



NHS Salford CCG Sick Day Guidance Final Report

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The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (NIHR CLAHRC) Greater Manchester is a partnership between providers and commissioners from the NHS, industry, the third sector and the University of Manchester. We aim to improve the health of people in Greater Manchester and beyond through carrying out research and putting it into practice. <u>http://clahrc-gm.nihr.ac.uk</u>

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Executive Summary

This report has been prepared by the project team from the National Institute of Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester. The NIHR CLAHRC GM project team included facilitation, project management and research staff. The project's Steering Group consisted of clinicians, pharmacists and managers based at NHS Salford CCG and Salford Royal NHS Foundation Trust and the NIHR CLAHRC GM project team, to support the delivery of, and to evaluate, an Acute Kidney Injury (AKI) medicines sick day guidance intervention.

Background

AKI is a current health priority, and resources aimed at reducing the harm associated with AKI are being developed nationally and regionally. A new group called SPARC (Salford Partnership for Advancing Renal Care) was created in December 2014. It aims to bring together all primary and secondary care initiatives to ensure a shared strategy and optimise kidney care across the City of Salford. This report focuses on the implementation and evaluation of one such primary care intervention – sick day guidance.

The Intervention

The original concept was conceived by Salford CCG, and the design of the intervention was further developed along with Salford Partnership for Advancing Renal Care (SPARC), in collaboration with NIHR CLAHRC GM. Sick day guidance was designed to raise awareness of kidney health and to reduce the risk of AKI occurring. The intervention was based in primary care and rolled out across the Salford Clinical Commissioning Group (CCG) area in general practices and community pharmacies. The ambition of sick day guidance is to reduce the risk of avoidable harm to patients taking certain medications. The materials for the Salford intervention consisted of a 'medicine sick day guidance' card, provided to patients who were taking the listed drugs, giving them advice about managing their medicines during episodes of acute illness. An information leaflet was provided to healthcare practitioners and administrators suggesting how to use and give the cards. An overly prescriptive approach was avoided to allow health professionals to develop processes that worked best for individual patients.

To support implementation, the Steering Group worked together, to design and facilitate educational events for general practice and community pharmacy staff. The sessions included education about AKI and information about the sick day guidance intervention.

Implementation of the sick day guidance intervention took place through two phases. During Phase One of the project, sick day guidance cards were provided to all general practices (n=48) and community pharmacies (n=60) in the Salford CCG footprint, with the aim that all patients who were prescribed the listed drugs were offered the cards. It was stated that the Read code '*Provision of written information about acute kidney injury: 80AG.*' should be used to record administration of sick day guidance cards on general practice clinical systems. Community pharmacists were not asked to code provision of the card as they do not have access to general practice clinical systems or to patient records and were not being remunerated for the work.

Phase two entailed practice pharmacists supporting the implementation of the sick day guidance intervention (along with several other projects) employed to work in general practices across three of eight neighbourhoods in Salford CCG. Salford CCG had employed the pharmacists through their innovation fund scheme to work within practices in these three neighbourhoods, to enhance medicines optimisation. Their sick day guidance work entailed identifying patients at risk of AKI using data from Salford Royal NHS Foundation Trust, and contacting those patients to discuss sick day guidance.

The Quantitative Evaluation

The aim of the quantitative evaluation was to ascertain the number and characteristics of patients who received the sick day guidance cards through general practices, by analysing the relevant Read code on the general practice information systems. Health practitioners had been asked to record every time a patient had received a card. However, evidence emerged that not every event was being recorded and there was also evidence that an inaccurate non-specific code was being used. In view of these methodological concerns surrounding both potential under-reporting and also potential incorrect reporting; a decision was made to limit analysis to 5 general practices where there was evidence of consistent coding of administration of sick day guidance cards. Within these 5 practices, virtually all 1,452 eligible patients (with the exception of two) were coded as receiving a card. In terms of comorbidities, 83.8% these of patients were hypertensive, 35.2% had Type 2 Diabetes and around 20% were Read coded with a CKD stage between three and five. Based on application of NHS England's national AKI algorithm, data suggested one quarter of patients may have had a past episode of AKI.

The Qualitative Evaluation

Through qualitative research methods, the evaluation explored the administration and use of the sick day guidance to understand processes that enable or constrain implementation. Data were generated through 29 interviews (7 GPs, 5 practice nurses, 5 community pharmacists, 4 practice pharmacists, 2 administrators, 1 health care assistant, and 5 patients). A key strength of the qualitative evaluation was to conduct an in-depth exploration of a systematic sick day guidance intervention roll out across a single healthcare setting with a variety of stakeholders including health care professionals and patients. Patient recruitment was discussed with clinical staff at general practices and community pharmacies, many of whom assisted by distributing patient recruitment literature. However, despite these efforts, patient recruitment proved challenging; in total, five patients took part in interviews. Therefore, the views and actions of patients, as interpreted and expressed by the other interviewees were also taken into account. Interview transcripts were subjected to analysis by the research team to organise content and identify themes.

Implementation of sick day guidance cards to prevent AKI entailed a new set of working practises across primary care. The temporary cessation of medicines during episodes of acute illness was not necessarily a straightforward concept to understand or communicate. Health professionals struggled to resolve a tension of aiming to provide high quality interpersonal care in terms of effective risk communication with patients and, at the same time, ensuring reach to all patients being prescribed the relevant medicines specified on the sick day guidance card. There was evidence that this tension drove the implementation of sick day guidance, with participants describing a range of approaches. In the main, participants tended to prioritise the need for face-to-face communication, though across accounts there was evidence of roll out through other strategies.

The interviews included many descriptions of how the guidance was implemented and through analysis of the data, five main approaches were discerned:

- administration of sick day guidance cards in conjunction with face-to-face communication;
- administration of sick day guidance cards to patients in conjunction with telephone consultations;
- postal administration of sick day guidance cards in conjunction with an explanatory patient leaflet;
- sick day guidance cards administered without verbal or written communication; and
- communication of AKI risk, but with limited use of a sick day guidance card.

Discussion

The quantitative evaluation was limited due to methodological concerns surrounding both potential under-reporting and potential inaccurate reporting in the coding of administration of sick day guidance cards. There was evidence that it was not always recorded. Also, there was evidence that non-specific codes were being used to record administration of sick day guidance cards. In addition, community pharmacists were not asked to record dispersal. General practices were being remunerated for their involvement as part of Salford CCG's Long Term Conditions strategy. These methodological issues need to be considered and addressed in future projects examining their implementation and effectiveness.

There was qualitative evidence to suggest that sick day guidance cards were more readily integrated into existing long-term condition review appointments with practice nurses, as well as both 'over the counter' and medicine use reviews (MURs) carried out in community pharmacy. Practice-based pharmacists valued and engaged with the sick day project. However, they outlined numerous difficulties implementing the intervention including: being able to access patient data; more potentially relevant patients than anticipated; and fitting the work in with their pre-existing schedule. Qualitative data also indicated that health professionals struggled to ensure sick day guidance reach to all patient groups being prescribed the relevant medicines, particularly more vulnerable people e.g. those with reduced cognitive capacity. Risk communication to prevent AKI may help to address evidence of a gap in patient and public understanding of the importance in the maintenance of kidney health. However, communicating the concept of temporary cessation of medicines is a particular challenge to patient populations at higher risk of AKI. The qualitative analysis suggests that sick day guidance cards that focus solely on medicines management may be of limited benefit without either adequate resourcing, or if delivered as a standalone intervention.

1. Introduction

1.1 Background to the Salford sick day guidance intervention

Tackling the harm related to Acute Kidney Injury (AKI) is a worldwide health priority.[1, 2] AKI is a clinical syndrome entailing a sudden reduction in kidney function over hours or days.[2-4] Its diagnosis and severity is classified according to kidney function tests in terms of acute biochemical changes in serum creatinine and/or changes in urine output (see Box 1).[2, 3] There are many causes for AKI though it is often caused by an acute (rapid and brief) illness, such as flu, gastroenteritis, urinary tract infection or chest infection.[2-4] Older people living with multiple long term conditions such as diabetes, heart failure, dementia and/or pre-existing chronic kidney disease (CKD) are at higher risk of developing AKI during episodes of acute illness (see Box 2) [2-13]

Box 1 Staging of Acute Kidney Injury [2, 3]

Adults:

AKI stage 1 is a rise of \geq 1.5x baseline level, which is known or presumed to have occurred within the prior 7 days; or of >26 micromol/L within 48h, or a urine output <0.5mL/kg/h for 6-12h

AKI stage 2 is a rise of $\geq 2x$ baseline or a urine output <0.5mL/kg/h for $\geq 12h$

AKI stage 3 is a rise of \geq 3x baseline or a rise of \geq 1.5 baseline to >354 micromol/L, a urine output <0.3mL/kg/h for \geq 24h or anuria for \geq 12 h

For age <18 years, AKI stage 3 is also defined as a rise in serum creatinine to >3 x the upper limit of the age-related reference range. The urine output criteria also differ for age <18 years: stage 1 is <0.5mL/kg/h for >8h; stage 2 is <0.5mL/kg/h for more than 16h; stage 3 is <0.3mL/kg/h for 24h or anuria for 12h.

