

Domiciliary subcutaneous furosemide in patients with CKD and HF: a quality improvement project

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ABSTRACT

Hospital admissions to treat fluid overload are common in patients with both heart failure and chronic kidney disease (CKD-HF). This is a population with high levels of frailty. Recurrent hospital admissions are costly to both patients and healthcare systems. We designed a proof-of-concept, multidisciplinary quality improvement project to deliver at-home subcutaneous furosemide to treat fluid overload in patients with CKD-HF. This project involved collaboration between a hospital, community remote monitoring hub and hospital-at-home team, including general practitioners, secondary care physicians, nurses and pharmacists. Patients were considered suitable for the intervention if they had CKD-HF, fluid overload and were haemodynamically stable. Following review, suitable patients were treated at-home with 80 mg subcutaneous furosemide over 5 hours, for 5 days. This was administered by the hospital-at-home team in liaison with hospital specialists, with continuous patient monitoring provided by the remote monitoring hub. Renal function and weight were assessed daily. Following treatment, patients were reviewed by the secondary-care team to adjust their maintenance medications. Data collected and analysed included daily weights, renal function and observations, as well as the number of hospitalisations and/or death at 30 days following the intervention. 10 patients successfully completed treatment. All potentially required hospitalisation at baseline and all avoided hospitalisation during the 5-day course of subcutaneous furosemide. One patient was admitted to the hospital following their final hospital review, and two patients were hospitalised for 4 and 14 days respectively, after their final dose of subcutaneous furosemide. Renal function and potassium did not significantly change throughout the treatment. No major safety concerns were identified. Patients welcomed the intervention. This quality improvement project demonstrates that it is logistically feasible, with primary care collaboration, to treat fluid overload in patients with CKD-HF at-home using subcutaneous furosemide.

INTRODUCTION

Problem

Approximately 50% of patients with heart failure also have chronic kidney disease (CKD-HF).¹ These patients are at greater risk of adverse outcomes (OR of all-cause

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Hospital admissions are common in patients with heart failure and costly both to patients and healthcare systems. Patients with concomitant chronic kidney disease and heart failure (CKD-HF) are at even greater risk of hospitalisation and this population has high levels of frailty. Subcutaneous furosemide is emerging as an exciting alternative method to intravenous furosemide to provide parenteral diuretics to HF patients with fluid overload.

WHAT THIS STUDY ADDS

⇒ It is logistically feasible and appears safe to treat patients with CKD-HF with fluid overload at-home using subcutaneous furosemide.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The results of this multidisciplinary quality improvement project have informed the design of a feasibility randomised controlled trial comparing usual care with a novel pH-neutral formulation of furosemide delivered subcutaneously at-home via a pump device. We hope that eventually subcutaneous furosemide may allow patients with CKD-HF to be treated at-home which may reduce recurrent hospital admissions and improve patients' quality of life, as well as increase the acute capacity of hospitals.

mortality 2.34, 95% CI 2.20 to 2.50, $p < 0.001$), compared with those without CKD.¹ Despite their increased risk of hospitalisation and death, patients with CKD-HF are less likely to be established on evidence-based guideline-directed medical therapies, compared with those without CKD.² In our tertiary centre University teaching hospital, we established a novel multidisciplinary cardio-renal clinic with input from cardiologists and nephrologists to improve management of this high-risk cohort.³ As is seen nationally,⁴ we noted that recurrent hospital admissions were a considerable problem in this population. An analysis of a sample of 318 of these patients revealed

a total of 667 all-cause admissions over 443 person-years follow-up.⁵ 110 (34.6%) of these patients had an admission for worsening HF in this time-period.⁵ Furthermore, frailty levels are high in this population (49.5% as defined by the modified frailty phenotype in a cross-sectional sample of 103 patients with CKD-HF from our centre),⁶ with studies consistently showing that maintaining quality of life is one of the most important healthcare outcomes to patients both with HF or CKD.^{7,8}

Accordingly, we designed a quality improvement project (QIP) which aimed to reduce hospital admissions and improve quality of life, in this frail cohort of patients. The aim of this project was to assess the feasibility and acceptability of administering at-home subcutaneous (SC) furosemide to treat fluid overload in a small number of patients with CKD-HF.

