising and viewing relevant information in a format which allows seamless and enhanced clinical decision-making. In the UK, general practice recognised the value of customised viewing of clinical data early, and primary care IT systems are more intuitive to the clinicians' needs.²² However, in the hospital setting a paradox exists, where systems commonly detract from patient contact due to dependence on user interaction to view data.^{23, 24} An early study by Zeng et al evaluated concept-orientated views of clinical data versus traditional chronological presentation of data in current EPRs. They demonstrated that visualising data around clinical context such as disease or organ system reduced information overload and accuracy of data retrieval.²⁵ Based on the data fields identified in this study, for kidney transplantation this would include presenting a single-screen summary of relevant demographics, medical and social history with details pertinent to dialysis and previous surgeries. This would allow clinicians to focus on the patient at the time of an encounter, and complete relevant clinical details not previously recorded in any IT system, such as residual urine output, exercise tolerance or examination findings.²⁶

Findings from this study highlight the technical requirements for a transplant-specific solution; regional integrated data store across the necessary organisations with an application processing interface that

meets the needs and requirements of the clinical workflow (*Fig. 6*). Separate data and application layers for healthcare IT may help overcome current interoperability barriers and enable development of modular service-specific solutions.²⁷ Centralised clinical data repositories may facilitate application of model-view-controller software development, giving individual clinical areas the opportunity to design views to suit their context.²⁸ Semantic interoperability across systems allows data to be exchanged, analysed and interpreted readily, and is a pre-requisite for meaningful digital transformation. In contrast, digital data stored in isolated databases not only slows down medical progress, but also limits technological innovation such as real-time analytics or reuse of data for research.^{19, 26} Solutions such as Fast Healthcare Interoperability Resources protocols and OpenEHR archetypes may address these challenges going forward, however still require development and widespread adoption.^{29, 30}



Figure 6: conceptual overview of a proposed solution including a regional integrated data repository with a web-based clinical user interface.

HIMMS has defined digital maturity of individual healthcare providers based on capabilities, interoperability and governance.³¹ However, due to the multi-centre nature of transplant services, we identified that digital maturity was limited by the least mature organisation that formed part of delivering the service. Thus, even if the transplant centre had an advanced and unified EPR, the fact that patients were referred by other organisations unable to share data, implied that clinical processes could not be adequately supported. Evaluating the potential impact of any novel solution should therefore be undertaken using interoperability frameworks.³² In addition, capturing quantitative data, such as time taken to be added to the transplant waiting list, could provide a measure of impact.

Across healthcare, clinical data remains constraint to organisational boundaries and new EPR procurement does not actively consider regional workflow and data sharing reinforcing vendor lock-in.³³ In response to this, NHS England launched the 'Local Health and Care Record Exemplars', tasked with increasing clinical information sharing across primary, secondary and social care within a region.^{34, 35} Transplantation may be an excellent use case for such interoperability initiatives to demonstrate value

to clinicians, policy-makers and crucially patients. Linked data will provide the basis for learning health systems that are intuitive to their populations' needs and inform timely interventions to improve long-term health and social care outcomes.^{36, 37}

4.3 Limitations of this study

A number of other models to evaluate health information technology infrastructure exist. The data journey model and LOAD framework have been developed based on the UK-healthcare context and were chosen as the most appropriate tools to use.³⁸ However, they have not been widely applied in other clinical areas, potentially because they rely heavily on domain expertise to input during the modelling process. In our case, the study was led by a clinical research fellow who was able to help bridge the gap between the clinical and academic stakeholders. Finally, this study looked at a single regional transplant centre only. This leaves it unknown to what extent our findings would translate to other regions, which warrants further investigations.

4.4 Conclusion

Complex clinical care pathways must be fully understood to allow meaningful solutions to be presented as part of digital transformation initiatives. Data journey modelling successfully provided valuable sociotechnical factors for health IT in kidney transplantation. It highlighted how a lack of interoperability led to time-consuming manual interaction with multiple systems to summarise data for transplant referral. Data crossed multiple organisational boundaries, and all movement of data depended on actor interaction, even though no data was transformed or manipulated. Future solutions must consider regional interoperability, bespoke views that meet clinical requirements, and automate processes to free clinical staff from administrative burdens.

Conflict of interest

None declared

Abbreviations

EHR: electronic patient record GP: general practice LOAD: landscape, organisations, actors, data IT: information technology NHS: national health service UK: United Kingdom

Appendix

Data journey modelling: step-by-step methodology

Table 2: Summary of the research methods steps used in this study

| Step | Example from this study |
|--|---|
| Identify the clinical context for which the data | The research question related to the |
| journey model is to be developed | management of clinical data at a kidney |
| | transplant centre |
| Conduct document review | We reviewed departmental protocols and |
| | national guidelines pertaining to the clinical |
| | practice of kidney transplantation |
| Draw a baseline data journey model | We drew a first iteration of the data journey |
| | model so domain experts would be able to |
| | provide feedback, rather than starting from a |
| | blank canvas. |
| Define domain experts | We defined domain experts as any member of |
| | the clinical or administrative team involved in |
| | direct patient care or back-office management |
| | of transplant-related data. |
| Gather data through field interviews and/or | We conducted informal interviews and small |
| small group meetings/workshops | group meetings with domain experts using a |
| | pre-defined topic guide to gather information |
| | needed to develop the model. We ensured that |
| | we spoke with all necessary actors identified |
| | through document review and baseline iteration |
| | of the model. |
| Iterate data journey model | Based on immediate feedback from domain |
| | experts we re-drew the data journey model by |
| | hand, which was then digitised using a |
| | diagramming software |
| Draw conclusions through LOAD analysis | We drew conclusions regarding barriers to the |
| | movement of data and potential risks by |
| | analysing the completed model based on the |
| | LOAD framework. |

Topic guide used for informal field interviews and small group discussions:

- 1. What types of clinical data do you typically collect and manage in daily practice?
- 2. What IT systems are used and how is data captured and shared across different

systems and organizations?

- Follow-up: what is your experience of this?
- 3. What challenges do you face in the management of clinical data?

Show the latest iteration of the data journey model

- 4. Does this model reflect the IT systems, organizations, actors and the movement of data accurately?
 - Follow-up: what is missing or superfluous?
- 5. What improvements or innovations do you believe could be made to improve data

management and your workflow?

Table 3: the 247 data fields identified on the transplant listing form including the presence of SNOMED-CT codes for each

| Field | SNOMED-CT | Structured data available | Current format |
|-----------------------------------|-----------|---------------------------|----------------|
| Kidney Transplant assessment form | | | |
| Surname | Υ | Y | Free text |
| Forename | Υ | Y | Free text |
| Date of Birth | Y | Y | Free text |
| Age | Y | Y | Free text |
| Gender | Y | Y | Dropdown |
| Referring Consultant | Y | Ν | Free text |
| Referring Hospital | Ν | Y | Free text |
| MRI No | Ν | Y | Free text |
| NHS No | Y | Y | Free text |
| Interpreter required | Y | Ν | Y/N |
| Language | Y | Ν | Free text |
| Assessment date | Y | Y | Free text |
| Address | Y | Y | Free text |
| Landline | Y | Y | Free text |
| Mobile | Y | Y | Free text |
| Renal History | | | |
| Primary Disease | Y | Y | Free text |
| EDTA Code | Y | Y | Free text |
| Renal Bx | Y | Y | Y/N |
| Bx Date | Y | Y | Free text |
| Bx Hospital | Ν | Y | Free text |
| Previous treatment (IS) | Y | Ν | Free text |
| Adverse reaction to IS | Y | Ν | Y/N |
| Current dialysis modality | Y | Y | Dropdown |
| eGFR | Y | Y | Free text |
| Modality RRT | Y | Y | Free text |
| Years RRT | Y | Y | Free text |
| Dialysis complications | Y | Ν | Y/N |

| Previous transplant (dates) | Y | Ν | Free text |
|--|--------|---------|-----------|
| Cause of failure | Y | Y | Free text |
| Residual UO | Y | Ν | Free text |
| Recurrent UTI | Y | Ν | Y/N |
| Incontinence | Y | Ν | Y/N |
| Outflow Obstruction | Y | Ν | Y/N |
| Kidney Stones | Y | Ν | Y/N |
| Investigations/referrals | Y | Ν | Free text |
| Past medical history | | | |
| Cardiovascular history | | | |
| Exercise Tolerance | Y | Ν | Free text |
| Walk 1 Mile | Ν | Ν | Y/N |
| Climb 10 Steps | Ν | Ν | Y/N |
| Diabetes | Y | Y | Y/N |
| Diabetes duration | Y | Y | Free text |
| Diabetic control | Y | Ν | Dropdown |
| IU/Day | Y | Ν | Free text |
| HbA1c | Y | Y | Free text |
| C-Pep | Y | Y | Free text |
| Diabetic complications | Y | Ν | Y/N |
| HTN | Ý | Ŷ | Y/N |
| Angina | Ý | Ŷ | Y/N |
| MI | Ý | Ŷ | Y/N |
| TIA/Stroke | Ý | Ŷ | Y/N |
| DVT | Ŷ | Ŷ | Y/N |
| Claudication | Ŷ | N | Y/N |
| ECG date | Ŷ | Y | Free text |
| Results | Ŷ | N | Free text |
| Echo date | Ŷ | Y | Free text |
| Results | Ŷ | Ň | Free text |
| Stress Test date | Ŷ | Y | Free text |
| Results | v | N | Free text |
| Angiogram date | V V | Y | Free text |
| Results | v | N | Free text |
| CABC date | v v | V | Free text |
| Results | V V | N | Free text |
| Coronary Stenting date | v v | V | Free text |
| Poculte | I V | N | Free text |
| Deppler Lower Limbs date | I V | | Free text |
| Populte | I V | I N | Free text |
| CPET data | I V | N V | Free lext |
| CFET udle Regulto | T V | T N | Free text |
| Results | r V | IN N | Fiee lext |
| | r V | IN N | |
| Results | ř | IN | Fiee lexi |
| A other of the second s | V | V | X/N |
| Astrina | ř | ř | Y/N |
| | Y | Ŷ | Y/N |
| IB | Y | Y | Y/N |
| | Ŷ | Ý | Y/N |
| Smoker current | Ŷ | Ŷ | Y/N |
| l otal duration | Ŷ | Ŷ | Free text |
| Quantity | Y | Y | Free text |
| GI history | | | |

| GI Disorder | Y | Ν | Y/N |
|----------------------------|--------|--------|---------------------|
| Liver Disease | v | N | Y/N |
| Diverticular Disease | Y | V | Y/N |
| Oral Cavity Assessment | V | N | V/N |
| Broast | V | N | V/N |
| Details (mammogram) | V | N | Free text |
| Gypao | V | N | V/N |
| Dotails (cmoor) | T V | N | Fron toxt |
| Details (Sillear) | T V | IN N | |
| | ł V | IN N | T/IN Free text |
| Details (PSA) | ř V | N M | |
| | T | 1 | T/IN |
| Alashal/Drug Abusa | V | N | V/NI |
| Alconol/Drug Abuse | ř V | | Y/IN |
| Learning Difficulties | Y | N | Y/N |
| Best interest meeting date | N | N | Free text |
| Social History | N | N | Free text |
| Employment | N | N | Free text |
| Performance Status | Y | Ν | Free text |
| Medication history | | | |
| Allergies | Y | Y | Y/N |
| Aspirin | Y | Y | Y/N |
| Indication | Y | N | Free text |
| Clopidrogel | Y | Y | Y/N |
| Indication | Y | N | Free text |
| Warfarin | Y | Y | Y/N |
| Indication | Y | N | Free text |
| Indication | Y | N | Free text |
| Sensitization history | | | |
| Ethnicity | Y | Y | Click which applies |
| Blood group | Y | Y | Click which applies |
| Pregnancies | Υ | Ν | Y/N |
| Blood Transfusion | Y | Ν | Y/N |
| Previous Tx | Y | Ν | Y/N |
| Rituximab | Y | Ν | Y/N |
| ATG | Y | Ν | Y/N |
| Campath | Y | Ν | Y/N |
| Virology | | | |
| HCV | Y | Y | Pos/Neg |
| HBsAG | Y | Y | Pos/Neg |
| HBcAG | Ý | Ŷ | Pos/Neg |
| Anti-HBS | Ý | Y | Pos/Neg |
| CMV | Ŷ | Y | Pos/Neg |
| FBV | Ŷ | Y | Pos/Neg |
| HIV | Ŷ | Y | Pos/Neg |
| \/7\/ | v | v | Pos/Neg |
| Physical examination | • | | 1 03/1109 |
| Height | V | V | Free text |
| Weight | V | · · | Free text |
| BMI | Y | · Y | Free text |
| Hin/Waist Ratio | v | · V | Free text |
| Chaet | V | ' N | Frag taxt |
| Abdomon | i V | N | Froo toxt |
| | I | IN | |
| Liburiy | | | |

| Active | Y | Ν | Check box |
|--|--------|---------|-------------------|
| Suspended | Y | Ν | Check box |
| Reason for suspension | Y | Ν | Free text |
| Consultant nephrologist | Ν | Ν | Free text |
| Signature | Ν | Ν | Digital signature |
| Surgical assessment | | | |
| Surname | Y | Y | Free text |
| Forename | Y | Y | Free text |
| DoB | Y | Y | Free text |
| Age | Y | Y | Free text |
| Gender | Y | Y | Dropdown |
| Referring Consultant | Y | Ν | Free text |
| Referring Hospital | Y | Y | Free text |
| MRI No | Ý | Ŷ | Free text |
| NHS No | Ý | Ŷ | Free text |
| Assessing surgeon | Ŷ | N | Free text |
| Assessment date | Ŷ | Y | Free text |
| Height | v | Ý | Free text |
| Weight | v | V | Free text |
| BMI | v | V | Free text |
| Hin/Waist Patio | V V | V | Free text |
| Abdominal examination | I V | N | Free text |
| | r V | IN N | |
| Previous Surgery | ř V | IN N | f/IN X/N |
| | ř V | IN NI | t/IN |
| | Y | IN N | Y/IN |
| Hernia | Y | N | Y/N |
| Aneurysm | Y | N | Y/N |
| | Y | N | Y/N |
| Ulcers | Y | N | Y/N |
| Left Femoral Pulse | Y | N | Y/N |
| Right Femoral Pulse | Ŷ | N | Y/N |
| Left PT Pulse | Ŷ | N | Y/N |
| Right PT Pulse | Ŷ | N | Y/N |
| Left DP Pulse | Ŷ | N | Y/N |
| Right DP Pulse | Ŷ | N | Y/N |
| Potential LD | Y | N | Y/N |
| Cardiology R/V Required | Y | N | Y/N |
| Anaesthetic R/V Required | Y | N | Y/N |
| Israel Penn Registry Referral Required | N | Ν | Y/N |
| High risk category | | | |
| Severe Peripheral Vascular Disease | Y | Ν | Y/N |
| Poor Diabetic Control | Y | N | Y/N |
| Cerebrovasvular Disease | Y | N | Y/N |
| Infection Risk | Y | N | Y/N |
| High Cardiac Risk | Y | N | Y/N |
| Need of HDU/ITU Post Op | Y | N | Y/N |
| Expected Wait Time > 5 years | Y | N | Y/N |
| Donor acceptance criteria | | | |
| Accept LD | Y | N | Y/N |
| Accept DBD | Y | Ν | Y/N |
| Accept DCD | Y | Ν | Y/N |
| Accept ECD | Y | Ν | Y/N |
| Accept Dual | Y | Ν | Y/N |

| Accept Paed en Bloc | Y | Ν | Y/N |
|----------------------------|---|---|-------------------|
| Accept Cancer | Y | Ν | Y/N |
| Accept High Risk Behaviour | Y | Ν | Y/N |
| MDT Required | Y | Ν | Y/N |
| Listing | | | |
| Active | Y | Ν | Check box |
| Suspended | Y | Ν | Check box |
| Reason for suspension | Ν | Ν | Free text |
| Pending investigations/MDT | Ν | Ν | Check box |
| Consultant surgeon | Ν | Ν | Free text |
| Signature | Ν | Ν | Digital signature |
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Chapter 4

Manuscript title

The evaluation of digital transformation in renal transplantation in the United Kingdom: a national interview study

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Structured abstract

Background

Care pathways in renal transplantation involve multi-speciality coordination and administration of clinical data across organisational boundaries. The potential for information technology (IT) to support the service through data management, communication and national registration has been reported. However, no previous national-level evaluation on the current state of digital transformation has been undertaken.