Patient specific – Susceptibility	Situation specific – Exposure
 Older age Immunosupressed or deficient immunity e.g. malnutrition, patients with cancer CKD (eGFR <60) Diabetes mellitus Heart failure Liver disease Past history of AKI Neurological or cognitive impairment or disability, which may mean limited access to fluids because of reliance on a carer Symptoms or history of urinary tract obstruction, or conditions that may lead to obstruction 	 Hypovolaemia, dehydration, reduced oral intake Hypotension Sepsis Post-operative Use of iodinated contrast agents within the past week Use of drugs such as non-steroidal anti-inflammatory drugs [NSAIDs], angiotensin-converting enzyme [ACE] inhibitors, angiotensin II receptor antagonists [ARBs] and diuretics) within the past week, especially if hypovolaemic

Box 2	Risk	Factors	associated	with	Acute	Kidnev	Iniur	/ [3.	41
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AKI acts as a 'force multiplier' and is an important marker of illness severity.[3] It is associated with up to one in five unplanned hospital admissions.[9, 10, 11] Episodes of care complicated by AKI are associated with longer lengths of hospital stay, increased rates of rehospitalisation and high levels of mortality.[2, 6] It is associated with development or progression of chronic kidney disease.[2, 6] In England, AKI-related inpatient costs alone are estimated to be greater than 1% of the NHS budget, £1.02 billion in 2014.[14]

AKI is barometer of patient-safety.[15] As a clinical syndrome, the majority of cases of AKI are due to a combination of underlying infection, hypovolaemia (low circulatory blood volume), hypotension (low blood pressure) and medication effects.[3] Addressing these potentially modifiable factors is central to both the prevention and management of AKI and its associated burden.[2, 4] Self-management support is a key element of high quality care[16, 17] and recommended AKI preventative strategies include: reducing the risk of infection (e.g. flu vaccination for high risk individuals)[18]; encouraging fluid intake during episodes of acute illness to avoid hypovolaemia (i.e. that is, prevent people becoming short in salt and water); improving medicines management through routine reviews (e.g. reduce inappropriate use of non-steroidal anti-inflammatory drugs [NSAIDS]) as well as optimise medicines management at times of acute illness.[2, 4]

Identifying and supporting people at higher risk of AKI are key priorities to improve health outcomes and reduce costs. Globally, the '0by25' initiative (<u>http://www.0by25.org/</u>) has been launched to prevent avoidable deaths due to AKI.[1] In the United Kingdom, patient safety initiatives have been established to address the morbidity, mortality and costs linked to AKI.[3, 19, 20] In Scotland, informed by findings from a study conducted in NHS Highland, medicine sick day rules have been made available nationally through the Scottish Patient Safety Programme.[20, 21] The introduction of medicine sick day guidance relates to national advice, published by the National Institute for Health and Care Excellence as well as by the Royal College of Physicians of Edinburgh UK, which highlight a need to consider temporary cessation of medicines at times of acute illness.[4, 22] That is, during these episodes, 'any drug that reduces blood pressure, circulating volume, or renal blood flow' increases the risk of AKI.[3] Medicines that exacerbate this risk include NSAIDS, diuretics, ACE Inhibitors and angiotensin II receptor blockers (ARBs).[3] In addition, the Scottish medicine sick day rules refer to the temporary cessation of metformin, which may

accumulate at times of reduced kidney function, resulting in an increased risk of adverse effects.[20]

In England, within NHS England's Patient Safety Domain, the Think Kidneys Programme (https://www.thinkkidneys.nhs.uk/) has been established to tackle the harm associated with AKI.[21] This has entailed the development of a range of resources to be implemented across both secondary and primary care. Think Kidneys publications include an Interim Position Statement on 'sick day' guidance on (version 7 on 8th July 2015 and version 8 on 13th of November, 2015; see Appendix 1).[24] The statement refers to the potential benefits and reasons for providing advice to patients to temporarily withhold specific medicines during episodes of acute illness (see Box 3) [24]. The Interim Position Statement also states that 'although there is strong professional consensus that advice on sick day guidance should be given, and this approach is advocated in the NICE AKI guideline, the evidence that provision of such advice reduces net harm is very weak.' It highlights potential harms of this approach.[24] These are outlined Box 4 and include concerns about patients stopping and not re-starting prescribed medicines, such as diuretics or ACE Inhibitors used in the management of underlying heart failure or hypertension. As such, with a need for a better evidence base, the Think Kidneys Interim Position Statement indicates that 'it is reasonable for clinicians to provide sick day rules,' based on 'individual risk assessment', but recommends that widespread implementation should only be undertaken in the context a formal evaluation [24].

Box 3 Sick day guidance: potential benefits [24] Extract from Think Kidneys Interim Position Statement

Potential Benefits

There are three main reasons for providing such advice:

- 1. Non-steroidal anti-inflammatory drugs impair renal autoregulation by inhibiting prostaglandin-mediated vasodilatation of the afferent arteriole and may increase the risk of AKI.
- 2. Drugs that lower blood pressure, or cause volume contraction, might increase the risk of AKI by reducing glomerular perfusion. These drugs include:

a. ACE inhibitors (ACEI) and Angiotensin Receptor Blockers (ARBs), which reduce systemic blood pressure and also cause vasodilatation of the efferent arteriole. This impairs renal autoregulation and reduces glomerular perfusion pressure.

b. Diuretics, which can exacerbate hypovolaemia and electrolyte disturbance. This group also includes the mineralocorticoid receptor antagonists spironolactone and eplerenone, used frequently in heart failure.

c. Other blood-pressure-lowering drugs, which will lower systemic blood pressure.

3. Drugs might accumulate as a result of reduced kidney function in AKI, increasing the risks of adverse effects. These drugs include:

a. Metformin which is associated with an increased risk of lactic acidosis in high risk patients.

b. Sulfonylurea drugs which may have an increased risk of hypoglycaemia, as the drug is renally cleared.

c. Trimethoprim, which increases the risk of hyperkalaemia. This drug also interferes with tubular creatinine secretion, and therefore causes a rise in creatinine levels and may result in a 'false positive' diagnosis of AKI.

Box 4 Sick day guidance: potential harms [24] Extract from Think Kidneys Interim position statement

Potential Harms

It is possible that there are potential harms associated with widespread provision of 'sick day' rules or guidance, particularly when the patients have not been clinically assessed and where it is unclear at what level of ill health the medication should be discontinued. These include:

1. Decompensated heart failure when drugs blocking the RAAS system and diuretics are discontinued.

2. Development of poorly controlled hypertension with cessation of antihypertensive medication.

3. Reduced adherence to drug treatment which may have been incorrectly described as 'nephrotoxic'. Patients may consider that the potential harm outweighs the potential benefit and decide to stop taking the drug despite the absence of an acute illness.

4. Patients may over-interpret the advice and stop their drug treatment during even minor illnesses.

5. Patients may not re-start their drug treatment on recovery.

6. The drugs may not be titrated back to the previous evidence based levels even when there has been no evidence of AKI.

7. People may self-manage inappropriately and not seek professional help at an appropriate stage.

8. Issues related to removing medication from dosette boxes, requesting new dosette boxes and up titrating medication in dosette boxes.

9. Diabetes control may be adversely affected by inappropriate cessation of glucose lowering treatment.

1.2 Salford CCG AKI prevention intervention/sick day guidance

It was in this wider context that Salford CCG, in partnership with Salford Royal NHS Foundation Trust, embarked on a number of service improvement initiatives to address the harm associated with AKI as part of Salford Partnership for Advancing Renal Care (SPARC). To date, work has included rolling out AKI e-alerts to primary care; these were switched on in half of the general practices in Salford between January and June 2016 and then in the remainder in early August 2016, as well as face-to-face academic detailing sessions between renal consultants and practice clinical staff.

Initially, informed by the Scottish approach in conjunction with national guidance.[4, 20] Salford CCG sought to implement medicine sick day rules across general practices and community pharmacies within its boundaries (see Table 1). This was supported by a locally enhanced service that provided financial support for general practices undertaking this project. Salford CCG was a member of the Think Kidneys Implementation Workstream in 2014, with Think Kidneys being aware of the project from its outset.

With publication of the Think Kidneys interim position statement (8th July 2015 and 13th of November 2015) subsequent to project initiation (March 2015), national Programme Board approval was sought to ensure Salford's intervention and evaluation were in keeping with and aligned to Think Kidneys recommendations.[24] In doing so, the sick day rules were also renamed sick day guidance near the end of the intervention period.[24] The evaluation of the project included a need to understand processes surrounding the implementation of sick day

guidance in primary care, with a view to provide a platform for future larger scale evaluation. Details of the intervention are provided in Table 1 [25].

 Table 1
 The Salford sick day guidance service improvement intervention

Brief Name:	Salford Kidney Implementation Project
Why:	The Salford Partnership for Advancing Renal Care (SPARC) was established to
	The ambition of sick day guidance is to reduce the risk of avoidable harm to patients
	taking certain medications. Salford CCG in collaboration with SPARC defined the original implementation design of the sick day guidance intervention
What:	Medicines sick day guidance
Materials:	 Sick day guidance cards that suggested the temporary cessation of medicines
	during bouts of sickness were produced, the text was replicated from the NHS Highlands sick day rules card.
	• Two, one and a half hour, educational events were run for healthcare professionals, organised and delivered by the Steering Group. This included why AKI is important from a local and national context.
	• Information leaflet outlining the sick day guidance project and guidance on how to use the sick day guidance cards, and poster summarising this information for use in practice.
	Poster for patients promoting the sick day guidance card intervention to be used in waiting areas
Procedures:	 Training was offered to all general practitioners, practice nurses and the wider practice team, and to community pharmacists for the sick day guidance card implementation. During Phase One, the cards were distributed to all community pharmacies and
	2. During Phase One, the cards were distributed to all community pharmacles and general practices accompanied by an information leaflet and poster with patient engagement instructions. Distribution was carried out by project facilitators face to face, to explain and address any questions arising.
	3. Two further face to face visits were made to each general practice and pharmacy by the NIHR CLAHRC GM project team to reinforce the project/provide additional materials/support.
	 The cards were provided to patients receiving the drugs listed on the card by general practices and community pharmacies. Posters were displayed in practice waiting areas promoting the intervention to
	patients6. General Practitioners and other practice staff were advised to record the intervention in Salford Integrated Records using Read code 80AG.
	7. During Phase Two, the practice-based pharmacists accessed patient health records from Salford Royal NHS Foundation Trust to identify those at risk of AKI and constructed a database to record relevant data.
	8. The practice-based pharmacists were to contact and educate patients on the sick day guidance and to issue a card. They were also expected to complete a medications review.
	Approval was sought to ensure the project was in keeping with national Think Kidneys guidance.
Who:	The NIHR CLAHRC GM project team, (facilitation, project management, and
	 The Steering Group (clinical, pharmacist and managerial staff at Salford CCG
	and Salford Royal NHS Foundation Trust, plus the NIHR CLAHRC GM
	project team) Salford CCG general practices and community pharmacies
How:	The initial recruitment of general practitioners onto the project was implemented via
	email, and then three face to face visits were delivered per practice/pharmacy by
	NIHR CLAHRC GM project team to ensure full understanding of the sick day
Where:	General practices [n=48] and community pharmacies [n=60] in Salford 106 000
THUC.	cards were provided to general practices and community pharmacies for distribution.

2. <u>Aims and Objectives</u>

Within the context of a number of CCG kidney health projects taking place across Salford being delivered by Salford Partnership for Advancing Renal Care (SPARC), the ambition of this project was to attempt to reduce the risk of avoidable harm to patients by reducing incidence and severity of AKI. This entailed increasing patient and professional awareness about AKI and to consider the need to temporarily stop certain medications during episodes of acute illness.