Background

HF is an increasingly prevalent chronic disease, the burden of which is expected to rise further with shifting population demographics and a growing elderly population.⁹ HF hospital admissions are common and account for at least one million NHS patient bed days per year.¹⁰ The median length of stay for these admissions is 8 days,⁴ and these admissions are costly to both patients and resource-limited healthcare systems. Many of these admissions are indicated to treat fluid overload, and the mainstay of treatment is typically intravenous loop diuretics such as furosemide.¹¹

Recently, SC furosemide has emerged as an exciting alternative to treat fluid overload in HF and may facilitate at-home treatment.^{12–15} Treatment at-home offers obvious benefits to patients, as well as healthcare systems who could potentially reduce costs and bed days.¹⁶ A recent systematic review on the role of SC furosemide in HF concluded that the bioavailability and efficacy of SC furosemide are equivalent to intravenous delivery and superior to oral delivery.¹⁷ However, SC furosemide remains unexplored in the prevalent cohort of CKD-HF patients, who have high rates of hospitalisation and frailty, and may be more prone to diuretic resistance compared with those without CKD.¹⁶ Interventions to reduce hospitalisation in this frail population are necessary.

Thus, we designed a QIP to explore if treatment with SC furosemide would be a logistically feasible and acceptable option to treat patients in our area, and if this intervention could reduce the need for hospitalisation.

Measurement

The measurement of feasibility and acceptability was determined by whether patients would consent to participate in the intervention, whether the intervention could be delivered, whether patients would complete the full 5 days of treatment with the intervention, as well as the occurrence of any adverse events. Other measurements included any hospitalisations during the treatment period, as well as hospitalisations and mortality at 30 days after the intervention.

In addition to 24-hour monitoring, we also recorded two times per day observations (heart rate, blood pressure, oxygen saturations, respiratory rate, temperature), daily weight and daily blood tests (serum sodium, potassium, urea and creatinine levels). Point-of-care (POC) blood tests were measured daily, with formal laboratory blood tests (urea and electrolytes, as well as other clinically relevant bloods, as indicated) taken at baseline, day 2, day 5 and on the final visit.

Design

The intervention was a 5-day course of furosemide, delivered subcutaneously via a butterfly needle and standard T34 syringe infusion pump at a dose of 80 mg/day, over 5 hours. A standard formulation of furosemide was used. The SC furosemide was used to augment patients existing baseline oral diuretic regime. The idea for this project was conceptualised in discussions between cardiologists, nephrologists and pharmacists in the cardiorenal clinic. We soon realised that we would require the support of our primary care colleagues to deliver the intervention successfully and reached out to the primary care lead for cardiovascular projects in our local integrated care board. This enabled us to collaborate with primary care physicians, Central London Community Healthcare NHS Trust hospital-at-home team, and a remote monitoring hub. The hospital-at-home team were invaluable in the delivery of this project as they had experience in treating patients at-home, with the support of the remote monitoring hub. They also had existing governance structures in place, and thus, governance for this project was granted by and managed by Central London Community Healthcare NHS Trust hospital-at-home team, with institutional approval also obtained (Reference: MM030). This project was funded by Southwest London Integrated Care System Innovations Grant (IF003).

Strategy

This project involved two 'Plan Do Study Act' (PDSA) cycles. For the first cycle, once the above collaboration of professionals had been established, we collectively created a process map for this project. There were several aspects to consider, such as who would deliver the furosemide, who would hold ultimate responsibility for the project and how patient safety could be ensured at-home including out of hours. It was decided that the hospital-at-home team would deliver the intervention (ie, visit two times per day to set up and disconnect the SC furosemide infusion) and measure the required safety parameters as they had the capacity to provide a 7-day service. The community team were unable to provide vials of furosemide, so the secondary-care team were responsible for the prescribing and provision of furosemide. The community team provided the sharps bin for patients. We also needed to decide which patients would be suitable for the at-home intervention. It was decided that patients were suitable for the intervention if they met the following criteria: established diagnosis of CKD-HF (with estimated

