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Introduction

Over 5 million computed tomography (CT) scans are undertaken within the NHS annually [1], the majority of which are performed with the administration of intravenous (IV) iodinated contrast to improve image quality and diagnostic accuracy [2,3]. Recent evidence suggests that the contraindications to IV contrast media (CM) may be overestimated, with restriction of their use leading to poorer patient outcomes [2-7]. Patient safety remains paramount as it is still acknowledged that IV CM has potential risks if administered to individuals with impaired kidney function [4]. Whilst debate continues around post-contrast acute kidney injury (PC-AKI), a phenomenon defined as a decrease in kidney function following intravascular contrast media administration [4], international guidelines [8-12] still recommend that individuals are screened and stratified based on their risk.

Outside the acute or inpatient setting, the risk stratification process can be logistically challenging and the most common approach is to obtain a pre-appointment estimated glomerular filtration rate (eGFR) measurement for all adults referred for contrast-enhanced CT [13-15]. This can mean significant administration support and patients presenting on scan day without a current eGFR result may have to be re-appointed. This has repercussions for the patient in terms of potential delays to diagnosis and treatment, and the imaging department in relation to administrative costs and lost scanner capacity. The current 'test-all in advance' approach will become increasingly untenable with new targets for the diagnosis (or exclusion) of cancer [16], 'straight-to-test' referral pathways, and innovative service delivery models [17, 18]. Although cancer imaging places significant pressure on CT, a range of clinical pathways contribute to demand, including treatment monitoring.

Patients' experiences of diagnostic imaging services centre on the issues of availability and waiting times [19]. The impact of risk stratification and potentially more limited application of blood tests, on the effectiveness of service delivery has not yet been prospectively evaluated in the UK diagnostic imaging setting. Questionnaires have been suggested as a way to risk-stratify patients by eliciting information about co-morbidities, thereby identifying patients with potentially reduced kidney

function [8, 11, 20-23]. In this scenario, PoC creatinine has been suggested as an 'on-the-day' screening tool to test only those identified as having risk factors [20, 22-27].

This paper reports on the development and comparative evaluation of a risk-stratified pathway to determine potential costs and clinical impact. The aims were to map current CT pathways, develop an alternative pathway which could overcome delays and unnecessary resource use, and simulate a 'real-world' application of this pathway to facilitate comparison of associated costs and resource use to current practice.

Materials and methods

The research complied with all the relevant regulations, institutional policies and ran in accordance to the tenents of the Helsinki Declaration. Ethical approval for the study was granted XXX (REMOVED TO ENSURE BLINDING).

A multi-phase approach to the development and comparative evaluation of a personalised risk-stratified CT pathway was implemented (Figure 1).

Phase 1 Mapping current practice and development of the alternative pathway

Mapping current practice

The current pathway was initially mapped for 5 different NHS Trusts within the same geographic region. These sites included district general and tertiary teaching hospitals and represented both rural and urban populations within a regional integrated health and social care system (ICS). All possible sequences of clinical and care events arising from decision points were documented. Discussion with operational and clinical experts at each site enabled comparison of patient flow, clinical protocols and critical decision processes. Flowcharts describing the standard care pathway for each site were drawn. The processes associated with each stage were identified, in addition to points at which there may be delays to the patient flow.

Development of an alternative pathway

A new CT pathway, enabled by risk stratification using a screening questionnaire and on-the-day PoC creatinine testing was developed based on clinical expert opinion across diagnostic imaging, nephrology and pathology specialties, and informed by a local feasibility study [23]. The overarching objectives were to: 1) improve/maintain patient safety, 2) reduce delays to imaging, and 3) reduce unnecessary testing and associated resource use. Development of the alternative pathway took into account current UK IV CM administration guidance [8], previous local research [23] and referral criterion [28]. A flowchart describing the new pathway was drawn, and the processes required at each stage identified.

Figure 1 HERE

Phase 2 Measuring Resource Use and Analysis of Routinely Collected Data

Measuring Resource Use

Each of the tasks required along the current imaging pathway were observed at a single NHS Trust. Identification of individual tasks and the time taken to complete the task and responsible role were documented. Examples of tasks include vetting of each CT referral, booking and re-booking of appointments and provision of hydration advice. The salary bands of all clinical and administration staff were recorded. Some tasks were often split between multiple roles. In this case, discussion with the clinical teams facilitated estimation of the appropriate time-split. All activities impacting waiting times and associated NHS resources were identified.

