Appendices

Appendix I: Supplementary materials for research paper: Identifying and mapping measures of medication safety during transfer of care in a digital era: a scoping literature review

Literature search terms

Medline

Database: Ovid MEDLINE(R) ALL <1946 to May 19, 2022>
Search Strategy:
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1 (transfer* adj3 care).mp. (3892)
2 (escalation* adj3 care).mp. (558)
3 medic* discrepanc*.mp. (454)
4 medic* reconciliation.mp. (2508)
5 (transition* adj3 care).mp. (10410)
6 (hospital adj3 discharge).mp. (43449)
7 admission.mp. (235405)
8 Patient transfer/ (9417)
9 or/1-8 (290357)

10 insulin*.mp. or insulin/ or insulin passport*.mp. (453098)
11 (anticoag* or anti-coag*).mp. or anticoagulant agent/ (146420)
12 (("high alert" or "high risk") adj2 (medicine* or medication* or drug*)).mp. (1780)
13 (safe* or harm* or risk* or error* or hazard*).mp. (4559838)
14 (("high alert" or "high risk") adj2 (medicine* or medication* or drug*) adj4 (safe* or harm* or risk* or error* or hazard*)).mp. (1658)
15 ((insulin* or insulin passport*) adj4 (safe* or harm* or risk* or error* or hazard*)).mp. (7702)
16 ((anticoag* or anti-coag*) adj4 (safe* or harm* or risk* or error* or hazard*)).mp. (6653)
17 or/14-16 (15961)

18 9 and 17 (634)
19 limit 18 to (english language and humans) (480)

Embase

Database: Embase Classic+Embase <1947 to 2022 May 19>
Search Strategy:
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1 (transfer* adj3 care).mp. (7396)
2 (escalation* adj3 care).mp. (1240)
3 medic* discrepanc*.mp. (924)
4 medic* reconciliation.mp. (4382)
5 (transition* adj3 care).mp. (17795)
6 (hospital adj3 discharge).mp. (185175)
7 admission.mp. (536983)
8 Patient transfer/ (30946)
9 or/1-8 (714538)

10 insulin*.mp. or insulin/ or insulin passport*.mp. (922269)
11 (anticoag* or anti-coag*).mp. or anticoagulant agent/ (282900)
12 (("high alert" or "high risk") adj2 (medicine* or medication* or drug*)).mp. (3224)
13 (safe* or harm* or risk* or error* or hazard*).mp. (7041191)
14 (("high alert" or "high risk") adj2 (medicine* or medication* or drug*) adj4 (safe* or harm* or risk* or error* or hazard*)).mp. (2971)
15 ((insulin* or insulin passport*) adj4 (safe* or harm* or risk* or error* or hazard*)).mp. (11952)

16 ((anticoag* or anti-coag*) adj4 (safe* or harm* or risk* or error* or hazard*)).mp. (11555)
17 or/14-16 (26323)

18 9 and 17 (1763)
19 limit 18 to (human and english language) (1631)

Cochrane

Search Name: May22
Date Run: 20/05/2022 16:20:48

ID Search Hits
1. ((care near/1 model*)):ti,ab,kw OR ((model* near/1 service delivery)):ti,ab,kw OR ((model* near/1 (healthcare or health care or health-care))):ti,ab,kw OR ((transform* near/1 (service* or care))):ti,ab,kw (Word variations have been searched) 2641
2. MeSH descriptor: [Patient Transfer] explode all trees 166
3. (transfer near/3 care):ti,ab,kw OR (escalation* near/3 care):ti,ab,kw OR (medic* discrepanc*):ti,ab,kw OR (medic* reconciliation):ti,ab,kw OR (transition* near/3 care):ti,ab,kw 2754
4. #1 or #2 or #3 5410
5. ((safe* or harm* or risk* or error* or hazard*) near/4 (insulin* or anti-coag* or anticoag*)) 4690
6. ((safe* or harm* or risk* or error* or hazard*) near/4 ("high risk medicine" or "high risk medication" or "high risk medicines" or "high risk medications")) 70
7. ((safe* or harm* or risk* or error* or hazard*) near/4 ("high risk drug" or "high alert drug" or "high risk drugs" or "high alert drugs")) 37
8. ((safe* or harm* or risk* or error* or hazard*) near/4 ("high alert medicine" or "high alert medication" or "high alert medicines" or "high alert medications")) 6
9. #5 or #6 or #7 or #8 4796
10. #4 and #9 in Trials 38