glomerular filtration rate $<60\text{ mL/min/1.73m}^2$), acute fluid accumulation ($\geq 5\%$ increase in ideal body weight and/or oedema and/or bilateral basal chest crackles), already taking oral diuretics, mobile, and able and willing to provide informed consent. Patients were not suitable if they had electrolyte abnormalities, presence of an underlying illness requiring admission (eg, acute coronary syndrome or arrhythmia) or haemodynamic instability (heart rate >100 beats per minute, systolic blood pressure $<95\text{ mm Hg}$, respiratory rate >25 , oxygen saturations $<95\%$, temperature $>37.5^\circ\text{C}$, signs of respiratory distress). Patients were identified via the Emergency Department, outpatient clinics, community HF nurses or primary care physicians. Educational sessions were provided to staff working in the Emergency Department and acute medical unit to enable the referral of potentially suitable patients for consideration of the intervention.

The secondary-care team were responsible for the initial review of patients to determine their suitability. If suitable, a medication review was performed by our renal pharmacist, who then provided patients with seven vials of 80 mg furosemide at 10 mg/L . Patients were also provided with a holster bag for the syringe driver, as well as a chart to document their daily observations and an alert card containing the details of the project.

Following this initial review, the intervention was delivered primarily by the hospital-at-home team. They visited two times per day to set up and disconnect the SC furosemide infusion, measure the above-described parameters, including daily point-of-care blood tests and formal laboratory tests on days 2 and 5, and to ensure patient safety. If additional prescriptions were needed (eg, potassium supplements or oral diuretics), they provided these. The team also set up the remote monitoring equipment on

their first visit. This technology measured skin temperature, heart rate, oxygen saturations and respiratory rate continuously and sent this information to a remote monitoring hub. Patients could also measure their own blood pressure and submit this to the hub via Bluetooth. If these parameters fell outside of the prespecified range, this would be detected by the 24-hour monitoring hub, and staff from the hub would attempt to contact the patient to ensure that the equipment was correctly applied. If it was, and parameters were still out of range, or if they were unable to contact the patient, they would escalate; either to the hospital-at-home team during working hours, or the emergency services out of hours (the interactions between teams are depicted in figure 1). It was decided that the secondary-care team should provide remote clinical oversight for all patients, provide advice to the hospital-at-home team, where necessary, and review all patients face-to-face on day 7 to assess their response and adjust maintenance medications.

Following the initial planning stage, we recruited and began delivering the at-home intervention to the first five patients. After five patients had received the intervention, we studied what had gone well and what could be improved in a multidisciplinary meeting between primary and secondary care. Changes were made based on this discussion. Following this, the second PDSA cycle recruited and delivered the intervention in another five patients (figure 2).

The first PDSA cycle illustrated the difficulty in initiating frequent, timely changes to patient's regular medications as most of the participating patients used a blister pack. This introduced confusion for some patients regarding which of their regular medications they should be taking, as well as introducing delays as local pharmacies were