The objectives of the evaluation were:

- to deliver and understand processes surrounding the implementation of sick day guidance and other preventative AKI interventions in primary care;
- to inform the design of a sustainable model of care to support better medicine management in primary care; and
- to provide a platform for potential larger scale evaluation.

3. Approach

3.1 Educational events

The project was launched in March 2015 with two educational events. The events were designed and delivered by the Steering Group; they lasted one and a half hours and included presentations from clinical members of the Steering Group as well as the project team. The presentations included education about AKI, information about the project, and how it was envisaged the cards would be delivered (see Appendix 2). A list of additional reading/resources was provided to all attendees (Appendix 3).

The first session was delivered in the evening as this was anticipated to be more accessible for pharmacists. The second was delivered at lunchtime to primarily attract general practice staff. The lunchtime learning session was the most popular. The sessions were attended by a range of healthcare professionals and managers; 18 general practices and 7 pharmacies were represented by over 60 attendees.

Table 2	Healthcare	professionals at the education events

Staff role that accessed the educational event	Percentages of attendees
general practitioner	25.6%
practice nurse	23.1%
hospital pharmacist	15.4%
general practice manager	10.2%
employee community pharmacist manager	7.7%
owner community pharmacist	7.7%
community pharmacy support staff (including dispensing assistant, medicines counter assistant)	7.6%
locum community pharmacist	2.6%

The educational sessions were evaluated using questionnaires; attendees were asked to rate their knowledge about AKI and their confidence in advising patients about being at risk of AKI, before and after the sessions. Before the events, around a third (34%) of respondents rated their *knowledge* as 'low' or 'very low' and only 8% rated it as 'high'. After the events, 45% of respondents rated their knowledge level as 'high' or 'very high'. In terms

of *confidence*, almost half (48%) of respondents rated their confidence as 'low' or 'very low' and 5% rated it as 'high'. After the events, 37% of respondents rated their confidence as 'high'. Attendees were also asked how useful they found the training session and 90% rated it as 'useful' or 'very useful'.

Subsequently, one of the pharmacy chains requested an additional learning event for their pharmacy staff who were unable to attend the first round of events; this was not evaluated.

3.2 Card dissemination

The NHS Highland sick day rules card was reproduced (Figure 1) with new logos [20, 21].



Figure 1 Sick day guidance card used during this project

The cards were distributed to all GP practices (n=48) and community pharmacies (n=60) across the Salford CCG footprint. Accompanying the cards was an information leaflet for professionals (Appendix 2), with a poster summarising that information again for professionals, and also a poster aimed at patients promoting the intervention (Appendix 4). In the information leaflet, it suggested that the cards should be given to all patients who were prescribed medication that may benefit from temporary cessation (those listed on the card) during episodes of acute illness by a healthcare professionals were encouraged to give an explanation about AKI and the intention of sick day guidance. Without wishing to dictate the exact wording used, the information leaflet (Appendix 2) provided by Salford CCG included a suggested approach/text on how to communicate sick day guidance with patients. It was also advised not to leave cards on display, to ensure that patients understood the information on the card and how to follow sick day guidance correctly.

Over the course of the project (March 2015 to January 2016) 106,000 sick day guidance cards were issued to practices/pharmacies. All 48 general practices and all except one of the community pharmacies within Salford CCG footprint agreed to take part in the project, and a supply of cards and information packs were hand delivered following the educational events. The packs contained: information about the project, guidance on issuing the cards, AKI education leaflets and a list of AKI web based resources which are included in the references section of this report. Any practices/pharmacies who did not attend the educational events were offered background information when visiting their practice for the first time. The Local Pharmacy Committee also supported dissemination to pharmacies. One pharmacy declined to take part in the project, as they specialised in dosette boxes (blister packs) and they were concerned patients would not know which medications to stop.

Following the initial visit to deliver the cards/packs, two further visits were made to each general practice and pharmacy by the NIHR CLAHRC GM project team to reinforce the project, monitor distribution of the cards, offer support and to provide further supplies of cards as required. In the majority of practice visits it was not possible to meet with the

clinician issuing the cards. However, it was occasionally possible to speak to the practice manager. In most cases contact was made with the receptionist who could check card stock and provide some insight into who was using the cards. The project team noted that community pharmacists were more accessible and often had time to discuss the progress of the project. The project team were also able to directly answer any questions they had raised. During these visits a number of issues were anecdotally raised by participating healthcare professionals. Several pharmacists commented on the need for cards in additional local languages, such as Urdu and Punjabi, and most that engaged in discussions suggested that the text font was too small for many elderly patients or those with sight difficulties.

One of the pharmacy chains requested additional education on AKI for pharmacists who were unable to attend the educational events. An additional educational session was arranged and delivered for this audience.

It was highlighted on a number of occasions, by pharmacists, that they thought there should be more education around AKI and how to discuss the sick day guidance with patients. Many pharmacists highlighted that the discussion with the patient could be time consuming and it would have been easier to implement if counter assistants were also trained.

3.3 Phase two - facilitated approach by practice-based pharmacists

The second phase of the project commenced in August 2015. This phase aimed to entail a more facilitated approach to implementation of AKI preventative interventions by practice (medicines management) pharmacists, who covered three of the eight neighbourhoods in Salford CCG. As an innovation pilot, Salford CCG had recruited general practice-based pharmacists earlier in the year to contribute to a number of CCG devised projects, to enhance medicines optimisation. Their activity was led and managed by Salford CCG (see Appendix 5 for the breakdown of this CCG designed work).

4. **Quantitative Evaluation**

4.1 Summary of study design

The Salford Integrated Record (SIR) was used to perform a quantitative evaluation of the implementation of the sick day guidance card intervention in Salford. We extracted data from SIR relating to the period 1st June 2015 to 31st January 2016, and defined provision of a sick day guidance card by the presence of Read code 'Provision of written information about acute kidney injury' (80AG.) in the patient's record. The aim of the quantitative evaluation was to ascertain activity levels at general practices, in terms of provision of the intervention, that is, the sick day guidance cards and to describe the characteristics of the patients receiving the cards.

4.2 Methods

4.2.1 Exposure to intervention

We assessed whether patients were provided with the sick day guidance card at general practices, measured by use of the Read code 'Provision of written information about acute kidney injury' (80AG.) (as outlined in Table 1).

4.2.2 Data sources

Data was extracted from the Salford Integrated Record (SIR). SIR is an anonymised electronic health record (EHR) database used in the UK city of Salford (population

approximately 234,000). SIR contains all primary care data of patients registered with a general practice in Salford and some information from secondary care (Salford Royal NHS Foundation Trust) mostly related to chronic care management. Consistently in line with the rest of UK primary care, the information collated in SIR is stored in Read codes.

A protocol of the study for the quantitative evaluation was submitted to the SIR board in November 2015. The study was approved in December 2015 (SIR request ID 221), and data were extracted from the SIR database in February 2016.

4.2.3 Study population

We included all patients who were over the age of 18, registered with a general practice in Salford CCG and for whom data were available in the Salford Integrated Record (SIR). We also included patients who were prescribed with medications in the sick day guidance card intervention inclusion criteria (see Figure 1) over the period of 1st June 2015 to 31 January 2016 (i.e. sick day guidance card intervention period). During this period we also explored data for patients who were not prescribed with the medications in the inclusion criteria, but were coded with having received a sick day guidance card.

During implementation of the intervention, evidence emerged that not every event was recorded and there was also evidence that an inaccurate non-specific code ('9bK5'; 'special patient note') was being used to record administration of the card. In view of these methodological concerns surrounding both potential under-reporting and also potential incorrect reporting; a decision was made to limit analysis to five general practices (top 10% of prevalence) where there was evidence of consistent coding of administration of sick day guidance cards.

4.2.4 Variable evaluation

Read codes were retrieved from *clinicalcodes.org* to extract clinical and laboratory variables from the SIR database.[27] *Clinicalcodes.org* is a repository of Read codes used in previously published articles; we used Read codes from six studies.[26-31] We identified relevant comorbidities [32] in SIR (e.g. hypertension, cardiovascular diseases or diabetes) by looking in patient's records for the related diagnostic Read codes prior to the date each patient received the sick day guidance card (e.g. 80AG. in SIR). For medications we looked at any prescription received during the study period. We also assessed the presence of 'triple prescribing', i.e. patients receiving prescriptions of NSAIDs, ACE Inhibitors/ARBs and/or diuretics simultaneously (which may impair renal function when used in combination). Finally, we assessed presence of potential past AKI episodes by applying the national AKI algorithm on patients' creatinine data.[19] The algorithm compares creatinine data with previous readings and looks for changes that might indicate AKI.[19]

4.2.5 Data analysis

For the 5 general practices, we evaluated:

- the percentage of eligible patients that received a sick day guidance card;
- the proportion of eligible patients that were coded as having received the cards;
- the number of patients that were not eligible but were coded as having received a sick day guidance card;
- trends over time in the incidence of Read code 8OAG., and
- clinical characteristics of patients recorded as receiving a sick day guidance card. (Larger numbers of patients may have been given a card but it might not have been recorded by the health practitioner).

4.3 Results

As described in the methods, we focused our analysis only in the practices that had the top 10% of prevalence of sick day guidance Read coding (five practices). The following results are therefore limited to the data for those five practices.

4.3.1 Prevalence of sick day guidance card

Table 3 shows recording of the provision of sick day guidance cards, using Read code 80AG. in SIR for the five practices.

Table 3	Prevalence of	sick day	guidance	recording	in 5	general	practices	in	Salford
during th	e study period								

Source	Practice size	Number of patients that were coded as having received the sick day guidance card	Prevalence
Α	3,850	186	4.8
В	12,730	372	2.9
С	8,792	248	2.8
D	14,973	389	2.5
E	11,869	269	2.3

4.3.2 Eligible versus non-eligible patients that received the sick day guidance card

Table 4 reports the proportion of patients that received the medications included in the intervention and received the sick day guidance card during the study. In the top 10% of practices, all eligible patients (1,452) received a card with the exception of practice D that missed two eligible patients

Table 4Number and proportion of eligible patients that received a sick dayguidance card in the selected practices

Practice	Eligible patients	Number of eligible patients that received the sick day guidance card (%)
В	372	372 (100)
E	267	267 (100)
С	248	248 (100)
А	182	182 (100)
D	383	381 (99.5)
Total	1,452	1,450 (99.9)

4.3.3 Incidence of sick day guidance recording

Figure 2 shows the trend of incidence of sick day guidance card recording over the study period. The period of highest coding was towards the end of the intervention period in the latter part of 2015.