The same exercise was repeated during a local feasibility study [23] to facilitate, where possible, estimation of timings and resource use associated with the risk-stratified pathway.

Analysis of Routinely Collected Data

To populate the subsequent decision-analytic model, real-world data on patient flow was required. Data was provided by one of the regional hospitals involved in preliminary pathway mapping. The organisation provides acute district general hospital services, with some specialist tertiary facilities,

serving more than half a million people. Four CT scanners are installed across 3 hospital sites, examining a total of 41,652 scans in 2017. A convenience sample of one month of CT attendance data (February 2018) was retrospectively extracted from the radiology information system (Wellbeing Software, Mansfield, UK).

Individuals were included if they were a General Practitioner (GP) or outpatient (OP) referral for a contrast-enhanced CT scan and were over the age of 18. No patient identifiers were included. All relevant data points including dates of referral, blood tests, and scan were extracted in addition to details of any delays or cancellations. At this hospital, the screening questionnaire is routinely used, following a previous research study [23], allowing extraction of the proportion of patients with PC-AKI risk factors. The screening questions include: known kidney disease, change in kidney function, diabetes, heart failure, unwell in the last week (criteria considered as a factor include as hospital admission, diarrhoea and vomiting, or chest infection). Following discussions with key stakeholders, we compared the implication of the risk-stratified pathway on some other key outcomes of interest: 1) the number of unnecessary laboratory blood tests avoided, 2) the proportion of individuals with risk factors requiring a scan-day PoC creatinine test, 3) the number of delays to scan. These outcomes relate to patient safety assurance (capturing all patients at risk) and waiting time (from CT referral to scan).

Phase 3 Comparative Cost Evaluation

An evaluation of the comparative costs from the point of referral to the point at which the individual was ready for imaging was undertaken using decision analytic modelling. The structure of the model was developed in line with the comparative pathways mapped in Phase 1. The model evaluated the expected costs associated with the proposed risk-stratified pathway, compared to current practice.

The cost analysis was carried out from a NHS perspective. Costs excluded CT scanner equipment, image acquisition and other service delivery elements, as well as patient-related costs e.g. travel and time off work. NHS resource use and associated timings for each step in the model were identified as

described above and parameters relating to patient flow were determined based on the routinely collected data analysis. Salary costs were based on hourly unit costs from the Personal Social Services Research Unit (PSSRU) Costs of Health and Social Care 2018 report [29]. Additional to staff time, the cost to perform a PoC creatinine measurement includes the estimated cost per creatinine test strip/cartridge, the upfront device cost and the annual service cost for the i-STAT Alinity (Abbott Point of Care Inc. Princeton, NJ, USA) taken from a recent multivendor evaluation [30]. Cost-wise, this device represents a mid-range option [29]. Costs are reported in 2018 British pounds (£).

A number of assumptions had to be made regarding clinical decision points. It was assumed in the model that any individuals identified as being at high risk (i.e. with an eGFR measurement less than 30mL/min/1.73m2) were admitted as a day case for IV hydration. It was also assumed that all individuals without a recent eGFR result (i.e. within 3 months for low risk and 1 week for acute disease/deterioration [11]) would attend a phlebotomy appointment at the hospital or their local general practice to provide a blood sample.

To account for uncertainty in the parameter estimates, a probabilistic version of the model was built and run across 5,000 simulations. Beta distributions were fitted around the proportion estimates. Our observations of the timings associated with each task were not sufficiently large to estimate a standard deviation so we allowed these to vary 20% in either direction by fitting a uniform distribution to explore the impact that this would have on the costs. Fixed prices were obtained for salary costs, cost of the PoC creatinine test and serum creatinine measurement. The probability that the new alternative pathway is cost saving is reported.

The results are extrapolated across a one-year and five-year period. Seasonal variation is not expected and therefore we do not anticipate any issues in extrapolating the 4 week data across this period.

Results

The Current Pathway

The protocol at each site is described in Table 1. All sites employed an order communications interface and availability of a recent kidney function test was mandatory. Key differences included the personnel undertaking vetting (justification and protocolling) and cannulation procedures. Prophylactic hydration regimen varied (level and route) and a single Trust in the region preferred not to assign CT appointments for individuals without a recent blood test available, resulting in rejection of the referral after a fixed period (Site 3). Currently none of the sites offer PoC creatinine testing as an option for kidney function testing.