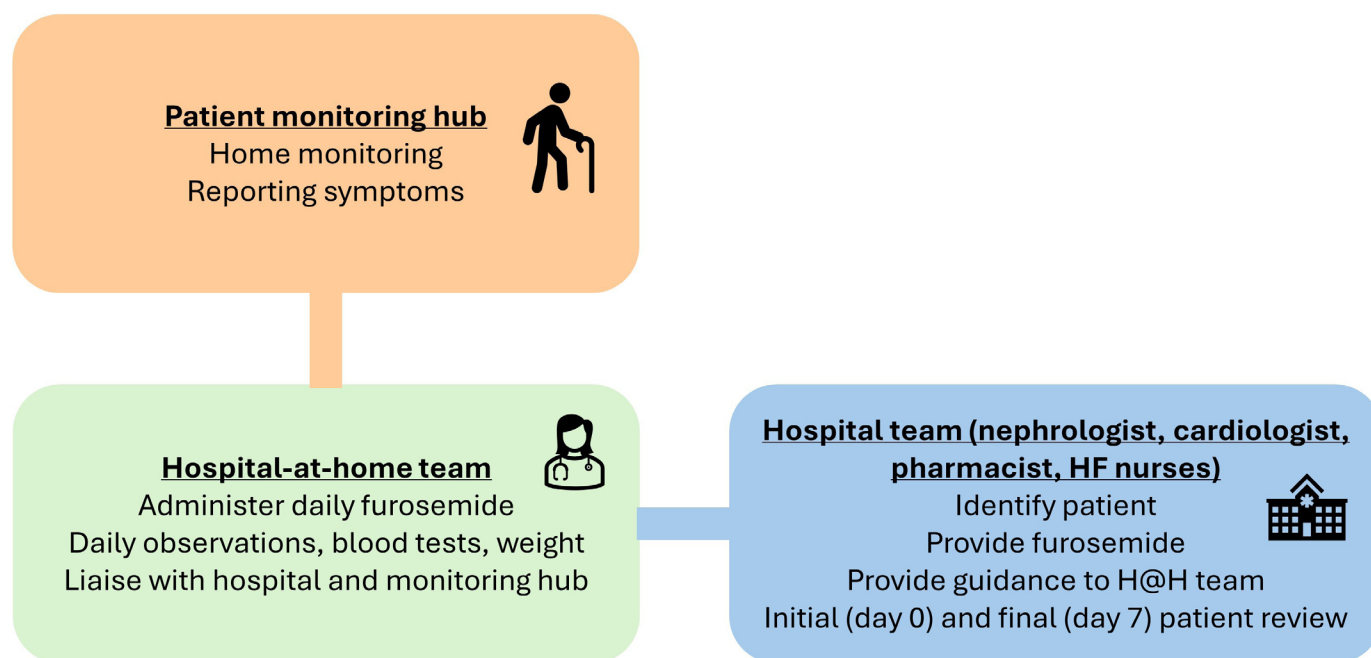


Figure 1 Team interactions between patient monitoring hub, hospital-at-home and the hospital team during the treatment period with subcutaneous furosemide. H@H, hospital-at-home.