Methods

We undertook structured phone interviews with transplant coordinators at all 23 transplant centres in the United Kingdom (UK). The interview covered topics including clinical workflows during transplant referral and current data management processes. Based on established frameworks, we elicited IT capabilities, readiness and infrastructure to evaluate the digital maturity at each centre. We analysed interview data thematically and synthesised results across centres to identify common challenges and inform recommendations.

Results

Transplant coordinators across centres reported similar care pathways with patients being referred by to transplant centres from regional renal referral centres. Analysis revealed that a key challenge revolved around the inability to access data across organisational boundaries. This resulted in dependence on postal or electronic mail to transfer clinical data, such as blood results or medication lists. Most centres had a hospital-wide electronic medical record, which was unable to meet the specific workflow requirements of transplantation. This was primarily because implemented solutions were unable to provide a single unified view of transplant-related data. As a result, transplant coordinators reported several workarounds to manage clinical data, such as paper folders, Excel© sheets and scanned files on hospital shared drives.

Conclusions

Existing front-line IT solutions and wider infrastructure did not support the requirements of care pathways in renal transplantation. Digital transformation should focus on the need to surface patient data across organisational boundaries and provide specific views of data that complement the clinical workflow. This study highlights how regional access to a representation of data remains a major priority to support multi-centre specialist services.

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1. Introduction

Transplantation is the best treatment for eligible patients with renal failure. It allows patients to live longer and more independent lives by alleviating the need for dialysis.¹⁻³ Timely transplantation has been shown to improve outcomes, as patients may receive an organ before or shortly after starting dialysis.^{4, 5} However, referral times for transplantation vary markedly between centres, and timely and equal access to transplantation continues to be limited by a range of challenges.⁶⁻⁹

Several practice reviews across the United Kingdom (UK), Europe and America explored referral pathways and clinical workflows to better understand barriers to timely transplantation.¹⁰⁻¹² These suggested that transplantation is delivered as a 'hub-and-spoke' model of care.¹³ This means that each transplant centre serves several surrounding hospitals, which refer patients to the centre when clinically necessary. In the UK there were a total of 23 transplant and 64 referral centres as per the 2019 Annual Renal Registry Report.¹⁴ The patient pathway and service model are summarised in Box 1.

Patients with chronic kidney disease who are approaching renal failure are assessed for suitability for transplantation by a nephrologist at a referral centre. This assessment includes review of medical history, co-morbidities and social circumstances as well as laboratory and radiological investigations. If the patient is deemed potentially suitable for transplantation they are referred to a transplant centre for surgical assessment by the transplant multi-disciplinary team. At the transplant centre, patients are reviewed by a transplant surgeon, who makes the final decision whether transplantation is a suitable treatment option. This may involve further investigations or review by additional medical services such as cardiology or anaesthesia.¹⁵ Once



the assessment is completed, patients are added to a national waiting list. In the UK, the waiting list is maintained nationally by NHS Blood and Transplant (NHSBT). Only patients on the waiting list can be the potential recipient of a donated organ.¹⁶ After transplantation, patients require close monitoring to maintain kidney function and review for side-effects of immunosuppression. However, once patients have recovered from the transplant operation and their kidney function is stable they are referred back to their respective referral centres for long-term follow-up.

Box 1: Renal transplant services are delivered as a hub-and-spoke model of care with each transplant centre receiving patients from several surrounding referral centres

Based on the above description of the clinical workflow, one of the key challenges revolves around the management of data along the pathway.^{17, 18} Patients cross speciality and organisational boundaries as they transition between referral and transplant centres. This requires coordination between clinical teams across organisations, management of investigations, and timely access to data for decision-making. This incurs a significant administrative burden on front-line healthcare professionals as they manually manage fragmented clinical data.¹⁹ In the UK, the *Transplant First* (2013) initiative identified

the potential to use of technology, such as electronic medical records (EMRs) to support data management, improve communication and reduce the current administrative burden on clinical teams. ²⁰ However, the current use of health information technology (IT) and the state of digital transformation of renal transplant services has not been previously investigated.

Replacing paper-based or manual processes by digital or automated processes has the potential to improve data management, enhance the quality of health records and limit medical errors.²¹ This digitisation process is often referred to as "digital transformation", which was defined by Vial (2019) as: "*a process that aims to improve an entity by triggering significant changes to its properties through combinations of information, computing, communication and connectivity technologies*."^{22, 23} This reflects a growing recognition that beyond the technology element, digital transformation encompasses wider change management based on cultural shifts through multiple stakeholder engagement.²⁴

Hospitals that have achieved a high-level of maturity through digital transformation have EMRs that result in a near paperless environment. In addition to supporting clinical documentation, advanced EMR capabilities can provide automated prompts, clinical decision support and performance analytics.²⁵ In the context of transplantation, implementation of EMRs has the potential to improve data management by centralising data across disparate IT solutions and providing a unified view of patient data to support workflows.²⁶ Understanding the current state of digital transformation in transplantation and front-line use of EMRs and other IT solutions is therefore critical in establishing the evidence-base necessary to inform meaningful change.

Outside of transplantation, studies have looked at overall hospital-level digital transformation, exploring the role of technological capabilities within a hospital as well as the importance of communication with other parts of the health system.^{27, 28} A study by Karuska et al emphasized a focus on wider transformational capabilities such as social and organisational enablers to understand the potential for effective digital change.²⁹ In kidney transplantation, there are some studies describing applications of IT to support specific aspects of transplant care such as medication adherence or donor registration.³⁰ Exploring the role of health IT to support multi-organisational data management and the overall patient pathway is likely to provide an understanding of the challenges for digital transformation.

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Therefore, this study aims to inform digital transformation strategies in kidney transplantation. The first objective is to establish the current front-line use of IT solutions and to what extent these support clinical workflows. The second objective is to evaluate technological capabilities at transplant centres, based on established digital maturity frameworks, to form an assessment of the current state of digital transformation. We addressed these objectives in the context of the UK healthcare system.

2. Methods

This was a qualitative, framework-informed interview study of transplant coordinators at UK renal transplant centres. This study is part of a wider project exploring the role of health IT in the management of clinical data in transplantation. As part of this, we have undertaken a data journey model, which helped identify barriers to data sharing across organisational boundaries as a key limitation of health IT to support the workflow.¹⁹ The present study builds on this workflow analysis. By applying a qualitative methodology, we aim to engage front-line healthcare professionals and explore perceptions and experiences, which would further enrich previous observations. In addition, through interviews across all transplant centres we aim to capture data on IT capabilities in relation to transplant workflow. By analysing these data, using established digital maturity frameworks, we aim to systematically evaluate the state of digital transformation at a national level. The study was led and coordinated by VS, a surgeon and health informatician, who conducted and analysed the interviews.

2.1 Participants

In the UK, transplant coordinators are central to the transplant service as they follow patients along the referral pathway and are responsible for administration of their clinical data. They were selected as the most suitable interview candidates as they maintain an overview of patients and coordinate the transfer of data between transplant and referral centres.³¹ In addition, it was expected that transplant coordinators would have the widest knowledge and experience of the different IT solutions in use and the capabilities of EMRs to support the workflow.

We approached them by contacting individual departments directly via telephone and interviewed one transplant coordinator per centre. A list of telephone numbers was available through the coordinators at our centre. Each centre was contacted up to three times to identify a coordinator for the interview and arrange a suitable interview time. The minimum experience for interview candidates was one year of front-line practice in the role.

2.2 Digital maturity frameworks

To systematically assess the level of digital transformation, we used established frameworks to analyse interview data and assign maturity scores to each centre. By establishing a baseline digital maturity using widely-accepted frameworks, future assessments of digital transformation may reflect upon the current state.

We selected the Healthcare Information and Management Systems Society (HIMSS) Electronic Medical Record Adoption Model (EMRAM) and the National Health Service England's Digital Maturity Index (NHS DMI) as frameworks. We used the sub-sections of the frameworks to inform our interview topic guide and the analysis of the interview data. Based on the responses of participants we assigned an EMRAM stage to each transplant centre.

The EMRAM is a widely established instrument to assess the level of digital maturity of hospitals, focussing on technological capabilities, including to what extent clinical workflows are supported by EMR functionalities.³² It has previously been used for national audits of overall digital maturity of hospitals.³³ The NHS DMI extended the EMRAM to better address human, organisational and social factors. It includes themes on access to a representation of data (i.e. ability of solutions to share data), organisational leadership and strategic alignment.³⁴ It was recently applied to evaluate 136 non-specialist NHS hospitals and explored the impact of organisational digital maturity on clinical outcomes.³⁵

2.3 Topic guide

We developed the topic guide with an aim to better understand local clinical workflows, available IT solutions and infrastructures, and to what extent these supported the workflows. We pilot-tested the topic guide for clarity and completeness among three transplant coordinators at one centre.

The interview topic guide covered the following themes:

- a) Local transplant referral pathway and clinical workflows; the four items for this theme were derived from the Renal Association/British Transplant Society guidelines for the assessment of the potential kidney transplant recipient.³⁶
- b) Information technology capabilities, readiness and infrastructure; based on the digital maturity frameworks. Topics included how IT was used to manage patient data along the referral pathway, organise orders/results, and facilitate communication between healthcare teams.
- c) Any anecdotal experiences of good practice, workflow challenges, communication roadblocks and organisational barriers.

The full interview topic guide is provided as appendix A.

2.4 Data collection and analysis

We conducted structured interviews by phone. In previous research, this method enabled collection of detailed data on staff views, operational workflows and perceptions of healthcare services.³⁷ Interviews took place during working hours at times convenient for the participants following verbal consent. The interviewer (VS) kept field notes, which were imported into Microsoft Excel® for analysis. Notes were used to populate columns as summarised in Table 1. Based on the data captured. EMRAM stages were assigned to each centre by mapping findings to the criteria sheet available at <u>https://www.himssanalytics.org/europe/himss-emr-adoption-model-criteria-sheet</u>. EMRAM stages range from 0 (no digitisation) to 7 (paperless environment). Higher stages are awarded for increasing EMR capabilities such as internal access to a representation of data or template-based data capture.

Table 1. interview data captured

| Patient pathway | Workflow |
|-----------------|---|
| | Name of IT solutions |
| | Number of IT solutions |
| | Data management challenges |
| IT capabilities | Records, assessments and plans |
| | Orders and results management |
| | Transfers of care |
| | Decision support |
| | Remote access |
| | Business and clinical intelligence |
| Readiness | Strategic alignment |
| | Leadership |
| | Resources |
| Infrastructure | Primary IT solution |
| | Single EMR |
| | Unique identifier |
| | Transplant-specific IT solution |
| | Regional access to a representation of data |

3. Results

Transplant coordinators from all 23 UK adult renal transplant centres agreed to participate in the study.

A list of the centres including their respective number of referral centres can be found in appendix B.

Telephone interviews lasted between 20 to 40 minutes and all interviewees contributed to all topics.

Table 1 and Figure 1 provide a high-level summary of the findings, which are discussed in greater detail

below.

Table 2. Clinical workflows and use of IT across centres (total n=23)

| values are numbers (%) unless stated otherwise | | |
|---|----|--------------------|
| Hub-and-spoke model of care | 23 | (100) |
| Number of referral units (median (range)) | 3 | (0-9) |
| Standardised referral process | 12 | (52) ^a |
| Number of IT solutions used in clinical workflow (median (range)) | 4 | (2-8) |
| Access to results across organisational boundaries | 3 | (13) |
| Regional information flow via post or email | 23 | (100) ^b |
| Electronic recording of notes | 19 | (83) |
| Electronic order entry | 21 | (91) |
| Hospital-wide EMR | 17 | (74) |
| Renal IT solution | 20 | (87) ^c |
| Clinical decision support system | 0 | (0) |
| Remote access | 10 | (43) |
| Departmental IT lead | 11 | (48) ^d |
| NHS number as primary identifier | 4 | (17) |
| Regional access to a representation of data | 4 | (17) |

a Four centres had a standardised referral process for patients referred from within the same organisation, however patients referred from other units did not have a standardised process.

b Two centres each relied on either post or email alone for regional information flow, whereas 19 used a combination of post and email.

c Renal IT solutions were used for transplant-related data management at six centres – however in most cases this was in addition to the hospital-wide EMR. d One centre only had a transplant clinician as a departmental IT lead, whereas ten had non-transplant nephrologists or non-clinical administrators fulfilling this role.



Figure 1: diagram summarising results of clinical pathway and workflow for renal transplantation demonstrating isolated data storage, mixed electronic and paper-based data management, multiple non-interoperable IT solutions, and reliance on manual data processes

3.1 Clinical workflows and use of IT solutions

All transplant centres offered a hub-and-spoke model of care, receiving referrals from at least one additional referral centre. In almost all clinical workflows (n=21) patients underwent medical assessment by a nephrologist at a referral centre, prior to surgical assessment at the transplant centre. Two workflows described the complete assessment taking place at the transplant centre. However, patients at these centres would undergo diagnostic tests at their local hospital, which meant that coordinators still had to arrange the transfer of test results across organisational boundaries. Referrals were transmitted in the form of paper letters (n=7), email attachments (n=5) or both (n=11). Documentation methods varied with 12 centres using a standard proforma or checklist to receive a predefined set of clinical data and 11 centres relying on non-standardised dictated letters. Interviews revealed, that even when a standard proforma was in place, its use was irregular and frequently incomplete with one coordinator noting that the "main bugbear is having to chase up other centres for tests and results".

Most centres used a hospital-wide EMR (n=17), but no centre could readily exchange all necessary clinical data with referral centres. The transfer of electronic data most commonly took place via portable document format (PDF) files attached to emails or paper copies through the post. Interviews revealed a range of methods in which transplant centres managed data received across organisational boundaries, but in all circumstances, there was a need to either manually enter data (n=7) or scan documents (n=8) into the local EMR, or to store paper copies in patient files (n=8). One coordinator highlighted how *"having everything on the computer was better than when it was all paper"*. However, another noted how *"scanning and uploading documents can take up a lot of my day"*.

Most transplant centres reported using shared drives on the hospital network to store clinical data (n=14), creating, in essence, heuristic electronic records for each individual patient. This workaround made it challenging to keep data up-to-date. For example, patients on the waiting list required annual cardiac tests, such as an echocardiogram; transplant coordinators had to manually check the date of each patient's result on the shared drives on a regular basis. It was anecdotally reported that *"it would be great if things were more centralised"* and *"it would be good if we could have it all on one system"*. To circumvent this challenge some centres reported using Microsoft Access® or Excel® files to help maintain an overview.

Results demonstrated variation in the use of IT solutions across transplant centres. Five centres still relied on handwritten notes, and no centre reported a complete paperless environment. Most centres (n=21) reported electronic order entry for investigations. Yet, results were not always available within the EMR, resulting in transplant coordinators having to log into additional IT solutions to complete the workflow. In addition, there was no access to order tests for patients at referral centres. Requests for investigations outside of transplant centres were communicated via dictated letters sent via email or post. These results would be manually returned in the same way. One transplant coordinator reported using virtual private network (VPN) to access to results at another hospital.

Just under half of all centres reported a dedicated IT lead (n=11). In all but one case these were in the nephrology department and not necessarily directly overseeing transplantation. In addition, two leads were reported to be from a non-clinical background. No transplant centre had a data strategy or formal data sharing agreement with referral centres. Four centres reported regional access to a representation of data, which allowed access to some results across organisational boundaries via stand-alone shared care records. Shared care records are integrated clinical IT solutions that aim to centralise data feeds from multiple healthcare organisational boundaries.³⁸ Access to a shared care records was reported to be beneficial to the workflow, however there was no integration between shared care records and transplant centre EMRs.

No centre reported the use of a transplant-specific IT solution. However, almost all centres (n=20) had a renal IT solution installed (Vital Data (©Vitalpulse Ltd.) or ClinicalVision (©Constellation Kidney Group)). These were used for transplant-related data management at six centres – however in most cases this was in addition to the hospital-wide EMR. Discussions around IT revealed that the main challenge for transplant coordinators revolved around the multitude of solutions required to complete the workflow. In addition, the inability of solutions "*speak to each other*" across referral and transplant centres was raised as a reason for wasted resources and delays.