Table 1 HERE

Although the protocols across acute Trusts differed slightly, it was possible to develop a common pathway (Figure 2A).

The alternative pathway

The risk-stratified pathway can be found in Figure 2B. In comparison with the traditional test-all pathway, referrals for CT would be vetted and assigned an appointment without checking for a recent eGFR measurement. All individuals would be recommended to orally hydrate at home prior to their scan as a prophylactic measure against PC-AKI, unless contra-indicated e.g. on fluid restriction. On attending the imaging department, patients would complete a short screening questionnaire; incorporating standardised risk factors (including diabetes, metformin, kidney problems, heart failure and relevant acute illness). If no risk factors are identified, individuals would have an IV cannula sited prior to administration of contrast media and scan. If any risk factors were identified, an eGFR measurement would be obtained by imaging staff using a PoC creatinine device.

FIGURE 2 HERE

Resource Use

Staff requirements and associated average timings for individual tasks on the pathways can be found in Table 2.

Table 2 HERE

Analysis of Routinely Collected Data

A total of 914 patients attended for a contrast-enhanced CT within the time period, however of these 98 were protocolled not to receive contrast and 816 contrast scans were performed. The majority (n=699/816; 86%) originated from OP clinics, the remaining (n=117) being referred by their GP. The number of patients on specific pathways varied between referral routes (Table 3), with many routine OP referrals being for planned follow-up investigations. Almost three quarters had been vetted by a radiographer (73%).

Table 3 HERE

Data on patient flow and risk of PC-AKI can be found in Table 4. Just over half (56%) did not have a recent (previous 3 months) eGFR measurement available at referral and therefore required an additional blood test prior to scanning. Where the eGFR was still not available at the time of the appointment booking, the imaging department sent blood test forms for 13% (n=104) of patients with their appointment letter, of which 12% (n=12) were on a fast-track suspected cancer pathway. For 3 of these individuals, the organisation of a kidney function test by the imaging department meant their scan had to be delayed to enable time for the patient to attend for the blood test, to the extent that they had breached the 14 day time-to-scan target. Fourteen (2%) patients attended their scan appointment with an expired blood test result (>93 days). No patients received IV hydration in advance of their scan.

A permanent record of the screening questionnaire was not available for a small number of individuals (3%, n=22/816) and therefore information regarding risk factors was not. On analysis of available

screening questionnaires, 21% had identified risk factors based on RCR 2017 criteria. Established on findings in the local feasibility study [23], a more cautious approach could be adopted where individuals reporting recent illness or heart failure are also regarded as being at risk (24%). Only one patient had an eGFR below 30mL/min/1.73m2 and they were identified as having a risk factor (diabetes) by the screening questionnaire. If the risk-stratified pathway was in place, these patients would have received a PoC creatinine test on the day of their scan. Importantly, of the patients undergoing blood tests following referral, 78% (n=347/447) could have potentially avoided this unnecessary intervention as they did not have any identified risk factors for PC-AKI.

Table 4 HERE

Time to scan for the standard CT pathway by referral urgency can be found in Figure 3. Around a tenth (9%, n=77/816) had appointments for planned follow up interval scans and therefore an eGFR available at referral was no longer valid at the time of scan. Of these, only 6% (n=5/77) had a recent eGFR measurement available at the time of referral (referrer ordered: 21% n=16/77, diagnostic imaging initiated: 73% n=56/77). Of those who rebooked their appointment (n=102), over half (59%, n=60/102) were on fast-track pathways (suspected cancer: n=45, clinically urgent: n=15).

Further details about this data and the implications for the risk-stratified pathway can be found in the supplementary material (Figures 1A and 1B).

Figure 3 HERE

Comparative Cost Analysis

The decision-analytic model compared the resource use and associated costs for each of the pathways described in Figures 2A and 2B. The costs for each resource can be found in Table 5.

Table 5 HERE

The 4 week costs, in addition to extrapolated costs for a one year and 5 year period can be found in Table 6. A significant proportion of the savings is driven by an overall reduction in the number of eGFR

193 measurements needed (4 week cost saving = £438.42 95% CI: £245.31 - £631.10). Although the total
194 cost (including salary time) of a laboratory creatinine test is cheaper than the PoC equivalent (£5.29
195 vs. £5.96), the screening questionnaire ruled out the need for an eGFR measurement in some patients.