Figure 2 Provision of sick day guidance in top five practices, by month

4.3.4 Patient characteristics

The characteristics of the 1,464 patients who received the sick day guidance card during the study period in the five practices are shown in Table 5. As noted, 14 patients were coded as having received the sick day guidance card but who did not receive the medications included on the card. The mean age was 67.4 years, 46.1% were female, and the majority of people (that had ethnicity recorded) were 'white'.

In terms of comorbidities, 83.8% of patients were hypertensive, 35.2% had Type 2 Diabetes and around 20% were Read coded with a CKD stage between three and five. Based on application of the national AKI Algorithm, the data suggests just over one quarter of patients may have had a past episode of AKI. All other comorbidities explored had prevalence below 15%.

Parameter		Value	Missing data (%)
Number of	patients	1,464	NA
Eligible pati	ents	1,450 (99)	
Age [mean	(SD)]	67.4 (12.7)	1 (0.1)
Female Gei	nder	675 (46.1)	None
Ethnicity	Not recorded (%)	848 (57.9)	NA
	White (%)	583 (39.8)	
	Other (%)	33 (2.3)	
Smoking	Non-smoker (%)	555 (38.2)	10 (0.7)
-	Ex-smoker (%)	693 (47.7)	
	Light smoker (%)	57 (3.9)	
	Moderate smoker (%)	68 (4.7)	
	Heavy smoker (%)	81 (5.6)	
BMI [kg/m^:	2] (mean, SD)	30.5 (6.7)	6 (0.4)
Proteinuria	(%)	75 (5.1)	466 (31.8)
CKD 3 (%)		274 (18.7)	NA
CKD 4 (%)		21 (1.4)	
CKD 5 (%)		1 (0.1)	
Hypertensic	on (%)	1,227 (83.8)	
Type 1 Diat	petes Mellitus (%)	11 (0.8)	
Type 2 Diat	petes Mellitus (%)	516 (35.2)	
Cerebrovas	cular disease (%)	134 (9.2)	
Peripheral v	vascular disease (%)	70 (4.8)	
History of m	yocardial infarction (%)	153 (10.5)	
History of st	troke (%)	119 (8.1)	
Congestive	heart failure (%)	97 (6.6)	
Cancer (%)		194 (13.3)	
Liver diseas	se (%)	19 (1.3)	
Potential Pa	ast history of AKI (%)	403 (27.5)	
COPD (%)		246 (16.8)	
NSAIDS rep	peated prescriptions (%)	63 (4.3)	
ACE Inhibit	ors prescription during study period (%)	907 (62)	
Angiotensin	2 Receptor Blocker prescription during	338 (23.1)	
study period	d (%)		
Metformin p	rescription during study period (%)	433 (29.6)	
Diuretics pr	escription during study period (%)	488 (33.3)	
ACE inhibite and NSAID	ors or Angiotensin 2 Receptors Blocker s prescribed during study period	112 (7.7)	
ACE inhibite and diuretic	ors or Angiotensin 2 Receptor Blocker s prescribed during study period	353 (24.1)	
NSAIDs and	d diuretics prescribed during the study	45 (3.1)	
'Triple prese	cription (%)	32 (2.2)	

Table 5	Characteristics	of patients	s that were	recorded	as receiving	the	sick	day
guidance	card in the select	cted practic	es during t	he study pe	eriod			

NA: Not applicable.

In terms of medications, ACE inhibitors were the most prescribed drug (62%) in the study population during the study period. 4.3% of patients had repeated prescriptions of NSAIDs when they were coded as being given a sick day guidance card. 24.1% of patients were prescribed ACE inhibitors or ARBs in combination with a diuretic, and 2.2% were prescribed the 'triple whammy' of medicines (simultaneous use of NSAIDs, ACE Inhibitors/ARBs and diuretics) during the study period.

5. **Qualitative Evaluation**

5.1 Study design

The study explored the administration, interpretation and use of sick day guidance cards across general practices and community pharmacies within Salford CCG. In addition to the project objectives, Normalisation Process Theory (NPT) provided a framework for data collection and analysis. NPT is a theory of social action that is concerned with understanding *'what people do rather than their attitudes or beliefs.'*[33, 34] It offers a structure for understanding the processes underpinning care, which enable or constrain the embedding and integration of a complex intervention into routine care. Consequently the interviews focused on sense-making, implementation and appraisal in clinical encounters, practice and service organisation, and on its potential use in everyday lives.

5.2 Methods

5.2.1 Data sampling

The sampling strategy was purposive; to explore the trajectory of the project across Salford CCG, staff and patients working at and using general practices and community pharmacies providing the intervention were approached to take part. General practices and community pharmacies were asked to pass on details of the evaluation to patients who had received a card. The final sample comprised: seven GPs; five practice nurses; one health care assistant; four practice-based pharmacists; two non-clinical managers; five community pharmacists/pharmacy staff; and five patients. Patient recruitment was discussed with clinical staff at general practices and community pharmacies, many of whom assisted by distributing patient recruitment literature. However, despite these efforts to recruit more patients to the study only five came forward to take part. Learning suggests that alternative, community methods of recruitment, such as through older persons organisations may have yielded higher numbers of participants. To address the issue, discussions relating to patients in other participant accounts were also used to inform the qualitative evaluation.

Table 6 Qualitative pa	rticipant sample by	/ group
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Group	Number of participants
GPs	7
Practice nurses	5
Health care assistant	1
Practice-based pharmacists	4
Non-clinical managers	2
Community pharmacists/pharmacy staff	5
Patients	5

5.2.2 Data collection

Two members of the NIHR CLAHRC GM research team conducted 29 semi-structured interviews with the participants at their place of work or home between June 2015 and April

2016. The interviews were audio recorded in compliance with participants' consent, and professionally transcribed.

5.2.3 Data analysis

A set of analytical questions arising from the objectives and NPT [33, 34] were asked of each interview transcript and its associated audio recording, to ensure accuracy. The questions asked of the health practitioner interviews were:

- How do they make sense of implementing the sick day card intervention?
- What work have they done to implement the intervention?
- How is the intervention being communicated or enacted by local others?
- What judgments have been made about the intervention?
- Comments on patient reactions/perceptions;
- Are there any competing demands, conflicts or meaningful silences present in the account? and
- What would be needed to continue this intervention in the future?

The questions we asked of the patient interviews included:

- How does the participant make sense of health and illness?
- What was the context of the participant receiving a card and guidance?
- How did they make sense of the card and implement the guidance in their own lives?

The resulting data from each case study was grouped according to participant role. This lead to the development of six groups of data (GP, practice nurse and health care assistant, administration, community pharmacist, practice pharmacist, patient). Thematic analysis was carried out on each group to understand and explain the findings. Key analytical findings from each group were compared with each other to make sense of the sick day guidance card implementation in varying contexts. The results were compared with the original transcripts, the group thematic findings and cross-checked within the research team to ensure rigour and accuracy.

5.3 Results

5.3.1 Overview

AKI was viewed as a new phenomenon and the implementation of sick day guidance cards entailed a new set of working practises. One GP said '...*it is all pretty sort of recent for us. I mean, we'll do our usual, you know, monitoring and medication reviews, dealing with the acute issues, but there was no sort of framework as such before these rules came in...*' (SKHIP20GP). A community pharmacist commented that patients had also expressed surprise and some hesitancy to follow the guidance 'I've had a couple in particular...on the Metformin side that are like...I can't just stop my diabetic medication, that wouldn't be right, *no-one's ever told me to do that before. I have explained that this is a new concept...*' (SKHIP6CP).

Analysis indicated that although valued, AKI prevention guidance was not necessarily a straightforward concept to understand, or to communicate. Health practitioners thought the cards required some knowledge of illness symptoms and medicines, and that patients had to decide how severe the symptoms were before acting, or re-starting their medication. One practice pharmacist stated '...patients don't understand what fever is...they think that if they've got a headache it's fever...we're trying to explain and they don't understand, or they say, well, if I had a bout of diarrhoea do I stop the medication...it's severe. Well, what is severe, you know? Obviously it's very subjective...' (SKHIP13PP). Concern was expressed

that if the guidance was not communicated and understanding assessed face-to-face, that patients may interpret and implement it differently to how it was intended.

Comparative analysis highlighted a tension between the need to reach patient populations deemed at risk (i.e. those on relevant medicines) and ensure comprehension, within the context of competing everyday demands. Factors such as consultation time limitations, multiple patient health needs and varied patient cognitive capacity, as well as implementing an evolving set of national and local incentivised health directives constrained the potential reach of this AKI preventative intervention. One GP highlighted the challenge of fitting everything into a consultation. 'And I think it's very difficult to fit that into what is already a crammed ten-minute appointment in general practice where people come with multiple problems' (SKHIP0GP).

Whilst the sick day guidance intervention can be considered a relatively simple intervention, our participants' experiences of implementing it seemed to connect to several complex issues, both in terms of patients - and their health, illnesses and medicines, as well as health care work and roles. The interviews included many descriptions of how the guidance was delivered to patients, and through analysis of the data, five main approaches were discerned:

- administration of sick day guidance cards in conjunction with face-to-face communication;
- administration of sick day guidance cards to patients in conjunction with telephone consultations;
- postal administration of sick day guidance cards in conjunction with an explanatory patient leaflet;
- sick day guidance cards administered without verbal or written communication; and
- communication of AKI risk, but with limited use of a sick day guidance card.

Other key factors that shaped the implementation of sick day guidance cards included: alignment or conflict with existing workloads; the perceived legitimacy of fit with professional roles, and appraisal of the intervention, which included concerns about the lack of evidence of positive patient outcomes. The following section sets out the five approaches to implementation defined above, and how they shaped and/or were influenced by the factors mentioned above.