3.2 EMRAM stages

Based on interview data on IT capabilities, readiness and infrastructure, we assigned an EMRAM stage to each centre. Of the 23 centres, four (17%) were assigned stage 1, eight (25%) stage 2 and 11 (48%) stage 3. None of the centres reached a higher stage because EMR capabilities were unable to support the clinical workflow. This was primarily limited by the lack of a central data repository across organisational boundaries, which increased reliance on manual and paper-based processes. In addition, this limited the adoption of advanced capabilities, such as automated prompts and data analytics. The further complexity that emerged from speaking to transplant coordinators revolved around transplant laboratory IT solutions, which were completely siloed from any other solution. As significant transplant-related work revolved around tissue typing and organ matching, a disconnect with the laboratory impeded digital transformation. A summary of the data used to inform EMRAM stage allocation is provided in appendix C.

4. Discussion

This is the first study that interviewed front-line clinicians to explore the use of IT in supporting clinical workflows, and that evaluated the level of digital transformation of UK transplant centres. We found that the overall delivery of services was uniform, with patients being referred to transplant centres after undergoing pre-transplant assessment at local referral centres. However, no centre had a transplant-specific IT solution to manage clinical data along the pathway and there was a wide variation reported in available EMR capabilities. A number of centres received additional IT support through renal

departments, however most lacked an IT strategy or departmental leadership in this area. Most centres relied on paper-based or locally developed, heuristic digital data management solutions, such as Microsoft Excel® files and shared folders on hospital networks. Transfer of data across organisational boundaries depended on manual processes, such as post and email. Overall, EMRAM stages of digital maturity for transplant services ranged between one and three, implying significant potential for improvement.

4.1 Relation to other studies

This study showed that there was variation in data management and digital maturity across transplant centres. A similar service review from 2014 reporting on 156 transplant centres in America found that only 43% used electronic order entry and 59% had electronic recording of notes.³⁹ Studies on digital transformation in transplantation, and more widely of hospital services, are sparse. Within transplantation, a retrospective review from Pittsburgh, America observed a decrease in time from referral to assessment and time from assessment to listing post-EMR implementation at their centre.⁴⁰ However, it is unclear how this was achieved, whether any confounding interventions coincided and if these results were reproducible across centres.

Outside of transplantation, a recent review of 136 hospitals in England evaluated the impact of organisational digital maturity on clinical outcomes using the NHS DMI. Though the study found an association between higher levels of digital maturity and improved length of stay and harm-free care episodes, suggesting a positive impact of technology, the authors highlighted how digital maturity is also associated with confounding institutional factors such as willingness to change ways of working or openness to risk-taking.³⁵ A study in primary care investigating the use of digital health services revealed benefits for GPs in the form of time released, more precise communication and reduced phone load.⁴¹

The lack of studies in this area may be partly explained by the fact that methods to evaluate digital maturity are not yet widely adopted.⁴² A literature review by Carvalho et al in 2016 identified 14 digital maturity models for health, including the EMRAM.⁴³ The authors also identified models to evaluate

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access to a representation of data⁴⁴ and hospital cooperation⁴⁵, which could be potentially relevant when assessing transplant services. Flott et al proposed an additional, more patient-centric digital maturity model. In their paper, they suggested that existing models are too organisation, service or technology-centric, which may limit the evaluation of digital maturity of the patient pathway. Their model included impact on patient care as an assessment domain with a view to capture more meaningful results and inform improvements to digital transformation.

Our study enhanced the understanding of data management and workflow challenges in transplantation. The findings support the view that, due to the regional nature of transplantation, cross-centre EMR connectivity and data sharing is likely to improve the pathway and benefit patient care.⁴⁶ Furthermore, due to the complex patient pathways and multiple actors involved, it has been previously proposed that existing EMRs do not meet the requirements of transplant services.⁴⁷ A recent data journey modelling study suggested that novel solutions are needed that integrate data across transplant and referral centres to reduce the manual administrative effort.¹⁹

4.2 Implications for practice and research

Our study identified a range of EMRAM stages, with several centres at a more mature stage. This demonstrates a potential opportunity for shared learning. A recent study of the Global Digital Exemplar and Fast Follower programme in the UK highlighted the benefit of inter-organisational collaboration to drive digital transformation.⁴⁸ There may thus be a role for the more mature transplant centres to share ways of working and digital solutions with less mature sites.

This study has highlighted how access to a representation of data remains a priority to improve workflow in transplantation and similar multi-organisational clinical services. Efforts to better understand social and technical barriers are required to inform IT infrastructure that will meet the needs and requirements of such clinical domains. This is supported by a review of the UK National Programme for IT, which identified access to a representation of data, user-centric design and data sharing as key principles for successful digital transformation of hospital services.⁴⁹

The potential for IT solutions to improve data management, streamline pathways and clinical processes is well established.^{50, 51} However, existing EMR solutions are unable to provide a view of clinical data that complements the workflow. We recently reported on the pilot-testing of a prototype that may address many of these challenges, providing a promising way forward.²⁶

The successful development and implementation of such speciality-specific solutions relies on centralisation and standardisation of data across organisational boundaries.⁵² The traditional focus on connecting clinical IT solutions by focussing on messaging between pieces of software (based on proprietary data models) across multiple healthcare organisations has not achieved the level of access to a representation of data required to support contemporary healthcare.⁵³

Based on the increasing need for healthcare data to be readily and safely available when and where it is needed, alternative ways of approaching health IT are warranted.⁵⁴ National-level policy that mandates vendors to comply to data standards may achieve semantic access to a representation of data with a standardisation of healthcare data at the level of storage.^{55, 56} Standards-based data strategies, such as the openEHR platform approach or Substitutable Medical Application and Reusable Technologies on Fast Healthcare Access to a representation of data Resources (SMART on FHIR) implementations, have the potential to separate the data and application layers.^{57, 58} With the adjunct of cloud computing, regional clinical data repositories can facilitate multi-organisational data sharing and development of application programme interfaces that meet workflow requirements. This could not only enhance front-line service delivery but also unleash the potential of big data in healthcare for analytics and research.^{59, 60}

4.3 Strengths and limitations

This was a study on the front-line use of health IT in renal transplantation. It may provide insights in to data management and workflow challenges in other multi-organisational clinical services. The structured topic guide resulted in comprehensive data on clinical workflow and IT capabilities. It helped reveal common challenges across transplant centres, which can potentially inform scalable improvements. By drawing on the lived experience of transplant coordinators' experience of

coordinating care and managing clinical data across organisations, we were able to identify sociotechnical challenges such as a reliance on e-mail attachments for clinical correspondence. Future studies may include interviewing healthcare professionals at referral centres, to understand how the lack of access to a representation of data impacts their workflow. In addition, involving patients in such a study may further uncover challenges that they face as a result of a reliance on manual processes to move their data across organisational boundaries.

We selected well-established frameworks to analyse our findings. These added value in terms of being able to infer a level of digital maturity for transplant centres based on interview data. However, the EMRAM tool was designed to assess a single healthcare organisational maturity and as we uncovered through the results of this study, based on the multi-organisational nature of transplant services, the digital maturity of individual organisations meant little in terms of impact on clinical workflow. Alternative frameworks could be considered in the future that focus on the digital maturity of clinical services, rather than organisations to provide a more patient-centric assessment of the impact of health IT on workflows.⁶¹

An additional limitation was that we asked several technical questions to transplant coordinators, who are clinically trained but with no informatics expertise. As a result, some detail of IT capabilities may have been misunderstood or missed. In addition, transplant coordinators described a range of work-arounds, such as the use of Excel® sheets, which were often longstanding solutions. Not all respondents may have been fully aware of alternative, newer IT solutions that may have supported their data management, potentially leading to an underestimation of centres' digital maturity. Future studies may therefore include interviewing IT staff as relevant stakeholders to provide in-depth technical capabilities.

4.4 Conclusion

The role for IT to support data management and workflows in renal transplantation is limited with no standardised solutions and low levels of digital maturity across centres in the UK. Individual departments have developed local, heuristic solutions to manage data and share information to support

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their services, however, these are rarely scalable and largely rely on manual processes. Significant time and effort is spent on data management as patients are referred across organisational boundaries with limited access to their real-time data.

Results from this study suggest two distinct priorities for future digital transformation: 1) greater regional access to a representation of data to allow data sharing and information flow across referral and transplant centres and 2) introduction of a centralised user-friendly transplant-specific EMR that supports and aligns with the clinical workflow. These conclusions can be translated to other regional clinical services, which naturally rely on patients receiving care across organisations.

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Statement on conflicts of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Table 3. summary table

| What was already known on the topic | | | |
|-------------------------------------|--|--|--|
| • | Renal transplantation is a complex clinical service with care pathways that involve multi- | | |
| | speciality coordination and administration of clinical data across organisational boundaries | | |
| ٠ | The evaluation of IT solutions in healthcare settings is critical to the understanding of social | | |
| | and technical barriers to digital transformation. | | |
| ٠ | IT has the potential to support data management, communication and national registration | | |
| | in transplantation | | |
| • | No previous national-level evaluation on the current state of digital transformation of | | |
| | transplant services has been undertaken | | |
| | What this study added to our knowledge | | |
| ٠ | Existing front-line IT solutions and wider infrastructure did not support the requirements of | | |
| | care pathways in renal transplantation. | | |
| ٠ | Individual departments have developed local, heuristic solutions to manage clinical data and | | |
| | share information to support their services | | |
| ٠ | This study highlights how interoperability remains a major priority to support multi-centre- | | |
| | specialist services. | | |
| ٠ | There remains a need for research evaluating the impact of digital transformation on clinical | | |
| | services to continue to drive improvement in care and outcomes. | | |

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APPENDIX A

Structured topic guide for telephone-based survey of UK renal transplant centres

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Centre Date and time Personal details (name, role, age – kept confidential)

Introduction

We are doing a survey of transplant listing pathways across the UK and how centres use IT to support their work. All the information you share will be kept confidential and not shared with any other centre. The results will be published anonymised in a scientific journal and will hopefully help our understanding of how patients are added to the list and what we can do to improve and standardise access to transplantation across the UK.

Clinical pathway

- 1. How does your current listing pathway work?
- 2. How many IT systems do you use in the listing pathway?
- 3. Is there a digital solution for transplant listing?
- 4. How do you share information across your regional transplant network?
- Current workflow
- Total number of systems
- Manual processes
- Regional information flow

Capabilities

- 1. How do you record notes, assessments and plans?
- 2. How do you order tests and receive results?
- 3. How do you transfer care of patients between specialities/organisations?
- 4. Can you access any patient records remotely?
- 5. Do you have any business or clinical analytics/automated systems?
- Records, assessments and plans
- Orders and results management
- Transfers of care
- Decision support
- Remote and assistive care
- Business and clinical intelligence

Readiness

- 1. Does the department have an IT strategy/plan?
- 2. Is there an assigned transplant department IT lead?
- 3. Are there any IT support resources available?
- Strategic alignment
- Leadership
- Resourcing

Infrastructure

- 1. What is the primary IT system?
- 2. Is there a centralised EPR? If so, which?

- What unique identifier do you use?
 Is there any transplant-specific IT solution?
 Is there any alignment of IT systems across the region?
- Primary IT system ٠
- Centralised EPR •
- Use of unique identifier •
- Transplant-specific EPR •
- Regional interoperability of IT systems •

Anecdotal experiences

APPENDIX B

Table 4: list of all 23 UK transplant centres and number of renal referral centres

| Transplant centre | Number of renal referral centres |
|-----------------------|----------------------------------|
| Belfast | 6 |
| Birmingham | 5 |
| Bristol | 3 |
| Cambridge | 6 |
| Cardiff | 1 |
| Coventry | 2 |
| Edinburgh | 5 |
| Glasgow | 3 |
| Leeds | 6 |
| Leicester | 9 |
| Liverpool | 5 |
| London – Guy's | 4 |
| London – St George's | 1 |
| London – West London | 3 |
| London – Royal London | 3 |
| London – Royal Free | 5 |
| Manchester | 5 |
| Newcastle | 3 |
| Nottingham | 1 |
| Oxford | 5 |
| Plymouth | 2 |
| Portsmouth | 1 |
| Sheffield | 1 |

APPENDIX C

Table 5: summary of anonymised data captured during structured interviews with transplant coordinators

| Centre no | Workflow | Digital capabilities | Infrastructure | Readiness for transformation |
|-----------|--|--|---|--|
| 1 | Standardised proforma: yes Total number of IT systems: 2 Regional information flow: yes, via IT systems | Electronic notes: no, paper-based, which are scanned into EPR Electronic order comms: yes Transfers of care: via letters (email/post) Clinical decision support: no | Primary IT system: e-med Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: yes | Strategic alignment: no Digital leadership: none Resourcing: through renal department |
| 2 | Proforma: no Total number of systems: 3 Regional information flow: email/post | Electronic notes: no, paper-based, which are scanned into EPR Electronic order comms: yes Transfers of care: via email Clinical decision support: no | Primary IT system: Clinical Portal Unified EPR: no Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: none Resourcing: through renal department |
| 3 | Proforma: yes, local only Total number of systems: 5 Regional information flow: no email/post | Electronic notes: partially, combination of dictated letters and free text on EPR Electronic order comms: yes Transfers of care: via letters (post) Clinical decision support: no | Primary IT system: Proton Unified EPR: no Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: none Resourcing: trust IT |
| 4 | Proforma: yes Total number of systems: 2 Regional information flow: email/post | Electronic notes: yes Electronic order comms: yes Transfers of care: via email Clinical decision support: no | Primary IT system: Epic Unified EPR: yes Use of unique identifier: hospital number Transplant-specific EPR: transplant module in Epic Regional interoperability: no | Strategic alignment: no Digital leadership: none Resourcing: trust IT |
| 5 | Proforma: no Total number of systems: 4 | Electronic notes: partially, combination of dictated letters and free text on EPR | Primary IT system: Vital Data Unified EPR: yes Use of unique identifier: hospital number | Strategic alignment: no Digital leadership: none Resourcing: through renal department |

| | Regional information flow: yes, some via IT systems rest via email/post | Electronic order comms: partially, some handwritten Transfers of care: via letters (post) Clinical decision support: no | Transplant-specific EPR: no Regional interoperability: yes, some | |
|----|---|---|--|--|
| 6 | Proforma: yes Total number of systems: 3 Regional information flow: email/post | Electronic notes: no Electronic order comms: yes Transfers of care: via letters (post) Clinical decision support: no | Primary IT system: in house Unified EPR: no Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: yes (non-clinical) Resourcing: through renal department |
| 7 | Proforma: yes, local only Total number of systems: 3 Regional information flow: email/post | Electronic notes: hand-written, then transcribed on the EPR Electronic order comms: yes Transfers of care: via letters (post) Clinical decision support: no | Primary IT system: Vital Data Unified EPR: yes Use of unique identifier: CHI number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: none Resourcing: none |
| 8 | Proforma: no Total number of systems: 4 Regional information flow: yes, some via IT systems rest via email/post | Electronic notes: yes Electronic order comms: yes Transfers of care: via letters (post) Clinical decision support: no | Primary IT system: Vital Data Unified EPR: yes Use of unique identifier: CHI number Transplant-specific EPR: no Regional interoperability: yes, some | Strategic alignment: no Digital leadership: none Resourcing: through renal department |
| 9 | Proforma: no Total number of systems: 4 Regional information flow: no | Electronic notes: yes Electronic order comms: yes Transfers of care: via letters (post) Clinical decision support: no | Primary IT system: Patient Pathway Manager (in house) Unified EPR: yes Use of unique identifier: NHS number Transplant-specific EPR: no Regional interoperability: yes, some via shared care record | Strategic alignment: yes Digital leadership: yes (non-clinical) Resourcing: none |
| 10 | Proforma: yes Total number of systems: 4 | Electronic notes: no Electronic order comms: yes | Primary IT system: Proton Unified EPR: no | Strategic alignment: no Digital leadership: yes (renal) |