196 **Table 6 HERE**

197 The timings broken down by role can be found in Table 7. The remaining cost savings are largely due
198 to a reduction in the amount of administrative time required.

199 The probability of the risk-stratified pathway being cost saving was 94%, based on the cost difference
200 between the two pathways across the 5000 simulations.

201 **Table 7 HERE**

202 **Discussion**

203 This study focuses on re-designing the CT pathway related to assessment of kidney function prior to
204 the administration of iodinated IV CM. We employed pathway mapping and decision-analytic
205 modelling to develop and evaluate a proposed risk-stratified pathway. When considering the potential
206 impact of the new pathway, we observed that 56% of patients did not have a recent eGFR at the time
207 of referral. Administrative processes were required either on behalf of the referrer or the imaging
208 department to ensure that this was rectified before the scan appointment. This is exacerbated by fast-
209 track pathways and long-term interval CT disease monitoring. However, despite fail safes patients may
210 still attend for scan without an eGFR in up to 5% of cases [23, 33, 34].

211 Regional evaluation demonstrated site variation in a range of processes within the CT pathway.
212 Notably, some Trusts do not book appointments without a pre-examination eGFR being available,
213 impacting on referral to diagnosis times. Based on the data in this study, if this was the case (as in one
214 regional site) approximately 13% of those referred would have their referral rejected. This will
215 undoubtedly impact overall patient waiting times, beyond the diagnostic component. Despite the
216 between-site variations, it was feasible to design a single pathway that would be transferrable across

hospitals. Best-practice guidelines [8-12] safeguard patients at risk of PC-AKI and do not advocate blanket testing, although this is often a service standard. The alternative pathway implemented 3 key changes to current practice: 1) oral hydration recommended for everyone prior to CT, unless contraindicated, 2) the use of a screening questionnaire to identify those at risk of PC-AKI, and 3) the use of a POC Creatinine device to obtain on-the-day eGFR measurements for those identified as being at risk. Although both pathways have been designed to enable high risk patients to be admitted for IV hydration, this did not occur in practice. As this was included in both scenarios the cost differential would not have been impacted.

The economic modelling predicted that this risk-stratified pathway is likely to be cost-saving compared to the current pathway, largely due to costs saved by only testing those individuals highlighted as being at risk of PC-AKI by the screening questionnaire. Recognising that there is still debate around optimal prophylactic regimen pre IV CM [14, 35], advising individuals to orally hydrate on the day of their appointment to avoid dehydration, rather than only those at moderate risk also saved some time. The screening questionnaire does add a minor increase in administration, however the cost and time associated with this change is offset by the reduction in the overall number of tests needed and improved efficiency at other points in the pathway. It could be implemented through electronic referral with supplementary safety-net procedures on the scan day to identify any acute changes in health status or interval blood tests. Although upfront PoC device procurement and consumable costs per test are greater than those of the laboratory blood test, this study corroborates previous findings [36] that the benefits of PoC are likely to be realised through operational efficiency. Critical to the implementation of such a pathway is appropriate resource allocation as currently imaging departments are not responsible for the cost of the pre-scan eGFR. In addition, the resources required for training, maintenance of infrastructure, facilitation of results tracking to electronic patient records and appropriate governance systems would require investment at a local level [37], as such they have not been included in this evaluation.

Implementation of the screening tool was intrinsic to the cost and efficiency savings demonstrated in this study; blanket testing everybody with the PoC Creatinine device would result in notably increased costs. Compared to the RANZCR guidelines [8], the screening tool employed in this study incorporated some additional factors including checks for a history of heart failure and recent illness. There was limited evidence from the feasibility study [23] that, in a small minority of cases, an old eGFR measurement may miss recent deterioration of kidney function due to acute illness which would be picked up by the screening questionnaire. The addition of antibiotic therapy, as a known nephrotoxic risk factor, is also not included in other screening tools [8, 11] although a recent study suggested a specific link to PC-AKI [38]. This may have resulted in a slight increase in the number of individuals requiring a PoC test compared to limiting the screening tool to the RANZCR guideline criteria. Since the completion of this study, the National Institute of Health and Care Excellence (NICE) have published diagnostic guidance (DG37) on PoC creatinine devices to assess kidney function before CT imaging with intravenous contrast [37]. The committee felt that further research on the development, or validation, of an appropriate screening tool is required [37].