5.3.2 Administration of sick day guidance cards in conjunction with face-toface communication

Analysis indicated a tendency for the sick day guidance cards to be valued but that they needed to be administered in conjunction with face-to-face verbal communication. A common theme was health professionals valuing the need to explain the guidance in person. This was also reflected in patient accounts. One patient expressed her concerns '*I* don't think that it should be just put on a counter for people going to buy a bottle of aspirins, oh what's that? I'll pick one up and take it away. Quite honestly, I don't think, number one, they'll read it, number two, they'll digest what's on it, or number three, they'll apply it to themselves' (SKHIP22PA). A practice nurse thought dialogue was important to reduce miscommunication, patient confusion and additional GP workload:

'I always explain ...There's no point giving someone a card if they don't understand what it's for...my grandma wouldn't understand that. She'd probably misinterpret that and, you know, stop taking everything or she'd sit there and go, I don't know which ones I'm on of these and which ones I'm not. Should I be on that? She'd be back at the doctor saying, it says here... but I don't take this. So if you explain it then you avoid all those errors, don't you, really' (SKHIP25PN). Analysis of health practitioner and patient accounts revealed that patients responded to the guidance in a variety of ways, not always as intended. One patient participant used the terms sickness and illness interchangeably and spoke of different classifications of illness. She asked which type the guidance card was referring to, so she could be confident of following the instructions properly. 'What do you define as illness that would stop you from ...? Well, I suppose I don't know ... I've got arthritis, that's not an illness it's just a thing of life when you get older that you live with... I've had spinal surgery, but they're not illnesses...' (SKHIP22PA). In accounts of two other cases, patients with medication-related rather than sickness-related diarrhoea stopped taking their tablets after they received a guidance card. In both of these cases patients reportedly saw a health professional, which lead to a positive unintended outcome. Through dialogue, the accounts reported a switch to a new prescription to alleviate the side effect. Other patient participants' accounts revealed a lack of willingness to follow the guidance as it had not been implemented by their hospital specialist, whose opinion they trusted, and they did not want to make their condition worse by ceasing medication, even temporarily. 'I'd rather feel sick than have a problem with the high blood pressure...' (SKHIP31PA).

The concept of temporary cessation of medicines was new to both patients and health professionals and were seen to require careful consideration, for example when to stop, when to restart and what dosage to restart on. 'We don't have enough data or...best practice, for example, if you stop the metformin or whatever medication how long do you stop it for...? Then after a week are you going to restart them again on the ten milligram or are you going to start them on the 1.5, the 2.5...?' (SKHIP14GP).

Although valued by health practitioners interviewed, implementation of sick day guidance as a new intervention demanded extra work. In general practice, this was deemed less problematic when it fitted into existing long-term condition review appointments, particularly with practice nurses or healthcare assistants. One practice nurse felt that though there was additional work, it fell within her remit and sick day guidance success may lead to reduced numbers of AKI patients in the future:

'Everything's extra work with us, you know; it's all extra work. In addition to this we have this long term condition care plan now that we have to bring out, we have a patient and practice agreement; this is all in say one review. Obviously now we've got this sick day card, so it is something extra and I think that may be for some nurses, oh it's something else, but...there's no point digging our heels with it...It's part of our review which is already busy anyway, but there is a benefit to it. So, it may be by giving these out then we may have less patients that we do reviews on kidney' (SKHIP25PN).

In community pharmacies, implementation sat more readily within face-to-face medication review appointments or opportunistic over-the-counter interactions, including the purchase of non-steroidal anti-inflammatory drugs (NSAIDS, such as ibuprofen). One community pharmacist used the purchase of anti-diarrhoeal or sickness medications as an opportunity to administer AKI guidance. 'We've had a couple of times when people have been coming into buy stuff for sickness or diarrhoea and obviously as part of sorting a suitable product we ask them what medication they're on. If it turns out that they're on one of the medications that's on the card then we'll give them a card then as well and explain about it' (SKHIP5CP).

There were boundaries to the implementation of sick day guidance in patient populations who were identified at higher risk of AKI. Concerns were expressed across the range of health professionals interviewed that sick day guidance cards (and its focus on temporary cessation) were not necessarily suitable for patients with cognitive impairments such as Alzheimer's Disease, those with other mental health conditions, reduced literacy in English, those with advanced learning difficulties or visual impairments, or for elderly housebound

patients taking multiple medicines. One community pharmacist commented on the difficulties facing patients and carers using dosette box systems:

'Some of them (patients), they might have four or five tiny little white ones, and then if they're elderly or they can't see the markings, they don't know what tablet they should be stopping for the 48 hours. So I would just be concerned we'd just confuse people a little bit more. I mean, if it was a family member looking out for it, that would be I guess possible, but a lot of the carers are not allowed to alter any medication, or wouldn't be authorised or have permission to say, I'm just stopping this for two days because you've been poorly...' (SKHIP7CP).

The challenge of communicating sick day guidance and ensuring patient understanding and intended usage was seen to be compounded by the fact that more vulnerable patients might use dosette packs. As several small and similar looking tablets might be placed in one daily container, patients may not know which tablet(s) to cease temporarily, particularly if they had reduced cognitive capacity and/or poor eyesight. Though there were instances where health professionals suggested taking extra steps with patients such as asking them to phone or visit to discuss the matter, in the main, accounts centred on difficulties implementing sick day guidance in higher risk patients and harder to reach populations.

5.3.3 Administration of sick day guidance cards to patients in conjunction with telephone consultations

Phase Two of the project entailed Salford CCG employed practice-based pharmacists supporting the implementation of the sick day guidance cards in general practice (see Table 1). All of the four practice pharmacists valued and engaged with the project. However, they outlined difficulties fitting the intervention into their pre-existing workload. There were more patients to work with than anticipated, and the database searches, writing to patients, verbally communicating with them and feeding the results back to GPs took longer to complete than the pharmacists described having time for. In particular, they only had half a day every two weeks in each practice. One interviewee highlighted these difficulties ...'there are 500 or 600 patients across your patch that would probably be eligible if we did everybody...probably about 15, 20 minutes per medicine review, and then a 15 minute conversation...and then if I do flag up something, I've then got to speak to the GPs... It's a really good project but it's such a shame that I've got other work to do' (SKHIP9PP). In addition, these were exacerbated by difficulties accessing patient information 'there's issues obviously around patient identification, and clinical governance, there's always issues around those, and confidentiality' (SKHIP12PP).

The intervention resulted in less time to enact their pre-existing medicines review work. The pharmacists described feeling anxious about the lack of time and concerned that some GPs were unhappy about the additional workload. 'A particular problem that I've had is that it was never made particularly clear to the GPs that I would be doing that work...So then when I turned round and said, oh no, I'm doing the work, some GPs weren't particularly happy because they were saying, well, I dictate your workload, so who's given you this work to do in my practice?' (SKHIP9PP).

To implement the project in this context, a decision was made to have telephone conversations with patients rather than face-to-face interactions. However, this shift created additional challenges. The phone calls took just as long as the face-to-face encounters as the pharmacists expressed professional need to do things '*properly*'. They reported patients not always being happy to talk with a perceived stranger on the phone about their health. Patient understanding was harder to assess than in person, and patients did not necessarily agree to enact the guidance if they became ill. Unlike the face-to-face GP and practice nurse consultations, patients on the other end of the phone had no prior trusting relationship with

the practice-based pharmacist in an era of telephone based '*cold-calling*'. One pharmacist tried to mitigate some of these issues by talking with a GP in advance of making the calls

"...I thought to myself right I'm not going to just pick up the phone and ring this patient now I'm going to ask the GP what he thinks about me ringing the patient... for the slightly elderly some patients perhaps mental health issues, one doctor said to me obviously don't bother ringing that patient....They obviously know their patients much better than I do so I always take their advice and find out what they think' (SKHIP11PP).

The community pharmacists spoke of telephoning patients to discuss the temporary cessation of medication. One spoke of the difficulties of assessing patient comprehension in this way. 'I've had to phone patients, you know sometimes if you've got a query or the prescription will be changed or we'll want to question something with the patients, sometimes they're on the ball, they completely know, and sometimes they're just so confused and they'll have a pack delivered and they'll just take what they're told to take. It's a fine line, really' (SKHIP7CP).

5.3.4 Postal administration of sick day guidance cards in conjunction with an explanatory patient leaflet

One practice pharmacist developed an AKI patient information sheet to be posted with a card and explanatory letter, and offer of a follow up conversation to enable greater reach and comprehension (than the cards alone) in a time efficient manner. 'you want to go through it (the card) with them, but even a 5-10 minute phone call is the same as them coming in for an appointment, and it's getting through that work is very difficult. And that's what led me to develop this leaflet, to try and use it as a postal campaign' (SKHIP13PP). The A4 sized, double-sided leaflet to save on costs, gave AKI risk factors, and encourage patients to contact the practice if they had queries. The pharmacist reported difficulties in getting the practices to cover the anticipated £500 cost of printing and posting a leaflet, guidance card and explanatory letter to patients identified as being at risk of AKI 'it's actually a barrier because of the cost that's associated' (SKHIP13PP). A practice manager's account also highlighted administration and mailing costs as barriers to implementation. ... if there was some money attached to it (a future sick day guidance intervention) that would pay for us to have someone send out letters and then attached to the sick day rules, tell the patient exactly what it is. And we could do a search on everybody who is on those drugs or got those conditions, and then write to them with the cards, with information...but it's not something people could do without having the cost of it paid for...' (SKHIP3PM).

5.3.5 Sick day guidance cards being administered without verbal or written communication

Though instructions communicated to health practitioners (via the information leaflet; see appendix 2, education events and through on-going facilitated support visits) stressed the need for dialogue with patients to ensure understanding, accounts indicated the sick day guidance cards were not always administered with a verbal explanation. Reasons for not verbally engaging with patients included other demands during a practice-based consultation, limited time for dialogue, forgetting to discuss it, and some lack of confidence about what to say (partly because of the limited evidence base and so as not to 'frighten' patients). One community pharmacist stated 'Half the time it's remembering to do it because you're thinking about that many different things' (SKHIP5CP). In addition, they did not always have face-to-face contact with patients to explain 'we just make the MDS (blister packs) so we're ordering the repeat medication for...we've got like 900 of our own patients. And we just make the packs and then send them out and delivery, so we don't actually have that much patient contact' (SKHIP7CP).

Some health practitioners felt that the cards were self-explanatory and did not need any further explanation. One practice nurse said '*vomiting is vomiting and diarrhoea is diarrhoea*' (SKHIP25PN). One GP tried adding the card to a prescription, but found it an inadequate method to ensure patient understanding '*one thing I would really like to do is be sticking these to prescriptions, because we could get such a massive volume out there and the message out there, but that on its own, patients were just confused'* (SKHIP14GP).

A few of the patient accounts and one GP account referred to cards being available in public information areas in general practices and community pharmacists, or to finding them stapled to, or on the inside of a prescription bag. One patient who found a card in this manner wanted to share the sick day guidance message '...when I went into the pharmacy last week, they were on the counter...I picked one up and brought it home ...I mean I think it's such a good idea that I've given one to my sister' (SKHIP22PA).