| | Regional information flow: yes, some via IT systems rest via email/post | Transfers of care: via letters (email/post) Clinical decision support: no | Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: yes, some via Proton EPR | Resourcing: through renal department |
|----|---|--|---|--|
| 11 | Proforma: no Total number of systems: 6 Regional information flow: email/post | Electronic notes: yes, including scanned dictated letters Electronic order comms: yes Transfers of care: via letters (post/email) Clinical decision support: no | Primary IT system: none Unified EPR: no Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: none Resourcing: none |
| 12 | Proforma: yes, local only Total number of systems: 3 Regional information flow: email/post | Electronic notes: yes, including scanned dictated letters Electronic order comms: yes Transfers of care: via EPR Clinical decision support: no | Primary IT system: iSoft Unified EPR: yes Use of unique identifier: NHS number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: none Resourcing: trust IT |
| 13 | Proforma: yes, local only Total number of systems: 4 Regional information flow: email/post | Electronic notes: yes Electronic order comms: yes Transfers of care: via EPR and letters (post/email) Clinical decision support: no | Primary IT system: Cerner Unified EPR: yes Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: yes (renal – non- clinical) Resourcing: trust IT (digital champions) |
| 14 | Proforma: no Total number of systems: 3 Regional information flow: email/post | Electronic notes: yes, including scanned dictated letters Electronic order comms: yes Transfers of care: via EPR and letters (post/email) Clinical decision support: no | Primary IT system: Cerner Unified EPR: yes Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: none Resourcing: none |
| 15 | Proforma: no Total number of systems: Regional information flow: email/post | Electronic notes: yes, including scanned dictated letters Electronic order comms: yes Transfers of care: via EPR and letters (post/email) | Primary IT system: Cerner Unified EPR: yes Use of unique identifier: hospital number Transplant-specific EPR: no | Strategic alignment: no Digital leadership: none Resourcing: none |

| r | | 1 | | |
|----|---|--|---|--|
| | | Clinical decision support: no | Regional interoperability: no | |
| 16 | Proforma: yes Total number of systems: Regional information flow: email/post | Electronic notes: yes, including scanned dictated letters Electronic order comms: yes Transfers of care: via EPR and letters (post/email) Clinical decision support: no | Primary IT system: Cerner Unified EPR: yes Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: none Resourcing: none |
| 17 | Proforma: y Total number of systems: 5 Regional information flow: no | Electronic notes: yes, typed in Microsoft word Electronic order comms: yes Transfers of care: via letters (email/post) Clinical decision support: no | Primary IT system: in-house Unified EPR: yes Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: none Resourcing: through renal department |
| 18 | Proforma: n Total number of systems: 3 Regional information flow: email/post | Electronic notes: yes, typed in one system then copied and pasted into another Electronic order comms: yes, but not all on the same system Transfers of care: via letters (post) Clinical decision support: no | Primary IT system: e-record Unified EPR: yes Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: none Resourcing: none |
| 19 | Proforma: n Total number of systems: 4 Regional information flow: email/post | Electronic notes: yes, partial Electronic order comms: yes, but not all on the same system Transfers of care: via letters (email/post) Clinical decision support: no | Primary IT system: E-med Unified EPR: no Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: none Resourcing: none |
| 20 | Proforma: n Total number of systems: 3 Regional information flow: email/post | Electronic notes: no Electronic order comms: partially, some handwritten Transfers of care: via IT system Clinical decision support: no | Primary IT system: Cerner Unified EPR: yes Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: yes Digital leadership: yes Resourcing: none |

| 21 | Proforma: yes Total number of systems: 4 Regional information flow: email/post | Electronic notes: yes, partial Electronic order comms: yes Transfers of care: via letters (post) Clinical decision support: no | Primary IT system: Vital Data Unified EPR: no Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: none Resourcing: through renal department |
|----|---|---|--|--|
| 22 | Proforma: no Total number of systems: 3 Regional information flow: email/post | Electronic notes: partial Electronic order comms: yes Transfers of care: via letters (email/post) Clinical decision support: no | Primary IT system: in-house Unified EPR: yes Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: no | Strategic alignment: no Digital leadership: no Resourcing: trust IT |
| 23 | Proforma: no Total number of systems: 8 Regional information flow: yes, some via IT systems rest via email/post | Electronic notes: partial Electronic order comms: yes Transfers of care: via letters (email/post) Clinical decision support: no | Primary IT system: E-med Unified EPR: no Use of unique identifier: hospital number Transplant-specific EPR: no Regional interoperability: yes, some via ICE order comms system | Strategic alignment: no Digital leadership: yes (non-clinical) Resourcing: trust IT |

Chapter 5

Manuscript title

KidneyCloud: a clinically co-designed solution to support kidney services with assessing patients for transplantation

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Abstract

There is a need for IT systems that support the complex needs of data management in kidney transplantation. The KidneyCloud project aims to inform a transplant-specific digital solution by exploring patient pathways and data journeys. This paper reports on the early prototyping of the KidneyCloud clinician interface using an iterative codesign methodology. User workshops identified that –for making clinical decisions and adding patients to the national waiting list— transplant teams relied heavily on manual processes to access data across systems and organisations. Based on the requirements gathered, a prototype interface was designed to provide a unified view on the available patient data, which aligned with clinical workflow. Interactive prototype screens allowed users to gain hands-on experience and provide rich real-time feedback. This informed the necessary functionalities of the interface, but also helped understand the capabilities required of the back-end solution.

Keywords:

User-Centered Design, Health Information Interoperability, Organ Transplantation

Introduction

End-stage renal disease (ESRD) carries a significant global health burden.¹ A kidney transplant is the only treatment that improves quality of life and offers a sustainable cure.^{2, 3} In the United Kingdom (UK), over 5,000 patients receive a kidney transplant each year and a further 4,000 new patients are added to the national waiting list.⁴ Owing to the increasing demand, there is a need to streamline processes, increase donation opportunities and upscale services.⁵

The referral process for a kidney transplant is complex. Transplantation is typically delivered at large university hospitals, treating patients across a wide region and from local general hospitals. In the UK, the National Health Service (NHS) delivers kidney transplant services through 23 regional centres. Patients are commonly referred by a nephrologist at their local hospital and undergo pre-transplant assessment and investigations before attending the transplant centre for surgical evaluation and waiting list registration.⁶ This means that transplant assessment involves a host of clinical appointments, investigations and patient education. These are directed by multi-disciplinary clinical teams across the multiple healthcare organisations involved. Furthermore, patients undergoing transplantation often suffer from multi-morbidity with complications from dialysis and additional sequelae of kidney failure. The assessment pathway therefore results in large volumes of heterogeneous clinical data collected by multiple services and organisations, which requires meticulous management to prevent delays and errors.

Little previous work has been undertaken in this clinical area, and there is a scarcity of literature reporting the use of health information technology (IT) in kidney transplantation.⁷ As a result, data management frequently relies on clinical and administrative staff to manually access, organise and summarise data for timely decision-making and communication. Owing to the complexity of the referral process from a clinical and data perspective, significant human resources are utilised to deliver the service. Current electronic health records (EHRs) are not able to provide a view of patient data that meets the needs of the transplant workflow.⁸ There is thus a potential for digital solutions to improve the service by replacing paper-based data management, automating administration and improving data completeness and, accuracy. However, this potential currently remains unharnessed.

To address this gap and develop a solution that meets the needs of kidney transplantation, we initiated the KidneyCloud project (Department of Renal and Pancreatic Transplantation, Manchester, UK). As part of the first phase of KidneyCloud, we explored the kidney transplant assessment pathway from a data management perspective and understand how IT is currently used to support the workflow. This will inform the design, functionality and, capabilities of a transplant-specific solution. The current paper reports on the early prototyping and iterative codesigning of the solution's clinician interface.

Methods

Project background

By exploring patient pathways, data journeys and digital solutions, the KidneyCloud team identified that the multi-speciality and cross-centre nature of kidney transplant services required a specific solution that integrates health and social care data from community and hospital providers across the Greater Manchester region. As such we are developing an integrated clinical data repository (back-end) The front-end solution is being designed in collaboration with the Digital Health Software team at the University of Manchester. To better understand socio-technical and organisational barriers to future implementation, we undertook early prototyping of the clinician interface.

We used an iterative codesign methodology to design our prototype. We undertook repeated cycles of requirements gathering and workshops to allow users to provide input throughout the design process. A member of the research team (VS), who is also a clinician within the transplant team, acted as a clinical super user and coordinated the requirement gathering process. The super-user's domain expertise, combined with cross-over skills in health informatics, allowed them to readily engage clinical staff and effectively communicate feedback to a user experience (UX) designer (SF). Fig. 1 summarises how our approach combined patient journey modeling, requirements gathering and prototype design. We describe this approach in more detail below.



Figure 1: summary of iterative codesign approach

Patient journey modelling

To establish the scope of the clinical pathway, we used customer journey modelling language (CJML), an established swimlane-based methodology to map the patient journey.⁹ It visualises complex pathways as well as the actors, clinical touchpoints (appointments, investigations, correspondence, etc) and transitions between specialities/organisations. CJML allowed us to centre the project around the patient journey and design a prototype that accurately supported the clinical workflow. In particular, we were interested to identify how clinicians accessed, organised and communicated data as patients progressed along the pathway.

We reviewed departmental protocols and guidelines to gain a basic understanding of the pathway from initial referral to registration on the national transplant waiting list. This included the current paper transplant listing form which can be found in the appendix. To complement the review, we conducted and took notes at individual user workshops with four patients and six healthcare professionals. Sessions lasted 30 minutes and we presented participants with a draft swimlane diagram of three key clinical touchpoints: nephrology review, transplant surgery review and registration, prompting them to identify additional actions, actors and transitions on the pathway. A summary of these methods is provided in the appendix.

Initial interface design

Based on our improved understanding of the patient journey, we designed a prototype clinician interface for desktop screen size using Adobe XD, part of the Adobe Creative Cloud© suite. Patient journey modeling had revealed that as part of the pathway workflow, members of the clinical team must manually complete a 10-page paper proforma. We used this as the basis for the first iteration of the proposed clinician interface. We created screens that mapped onto steps in the pathway workflow, with each screen presenting users with fields for data entry relevant to that particular step. Five screens were created that followed the clinical pathway starting at nephrology review and ending at multidisciplinary decision to register the patient on the waiting list.

The main functionality of the interface was for data fields to autopopulate once the user entered a patient identifier (NHS number) on the first screen at the start of the workflow. Additionally, we identified that several data fields on the paper form were dependent on answers to previous fields. In our interface, we were thus able to hide fields until indicated and reduce the initial number of visible fields.

The interface was designed following the Web Content Accessibility Guidelines (WCAG 2.1 AA) (<u>https://www.w3.org/TR/WCAG21/</u>). The design framework was derived from the NHS service manual (<u>https://service-manual.nhs.uk/service-standard</u>). The typeface used throughout was Helvetica Neue, a versatile sans serif font that is optimised for digital legibility. By complying with international guidelines and NHS design standards we aimed to reduce future barriers to implementation.

We subsequently imported the user interface screens into MarvelApp (Marvel Prototyping Ltd.), a collaborative design platform for prototyping and user testing. This would enable us to employ a rapid prototyping methodology, where we could quickly turn ideas and corresponding feedback into tangible and interactive high-fidelity prototypes that could easily be shared with participants via a web link. Additionally, MarvelApp allowed us to design a prototype without the need to code reducing the development cost.

Iterative codesign process

Having established the scope and initial interface, we undertook repeated cycles of requirements gathering to drive the clinical co-design process. Codesign, a form of user-centric design, allows

expertise from multiple stakeholders to organically contribute to a solution, moving from designing *for* users to designing *with* users. It relies on participatory creativity, experience and feedback throughout the entire design process.^{10, 11}

Requirements were gathered through repeated cycles involving individual user workshops and a group demonstration. This allowed an iterative and incremental increase in prototype design and functionality. In both formats, we used Microsoft® Teams to share our screen allowing participants to view the design, interact with the prototype and provide real-time input. Observations and participant feedback were recorded as written notes.

For the eight individual user workshops, we set up virtual meetings with two transplant coordinators, two nephrologists, two transplant surgeons and, two administrative staff. We presented a single-slide summary of the project to provide background information. We subsequently opened the prototype in a web browser and shared our screen to give participants control of the prototype. We allowed them to freely click through the different screens and experience the functionalities. We asked them to complete tasks such as navigate to the homepage or review a test result. We observed their user journeys and allowed them to verbalise their experiences. After each workshop, the super-user met with the UX designer to incorporate feedback into the prototype.

Following the individual user workshops, we set up a virtual meeting for a group demonstration with the multi-disciplinary transplant team, which was attended by 14 participants (four transplant consultants, three transplant registrars, six transplant coordinators and, one outpatient department sister). We presented the patient journey model, the current paper form and, our protoype. The contextual functionality of our solution was shared through demonstration of its role in the clinical workflow.

Results

Kidney transplant patient journey

The patient journey model confirmed the complexity and regional multi-speciality nature of the transplant pathway. As summarised in Fig. 2, we identified that patients had a minimum of 53 clinical touchpoints along the assessment pathway and interacted with at least 12 different clinical actors. At each touchpoint, there was a need to retrieve existing or store new clinical data in electronic or paper format. There were five different IT systems involved in the management of data and these were unable to share information between them. Currently, six modes of communication (email, telephone, SMS, post, fax and, face-to-face) were used to relay information amongst clinical team members and to patients. A total of five organisations were involved in the patient journey including three hospital providers, general practice and, the national organ transplant body (NHS Blood and Transplant). Fig. 3 demonstrates an illustrative segment from the overall model. Interviews with clinical staff highlighted a lack of interoperability of IT systems within, and across, the involved organisations. This resulted in significant time spent on manual data administration. Staff had devised heuristic solutions to manage
transplant data, such as the use of individual paper packs for each patient stored alphabetically in filing cabinets on the hospital ward.



Figure 2: summary of results from patient journey modeling



Figure 3: extract of patient journey swimlane model

KidneyCloud user interface

The initial prototype design focussed on simplicity to transform the user experience from completing an onerous paper proforma to an intuitive web-based interface. The paper form included a total of 247 data fields that needed to be completed. A copy of the form is included in the appendix. Most fields (148) were free text such as address, past medical history and, medications. A further 78 were 'yes/no' fields, such as smoker, allergies and, previous surgery. 58 out of 78 'yes/no' fields required further free text data depending on the initial answer. The use of dropdown menus and collapsible fields reduced the initially visible fields from 247 to 134 and allowed us to shorten the 10-pages of the paper proforma into five screens.

The autopopulate functionality aimed to transform the workflow experience of completing the proforma, replacing a time-consuming hand-written task with automated data visualisation. The user could now focus on confirmation of data accuracy and completeness, rather than manual data input. (Fig. 4)

| Demographics | | Demographics | |
|---------------|-----------------------------|---------------------|--------------------------------------|
| NHS Number | Address | NHS Number | Address |
| 793 577 4538 | | 793 577 4538 | 23 Tarporley Road |
| Full name | | Full name | |
| | Town/city | lan Kilburn | Town/city |
| Date of birth | | Date of birth | Manchester |
| | Post code | 13 $$ 02 $$ 1970 $$ | Post code |
| Age | | Age | M56 2BA |
| | Next of kin | 50 | Next of kin |
| Gender | | Gender | Lucy Kilburn |
| | Relationship of next of kin | Male \sim | Relationship of next of kin |
| Phone number | | Phone number | Wife \vee |
| | Referring hospital | 0044 7653 123 456 | Referring hospital |
| | | | Manchester University NHS Foundation |
| | Preferred language | | Preferred language |
| | | | English |
| Continue | | Continue | |

Figure 4: initial user interface showing auto-population of data for a fictional patient across screens following entry of NHS number

Iterative prototyping

Participants reacted positively to the initial user interface, particularly commenting on the clear layout of the screens. User feedback revealed that besides the form view, a summary view would add a useful snapshot of clinical data for decision-making (Fig. 5). When using the paper form it was not possible to know which clinician was responsible for the completion of the data fields. We thus introduced a log-in page at the start of the prototype and displayed a user profile with a name and photo of the current user at the right top corner of the screen. We further added a progress bar, including green and amber ticks, allowing the user to track which parts of the form had been completed and which still required input.