Some of the data within this study was used to inform the economic evaluation underpinning the NICE guidance [37], comparing multiple screening strategies consisting of different combinations of laboratory testing, risk factor screening and POC testing [37]. Some devices (ABL800 FLEX, i-STAT Alinity and StatSensor) are now recommended where 1) current practice is to obtain a recent eGFR measurement, 2) an individual does not have a result available, and 3) the individual has risk factors for AKI. Interestingly, although a 'no testing and manage all with contrast enhanced CT' was not included in the main analysis as it was deemed contradictory to current clinical guidelines, it was included as a separate scenario analysis and estimated to produce the highest net benefit of all the strategies [37]. There was however a general lack of evidence showing an increase in risk of AKI due to the use of contrast media and the efficacy of prophylactic management in reducing the risk of PC-AKI, highlighting the need for further research to ensure that the benefits of measuring eGFR are sufficient to warrant the additional cost and resource use.

Limitations of the study

The key limitation of this study is that it is focused primarily on comparing operational workflows and resource use relating to the alternative pathway rather than clinical outcomes. In our recently published methods comparison study [36], we found that there were no individuals at an increased risk of PC-AKI missed when using the i-STAT PoC result compared to the laboratory reference measure. We therefore did not have any direct data to support any potential downstream harms on patient outcomes. The NICE economic evaluation used a linked evidence approach, using data from the literature to model any potential downstream impact on patient outcomes [37]. In their evaluation, the key drivers of cost-effectiveness were the cost of testing and the cost of managing those with 'false positive' results, suggesting that the downstream reduction of PC-AKI risk and associated treatment do not impact significantly on the decision problem [37].

This study has also only analysed the pre-examination phase of the elective CT pathway in order to focus on specific needs of the service. The different pathways in operation across the region were accurate at the time of data collection. We did not measure or factor in any opportunity cost associated with delays in the patient flow such as the ability to accommodate acute or urgent CT referrals which are important metrics for future prospective clinical studies. Imaging is under continued pressure to reduce scan waiting times and provide more responsive services across a range of referral pathways, but particularly cancer [16-18, 33]. The increase in straight-to-test pathways will require innovation to support delivery [33]. Rapid turn-around blood tests are feasible but may not support 7-day imaging provision, or extended periods of scanner utilisation. In this study, three patients exceeded the 14-day time to scan target delaying diagnosis, the sole reason being an absence of a pre-examination eGFR. This illustrates the challenge of managing current workflows with current patient safety expectations.

Further to this, the model reported here is a local evaluation of a novel care pathway, based on retrospective data from a single site and local staff input and clinical expert opinion. The model is likely

to need to be adapted to be applicable to other imaging pathways across the country as savings may be greater or less depending on different processes employed. Furthermore, because this evaluation was based on routinely collected data, there was no opportunity to collect the costs of additional or lost appointments from the patient perspective. In a future evaluation, such information would broaden the perspective of the cost comparison. Our analysis has also focused on the iSTAT which was the PoC device evaluated in our previous feasibility study [23]. When considering a PoC device, evidence is needed to ensure method comparability with the laboratory reference standard. The varying cost of the devices would also need to be considered, in addition to any practical considerations of using the device in an imaging setting such as who would be responsible for maintenance and quality assurance.

In conclusion, the availability of pre-examination eGFR can dictate whether iodinated IV CM is administered or withheld and can delay diagnosis in the elective out-patient setting. If positioned within a risk-stratified pathway, PoC creatinine testing has potential value to guide on-the-spot decision-making and minimise disruption to an already overwhelmed imaging pathway [39]. Our economic modelling predicts that in comparison to the traditional test-all approach, a risk informed CT pathway is potentially cost-saving. There are however key evidence gaps which make it challenging to model the downstream implications of the proposed risk-stratified pathway on patient outcomes. A multicentre appraisal would facilitate further validation and demonstrate the downstream clinical impact of embedding this at a wider NHS level.

Keywords: Computed Tomography; patient safety; creatinine; estimated glomerular filtration rate; post-contrast acute kidney injury; PC-AKI; CI-AKI; point of care testing; health economics; care pathway modelling

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