5.3.6 Communication of AKI risk but with limited use of a sick day guidance card

One GP worked exclusively with patients in care homes across the CCG, which included those who were diagnosed with cognition limiting conditions like Alzheimer's disease or those who had mental health conditions. Though these groups of patients were felt to be more vulnerable to AKI, the cards were not thought appropriate to administer directly due to a potential lack of understanding and uncertainty over use. The need for appropriate training for carers, nursing staff and associated social workers was raised, beyond the level of sick day guidance. Specifically there was felt to be an on-going need for health practitioners to highlight the importance of fluid management in conjunction with medicines management, and to review patient medications. 'Most of our patients, they've been on years and years of these nephrotoxic medications, and nobody did any medicine management reconciliation...' (SKHIP14GP).

Accounts highlighted the need for clarification of a carer's responsibilities regarding temporary medication cessation '...we need to clarify that carers would be okay to omit someone's medicines, because literally they rely on signing to say they've given it and they get very precious about that...because they get in trouble for not giving someone's medis (medications)' (SKHIP6CP).

5.3.7 Appraising the use of sick day guidance

Based on their experiences with patients there was evidence of sick day guidance appraisal by health practitioners. However, this tended to be individualistic and focused on the implementation of the cards, rather than potential influences on patient health outcomes or ways to enhance communication about AKI prevention within and between organisations.

'Receptionists could as they're doing the prescriptions, you know, we've got two receptionists who are prescription receptionists. If they or we help them to identify which patients to attach this to, they could do that, and receptionists handing out prescriptions could say, oh, just to let you be aware, read this form, it's just about kidney health. If you've got any questions, blah, blah, blah... (SKHIP19GP).

6. Discussion

6.1 **Principal findings**

The evaluation indicated variable coding of the administration of sick day guidance cards in general practices. In view of these methodological concerns surrounding both potential under-reporting and also potential inaccurate reporting; a decision was made to limit the

quantitative analysis to 5 general practices where there was evidence of consistent coding of administration of sick day guidance cards. Within these 5 practices, virtually all 1,452 eligible patients (with the exception of two) were coded as receiving a card. In terms of comorbidities, 83.8% these of patients were hypertensive, 35.2% had Type 2 Diabetes and around 20% were Read coded with a CKD stage between three and five. Based on application of the national AKI algorithm [19], data suggested approximately one quarter of patients may have had a past episode of AKI.

Implementation of sick day guidance cards to prevent AKI entailed a new set of working practises across primary care. The temporary cessation of medicines during episodes of acute illness was not necessarily a straightforward concept to understand or communicate. Comparative analysis of participants' accounts highlighted a tension between ensuring reach in administration of sick day guidance cards to at risk populations whilst being confident to ensure patient understanding of their purpose and use.

There was evidence that this tension drove the implementation of sick day guidance, with participants describing a range of approaches. In the main, participants tended to prioritise the need for face-to-face communication, though across accounts there was evidence of roll out through other strategies. Factors that shaped implementation of sick day guidance cards included alignment with existing workload, perceived fit with professional role and concerns about patient cognitive capacity.

6.2 Strengths and limitations of this evaluation

The quantitative analysis relied entirely on GPs/practice nurses coding all patients who were given a card, and coding using the correct (sick day guidance specific) Read code. Therefore the number of patients who have received a card could be greater than reported, as recording did not always occur and some incorrect Read coding was reported. In order to more confidently understand trends over time and clinical characteristics of patients who were coded as having received a sick day guidance card, a decision was taken to limit the analysis to the top 10% of practices (5 out of 48 in Salford). Furthermore, though community pharmacists also handed out the cards they were not required to record how many had been distributed as they were not remunerated for taking part. In order to gain a greater understanding of implementation and outcomes, future projects would benefit from ensuring accurate and consistent coding of administration of sick day guidance by each partner organisation.

The quantitative analysis suggested that just over a quarter of the patients eligible to receive a sick day guidance card may have had a past episode of AKI. However, caution is required interpreting this finding. The results are based on analysis of only five practices and importantly, the analysis is based on application of the AKI algorithm without case note review, limiting the ability to place the findings in a clinical context.[3, 19] As stated in Think Kidneys Best Practice Guidance for primary care, '*AKI is a clinical diagnosis –The gold standard for AKI diagnosis is clinician review of current and previous blood results – taking clinical context into account – and comparing against AKI diagnostic and staging criteria.*[3] The development of the AKI classification system and the subsequent national AKI algorithm is founded upon secondary care databases with limited validation in primary care. 190, 35] However, irrespective of whether the application of the national algorithm leads to confirmed AKI or instead flags progression of CKD, there is evidence that it is identifying patients at risk of poor health outcomes. [36, 37] As such, the results may warrant further evaluation in other settings, particularly as patients with a past history of AKI and/or pre-existing CKD are deemed at higher risk of future events [3, 4].

Through qualitative research methods the evaluation sought to understand processes that enable or constrain the implementation of sick day guidance cards to prevent AKI. Building on an earlier study, [38] a key strength of this evaluation is that it has explored the systematic roll-out of the sick day guidance cards across a single health care setting (i.e. Salford CCG). Normalisation Process Theory provided a framework to ensure that a range of individual and collective working practises were explored.[33, 34] This included sampling types of work undertaken in both general practices and community pharmacies and their use by a range of health professionals in these different settings.

The study entailed comparative analysis of both patient and professional accounts in order to explore their use in clinical interactions as well as in everyday life. Though professional accounts allowed descriptions of experiences of use by patients, difficulties were encountered recruiting patient participants who had experiences of having used a sick day guidance card at times of acute illness. Future studies may benefit from sampling patients who have been coded in general practice as having been provided sick day guidance (i.e. Read code 80AG. 'Provision of information about Acute Kidney Injury')[39] and also who have been coded with an episode of acute illness (e.g. gastroenteritis, acute respiratory infection). The qualitative interviews took place prior to quantitative analysis. Understanding may have been enhanced by sampling practices according to high and low levels of implementation. Future studies may benefit from greater alignment between quantitative and qualitative elements of an evaluation.

The study was hypothesis generating and sought to identify key issues underpinning implementation rather than seek statistical representativeness. There is the potential that this evaluation only recruited professionals interested in AKI. However, analysis of participants' accounts still illuminated a variety of approaches surrounding their implementation. Sampling general practices and community pharmacies according to quantitative evidence of implementation (and outcomes) may further enhance understanding.

6.3 Comparison with other studies

In terms of professional responsibility, there are recognised boundaries, or limits to the role of general practitioners in supporting self-management [40]. The findings of this study resonate and build on results of an earlier qualitative study [38], which also highlighted issues around the consistency of clinical message, as well as the extra work required surrounding implementation of strategies to prevent AKI, particularly for higher risk patient populations. The Salford CCG project was conducted at a time when UK general practice workload is deemed to be at 'saturation point.'[41] Results indicated that health professionals struggled to resolve the tension of aiming to provide high quality interpersonal care in terms of effective risk communication with patients and, at the same time, ensuring reach to all patients being prescribed the relevant medicines specified on the sick day guidance card.[42]

There was evidence to suggest that sick day guidance cards were more readily integrated into existing long-term condition review appointments with practice nurses as well as both 'over the counter' and medicine use reviews (MURs) carried out in community pharmacy. Risk communication to prevent AKI may help to address evidence of a gap in patient and public understanding of the importance in the maintenance of kidney health. A survey conducted in 2014 on behalf of NHS England indicated that 'just about half of the population in Great Britain don't think their kidneys make urine' and 'only an eighth (12%) of interviewees thought their kidneys had a role in processing medicines'.[43] Previous studies have highlighted a wariness by GPs and practice nurses to discuss a diagnosis of chronic kidney disease (CKD).[44-48] This restraint relates to concerns about the potential impacts of over-diagnosis (medicalisation) and patient anxiety, particularly in older people. There is now trial based evidence to support CKD disclosure without a negative effect on patient anxiety.[49] Historically CKD guidance has focused on blood pressure control and the

introduction of AKI prevention may provide an opportunity to widen the dialogue around CKD to both the maintenance of vascular health as well as measures to improve management of episodes of acute illness.[45, 48, 50]

6.4 Implications for clinicians, policy makers and future research

This project was undertaken in the context of published consensus based guidance though with a limited empirical evidence base.[4, 22] Findings suggest this may have constrained professionals' engagement with the implementation of sick day guidance cards. A systematic review is being conducted synthesizing evidence for the efficacy of discontinuing diuretics, angiotensin-converting enzyme inhibitors/angiotensin receptor blockers/direct renin inhibitors, NSAIDS, metformin or sulfonylureas to prevent or delay onset of AKI or associated complications.[51] The results of this review also aim to inform the future development and evaluation of AKI prevention strategies.

The NHS England Urgent and Emergency Care Review emphasised the need for better support for people to self-care.[52] The findings from this evaluation suggest sick day guidance cards may be a starting point but in isolation are unlikely to be sufficient to reduce the harm associated with AKI. Specifically, the findings suggest other strategies need to be resourced to prevent AKI in higher risk populations, particularly people with complex health and social care needs such as those living with dementia. A key issue raised was to provide better education and support for carers (both professional and informal). The Royal College of General Practitioners has provided guidance on the development of 'carer friendly' practices and the establishment of Patient Participation Groups, a core contractual requirement, may be a mechanism to resource and integrate support for carers into the organisation of care.[53, 54] Communicating effectively and consistently with patients and carers about how to optimise medicines management is important to reduce the potential for AKI. Our findings suggest that patients may be reluctant to alter their medication regimes on the advice of primary care professionals, if they have been prescribed the medicine by a hospital specialist. Future interventions and research should take account of the complexities of patient journeys and investigate ways to improve joined up working between secondary and primary care.