A participant (transplant coordinator) raised the point that the current paper proforma is frequently incomplete with missing data fields. An administrator further highlighted that, as several members of the clinical team interact with the proforma, it is common for multiple versions to be created, resulting in duplication of work. They reported that these data management challenges lead to delays in the patient journey and additional resources spent on manual data completion. As a result, we introduced mandatory completion of fields before the form may be rendered complete. A central clinician interface that all users can access would prevent multiple versions. We added a save function to the interface which meant that several users could complete parts of the workflow without replacing work undertaken by other team members.

An additionally identified workflow constraint was the inability to view the various pre-transplant investigations within one digital solution. As the proposed prototype was designed to provide a view from an integrated clinical data repository we could demonstrate how this may be addressed in the prototype through buttons to investigation results and pop-up boxes within the interface.

| Laura House | | Summary | Listing form | Results | Flow chart | Documents v |
|-----------------------------------|------------------------|---------------|------------------|---------|---------------|-------------|
| Patient profile | Medical summary | | | | Investigatio | ns |
| NHS number: | Primary renal disease: | Base hospital | | | ECHO | |
| 793 577 4538 | FSGS | Salford Roya | I NHS Foundation | Trust | | |
| Date of birth: | Current eGFR: | Nephrologist: | | | CPET | Request |
| 07/04/1989 (31) | 10 | Dr Delbert Fa | awn | | Transplant Is | ab complex |
| Walting liet status | Dislueie etatue: | Transplant Su | raeon: | | Transplantia | ab samples |
| Active on transplant waiting list | Peritoneal dialysis | Miss Cindra | Wren | | Annual revie | w |
| | | | | | | |
| Organ: | Waiting time: | GP History: | diaardar | | | |
| Kidney | 372 days | End-stage re | nal disease | | | |
| | BMI: | | | | | |
| | 21 | | | | | |
| Save as PDF 🔓 Print 🛡 | | | | | | |

Figure 5: prototype summary screen following user workshops

Discussion

Summary of findings and comparison to existing literature

This study designed a transplant-specific user interface that met the needs and requirements of the clinical workflow. Specific requirements revolved around a need to view clinical data in a single solutions and automating completion of data fields to reduce dependence on manual input. Our solution demonstrated to transplant clinicians how complex data collection can be more effecient, accurate and complete by using information technology. This will align expectations of intended benefits between the clinical and informatics teams and reduce resistence to future adoption.

Little published work on clinical workflow and data management in transplantation exists. An experimental study using bussiness process management in paediatric transplantation by Andelline et al demonstrated how the technology may improve resource optimisation and quality improvement.¹² A recent systematic review identified a further 17 studies on the use of health information technology in transplantation. However, none of those described the design of solutions, or discussed usability barriers to clinical implementation.⁷

The literature suggests that digital health interventions must embrace design as a key component to achieve widespread adoption.¹³ However, a study of eleven EHR providers in the USA showed that only four vendors had well-developed user-centered design processes.¹⁴ A lack of usability continues to limit the effectiveness, efficiency and, user satisfaction of clinical IT systems.^{15, 16} A recent review of EHRs in emergency departments in the UK showed that no current system achieved the minimally acceptable systems usability scale score (SUSS).¹⁷

Implications for practice and research

Design and usability

A strength of the overall KidneyCloud project, as reported in this paper, is the involvement of end users in the design process from the outset. Early feedback on layout, clarity and, user experience allowed the design of a prototype to suit a wide user group. Repeated workshops, with a diverse range of clinical and non-clinical staff, led to a rich contextual understanding of the workflow, which informed meaningful on-screen functionalities. The methodology laid out in this paper has the potential to be applied to other clinical areas undergoing digital transformation. It is however dependent on a high degree of flexibility of the proposed solution. Though current of the shelf EHRs allow customisation, particularly during the implementation phase, they currently do not meet specific workflow requirements in a way our prototype was able to.

Interoperability

To effectively support the workflow, clinical system must centralise large volumes of heterogeneous data and present a view that is intuitive, comprehensive, and minimises user input. Transplantation is not unique in this, with areas such as clinical genetics, oncology and neurology, operating with similar regional service models.¹⁸ A suitable software design concept that supports this requirement is the model-view-controller pattern. It includes a data model that includes all possible data points, a controller that actions requests/responses, and a view that displays the data to the user (Fig. 6).¹⁹



Figure 6: model-view-controller design pattern

Seperating data from the application layer is being recognised internationally as a key priority to health IT infrastructure improvement.²⁰ The findings of this study further supported this and demonstrated the need for regionally managed data models that allow services to develop user-specific views that meet specific workflow requirements.

To operationalise such concepts Health Level 7 Fast Healthcare Interoperability Resources (FHIR) may be used to create standards-based messaging and allow independent application programming interface (API) development. An example of this is Boston Children's Hospital where an interopeble medical apps platform was build based on FHIR profiles.²¹ In addition, open data standards such as OpenEHR can also realise EHR platforms based on openly available data models allowing a market of vendors to compete based on flexibility and functionalities.²²

Future work

Future work should include further analysis of usability, such as task-based user testing. This may provide quantitative measures of user journeys, such as time taken to navigate through screens or the number of misclicks. To judge the potential acceptance of our designs we conducted an early written survey amongst the 14 participants at the group demonstration. Survey respondents strongly agreed with the following statements: "improving IT systems to support my work and release time is important to me" (93%) and "ease-of-use of IT systems is important to me" (93%). All respondents agreed with the phrase "a system like KidneyCloud would be useful for me". In the current workflow, data collected manually on the paper proforma served no other purpose. However, the prototype solution offered the opportunity to reuse transplant patient data for audit and research. KidneyCloud has the potential to be accepted as a novel clinical solution and create additional value from routinely collected electronic health data.

Conclusions

We successfully designed an interactive prototype for kidney transplant referrals using an iterative codesign methodology. Continuous user input provided the necessary feedback to inform interface functionality and back-end capabilities. Early prototyping added value to the overall project and will inform the further development and implementation of the solution.

General take aways for practice include the need to access data across organisational boundaries (interoperability) and provide views of data that complement workflow (UX). Moving towards regional EHR platforms, enabled by FHIR profiles or OpenEHR standards will allow an ecosystem of digital health vendors to emerge that can meet this challenge.

Acknowledgements

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Appendix

Methods for patient journey modelling using CJML:

We used customer journey modelling language (CJML) to map the patient pathway in this study. CJML is a methodology used to map out the patient journey through a clinical pathway, visualising the different actors and touchpoints along the way. It is a swimlane-based method and can help identify areas for improvement in the workflow. To replicate this study the following steps must be taken:

- 1. Gather information about the clinical pathway through a review of departmental protocols and guidelines
- 2. Identify key clinical touchpoints along the transplant referral pathway
- 3. Design a draft swimlane diagram of the pathway, with each lane representing a different stakeholder. We used Microsoft Visio for our diagramming, but other software may be used.
- 4. Conduct individual user workshops with stakeholders to refine the diagram and identify additional actions, actors and transitions on the pathways.
- 5. Review the CJML diagram to identify areas of improvement in the workflow and apply these to understand how information flow may reduce bottlenecks and drive efficiency.

| Trai | splant Listing Pathv | ay | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------|----------------------|-------|------|--|-------------|-------|----------|----------------|---------|--------------|----------|----------------------|---------------|---|----------------|------------|---------|---------|------------|------------|-----|-------|-------|-----|--------------|-------|-------|---|-------|----------|--------------|-------|
| | | | | Transpl | lant Workup | | | | | | | | | | | | | | Transplant | Assessment | | | | | | | | | | | | |
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Figure 7: Customer Journey Modelling Language swimlane diagram

Prototype details

Requirements gathered were summarised using the 'must have, should have, could have, won't have' framework (MoSCoW). The MoSCoW framework is a technique used in project management to prioritize requirements based on their importance. It helped us make informed decisions about which features to include in the prototype (Figure 7). This is a link to the full interactive prototype.



Figure 8: MoSCoW analysis results of gathered requirements through iterative prototyping workshops and interviews.

KIDNEY TRANSPLANT ASSESSMENT PROFORMA

| Surname | | | Forename | | |
|---------|--|-----|----------|--------|--|
| DoB | | Age | | Gender | |

| Referring Consultant | | Referring Hospital | |
|----------------------|--------|--------------------|--|
| MRI Hospital N° | | NHS N° | |
| Interpreter required | Yes No | Assessment Date | |
| Language: | | | |

| Address | |
|----------------|-----------|
| Contact Number | Landline: |

• Pages 1 - 5 must be fully completed and signed by the referring physician.

• Pages 6 - 9 must be fully completed and signed by Consultant Transplant Surgeon assessing the patient.

• Page 10 must be filled if referral for MDT is required

• The data are required for patient registration with ODT, incomplete form will delay the patient registration

| | Renal History | | | | | |
|-------------------------|---------------|---------------------|--|--|--|--|
| Primary Renal Disease | Renal Bx | Bx Date and Hosp | | | | |
| (Date of presentation) | Yes No | | | | | |
| EDTA Code: | | | | | | |
| Previous treatment (IS) | Adverse Read | tion to IS Details: | | | | |
| (Others?) | Yes No | | | | | |
| | | | | | | |

| Current Dialysis | | Modality and Period on | - |
|------------------------|--------|------------------------|---|
| Modality | | RRT | - |
| | eGFR: | | - |
| | | | - |
| Dialysis Complications | Yes No | Details: | |
| | | | - |
| Previous Tx (dates) | - | Cause of Failure | - |
| | - | | - |
| | - | | - |
| | - | | - |
| Residual UO (24 hrs): | | Notes: | |
| Recurrent UTI | Yes No | Details: | |
| Incontinence | Yes No | Details: | |
| Outflow obstruction | Yes No | Details: | |
| Kidney Stones | Yes No | Details: | |
| | | | |

| Other Notes: | |
|--------------------------|--|
| | |
| Investigations/referrals | |

| Cardiovascular History | | | | | |
|------------------------|--|------------------|--------|--|--|
| Exercise Tolerance | | Walking (1 mile) | Yes No | | |
| | | Climb 10 steps | Yes No | | |

| | | Details: | |
|--------------------------------|------------------|------------------|--------|
| DiabetesYesNoDuration (years): | Type 1 Type 2 | Diabetic Control | IU/day |
| HbA1c: mmol/mol | C-Pep: nmol/L | Medications: | |
| Diabetic Complications | Yes No | Details: | |
| HTN | Yes No | Details: | |
| Angina | Yes No | Details: | |
| MI | Yes No | Details: | |
| TIA/Stroke | Yes No | Details: | |
| DVT/PE | Yes No | Details: | |
| Claudication | Yes No | Details: | |
| Other Notes: | | · | |

| Investigations/Interventions | | | | | | | |
|------------------------------|------|---------|--|--|--|--|--|
| Investigation | Date | Results | | | | | |
| ECG | | | | | | | |

| Echo | | |
|-------------------------|---------|----------------------|
| | | |
| Stress Test | | |
| Angiogram | | |
| 7 mgiogram | | |
| CABG | | |
| Coronary Stenting | | |
| | | |
| Doppler Lower Limbs | | |
| CPFT | | |
| | | |
| Specialist Consultation | | |
| (Cardiology, | | |
| Anaesthetic) | | |
| Other | | |
| | | |
| | | |
| | Res | piratory History |
| Asthma | Yes No | Details: |
| CORD | | |
| COPD | Yes No | Details: |
| ТВ | Yes No | Details: |
| Smoker | Vac No | Total Duration: |
| SHUKU | | |
| | Current | Quantity(Pack/year): |

| | Yes | No |
|----------------|------|---------|
| Other Notes | | |
| Investigations | Date | Results |
| | | |
| | | |
| | | |
| | | |

| | GI History | | | |
|----------------------|-------------------|---------|----------|--|
| GI disorder | Yes | No | Details: | |
| Liver disease | Yes | No | Details: | |
| Diverticular disease | Yes | No | Details: | |
| Other Notes | | | | |
| Investigations | Date | Results | | |
| | | | | |
| | | | | |

| Other PMH/Social History | | | | |
|---|---------------------------------|----|-----------------------|----------------|
| Oral cavity assessment Yes No Details: | | | | |
| Breast | Yes No N/A Details (Mammogram): | | | |
| Gynae assessment Yes No N/A Details (Smear test): | | | Details (Smear test): | |
| Prostate assessment | Yes | No | N/A | Details (PSA): |

| Malignancy | | Yes No Details: | | | | | |
|---|----------------------|--------------------------|--|---|-------------|---------------------------|-----------|
| Hx Alcohol/ | Drug abuse | Yes | Yes No Details: | | | | |
| Learning di | fficulties | Details: | : | | | | |
| Yes No | | Best Int | terest Meeting (date | e): | | | |
| Social Histor | ry | | | | | | |
| Employmen | t | | | | | | |
| Performanc | e Status | Karnofs | sky Score: | | | | |
| Other Notes | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | Medicatio | on History | | | |
| Allergies | Yes No | D | Medicatio | on History | | | |
| Allergies Asp | Yes No | D | Medication Details: Clopidrogel | on History War | farin | Oth | ner |
| Allergies Asp Yes | Yes No irin No | D (Ye | Medication Details: Clopidrogel es No | on History War Yes | farin No | Oth Yes | ner No |
| Allergies Asp Yes Indication: | Yes No irin No | D (Ye Indicati | Medicatio | on History War Yes Indication: | farin No | Oth Yes Indication: | ner No |
| Allergies Asp Yes Indication: | Yes No | D (Yo Indicati | Medicatio | on History War Yes Indication: | farin No | Oth Yes Indication: | ner No |
| Allergies Asp Yes Indication: Other Medie | Yes No irin No | D (Ye Indicati | Medicatio | on History War Yes Indication: | farin No | Oth Yes Indication: | ner No |
| Allergies Asp Yes Indication: Other Medie | Yes No | D (Ye Indicati | Medicatio | on History War Yes Indication: | farin No | Oth Yes Indication: | ner No |
| Allergies Asp Yes Indication: Other Medie | Yes No irin No | D (Ye Indicati | Medicatio | on History War Yes Indication: | farin No | Oth Yes Indication: | ner No |
| Allergies Asp Yes Indication: Other Medie | Yes No | D V Y Indicati | Medicatio | on History War Yes Indication: | farin No | Oth Yes Indication: | ner No |

| Sensitization History | | | | | |
|-----------------------|-------|-------|---------|-------|--------|
| Ethnicity | White | Black | Chinese | Asian | Other: |

| Blood Group | 0 | | A | В | AB | Rh + Rh - |
|--|---------------|-----|----------|------------------|----|--------------|
| Pregnancies | | Yes | No N/A | N°/Partners/Date | s: | |
| Blood Transfusion Yes No | | No | N°/Date: | | | |
| Previous Transplant Yes No | | No | N°/Date: | | | |
| Rituximab | uximab Yes No | | Date: | | | |
| ATG | | Yes | No | Date: | | |
| Campath | | Yes | No | Date: | | |

| Virology | HCV | HBsAg HBcAb Anti-HBS | HIV | VZV | CMV | EBV |
|----------------|-----|----------------------------|-----|-----|-----|-----|
| Other Notes | | | | | | |

| Physical Examination | | | | | | |
|----------------------|----|---------|----|------|-------------------|------------------|
| Height: | cm | Weight: | Kg | BMI: | Kg/m ² | Hip/Waist Ratio: |
| Chest | | | | | | |
| Abdomen | | | | | | |
| Other Notes | | | | | | |

| | General Comments | | | | |
|-------|------------------|--|--|--|--|
| | | | | | |
| | | | | | |
| | | | | | |
| | Relevant Updates | | | | |
| Date: | | | | | |
| | | | | | |
| Date: | | | | | |
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| Date: | | | | | |
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| Date: | | | | | |
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| Date: | | | | | |
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| Date: | |
|-------|--|
| | |

| Active | |
|----------------------------|------------------------|
| Suspended | Reason for suspension: |
| Consultant Nephrologist | |
| Signature | |
| | |
| Date | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |

| | | Surgical A | Assessment | | |
|---------|--|------------|------------|--------|------|
| | | | | | |
| Surname | | | Forename | | |
| DoB | | Age | | Gender | Male |

| Referring Consultant | | | Referring | g Hospital | |
|----------------------|---------|----|-----------|-------------------|------------------|
| MRI Hospital N° | | | NHS N° | | |
| Assessing Surgeon | | | Assessme | ent Date | |
| | | | | | |
| Height: cm | Weight: | Kg | BMI: | Kg/m ² | Hip/Waist Ratio: |