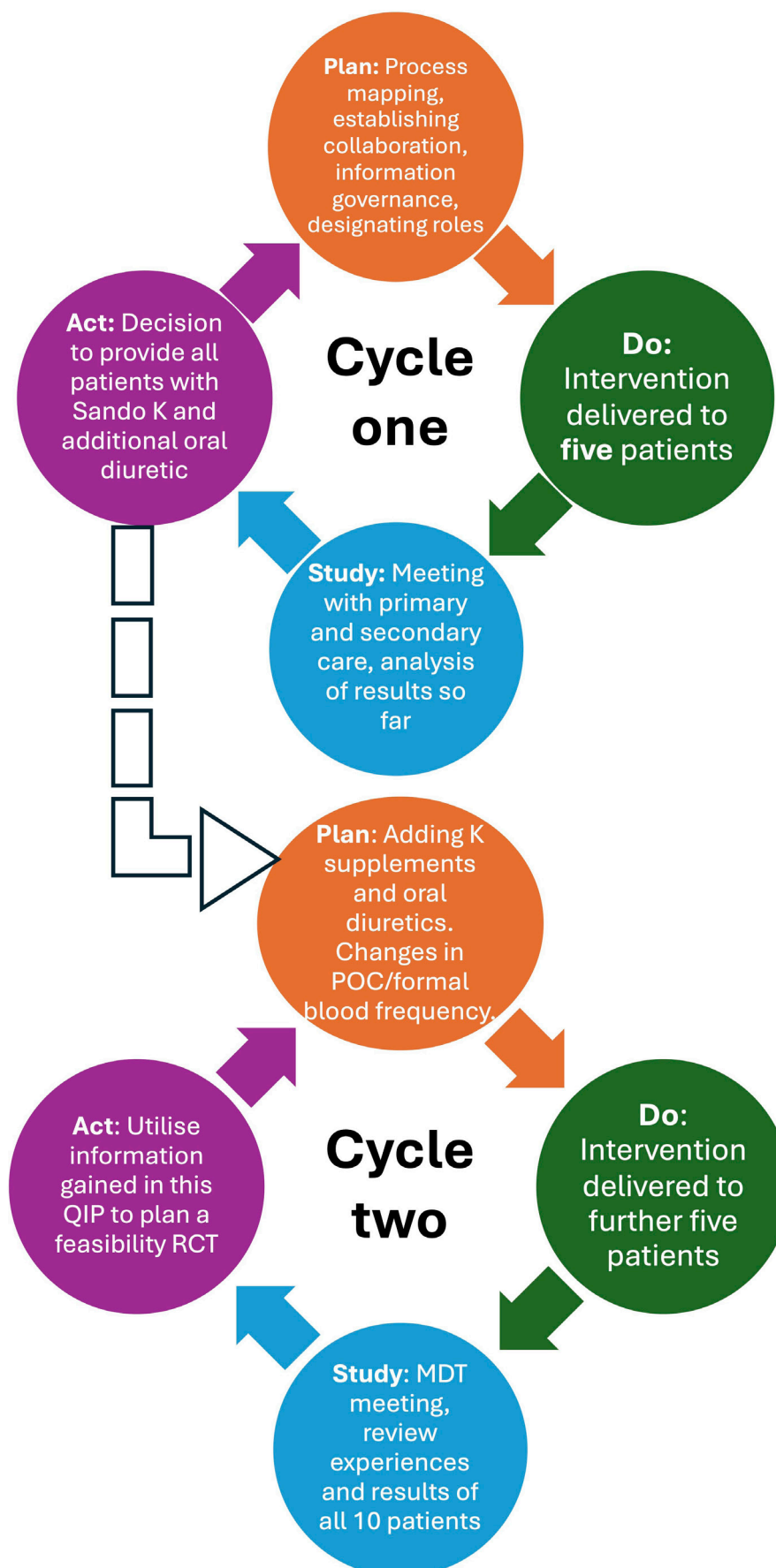


Figure 2 Figure depicting the two plan do study act (PDSA) cycles involved in this quality improvement project. MDT, multidisciplinary team; POC, point-of-care; QIP, quality improvement project; RCT, randomised controlled trial.

having to regularly uptake blister packs. On review of this, we decided that during the first visit in secondary care, all participating patients would be provided with a pack of potassium supplements and additional tablets of oral loop diuretic (furosemide or bumetanide, based on what they were taking at baseline). Patients were advised not to take this medication unless instructed. Thus, if patients required potassium supplementation or oral diuretics during the treatment period, the medication was readily available to them, which streamlined the process and enhanced patient safety. This was implemented in the second PDSA cycle with positive results.

Furthermore, in the first cycle, we learnt that the POC blood test results could vary considerably from the formal laboratory result. Consequently, we updated the protocol to repeat the point-of-care test and send formal laboratory blood tests, whenever the initial point-of-care blood test was unexpected. The formal laboratory blood tests were considered the 'gold standard' measurement.

There were also several successful components of our protocol. For example, we decided that the SC infusion should be given into patient's arm (rather than the abdomen), to avoid any potential absorption challenges caused by abdominal oedema. Each day, the hospital-at-home team checked the site of infusion for any discomfort, skin reactions and infusion failure. However, none of the above occurred and the delivery of SC furosemide was successful. Furthermore, using the holster bag to carry the syringe driver allowed patients to remain mobile while the infusion was running, which was appreciated by patients and caused no concerns.

Statistics used to evaluate the results

The Wilcoxon matched-pairs signed-rank test was used to compare average baseline and final-day parameters (weight, sodium, potassium, urea, eGFR, creatinine). Changes from baseline and daily rates of change of the above parameters per individual were estimated and adjusted for the corresponding baseline values. Mixed models were fitted to investigate the data trends with follow-up time. Between and within individual variability was accommodated for, and missing data were assumed to be missing at random.