Patient populations at high risk of AKI include: people with existing CKD; those with neurological or cognitive impairment or disability, which may mean limited access to fluids because of reliance on a carer; and people who have had a past history of AKI (see Box 2).[3, 4, 55] For patients who have had a hospital admission complicated by AKI, there is evidence to indicate high levels of mortality, high levels of hospital readmission, and high levels of development or progression of CKD.[2, 6] For example, data from a Welsh study showed that out of 1020 patients with an AKI related admission, 49.7% had died within 14 months.[6] This comprised 28.1% in-hospital deaths and 21.6% deaths after hospital discharge. In addition, there were 492 re-hospitalisation events within six months of discharge.[6] Furthermore, of those that were still alive at 14 months, between 30 to 40% of patients had development or progression of CKD.[6] Existing observational data highlights that AKI is significant marker of vulnerability. The findings from our current project highlight the boundaries in the potential for sick day guidance cards alone as a measure to prevent AKI in higher risk patient populations, particularly people with cognitive decline. There were only a few accounts of attempts or suggestions to resolve the tension of ensuring reach in risk communication. The findings reiterate the need to resource alternative strategies (e.g. education for carers) as well as align AKI prevention within existing working practises. In England, avoiding unplanned admissions through proactive case finding and patient review for vulnerable people is a GP contractual requirement.[56] However, there is evidence to suggest that this current approach to case management may not be an 'effective intervention for reducing emergency admissions, despite the effort it requires from the primary care team.'[57] Existing tools being used to predict and identify people at risk of emergency admission do not currently take AKI into account.[58] Targeting interventions that are initiated during hospital admission for patients who have had an episode of care complicated by AKI may warrant development and evaluation.[57, 59, 60]

Evidence of impact, in terms of clinical effectiveness and cost-effectiveness, is needed to inform professional engagement with AKI prevention interventions in primary care. To date, research has been largely observational or focused on interventions in secondary care.[61] There is evidence that targeted audit and feedback interventions, aligned with financial incentives have the potential to support behaviour change and improve patient safety in primary care.[62-64] This approach is more effective when: there is a focus on areas of low baseline performance, education and feedback is provided by a supervisor or colleague and it is delivered in both verbal and written formats, and when it includes explicit targets and an action plan.[63]

In order to address the increasing workload associated with a shift in care into the community, a report by the Primary Care Workforce Commission highlighted that a broader range of health professionals need to be involved in delivering primary care to patients.[65] There is increasing evidence that practice pharmacists may have an important role in improving medicines management and patient safety.[66, 67] In order to support the sustainability of this new workforce, findings from evaluation of Phase Two resonate with previous research that highlights the centrality of professional working relationships; and that greater consideration needs to be given to the integration of practice-based pharmacists into existing primary care teams.[65, 68]

7. <u>Conclusions</u>

The sick day guidance project was one of a number of interventions designed to prevent AKI and to promote greater awareness of kidney health across Salford. Evaluation of the sick day guidance education sessions indicated that AKI knowledge was variable amongst health practitioners prior to attending, and that new learning did occur. Evidence of variable coding limited the quantitative analysis of implementation of the intervention. These methodological issues need to be considered and addressed in future research examining their implementation and effectiveness.

Despite this limitation, there was evidence to suggest that health practitioners have been having conversations with patients about AKI prevention. However, the findings from the qualitative evaluation of Phase One of the project indicate that there are boundaries to the implementation of sick day guidance cards. A common theme was the need to ensure patient understanding of their purpose and use. Communicating the concept of temporary cessation of medicines was a particular challenge and limited their administration to patient populations at higher risk of AKI. The analysis suggests that sick day guidance cards that focus solely on medicines management may be of limited benefit without either adequate resourcing, or if delivered as a standalone intervention. Evaluation of Phase Two of the intervention indicates that greater consideration needs to be given to the integration of practice-based pharmacists into existing primary care teams. To sum up, development and evaluation of a range of primary care interventions, including those with a focus on patient health outcomes is urgently warranted to tackle the harm associated with AKI.

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10. Appendices

Appendix 1 Interim Position Statement from Think Kidneys



The NHS campaign to improve the care of people at risk of, or with, acute k dney injury www.thinkkidneys.nhs.uk

Version 6: 8 July 2015 "Sick day rules" in patients at risk of Acute Kidney Injury: an Interim Position Statement from the Think Kidneys Board

Griffith K, Ashley C, Blakeman T, Fluck R, Lewington A, Selby N, Tomlinson L, Tomson C.

As health professionals one of our key aims is to reduce the risk of avoidable harm to our patients. Some people are at increased risk of Acute Kidney Injury (AKI), for example those with Chronic Kidney Disease (CKD), heart failure, or those taking particular medications (1). Many health care professionals provide advice to such patients that certain drugs should be temporarily discontinued during acute intercurrent illnesses, particularly where there is disturbed fluid balance. This advice is commonly described as 'sick day rules' or to take a 'drug holiday'.

This Interim Position Statement refers to such advice given to patients when they are well, about how to manage their own medication should they become unwell. It does not relate to clinical management of known or suspected AKI by health care professionals.

The definition of 'acute illness' in this context has to be simple enough to be understood by patients at risk. The NHS Highland definition (2) is a good example:

- 'when you are unwell with any of the following;
 vomiting or diarrhoea (unless minor)
 - fevers, sweats and shaking'

There are three main reasons for providing such advice:

- Non-steroidal anti-inflammatory drugs impair renal autoregulation by inhibiting prostaglandin-mediated vasodilatation of the afferent arteriole and may increase the risk of AKI.
- Drugs that lower blood pressure, or cause volume contraction, might increase the risk of AKI by reducing glomerular perfusion. These drugs include:
 - ACE inhibitors (ACEI) and Angiotensin Receptor Blockers (ARBs), which reduce systemic blood pressure and also cause vasodilatation of the efferent arteriole. This impairs renal autoregulation and reduces glomerular perfusion pressure.



Think Ridneys is a national programme led by NHS England in partnership with UK Benal Registry.

- b. Diuretics, which can exacerbate hypovolaemia and electrolyte disturbance. This group also includes the mineralocorticoid receptor antagonists spironolactone and eplerenone, used frequently in heart failure.
- c. Other blood-pressure-lowering drugs, which will lower systemic blood pressure.
- Drugs might accumulate as a result of reduced kidney function in AKI, increasing the risks of adverse effects.

These drugs include:

- Metformin which is associated with an increased risk of lactic acidosis in high risk patients.
- b. Sulfonylurea drugs which may have an increased risk of hypoglycaemia, as the drug is renally cleared.
- c. Trimethoprim, which increases the risk of hyperkalaemia. This drug also interferes with tubular creatinine secretion, and therefore causes a rise in creatinine levels and may result in a 'false positive' diagnosis of AKI.

Although there is strong professional consensus that advice on sick day rules should be given, and this approach is advocated in the NICE AKI guideline (3), the evidence that provision of such advice reduces net harm is very weak. The major evidence comes from observational studies and case series that demonstrate an association between receipt of ACEI, ARBs and NSAIDs, and a risk of AKI during acute illness (4, 5, 6). However, these studies may be confounded by indication. For example patients receive ACEIs or ARBs because they have a pre-existing condition - for example, heart failure with a poor cardiac output - that is independently associated with an increased risk of AKI.

It is possible that there are potential harms associated with widespread provision of 'sick day rules,' particularly when the patients have not been clinically assessed and where it is unclear at what level of ill health the medication should be discontinued. These include:

- Decompensated heart failure when drugs blocking the RAAS system and diuretics are discontinued.
- Development of poorly controlled hypertension with cessation of antihypertensive medication.
- Reduced adherence to drug treatment which may have been incorrectly described as 'nephrotoxic'. Patients may consider that the potential harm outweighs the potential benefit and decide to stop taking the drug despite the absence of an acute illness.
- Patients may over-interpret the advice and stop their drug treatment during even minor illnesses.
- 5. Patients may not re-start their drug treatment on recovery.
- The drugs may not be titrated back to the previous evidence based levels even when there has been no evidence of AKI.
- People may self-manage inappropriately and not seek professional help at an appropriate stage.
- Issues related to removing medication from dossette boxes, requesting new dossette boxes and up titrating medication in dossette boxes.
- Diabetes control may be adversely affected by inappropriate cessation of glucose lowering treatment.



Think Kidneys is a notional programme led by NHS brighted in partnership with UK Renal Registry It is also a theoretical possibility that ACEI and ARB treatment might reduce the severity or duration of AKI, at least in a subset of patients. These drugs, by causing efferent arteriolar vasodilatation, increase blood flow to the renal tubules: and it is tubular injury that causes persistent AKI and the increased risk of subsequent chronic kidney disease.

A systematic review of the published evidence on this topic is under way. This position statement is provided as a temporary measure until that review is completed. It has been agreed by specialists in kidney medicine and also by representatives from primary care. Aligned with NICE Quality Standard 76, the NHS England Think Kidneys Programme Board recommend that health professionals communicate risk of AKI with patients and carers (1). This should include discussion about possible causes including the need to maintain fluid balance during episodes of acute illness. In terms of medicines management, advice from the Think Kidneys Programme Board is that it is reasonable for clinicians to provide "sick day rules" guidance on temporary cessation of medicines to patients deemed at high risk of AKI based on an individual risk assessment. However, we consider that investment in a systematic approach to increase uptake of 'sick day rules' by patients should only be undertaken in the context of a formal evaluation.

We welcome comment and debate on this issue, and contact with those people who have already rolled out local programmes, or who have evidence on the implementation and effectiveness of this approach to add to the review. Please respond to <u>thinkkidneys@renalregistry.nhs.uk</u>

- 1. Acute Kidney Injury: NICE Quality Standard 76: http://www.nice.org.uk/guidance/qs76
- NICE NHS Highland interim report. http://www.knowledge.scot.nhs.uk/media/CLT/ResourceUploads/4061736/NHSH%20 updated%20evaluation%20medicine%20sick%20day%20rules%20April%202015.pdf
- NICE CG169: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy. http://www.nice.org.uk/guidance/cg169
- Loboz K.K. & Shenfield G.M.(2011). Drug combinations and impaired renal functionthe triple whammy. Br J Pharmacol, 59.2, 239-243
- Plataki, M,et al (2011). Predictors of Acute Kidney Injury in Septic Shock Patients: An observational Cohort Study. Clin J Am Soc Nephrol 6: 1744-1751
- Adhiyaman, V., Asghar, M., Oke, A. and Shah, I.U. (2001) Nephrotoxicity in the elderly due to co-prescription of angiotensin converting enzyme inhibitors and nonsteroidal anti-inflammatory drugs. J R Soc Med, 94: 512-514



Clinicians leaflet explaining sick day guidance





Salford Clinical Commissioning Group

Applied Health Research and Care (CLAHRC) Greater Manchester

Please find enclosed some new patient information cards.

These cards support a new patient safety initiative. Some information about the initiative is provided overleaf. Please circulate this information to all health professionals in your team.

This initiative has been developed in collaboration with NHS Salford Clinical Commissioning Group (CCG), Salford Royal NHS Foundation Trust (SRFT), and the NIHR Collaboration for Leadership in Applied Health Research and Care Greater Manchester (CLAHRC GM).

Please support this safety initiative by distributing the cards to patients on the medications as detailed overleaf.

For further supplies of cards or for further information please contact Lorraine Burey, CLAHRC GM Project Manager, via Lorraine.Burey@srft.nhs.uk.

With many thanks for your support.