| Abdominal | | |
|------------------|--------|----------|
| Examination | | |
| Previous Surgery | Yes No | Details: |
| Previous Tx | Yes No | Details: |
| Resting Conduit | Yes No | Details: |
| Organomegalies | Yes No | Details: |
| Hernia | Yes No | Details: |
| Aneurysm | Yes No | Details: |
| APKD | Yes No | Details: |
| Ulcers | Yes No | Details: |
| Other Notes | | • |

| Pulses | Femoral | РТ | DP |
|-------------|---------|------------|------------|
| Left | Yes No | Yes No N/A | Yes No N/A |
| Right | Yes No | Yes No N/A | Yes No N/A |
| Other Notes | | | |

| Potential LD | Yes No | Details: |
|-------------------------------|--------|----------|
| Cardiology R/V requested | Yes No | Details: |
| Anaesthetic R/V requested | Yes No | Details: |
| Other Specialties R/V | Yes No | Details: |
| requested | | |
| Israel Penn Registry referral | Yes No | Details: |
| requested | | |

| Date: | |
|-------|--|
| | |
| Date: | |
| | |
| | |

| High Risk Criteria | | | |
|----------------------------|--------|----------|--|
| Complex Surgical History | Yes No | Details: | |
| BMI >35 | Yes No | Details: | |
| Severe Peripheral Vascular | Yes No | Details: | |
| Disease | | | |
| Poor Diabetic Control | Yes No | Details: | |
| Cerebrovascular Disease | Yes No | Details: | |
| Infection Risk | Yes No | Details: | |
| High Cardiac Risk | Yes No | Details: | |

| Need of HDU/ITU post op | | Yes No | Details: |
|---------------------------------|--|---------------|--------------------|
| Expected waiting time > 5 years | | Yes No | Details: |
| | | | |
| | Docu | mented Risk/l | benefit Discussion |
| General Discussion | Average Waiting Time 3- 3.5 years Predicted length of Hospital Stay Backup System | | |
| Standard Benefits | Improvement in both quality and quantity of life with successful transplantation. 1-year graft survivals: 92-93% with deceased donor, 97-98% with live donor transplantation | | |
| Standard Risks | Re exploration 2-3%, bleeding 1-2% and Collections 1-2% Venous and Arterial Thrombosis 1-2% Urinary complications (leaks & stenosis) 3-5% Incisional hernia Requirement for lifelong immunosuppression Infection (wound, urinary, chest) Malignancy (particularly skin & haematological), Post-transplant diabetes mellitus Chronic transplant dysfunction | | |

| | • Risk of rejection within the first year after transplantation 20% | | | |
|------------|--|--|--|--|
| | • DGF (30-50%) and PNF (1%) | | | |
| | • Increased risk related to the use of ECD, Dual Tx, Pediatric En-Bloc | | | |
| | • Risk of transmission of disease from the donor to the recipient. | | | |
| | • Approximately 2-3% risk of death within the first year following transplant. | | | |
| Additional | • | | | |
| Risks | • | | | |
| | • | | | |
| | • | | | |

| Donor Acceptance Criteria | | | | |
|---------------------------|--------|----------|--|--|
| Discussed & Accepted | | | | |
| LD | Yes No | Details: | | |
| DBD | Yes No | Details: | | |
| DCD | Yes No | Details: | | |
| ECD | Yes No | Details: | | |
| Dual Tx | Yes No | Details: | | |
| Paediatric En Bloc | Yes No | Details: | | |
| Donor with previous | Yes No | Details: | | |
| Cancer | | | | |
| Donor with high risk | Yes No | Details: | | |
| behaviour | | | | |

General Comments

| Active | |
|-------------------------------|---|
| Suspended | Reason for suspension: |
| Pending investigations/MDT | |
| Consultant Surgeon | |
| Signature | |
| | |
| Date | |
| | |
| • Following review by th | e Consultant Transplant Surgeon and discussion at MDT return form to: |

| The Transplantation Laboratory, 2 nd Floor, Manchester Royal Infirmary via email to |
|--|
| Judith.Spencer@cmft.nhs.uk and Donna.Whiteoak@cmft.nhs.uk |

MDT

| Surname | | Forename | | |
|---------|-----|----------|--------|--|
| DoB | Age | | Gender | |

| Referring Consultant | Referring Hospital |
|----------------------|----------------------|
| MRI Hospital N° | NHS N° |
| Assessing Surgeon | Referral to MDT Date |

| MDT discussion required | Yes No | Assessing Clinician to be present at MDT | Yes No |
|-------------------------|--------|---|--------|
| Reason of discussion: | • | | |
| | • | | |
| | • | | |
| Outcome of MDT (date): | • | | |
| | • | | |
| | • | | |
| | • | | |
| Action Points: | • | | |
| | • | | |
| | • | | |

| Active | |
|------------------|------------------------|
| Suspended | Reason for suspension: |
| Not Suitable for | |
| listing | |
| MDT Coordinator | |
| Signature | |
| | |
| Consultant | |
| Surgeon | |
| Signature | |
| | |
| | |
| Date | |

 Following review by the Consultant Transplant Surgeon and discussion at MDT return form to:
 The Transplantation Laboratory, 2nd Floor, Manchester Royal Infirmary via email to <u>Judith.Spencer@cmft.nhs.uk</u> and Donna.Whiteoak@cmft.nhs.uk

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Chapter 6

Manuscript title

Development of an openEHR information model for UK kidney transplant services

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Objective

Kidney transplantation is a multi-centre specialist service with patients referred across organisational boundaries as part of the clinical pathway. There is a need for regional data solutions that allow access to clinical information for timely decision-making. There is an additional requirement to centralise data at national level to manage waiting lists, allocate donated organs and register transplant activity. There are currently no national or international data standards in transplantation. This study aimed to develop a clinical information model required for the assessment of a living kidney donor in the UK using the openEHR approach.

Methodology

We applied business process mapping to understand the clinical pathway and establish the clinical concepts collected during the assessment of potential living kidney donors. We then searched the openEHR Clinical Knowledge Managed (CKM) (Apperta Foundation©) for existing archetypes and identified the concepts that had not previously been modelled. We modelled these concepts as new openEHR archetypes using Archetype Designer (Better©). Archetypes are planned for review by clinical domain experts through two rounds of Delphi survey using the CKM validation tool.

Results

Process mapping identified 43 clinical concepts related to the living kidney donor assessment. 38/43 clinical concepts had been previously published in the CKM, one was currently undergoing review and two clinical concepts had not been modelled previously. These were 'human leucocyte antigen type' (used for matching potential organ donors with recipients) and a new transplant-specific concept, which we named 'living kidney donor details'.

Conclusion

This study produced a clinical information model encompassing all potential clinical concepts related to the assessment of potential living kidney donors in the UK. This provides the basis for standards-based data management and the potential to codesign user interfaces that support clinical workflow. Future work can apply our knowledge elicitation and clinical modelling methodology to additional use cases within transplantation, as well as to other clinical areas.

1. Introduction

1.1 Kidney transplantation, living donation and health information technology

With the increasing complexity and multi-disciplinary nature of healthcare, systems interoperability has been highlighted as a key priority to improve patient care and outcomes.¹⁻³ Healthcare services routinely depend on access to clinical data across organisational boundaries for accurate decision-making.⁴ This is particularly a priority for specialist services, such as oncology, genetics or neurology, that are regionally centralised to large academic hospitals and serve a large geographic area.⁵ Kidney transplantation is another such regional service. Each transplant centre typically serves several surrounding hospitals, which refer patients to the centre when clinically necessary. In the United Kingdom (UK), there were a total of 23 transplant and 64 referral centres in 2019.⁶

The patient pathway in transplantation naturally depends on data sharing. Patients cross speciality and organisational boundaries as they are transition from renal services at referral centres to specialist services at transplant centres.⁷ Because transplantation is the best treatment for suitable patients with kidney failure, timely referral is critical.^{8, 9} Patients receiving a transplant are likely to live longer and experience a better quality of life when compared to those receiving alternative treatments for kidney failure, such as dialysis.¹⁰ Patients requiring transplantation are known as recipients and due to complex medical needs must undergo extensive assessment to ensure their suitability for a transplant.¹¹

As part of this assessment, recipients explore the option of receiving a donated kidney from a living donor. Living donors are most commonly related to the recipient or part of their wider social network. They similarly undergo a detailed assessment process, which aims to ensure that they are medically safe to donate and that there is no coercion, monetary reward or ethical contraindication.¹² The assessment process involves several hospital appointments as well as specialist laboratory investigations, such as Human Leucocyte Antigen (HLA) typing, which confirms the genetic match between donor and recipient. Each transplant centre in the UK has living donor coordinators who support potential donors along the clinical pathway and manage the clinical data collected during the assessment.¹³ The management of this data has been reported to be challenging as investigations may be undertaken at referral centres or because results are returned across disparate IT systems. There is thus a dependence on manual and paper-based processes to summarise and coordinate data and current EHRs have been shown to be unable to support this workflow.¹⁴

Studies in transplantation have shown that EHRs are unable to: a) store data according to standards, b) support interoperability of IT systems within and across organisations and c) provide a view of clinical data to complement workflow.¹⁵ There is an additional requirement to centralise data at national level, for organ allocation, to manage transplant waiting lists and register clinical activity for follow-up and audit. There is thus a need for improved standardisation of clinical concepts into technical artefacts to support the multi-organisational clinical workflow and necessary secondary uses of data.

1.2 Interoperability and clinical information modelling

Meaningful interoperability depends on a common standard of health-related knowledge, which allows semantic exchange of data without the need for additional transformation across systems.¹⁶ To achieve this, development of EHRs has been evaluated as a methodology to create technical artefacts by involving domain experts in the standardisation process.¹⁷

openEHR is such an approach and has been applied to create data models (known as archetypes) and data sets (known as templates) in a range of clinical domains, including oncology¹⁸, obstetrics¹⁹ and genomics.²⁰ It has been successfully used to establish vendor-neutral clinical data repositories (CDRs) in several countries allowing the development of independent application programming interfaces (APIs) that meet service needs.²¹ In Norway, openEHR has been adopted for health information technology infrastructure with all vendors adhering to a national standard.²² This separation of data from application provides the potential for EHRs to move from complete enterprise suites (also known as monoliths) to regional data platforms (also known as ecosystems). This can enable healthcare organisations to develop or procure APIs that support local services and populations.

Transplantation has the potential to benefit from openEHR archetype development as it may drive regional interoperability and improve standardised national data capture. A vendor-neutral patient-centric approach may reduce the current onus on manual data management and need to duplicate records across organisations, with all the data integrity and reliability problems these processes cause. This paper reports on the development of OpenEHR archetypes for a living kidney donor assessment use case.

2. Methods

2.1 Context

This study was based at the Manchester University NHS Foundation Trust. The centre provides transplant services across the North West region of the United Kingdom (UK) and serves a population of over five million citizens. The centre undertakes 70-80 living donor transplants annually.

A living kidney donor is an individual who willingly donates one of their kidneys to another person.¹² Most commonly a living donor will donate to a relative or friend. This is known as directed donation. On rarer occasions an individual may decide to donate a kidney without a specific recipient in mind. This is known as non-directed or altruistic donation.²³ Living donors are typically healthy with little previous medical history. Transplant activity in the UK is regulated by NHS Blood and Transplant (NHSBT) and licensed by the HTA (Human Tissue Authority). NHSBT is a national body and is responsible for maintaining the waiting list, capturing activity and ensuring standards are upheld.

Previous work by our research team mapped the regional data journeys for the transplant pathway. This showed that the clinical pathway for living donor assessment at the Manchester University NHS Foundation Trust is currently supported by an in-house EHR, with additional IT systems for ordering tests, radiology and cardiac results. There is a further IT system in use by the renal department, which is not integrated with the EHR. In total, a minimum of five different IT systems are used by members of the transplant team to complete clinical workflows. There is no currently no common data model or interoperability across these IT systems.

Documentation remains paper-based and there is no transplant-specific data management solution in place. The department manages data in paper files, electronic documents stored as Portable Document Formats (PDFs) on shared drives and local Microsoft® Excel files. Besides local referrals, patients are referred from two additional nephrology departments at regional hospitals. Currently, there is no interoperability between IT systems across the three participating hospitals. Post, fax and email attachments are the main mediums for transferring clinical information across organisational boundaries.⁷

2.2 Study team

The lead author (VS) is a clinical informatician working in the transplant team as well as a researcher at the Centre for Health Informatics at the University of Manchester. VS acted as a study coordinator and forged the collaboration across clinical, academic and industry partners. This study was performed in collaboration with freshEHR©, an openEHR consultancy. The freshEHR© team consisted of three data modellers and one business process mapping consultant. An overview of the applied study method steps is shown in Fig. 1.



Figure 1: a diagrammatic overview of the methodological steps applied in this study. Note: clinical validation has been planned but not yet undertaken and thus not reported in this manuscript

2.3 Process mapping

We applied Business process mapping and notation (BMPN) to enrich our understanding of the living kidney donor patient pathway. BPMN has been shown to help understand end user interactions with EHRs and informs the technical requirements to support clinical workflows.²⁴. We undertook semistructured interviews with domain experts to capture data on patient touchpoints, clinical workflow, and administrative processes. We interviewed two living donor coordinators, one transplant nephrologist, one transplant surgeon and one transplant lab technician. Interviews lasted between 30 and 45 minutes and field notes were kept. We used Lucidchart©, a web-based diagramming tool to create process maps. We primarily focussed on identifying what data was collected at touchpoints along the pathway. The process mapping resulted in a context-specific list of clinical concepts that would make up the overall information model.

2.4 Clinical information modelling and archetype development

We searched the Clinical Knowledge Manager (CKM) (openEHR Foundation©) for archetypes that matched the clinical concepts identified through process mapping. Archetypes are structured models of domain content, such as 'blood pressure' or 'problem list' and are built with input from clinical domain experts.²⁵ Once validated, archetypes are published to the CKM, which acts as an open source library to support development of healthcare software. Archetypes are typically designed to cover all aspects of a concept. For blood pressure this means that besides modelling systolic and diastolic figures, the archetype includes elements such as cuff size, patient position and device details. This leaves the option to constrain elements of the model based on the given clinical context. Once configured to meet the use case in question, archetypes can be downloaded and used to develop user interfaces through a range of open-source and proprietary tools. We used the open modelling tool *openEHR Archetype Designer* (v1.23.0) provided by Better© and openEHR International© to undertake archetype development.

The identified archetypes that were already published and openly available in the CKM were constrained according to requirements shared by the clinical team at modelling sessions. We used an agile-inspired process working over twelve weeks with the freshEHR© team. Domain experts provided clinical input every two weeks. In addition, the study coordinator (VS) was available for support throughout the development. This allowed iterative development resulting in increasing completeness in the overall information model. Over the course of six modelling sessions, input was sought from the same domain experts as during BPMN and included one living donor coordinator, one transplant nephrologist and one transplant surgeon.

Any clinical concept, which had not yet been published as a validated archetype was modelled from scratch with specific domain expertise. For example, the clinical concept of 'HLA type' was modelled with input from a clinical scientist from the transplant laboratory. Newly developed archetypes are

subject to validation by a wider clinical community prior to being published to the CKM for use. This report does not include the validation exercise; however, this is planned as part of the overall project.

3. Results

3.1 process map

An example of the BPMN diagram created during process mapping can be found in Appendix I. A simplified infographic of the process map is shown in Fig. 2.