RESULTS

Primary findings

In total, 10 patients (median age 81 (Q1–Q3 73–86), median baseline eGFR 36 mL/min/1.73 m² (Q1–Q3 22–47)) took part in our QIP and completed 5 days of treatment with the intervention (table 1). The intervention was acceptable to patients, and the delivery of the intervention was feasible with considerable primary and secondary-care collaboration. All participants avoided hospitalisation during the 5-day course of SC furosemide. One patient (patient 5 in table 1) required hospitalisation from their final review due to an increase in body weight over the final few days of treatment (104 kg increased to

105.2 kg) with ongoing congestion and died of sepsis of unknown origin during this admission. Furthermore, patient 9 had gained 4.5 kg of weight since baseline with admission recommended at their final review. They had capacity to decline this and were treated with increased oral diuretics in the community, but consequently, agreed for hospitalisation for intravenous diuretics 4 days later. Another patient was hospitalised with fluid overload 14 days after their final dose of SC furosemide. Two adverse events were reported; one episode of postural hypotension and one asymptomatic episode of ventricular tachyarrhythmia at 184 beats per minute lasting 30 s, detected on monitoring, requiring anti-tachycardia pacing to terminate the episode (potassium 4.3 mmol/L.) The latter patient had known arrhythmias and later required valvular intervention.

Secondary findings

Although the purpose of this QIP was to assess feasibility, we collected and analysed some objective measures of diuresis which are presented below, for the reader's interest. The median final weight was 85.85 kg (Q1–Q3 79.6–105.2), which was lower than the median baseline weight of 90.45 kg (Q1–Q3 80.6–107); however, this did not reach statistical significance ($p=0.051$). Using mixed models, the daily change in weight from baseline coefficient was -0.076 kg, meaning that, on average, each day patients weight reduced by -0.076 kg compared with baseline. The average daily rate of change in weight was 0.270 kg per day, indicating that the rate of weight loss increased daily (95% CI 0.066 to 0.474, $p=0.010$). There was not enough evidence to suggest that the final median creatinine, eGFR, sodium or urea levels were different to baseline median levels (Wilcoxon signed-rank p values 0.152, 0.438, 0.121 and 0.846, respectively.) There was also not enough evidence to suggest that median final potassium levels were lower than baseline (median final potassium 4.0 mmol/L (Q1–Q3 3.5–4.1) vs median baseline 4.05 mmol/L (Q1–Q3 3.9–4.7), $p=0.05$).

Lessons and limitations

The aim of this project was to assess the feasibility and acceptability of administering at-home SC furosemide to treat fluid overload in a small number of patients with CKD-HF. Inspired from the high hospitalisation burden in our cardiorenal clinic, we wanted to assess if this intervention could represent a feasible alternative. For this to be achieved, extensive collaboration was required between several parties including hospital specialists, hospital pharmacists, primary care physicians, a hospital-at-home team and a remote monitoring hub. A process of iterative PDSA cycles enabled us to learn how to navigate the interplay between primary and secondary care, successfully deliver this project, and has enabled us to build on our findings to plan a definitive randomised controlled trial.

Our project was successful in demonstrating that this intervention is feasible with primary care collaboration and may reduce the rate of hospitalisation in this

Table 1 Baseline characteristics and end results of 10 patients who took part in this project

Baseline				Results										
Patient	Age	Ethnicity	Gender	LVEF (%)	Baseline oral loop diuretic dose (mg)*	Baseline eGFR (mL/min/1.73 ²)	Baseline K+ (mmol/L)	End eGFR (mL/min/1.73 ²)	End K+ (mmol/L)	Weight change (kg)	A/E during 5-day period	Admission during 5-day period	30-day hospital admission	30-day mortality
1	84	White British	Male	50	200	25	4.3	27	3.9	-4.5	1†	0	0	0
2	60	Other	Male	39	80	50	3.9	62	3.1	-8.0	1‡	0	1	0
3	86	Mixed	Male	35	120	36	5	37	4.8	-0.6	0	0	0	0
4	89	Other	Female	55	60	22	3.9	23	3.5	-1.0	0	0	0	0
5	85	Other	Male	40	120	19	3.7	18	4.2	-1.8	0	0	1	1
6	73	Black or Black British	Female	30	120	48	4.1	42	3.6	-2.8	0	0	0	0
7	78	Black or Black British	Male	50	200	36	4.8	34	4.1	-1.0	0	0	0	0
8	88	Other	Female	25	120	47	4.7	42	4.1	-0.6	0	0	0	0
9	73	White British	Female	60	240	18	4	15	4.1	+4.5	0	0	1	0
10	78	White British	Male	47	200	43	3.9	41	3.5	-1.0	0	0	0	0
Proportion														