For more information, please visit www.clahrc-gm.nihr.ac.uk/salford-sick-day-rules

Produced January 2015. Originally developed by NHS Highland

Appendix 2 continued







Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester

MEDICINES AND DEHYDRATION: SICK DAY RULES

BRIEFING FOR HEALTH PROFESSIONALS ON NEW PATIENT INFORMATION CARDS NHS Salford CCG, In conjunction with SRFT and CLAHRC GM, is launching a new patient safety initiative about medicines during sick days. This briefing explains why there is a need for this initiative and what it will involve.

What is the problem?

Dehydration can be a significant risk for people taking certain medicines. Therefore, "medicine sick day rules" patient information cards have been developed that list the medicines that should be temporarily stopped during lliness that can result in dehydration (vomiting, diarrhoea and fever).

What is my role?

Cards will primarily be distributed to patients through community pharmacies and GP practices. Pharmacies and practices are asked to give a card to every patient receiving any of the medicines listed on the card. A supply of cards is also being sent to SRFT to give to patients when initiating one of these medicines.

What advice should I give patients?

To ensure patients understand the information on the card, it is suggested that patients should be offered the following explanation at the time they are given a card:

- Some medicines shouldn't be taken when you have an illness that makes you
 dehydrated. This is because they can either increase the risk of dehydration or because
 dehydration can lead to potentially serious side effects of the medicine
- The medicine you are taking that fails into this category is [tell patient which medicine]
- Ilinesses that can cause dehydration are vomiting, diarrhoea and fever
- This advice does not apply to minor sickness or diarrhoea, which means a single episode
- If you have heart failure, you may stop these medicines for a maximum of 48 hours but after that you need to contact your GP or heart failure team for further advice
- If your heart failure condition has been unstable recently then please contact the heart failure team for advice (0161 206 1321).

Community pharmacists may find that provision of one of these cards could support a consultation under the Medicine Use Review (MUR).

What do the cards look like?

The cards are credit-card sized and printed on both sides (please see overleaf).

Why these medicines?

The list of medicines on the card is not exhaustive but they are highlighted because:

- Diuretics can cause dehydration or make dehydration more likely in an III patient
- ACE inhibitors, angiotensin II receptor blockers and NSAIDs may impair kidney function in a dehydrated patient, which could lead to kidney failure
- Metformin dehydration increases the risk of lactic acidosis, a serious and potentially lifethreatening side effect of metformin.

For more information, please visit www.clahrc-gm.nlhr.ac.uk/salford-sick-day-rules

Produced January 2015. Originally developed by NHS Highland

Appendix 3 List of resources

AKI workshop resource list

General

Kidney research UK

http://www.kidneyresearchuk.org/?gclid=CNGPytaTucMCFVHKtAodhFkAIQ

AKI NICE guidance https://www.nice.org.uk/guidance/cg169

NHS England AKI programme

http://www.england.nhs.uk/ourwork/patientsafety/akiprogramme/

RCP AKI app http://www.rcpe.ac.uk/policy-standards/acute-kidney-injury-app

Think Kidneys https://www.thinkkidneys.nhs.uk/

The renal association http://www.renal.org/home#sthash.C6PIHPiZ.dpbs

Pharmacists

Shaw et al (2012) Acute kidney injury management; Clinical Pharmacist Vol 4 p103-106 <u>http://www.pharmaceutical-journal.com/learning/learning-article/acute-kidney-injury-management/11098638.article</u>

University Hospital Leicester AKI Elearning (GPs/pharmacists) <u>http://www.uhl-library.nhs.uk/aki/</u>

General Practitioners

University Hospital Leicester AKI Elearning (GPs/pharmacists) <u>http://www.uhl-library.nhs.uk/aki/</u>

Nurses

NICE Elearning (nurses) http://elearning.nice.org.uk/enrol/index.php?id=5

Appendix 4 Sick day guidance patient poster



Appendix 5 Phase

Phase Two work stream

Salford Clinical Commissioning Group

Medicines Optimisation detailed aid

WORKSTREAM 2015/2: SICK DAY RULES IMPLEMENTATION

1. Aim and rationale

NHS Salford is introducing the use of 'sick day rules' cards within community pharmacies and in targeted practices that have a practice pharmacist resource. This forms part of the CCG Long Term Conditions Local Commissioned Service (LTC LCS) and practices will be remunerated for this work. This guide will clarify for practice pharmacists and GP practices what searches and outcomes are being implemented.

2. Acute Kidney Injury (AKI) and sick day rules

Acute kidney injury (AKI), previously known as acute renal failure, encompasses a wide spectrum of injury to the kidneys, not just kidney failure. The definition of AKI has changed in recent years, and detection is now mostly based on monitoring creatinine levels, with or without urine output. AKI is increasingly being seen in primary care in people without any acute illness, and awareness of the condition needs to be raised among primary care health professionals.

Patients with risk factors should be warned of the possibility of developing AKI if they become acutely ill, especially with diarrhoea and vomiting. They should be advised to increase their fluid intake and avoid certain medications while ill, the 'sick day rules'.

Dehydration can be a significant risk for people taking certain medicines. Therefore, NHS Salford has adapted "medicine sick day rules" patient information cards produced by NHS Highland that list the medicines that should be temporarily stopped during illness that can result in dehydration (vomiting, diarrhoea and fever).

3. Who gets AKI?

Central to improving outcomes in AKI is recognition of the 'at-risk patient', as intervention needs to be early, before there will be clinical manifestations of AKI in most patients. Any patient in whom renal perfusion may be reduced (e.g. vascular disease or poor left ventricular function) is at risk of

AKI, in particular if the kidneys' ability to maintain perfusion pressure is restricted by prescription of ACEi/ARB or NSAID/COX-2 inhibitor.

Risk factors for AKI, of relevance to primary care, which are of particular importance during acute illness are (*NICE CG169, Reference 1 below*):

- Age > 65 years
- Stage 3-5 chronic kidney disease (CKD 3-5, eGFR < 60 mL/min/1.73 m²)
- Cardiac failure
- Liver disease
- Diabetes mellitus
- History of AKI
- Oliguria
- Neurological or cognitive impairment that might restrict access to fluids
- Hypovolaemia
- Symptoms or history of urinary tract obstruction
- Sepsis

4. Practice pharmacists' intervention and sick day rules

- 4.1 Within NHS Salford GP practices it has been decided to pilot targeted use of the sick day rules cards. GP practices that have a practice pharmacist (Walkden and Little Hulton, Swinton and Broughton neighbourhoods) will use this resource to carry out targeted reviews of at-risk patients.
- 4.2 Practice pharmacists should identify the following patients:
 - CKD 4
 - CKD 3 with significant proteinurea (albumin/creatinine ratio, ACR>30mg/mmol)
 - History of AKI
 - Episode of AKI while in-patient at SRFT (SRFT to commence coding of AKI during 2015)

These patients will be identified by carrying out the following searches:

Identifiable group	Method
 CKD 4 CKD 3 with significant proteinurea 	Import the searches provided by the Data Quality Team.
History of AKI	K0412 acute kidney injury search provided by the Data Quality Team.
Episode of AKI while in-patient at SRFT	This list will be sent from SRFT to the CCG Medicines Optimisation Pharmacist who will then email directly to the practice pharmacists; <i>date of commencement to be confirmed with SRFT.</i>

The following actions should be taken for patients identified:

(Please note: Patients under the age of 18 years and patients with compliance aids should be excluded.)

Patient cohort	Suggested actions	Comments
 CKD 4 CKD 3 with significant proteinurea 	 Contact and educate patient on the sick day rules (face-to-face or by telephone). Issue sick day rules card (by hand or posted with accompanying letter). Clinical medication review for drugs which may be adversely affecting the kidneys. Check patient prescribed ACEi or ARB as per NICE guidance <u>CG 182</u>. If patient prescribed both an ACE and an ARB, review in line with NICE <u>CG 182</u>. GP to consider/discuss pharmacist's recommendations so action taken can be recorded. 	Code as: 14Om. 00 At risk of acute kidney injury 8OAG. 00 Provis ion of written information about acute kidney injury
History of AKI	 Contact and educate patient on the sick day rules and issue sick day rules card if he/she is on any eligible medicines. Medication review for drugs which may be adversely affecting the kidneys. 	Code as: 14Om. 00 At risk of acute kidney injury 80AG. 00 Provis ion of written information about acute kidney injury
Episode of AKI while in-patient at SRFT	 Medication review for any drugs which may be adversely affecting the kidneys. Avoid NSAIDs if possible; alert placed on system. In the absence of an obvious cause of AKI, consider if any new drugs have been introduced that have a relationship to the change in renal function, especially antibiotics and PPIs. Review medications to ensure those that need to be restarted are done so correctly. ACEi/ARB can be restarted once the renal function has stabilised; U&Es should be checked one week after reintroduction as per Derby primary care document (<i>Reference 4 below</i>). If a drug has been specifically implicated in causing AKI (e.g. PPI leading to interstitial nephritis or NSAIDs), practice records should be updated to prevent the patient receiving these in future. Contact and educate patient on the sick day rules. Issue sick day rules card. Ensure episode of AKI is coded on the patient's record. 	Code as: 14Om. 00 At risk of acute kidney injury 8OAG. 00 Provis ion of written information about acute kidney injury

4.5 The practice pharmacist should complete a data collection sheet so interventions can be collated.

5. Summary

The practice pharmacist should submit completed data collection sheets to the CCG Medicines Management Team with their quarterly activity summaries.

References:

1. NICE clinical guideline 169: *Acute kidney injury: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy.* August 2013. Accessed at https://www.nice.org.uk/guidance/cg169

2. Royal Pharmaceutical Society and Centre for Pharmacy Postgraduate Education (CPPE) Medicines Optimisation Briefing: *Acute Kidney Injury (AKI)*. Accessed at <u>https://www.cppe.ac.uk/wizard/files/news%20attachments/aki_mo_briefing_final.pdf</u>

3. NHS England Patient Safety Alert: *Stage Three: Directive Standardising the early identification of Acute Kidney Injury.* June 2014. Accessed at <u>http://www.england.nhs.uk/wp-</u>content/uploads/2014/06/psa-aki.pdf

4. Southern Derbyshire Shared Care Pathology Guidelines: *AKI guidelines for primary care.* Accessed at

https://www.derbyhospitals.nhs.uk/easysiteweb/getresource.axd?assetid=277344&type=0&servicet ype=1

Practice name:

Pharmacist:

	CKD register patient numbers	AKI patient numbers	Comments
Sick day rules explained and card given			
ACEi review			
ACEi+ARB combination stopped			
List drugs stopped			
Medicines restarted after admission			