Figure 2: simplified summary results of business process mapping

BPMN identified a total of 43 clinical concepts, which were relevant to living kidney donor assessment. After searching the CKM for these concepts, we identified 38 matching archetypes. A list of all clinical concepts and their archetypes, if present, can be found in Table 1. Table 1: list of clinical concepts relevant to living kidney donor assessment and matching archetypes

| Living kidney donor clinical concept | Archetype in CKM (Y/N) | openEHR archetype name |
|--------------------------------------|---------------------------|------------------------|
| Demographics | | |
| Name | Y | Individual's personal |
| | | demographics |
| Date of birth | Y | Individual's personal |
| | | demographics |
| Patient identifier | Y | Individual's personal |
| | | demographics |
| Address | Y | Individual's personal |
| | | demographics |
| Telephone number | Υ | Individual's personal |
| | | demographics |
| E-mail address | Y | Individual's personal |
| | | demographics |
| Next of kin | Υ | Individual's personal |
| | | demographics |
| Living kidney donor details | | |
| Type of donation (directed/non- | Ν | |
| directed) | | |
| Relationship to recipient | Ν | |
| Transplant centre | Ν | |
| UK living kidney donor sharing | Ν | |
| scheme | | |
| Biometrics | | |
| Height | Υ | Height/length |
| Weight | Υ | Body weight |
| BMI | Υ | Body mass index |
| Point of care results | | |
| Blood pressure | Y | Blood pressure |
| Urine dip | Υ | Urinalysis |
| ECG | Y | ECG result |

| Patient record | | |
|--------------------------------|---|---------------------------------|
| Medical history | Y | Problem list |
| Drug history | Y | Medication list |
| Allergies | Y | Allergies and adverse reactions |
| Occupation | Y | Occupation record |
| Smoking status | Y | Tobacco smoking summary |
| Transplant lab results | | |
| HLA type | Ν | |
| ABO blood group | Y | Blood matching |
| General lab results | | |
| Full blood count | Y | Laboratory result |
| Renal profile | Y | Laboratory result |
| Liver profile | Y | Laboratory result |
| Cholesterol | Y | Laboratory result |
| Thyroid function | Y | Laboratory result |
| Urate level | Y | Laboratory result |
| CRP | Y | Laboratory result |
| Clotting | Y | Laboratory result |
| Virology | Y | Laboratory result |
| HbA1C | Y | Laboratory result |
| Fasting lipids | Y | Laboratory result |
| Group and save | Y | Laboratory result |
| Urine albumin/creatinine ratio | Y | Laboratory result |
| Urine culture and microscopy | Y | Laboratory result |
| Imaging results | | |
| Chest x-ray | Y | Imaging examination result |
| Nuclear medicine scan | Y | Imaging examination result |
| Isotopic GFR measurement | Y | Imaging examination result |
| CT scan | Y | Imaging examination result |
| Clinical assessment | | |
| Physical examination | Y | Physical examination findings |

Note: The column titled 'structured data available' indicates with a Y or N whether data is already recorded electronically elsewhere and thus may auto-populate a field if interoperability allows

3.2 Archetype development

All clinical concepts with matching archetypes were constrained with domain expert input and saved in a new GitHub repository on Archetype Designer. There were five concepts that had not been modelled before. Four of those concepts related to administrative data of the potential living kidney donor and were thus grouped to create a new 'living kidney donor details' archetype. In addition, the laboratory result for HLA type was modelled based on the existing 'laboratory test result' archetype. Results of the modelled archetypes are displayed as mindmaps in Fig. 3 and Fig. 4.







Figure 4: openEHR archetype mindmap for 'HLA type'

4. Discussion

This study applied a collaborative approach to develop a complete information model for the assessment of potential living kidney donors in the UK. We identified a total of 43 clinical concepts, out of which 38 were associated with existing openEHR archetypes. An additional five clinical concepts
were modelled into new archetypes with direct input from domain experts. These archetypes are planned for review through the CKM validation tool prior to open publication.

4.1 Relation to other studies

The openEHR approach has been successfully applied to several other clinical domains. A recent publication by Wulff et al describes clinical information modelling to standardise microbiology data in to openEHR archetypes. The authors identified a minimal data set, which included nine clinical concepts. Five of these had been previously modelled and published, one was currently under review and three were modelled from scratch with domain experts. The authors describe the review process of their newly modelled archetypes through the CKM review tool, and highlight the additional value of receiving feedback from the wider openEHR community in the development of relevant, widely applicable and reusable archetypes.²⁶ A similar project was undertaken by Gomes et al in Brazil, who identified clinical concepts related to general nursing care as part of hospital admissions. With this approach they identified and modelled concepts such as nursing diagnosis and nursing intervention.²⁷ Our use case looked at a patient pathway and workflow to define a list of relevant clinical concepts. This approach similarly resulted in the identification and modelling of all concepts to complete the information model. Once validated, these may be used to create templates and applied to design a user interface to support the workflow in the future.

Other industries rely on the involvement and feedback from end-users throughout the life-cycle of their products. This approach is known as user-centred design and promotes shared ideation, a rich understanding of requirements and helps align incentives amongst stakeholders. It also encourages agility in the design process with an emphasis on incremental and iterative progress.²⁸ The openEHR approach brings these principles to the clinical information modelling process by creating a collaborative platform for clinicians and informaticians. A systematic review by Alfraihi et al has previously shown how MDD combined with an agile iterative approach may bring benefits to the development of new solutions.²⁹ We experienced that this approach added value to our final information model as it was immersed in the lived experience of domain experts.

The interoperability challenge stretches beyond standardised information models.³⁰ Harmonising clinical concepts in to standards-based technical artefacts is a fundamental requirement for semantic interoperability. However, there are several barriers to implementing these in to health systems. Oyeyemi et al investigated stakeholders views on major interoperability challenges in health and social care in England and identified organisational factors as the most commonly reported barrier.³¹ Current procurement of IT solutions, including EHRs, remain focussed on the needs and requirements of individual healthcare provides. A lack of regional and multi-organisational alignment results in the requirements of clinical services that span the wider healthcare system to be left unmet. This is despite the widely accepted recognition that healthcare systems need greater integration and coordination to serve the current population.³²

4.2 Implications for practice and research

Our study demonstrated the value of cross-disciplinary collaboration in the development of technical artefacts that can support health IT. Traditionally, the development of health IT solutions is undertaken by independent vendors who supply software to healthcare providers, such as the NHS. These companies do not always have sufficient clinical leadership or medical know-how.³³ As a result, a lack of input from domain experts has limited the accurate reflection of workflows in health IT solutions and studies have demonstrated the poor user experience of EHRs.^{34, 35} Though challenging, going forward it will be beneficial to encourage co-development of health IT solutions, with a view to better achieve intended benefits.³⁶

Current healthcare software vendors provide enterprise solutions. Existing EHRs are typically bound to a single healthcare organisation and regional data requirements are not necessarily considered during procurement. Once implemented, this monolithic approach traps healthcare providers within the confines of system capabilities of each individual vendor. This approach is inflexible and limits the opportunity for innovation and progress. In order to realise a health IT marketplace where solutions are designed with a deep understanding of clinical workflows and achieve intended benefits for patients and providers a new approach is necessary.³

A landscape where EHR vendors provide (cloud-first) data management based on open standards may overcome the current interoperability challenges faced by kidney transplant and other healthcare services. Separating data management and application development (platform approach) will allow providers to procure incrementally and adaptively based on evolving needs. In other industries, such as banking, this approach is described as a microservices architecture and provides several benefits such as agility, faster development and deployment cycles, and scalability of particular functionalities.³⁷ Adopting openEHR as an approach to standardise clinical information models used across EHRs enables third-party vendors to develop solutions to specific challenges.³⁸

However, there are organisational and social challenges with this approach.²⁵ Case studies outside of healthcare have shown successful MDD requires organisational commitment, integration with existing processes and a clear business focus.³⁹ There is currently no mandate for vendors to comply to data standards. Several Standards Development Organisations exist and even the openEHR foundation© has been in existence for over 20 years. In addition, Fast Healthcare Interoperability Resources (FHIR), another health data standard developed by Health Level 7 (HL7) is being investigated by the NHS policy-makers.⁴⁰ However, the uptake of standards by vendors to break proprietary data silos and improve interoperability has been left wanting.⁴¹

The output of this paper includes two new archetypes, which following validation may be published to the CKM for use by health IT vendors. A future line of research should explore how this information model may be used to design a clinical application. Early user interface prototyping by this research

team has iteratively produced high-fidelity mock-ups and explored usability barriers.¹⁵ We will now look to utilise the Design Studio tool provided by Better© to develop a template for data capture with clinical end-users. This translational pathway from modelling clinical concepts through to developing health IT solutions is a potentially novel and scalable approach that can bring benefits to populations and patients.

4.3 Conclusion

The openEHR approach is a collaborative and easy-to-use method to model clinical concepts in to technical artefacts for the use in health informatics. It facilitates the development of health IT standardising clinical content at the level of data storage. This study demonstrates the process of undertaking this work in a living donor kidney transplantation use case. The emergent outcome of an open information model is the potential for semantic interoperability and a platform approach to the management of data in kidney transplantation. Other workflows within transplantation, as well as other clinical specialities are likely to benefit from this approach and support multi-organisational working with communication across teams and healthcare providers.

Appendix

Living donor evaluation archetype selection

No previous attempts to develop an open information model for transplant related data or clinical practice has been described in the academic literature. Similarly, no standards development organisations have actively addressed the need for access to data across organisational boundaries to support interoperability in kidney transplant care. As this was the primary attempt at exploring this, I decided to use the evaluation of a living donor as an index use case. I purposefully selected living donors, because their clinical evaluation, medical history and investigations are less complex than those for transplant recipient assessments. However, living donors experience the same pathway of care with referrals from regional hospitals to central transplant centres. The aim of this study was thus to explore and prove the patterns that may be achieved by a vendor-neutral data platform, which allows interoperability by design through standardised information at its core.

Real-world deployment of openEHR archetypes

OpenEHR is an open standard for modelling, storing, and retrieving health data. Development of openEHR data models (known as archetypes) are dependent on a collaborative effort between technologists and clinicians. The Clinical Knowledge Manager (CKM) tool (Ocean Health Systems ©) provides a collaborative platform for the iterative design of archetypes and for an asynchronous peer review process. The CKM subsequently acts as a library of published archetypes that have been peer-reviewed and deemed suitable for real-world deployment. This provides an open community-based governance process for that management on archetypes. However, subsequently deploying openEHR-archetypes into practice remains challenging with a range of potential barriers and facilitators to consider.

Firstly, there remains a lack of awareness and understanding of the importance of open data models at the heart of the interoperability challenge, particularly amongst healthcare professionals and senior stakeholders in decision-making positions. Recently a number of national policies, such as the Scottish Health and Social Care: Data Strategy have started to include the need for openEHR and other open standards to promote interoperability in healthcare. However, the realisation of this is currently limited by limited resources and funding allocated to the support the development and deployment of standards-based information models. This is coupled with a resistance to change from established workflows and processes that makes it challenging to replace existing systems and migrate data into openEHR based repositories. Finally, stakeholders continue to report concerns around data privacy and security, particularly when using cloud-based solutions.

It is therefore critical to continue to educate healthcare professionals and policy-makers on the critical role information modelling and data standards play in the potential to make data available for patient

care. Increasing the awareness around openEHR and its benefits will require a collaborative approach healthcare professionals, IT specialists, and other stakeholders. This includes identifying funding for open-source software, such as the CKM tool that can continue to support the development and deployment of openEHR archetypes. Finally, regulatory support and incentives for EHR providers to adopt openEHR based solutions will further help deployment in the real-world setting.

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Appendix I: BPMN process map extract

Figure 5: an extract from the process map created in Lucidchart©



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Each chapter has a discussion as part of the manuscript. This chapter aims to assimilate these and inform a wider discussion that draws conclusions for clinical and academic stakeholders.

7.1 Summary of main findings

This thesis identified the complexities of workflows in kidney transplantation and explored the role of health IT in the management of clinical data. Findings are summarised under headings reflecting the objectives set out in the introduction of this thesis.

7.1.1 The current use of health IT in kidney transplantation

This objective was addressed in chapters 2 (systematic review), 3 (data journey modelling) and 4 (interview study). The systematic review established that currently, there is a paucity of literature on the use of health IT in transplantation. The reviewed literature reported on task-specific IT solutions; however, these were rarely evaluated for impact on care and outcomes. There were no studies reporting on solutions that effectively support the multi-disciplinary and multi-organisational nature of the transplant services.

Data journey modelling specifically established the roles of the organisations, IT systems and actors involved in the transplant assessment pathway. It helped illustrate how the movement of clinical data wholly depends on healthcare professionals physically accessing data across disparate systems and transcribing it on to paper forms. A lack of regional interoperability added additional administrative time and cost as transfer of data across organisations was dependent on post, fax, or email. Anecdotally, it delayed the registration of patients on the transplant waiting list. The coordination of care was largely dependent on individual actors, in particular transplant coordinators, who have devised heuristic methods to manually manage patient pathways and clinical data.

The interview study established that the state of digital transformation at UK transplant centres is poor. I did not identify any transplant-specific EHR in use, despite recurring feedback that a single system would be beneficial. Results from the study illustrated how front-line clinical teams most commonly rely on manually populated Microsoft© Excel and Access databases to manage clinical data. Though this served the purpose of centralising data across systems and organisations, it was reported to be timeconsuming and onerous. These solutions were rarely scalable or transferable across transplant centres.

Reflecting on these chapters, it was evident that the use of health IT in kidney transplantation is largely based on human actors rather than technology automating administration and supporting data management. A lack of interoperability and poor alignment of EHRs to support workflows further impacted the potential for IT to exert a positive impact. The unifying challenge revolved around the complexity of the multi-organisational nature of the kidney transplant service. Though major advances

have been made in laboratory-based science in transplantation, a legacy of local workflows practices combined with a lack of research into health IT means that little innovation has been achieved in this space.

7.1.2 current workflows and data management challenges

This objective was addressed in chapters 3 (data journey modelling) and 4 (interview study). From a social perspective, data journey modelling identified how people, rather than IT systems were critical to the management of clinical data. Workarounds were created to minimise manual processes, including copying and pasting results from one IT system to another and scanning and uploading paper documents on to EHRs. Though these methods promoted paper-free or paper-light work, they were still time-consuming. The interview study further highlighted a lack of digital strategies or leadership at transplant centres and reflecting on the feedback from transplant coordinators across the UK, it was evident that digital transformation was not an agenda item at present.

From an organisational perspective, both data journey modelling and the interview study confirmed that most transplant centres, being part of large specialist NHS Trusts, had EHRs implemented. However, no centre was able to manage all transplant-related data or patient pathways through a single system. This was firstly because most renal services still use customised renal-specific IT systems on top of unified EHRs. Secondly, all transplant centres received patients from outside of their own organisation with limited ability to share data across organisational boundaries automatically. Individual NHS organisations across regions, delivering shared pathways in transplantation have clearly failed to unify their processes, which has resulted in the current fragmented data management. Furthermore, though data sharing for direct care does not require additional legal permission, I did not identify any formal governance agreements between transplant and referral centres with regards to re-use of patient data for analytics, service improvement or research.

From a technical perspective, limited capabilities were reported by transplant coordinators with respect to implemented EHRs or other IT systems. Capabilities such as clinical decision support or data analytics were not used. With regards to systems interoperability, four centres reported some data sharing across organisational boundaries, which was beneficial to the workflow. However, at all transplant centres there was a need to access multiple IT systems to complete the workflow. A recurring piece of feedback from transplant coordinators emphasized this point with anecdotes such as "*it would be good if we could have it all on one system*". Even when an EHR was used, or there was access to data through a shared care record, the inability to visualise all the relevant data on a single screen resulted in time-consuming navigation through IT systems and manual transcription to provide a unified view.

7.1.3 The feasibility of a transplant-specific EHR

Based on the current state of health IT and socio-technical challenges identified in the first three manuscripts, I addressed this objective in chapter 5 (codesign prototype).

The codesign prototype allowed us to develop and test a high-fidelity user interface, which demonstrated the potential of a novel transplant-specific IT solution. It was based on the two main requirements gathered through the data journey modelling and interview study; 1) surface data across organisational boundaries, and 2) provide views that support the clinical workflow. Fig. 1 is a screen shot of the user interface and <u>this</u> is a link to the prototype, where you can click through various screens. We provided flexibility in the design process and iterated the user interface based on continues domain expert feedback. This resulted in a solution that potentially addressed the two requirements and provided a visual experience that conformed to international web design standards.



Figure 1: screenshot of the prototype solution codesigned with transplant healthcare professionals to meet the specific needs and requirements of the workflow. This image shows the views for the assessment of a potential living donor.