cohort. The findings from our project align with recently published studies which found that SC furosemide is well-tolerated with few side effects^{12 14} and achieves similar therapeutic levels and rates of diuresis as intravenous furosemide.^{13 15}

In terms of limitations, the weight loss observed in our project was less than expected,¹⁸ which may be partly attributable to diuretic resistance in patients with CKD-HF.¹⁹ In addition to this, data regarding fluid consumption were not collected. It is beyond the scope of this QIP with a small sample size and a lack of randomisation or comparison group, to comment on the efficacy of SC furosemide in CKD-HF patients. A hypothesis-testing trial is indicated, in which it will be important to explore diuretic resistance and optimal dosing of SC furosemide.

It is promising that eight out of the 10 patients who potentially required hospital admission at baseline were deemed not to require hospital admission following the SC furosemide course. This decision was based on a clinical evaluation and indices of decongestion, but we acknowledge that due to the 'open label' design of this project, bias may have influenced this decision. It will be important for the prospective trial to report several objective measures of congestion including weight, dyspnoea scale scores and NT-proBNP values, at baseline and the end of the study period. It will also be important to evaluate the health economics of such an intervention, as well as patient and carer experience and healthcare professional satisfaction.

Another limitation of this project is that, even in the final PDSA cycle, the process remained labour-intensive requiring two times per day visits from the hospital-at-home team nurses. This may limit the reproducibility of delivering this intervention in other locations, without a similar available workforce or resources. The prospect of novel pH-neutral furosemide solutions¹⁴ which can be infused subcutaneously using novel pump devices provides a great opportunity to reduce the number of staff required to deliver this intervention while increasing patient autonomy and improving the sustainability of such an intervention. In addition, while patient's primary care physicians were informed of their participation in this project and of any changes to their regular medications, they were not formally involved in the delivery of this intervention. Again, involving patient's own primary care physician may improve the sustainability of this intervention and protect against the dangers of siloed healthcare.

CONCLUSION

This novel QIP aimed to explore the safety and feasibility of SC furosemide to treat fluid overload in CKD-HF. Our experience suggests that with successful community collaborative, and an iterative quality improvement process, delivering this intervention is feasible and may reduce hospital admissions in this frail population. We believe that this intervention may help to preserve

patients' quality of life and functional status, as well as reducing the burden on healthcare systems. This exciting potential is important to pursue in a prospective randomised controlled trial.

Contributors DB and LA conceptualised the idea. ET, RM, AA, JN, VG, MA, MS, LB, TW, NA, GR, LA and DB all made significant contribution to the quality improvement project in its conception and execution, and the acquisition of data. ET, IC, SH and ICS performed the data analysis and interpretation. ET wrote the first draft of the manuscript, and all authors were involved in drafting, substantially revising, and critically reviewing the article, and agreed on the journal to which the article would be submitted. All authors have reviewed and agreed on the revised version of the article to submit and take responsibility and accountability for the work. DB is the guarantor.

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Competing interests None declared.

Patient and public involvement Patients and members of the public were not involved in the design or conduct of this quality improvement project but have been extensively involved in planning the subsequently required randomised controlled trial.

Patient consent for publication Not applicable.

Ethics approval This was a quality improvement project, the governance for which was granted by and managed by Central London Community Healthcare NHS Trust hospital-at-home team, with institutional approval also obtained (Reference: MM030). All patients gave informed consent to participate in this project. As it was a quality improvement project, further ethical approval was not indicated. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data will be available upon reasonable request from the corresponding author.

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