7.1.4 The use of open data modelling to support interoperability in kidney transplantation Taking the lessons learnt from the first four manuscripts, I recognised that to develop clinical IT systems that address workflow challenges in healthcare, we must separate the data from the application layer. Through the data journey model and the interview study, it was apparent that current EHRs and shared care records are not implemented based on this concept. This means there is still a need to develop clinical data repositories across organisational boundaries, which represent clinical concepts through vendor-neutral information models. This will allow new and existing vendors to build (ideally codesign) user interfaces that meet specific needs and requirements of service providers and their users.

However, in kidney transplantation, which forms the largest component of solid organ transplantation nationally and globally, no such information models exist and no previous attempts to create these have been reported in the academic literature. Having identified this gap, I used the openEHR approach to develop an information model for living donor kidney transplantation as a first use case. I selected living

donor recipient evaluation because the level of complexity is lower relative to the evaluation of a transplant recipient. Living donors are generally fit and well with minimal medical history. Their evaluation is also far more standardised and predictable compare to recipients. However, they still experience the same challenge of being referred across organisational boundaries and experiencing clinical encounters and investigations at both transplant centres and renal referral units, Interestingly, to overcome the established access to a view of the clinical data challenge that this brings, some centres have decided to centralise all appointments and investigations as a mitigating strategy, even if this means that the donor must travel a significant distance from their local region for each encounter. The increase uptake of living donor kidney transplantation in Northern Ireland has been partly attributed to this centralised service model.

After reviewing and analysing the living donor clinical pathway using a swim-lane method, I specifically identified the clinical concepts that had not previously been modelled and worked with domain experts to develop new archetypes to represent these. This included, in particular, human leucocyte antigen (HLA) type, which is a laboratory test necessary for matching organ donors with recipients and a new transplant specific archetype, which we named 'living kidney donor details'. These new archetypes are planned for review and validation through a Delphi exercise, prior to publication for use by the wider health informatics community.

7.2 Future clinical implications

7.2.1 IT vendors should develop solutions that are interoperable by design

Based on the findings in this thesis, there remains a clear need to improve the management of clinical data in kidney transplantation. For patients to experience a safe and efficient service with timely and equitable access to the transplant waiting list, relevant clinical data must be readily available at the point of care for all members of the multidisciplinary team involved in the listing pathway. To achieve this, there is a need to improve regional interoperability.

Interoperability has been recognised as a priority by the NHS for some time. Initiatives as far back as 2002 (Connecting for Health, succeeded by the National Programme for IT) included interoperability as part of their strategy.¹ The subsequent failure of this programme, besides being over-ambitious and over-centralised, was partly due to a lack of engagement with IT vendors as key stakeholders.² The subsequent Wachter Review (2016) pointed out how vendors considered interoperability as a desirable capability of IT systems, rather than fundamental to the viability of the programme.³

Integrating regional data for the delivery of care is only meaningful if all participating healthcare organisations and IT vendors agree to participate. As highlighted by the interview study, individual organisational digital maturity or IT system capabilities were irrelevant when evaluating regional services, as a lack of interoperability limited the ability of IT to support workflows. The results from data journey modelling demonstrated how regional data sharing was not considered during the development

or design of transplant services. It was unfortunate to conclude that currently no IT system can surface all relevant data in a single user interface, despite a clear need for such a solution.

For digital transformation to be successful going forward, solutions must be interoperable by design. IT vendors must prioritise access to relevant data at the point of care to achieve the intended benefits of health IT. Reflecting on the findings in this thesis, this can be achieved if IT vendors develop solutions that are based on open data standards, such as openEHR or Fast Healthcare Interoperability Resources (FHIR).

Building on the data journey modelling work, semantic harmonisation of clinical data based on open standards may allow the development of integrated clinical data repositories. Such regional solutions may store standardised healthcare data across organisations, creating a platform for innovation. The current shared care records across regions of the NHS may form an intermediate source as some centralisation and harmonisation has already occurred at this level.⁴ Specifically, in the use case of transplantation, this may enhance workflows through custom-designed clinical applications and improve messaging of data centrally to NHS Blood and Transplant for registry and quality assurance. A conceptual data journey model to this effect illustrating an extract, transform, load (ETL) pipeline from a shared care record solution to an openEHR based clinical data repository is shown in Fig. 2.



Figure 2: centralised clinical data repositories based on open standards may allow the development of transplant-specific clinical application and standardise the capture of data for NHS Blood and Transplant purposes. Shared care records could populate these standards-based repositories

As the NHS in England now moves towards integrated care systems (ICSs), there may be an opportunity to embed such integrated data repositories at ICS level and support the wider delivery of health and social care across regions.⁵ These may be based on openEHR, or other vendor-neutral data and messaging standards, such as FHIR. Through open application programming interfaces (APIs) the data may be surfaced on different applications that provides visualisations that meet specific clinical or

patient/citizen needs (Fig. 3). Cost-based analyses from outside the UK have modelled the value of investing in such region-wide interoperability citing potential financial benefit. ⁶



Figure 3: ICS-wide clinical data repositories may allow a range of vendors to develop applications that address specific workflow needs and transmit data centrally through the NHS secure electronic file transfer service (SEFT).

Real-world implementations of such integrated clinical data repositories exist. The HiGHmed consortium in Germany is an example of an open multi-organisational health data platform.⁷ The project brought together 24 academic and industry collaborators to establish a shared governance framework and technical architecture based on openEHR. The ongoing work by this group has demonstrated a number of successful use cases such as the standardisation of medical microbiology data across systems and organisations.⁸ Specific to renal medicine, the HiGHmed consortium has applied the interoperable data platform approach to digitise nephrology care and develop a clinical decision support system to help detect early deterioration of renal function and predict cardiovascular events.⁹

Another good example of open standards to support clinical care through interoperability is the Substitutable Medical Application and Reusable Technologies (SMART) programme at Harvard Medical School and Boston Children's Hospital in America. Here, developers worked with IT vendors to constrain and extend FHIR resources adding standardised terminologies to create so-called FHIR profiles. These FHIR-based information models provided the semantic interoperability necessary to create an app-based ecosystem where third-party vendors were able to develop plug-and-play solutions capable of surfacing data from the local EHR.¹⁰ This implementation has been shown to have specific benefits such as improved access to specialist care.¹¹ Interestingly, the project team reported initial resistance from IT vendors and unfortunately adoption of this approach has not been widely reported elsewhere. This is likely because this approach still required substantial local customisation to standardise several proprietary data models in to FHIR from each IT vendor.

Unfortunately, there are vendors that benefit from locking data into their proprietary siloes and charging healthcare providers for access or other vendors for integrations with their system.¹² There are pockets of innovation where solutions have been developed that are interoperable by design. However, the real-world adoption of open standards remains low. The openEHR approach, as well as the FHIR approach

if profiling is standardised, aim to create common information models across IT systems. Interoperability is thus an emergent consequence of this standardisation. These approaches potentially achieve semantic interoperability, which combined with uniform governance and legal standards could lead to HIMMS interoperability level four (organisational interoperability).¹³ IT vendors play a critical role in achieving this and industry-wide cooperation will ultimately bring the anticipated benefits of health IT to patients.

7.2.2 Policy-makers need to drive the adoption of open standards

In the NHS, various attempts to drive interoperability have come and gone. The most recent coordinated project was the Local Health and Care Record, which provided funding to integrate health and social care data for direct care across five regions of the UK. This national programme aimed to accelerate the development of shared care records and the funding ended in 2021. Though individual successful use cases have been reported, even within individual regions selected for the project, NHS organisations failed to collaborate and approve necessary data sharing agreements.¹⁴ In the Greater Manchester region for example, alongside the Local Health and Care Record, a second shared care record project was developed almost simultaneously called the 'Greater Manchester Care Record'. Both projects were developed by separate vendors and supported by different NHS trusts. Transplantation is an example of a clinical service that suffered from this lack of regional vision as patients are regularly treated across both NHS trusts. Besides the technical challenges of interoperability, a culture of organisational collaboration and data sharing for patient benefit still needs to be stimulated.

The more recent (2022) Department of Health and Social Care's Data Saves Lives policy paper places an emphasis on data standards and separation of data and application layers. However, the paper falls short of mandating IT vendors to comply to these standards.¹⁵ A recent report on integrated health information systems in the Netherlands by the Organisation of Economic Co-operation and Development made bold recommendations for the role of national policy to improve interoperability. Recommendations included agreeing national standards for health data semantics and certification for health IT vendors' compliance to those standards. Additional levers were described in the form of financial incentives for IT vendors that demonstrate that their solutions are verifiably interoperable.¹⁶

Current NHS policy can strengthen its position to move towards this vision. As a centrally regulated healthcare system, the NHS has the unique potential to develop and implement unified policy that unfortunately, we continue to see investment in traditional monolith EHR solutions, which have repeatedly been shown to demonstrate modest adoption of data standards and poor interoperability records.¹⁷ To move towards a platform approach, as described in the clinical information modelling chapter of this thesis, it is important that the adoption of standards is fast-tracked. The data layer of health IT should be seen as a separate enterprise to the development of applications.¹⁸ This will allow a marketplace of health IT to emerge, where vendors do not compete over data, but compete based on capabilities of their solutions, such as user experience or integrated clinical decision support.

7.3.3 Health IT developers must embrace user-centred design

Through our systematic review, I identified that EHR systems that support kidney transplantation do exist, however no academic literature on how their user interfaces were designed had been published. The wider literature suggests little application of user-centred design or codesigning in health IT, which reflects the poor usability feedback from clinicians.¹⁹ A study by Ratwani et al found that EHR vendors frequently lack user-centred research or design strategy as part of their business.²⁰ This is likely because EHRs were originally developed as software to electronically record clinical activity for billing purposes, rather than direct care.²¹ However, as requirements have changed over time, EHRs underpin the delivery of clinical care, yet their design has remained largely unchanged.²²

Developing novel solutions that better support workflow, reduce cognitive overload and improve patient experience are therefore still a necessity. Though the literature supports the notion that EHRs positively impact the quality and safety of care overall, there is also growing evidence that they negatively affect the doctor-patient relationship through reduced eye contact, rapport and emotional support.²³⁻²⁵ Involving end-users (clinicians and/or patients) in the design of health IT solutions is therefore critical to optimise the balance between workflow support and human contact.²⁶

The Wachter Review recognised this, citing user-centred design as one of the ten principle learnings from the National Programme for IT. Successful innovation considers the viability, feasibility and desirability for any new product or service at the start of the design process (Fig 4).²⁷ Public healthcare systems, with limited funding, typically prioritise the viability and feasibility domains, with desirability considered non-critical.²⁸ However, as the role of EHRs and computer-based work has become ubiquitous in healthcare, the user experience of these systems can impact the quality of care delivered.²⁹ A way to achieve desirability in health IT could be by embedding user-centred design teams within NHS organisations and creating a culture that values human experiences to shape services and solutions. Examples of this are emerging with Surrey and Borders Partnership NHS Trust directly employing a specific design team, which consults internally on quality improvements projects. Centrally, NHS Digital has published extensive guidance on how to apply user-centred approaches in NHS organisations. As reflected in our codesign prototype experience, applying these is likely to reduce barriers to adoption and increase the potential impact an innovation.



Figure 4: viability, feasibility and desirability must all be considered during the design of a new innovation

7.3 Future research implications

The chapters of this thesis built on each other and answered questions arising from each preceding piece of work. Below, I identified areas of future research.

7.3.1 Evaluating health IT solutions

Firstly, as highlighted in the systematic review, methods to evaluate health IT critically and aptly are still required. A paradox can be observed in health IT, where those interventions that are thoroughly evaluated and have a strong evidence base are often poorly adopted whilst interventions with seemingly little scientific backing are widely implemented. An example of this is Babylon Health, a telemedicine and chatbot service, which has over 100,000 registered users in the UK alone. Despite its widespread use, there is little to no evidence of the safety, efficacy or patient experience of the service.³⁰

This may partly be explained by the fact that the speed of innovation does not match the speed of academic evaluation. This begs the question whether digital health research requires a re-think of how to evaluate new interventions. It similarly raises concerns of how new technologies enter the market without meaningful evaluation. Ways to improve this could include setting up digital health laboratories; physical spaces with computers, laptops, tablets, etc where researchers can readily invite participants and test their solutions with real users. This would be akin to how traditional clinical research involves participants who volunteer to take part in a trial. In this thesis, I presented our codesigned prototype, which I pilot-tested with qualitative feedback from end-users. In addition, at a digital health laboratory, we could further objectively evaluate the user experience through user-testing. This could include experiments, such as giving end-users a specific task to complete within the prototype and analysing eye gaze, mis-clicks and time-to-completion. ³¹

Another approach to accelerate the evidence-generation process would be to integrate user experience analysis into the workflow of implemented solution. Other industries, in particular social media regularly capture user interaction data to continually improve their products and provide a better user experience. Interaction data, such as time spent on particular screens or number of uncompleted fields, are by-products of system use and may provide a quicker and applicable way to gather real-world data and iteratively drive improvements.

7.3.2 Research in health IT interoperability

Data journey modelling in this thesis illustrated a disconnected IT landscape, which, following feedback from transplant coordinators, impacted on the delivery of transplant services. A further understanding of what drives healthcare organisations to select stand-alone IT systems is necessary, particularly in the now common knowledge that data sharing across organisational boundaries is critical to the delivery of health and social care. Even today, aligning organisational incentives appears to be one of the main barriers to interoperability in health and social care.³² National policy in the UK as well as the United States of America highlights the importance of standards to drive interoperability, however there is currently no mandate for vendors of health IT to conform to those.^{33, 34}

Qualitative research with regional or national stakeholders to explore barriers to the adoption of standards would help understand how to improve conformity in health IT. The development of policies around interoperability also requires codesign approaches. Having stakeholders as active contributors to policy will reflect the necessary lived experience of clinical practice and likely increase the uptake and wider implementation. Specifically, for UK transplantation, this would include work with NHSBT, the UK Kidney Association and clinical domain experts from the 23 transplant centres. Here, the cross-section of health informatics research and quality improvement becomes apparent, as better understanding and collaboration, is likely to improve teamwork, communication, and ultimately patient care in transplantation.

7.3.3 The potential for the secondary use of data

The potential for the use of routine healthcare data for additional non-direct care purposes, such as population health, research, business intelligence and other secondary uses also requires centralising and harmonising data across multiple systems and organisations. In the UK, the National Institute of Health Research (NIHR) Health Informatics Collaborative (HIC) aims to build multi-centre databases for research purposes.³⁵ Underlying this project is an open and publicly available set of data models and terminologies (www.metadata-catalogue.org). This aims to standardise healthcare data imported across multiple EHRs with a view to create large datasets for advanced analytics such as machine learning. Recently, these efforts have been further unified by merging the HIC with Health Data Research UK (HDR UK), which provides a direct gateway for researchers to request access to health datasets for research. HDR UK encourages open data standards for research. Such an approach democratises access to data and may harness its potential to drive insights and innovations that are previously untapped.³⁶

The separation of data and application layers is a strategy that is increasingly voiced and has the potential to positively disrupt the health IT market.³⁷ The work presented in this thesis around clinical information modelling in openEHR is the basis for realising this vision. Further work to model other clinical concepts within transplantation, such as deceased donor transplantation, or in other solid organ domains, will build the technical artefacts needed for future implementations in clinical practice. This

approach has the ancillary benefit of front-line clinical data being captured in a standardised way, reducing the dependence on manual cleaning of data for research.³⁸

7.4 Final remarks

The clinical practice of kidney transplantation is complex and dependent on a wide range of clinical and organisational stakeholders. Though challenging, there is also tremendous potential for health IT to improve communication and data management as well as release burdened healthcare professionals from administrative tasks. The application of health IT in transplantation, and other multi-organisational clinical services, can bring significant benefits to the quality of patient care and outcomes. It is essential to involve end-users in the design of health IT solutions to achieve meaningful intended benefits.

Critically, the ability for health IT to have an impact depends on semantic interoperability, which in turn depends on data standards. To realise patient benefit at scale, across regions or nations, model-driven development of technical artefacts that standardise clinical concepts is key. These standards should be open and publicly available with adoption mandated from vendors that are part of the health IT market. Though this will be a time-consuming task and will likely face resistance from vendors, it tackles the interoperability challenge at its core. Ultimately, this will unlock the potential of health IT to support clinical care by making the right information available at the right time, as well as bring benefits of data-driven healthcare to patients and populations.

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