Cinahl

EBSCOhost

Friday, May 20, 2022 2:10:37 PM

#	Query	Limiters/Expanders	Last Run Via	Results
S52	S35 AND S51	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S51	S50 n4 S49	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S50	S39 OR S44	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S49	S45 OR S46 OR S47 OR S48	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S48	errors or mistakes or incidents or adverse events	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S47	hazard*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display

S46	harm	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S45	safety or danger or risks	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S44	S40 OR S41 OR S42 OR S43	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S43	high alert medicine	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S42	high alert medication	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S41	high risk medicine	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S40	high risk medication	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display

S39	S36 OR S37 OR S38	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S38	anti-coag*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S37	anticoagulant therapy or anticoagulants	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S36	insulin	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S35	S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S34	medication discrepancies	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S33	medication reconciliation	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display

S32	medicine reconciliation	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S31	hospital discharge	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S30	hospital admissions or hospitalization or hospitalisation or hospital stay	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S29	transition of care	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S28	escalation of care	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S27	transfer of care	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	Display
S26	S9 AND S25	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	2,062

S25	s24 n4 s23	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	41,850
S24	S13 OR S18	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	110,092
S23	S19 OR S20 OR S21 OR S22	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	1,515,702
S22	errors or mistakes or incidents or adverse events	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	219,238
S21	hazard*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	118,537
S20	harm	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	42,032
S19	safety or danger or risks	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	1,332,654

S18	S14 OR S15 OR S16 OR S17	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	559
S17	high alert medicine	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	5
S16	high alert medication	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	170
S15	high risk medicine	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	39
S14	high risk medication	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	348
S13	S10 OR S11 OR S12	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	109,625
S12	anti-coag*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	417

S11	anticoagulant therapy or anticoagulants	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	28,087
S10	insulin	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	81,424
S9	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	147,848
S8	medication discrepancies	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	294
S7	medication reconciliation	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	2,572
S6	medicine reconciliation	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	85
S5	hospital discharge	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	14,505

S4	hospital admissions or hospitalization or hospitalisation or hospital stay	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	133,984
S3	transition of care	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	1,808
S2	escalation of care	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	193
S1	transfer of care	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	429

Review Protocol:

Identifying and mapping measures of medication safety during transfer of care in a digital era: A scoping literature review

Background:

When people experience ToC, they are at heightened risk of medication-related harm, particularly from high-risk medications.[1] Anticoagulants and insulin are high-risk medications used long term across all care settings in people of all ages. They have been the focus of safety improvement work, and issues related to ToC are well documented.[2,3]

For successful ToC, multiple activities and processes must be performed. Ten Key Components of an Ideal ToC (KCoIToC) from a hospital to a community setting have been described by Burke et al.[4] They include: discharge planning, complete communication of information, availability, timeliness, clarity and organisation of information, medication safety, educating patients to self-manage, enlisting social and community support, advance care planning, co-ordinating care among team members, monitoring and managing symptoms after discharge and outpatient follow-up.

Safety in health and care is maintained by the resilient adaptations of the people involved in performing the processes of ToC in response to the varying requirements and demands of the work system.[5] The Systems Engineering Initiative for Patient Safety (SEIPS) is a human-factors based framework designed to support visualisation of the health and care system "nested within" Donabedian's quality model of structure, process and outcomes.[6–9] It was created as a tool to support the in-depth understanding of health and care work-systems, and to identify barriers and facilitators of safety within them.

Measurement portfolios also require measures that provide insight into what has happened in the past and monitor this over (lagging measures) in addition to measures that can highlight areas of potential risk (leading indicators).[10] Digital technology allows greater and more immediate access to data, which could facilitate the use of leading indicators.

Objective

The aim of the literature review is to identify measures used to evaluate interventions improve the safety of anticoagulants, insulin, and high-risk medications during or after transfers of care. It aims to evaluate the comprehensiveness of these measures as a measurement portfolio.

The objectives are:

1. To systematically identify studies that evaluated an intervention designed to improve the safety of insulin, anticoagulants or high-risk medications as a group of medications
2. To identify all measures used and to map them according to three frameworks:
    a. How the measures relate to work systems, processes or outcomes using the SEIPS framework.[6]
    b. Whether the measures can provide evidence for the key components of a successful transfer of care according to the framework developed by Burke et al.[4]
    c. Whether the measures were lagging, leading or real-time.[10]
3. To identify any gaps in the measurements when assessed against the three frameworks.
4. To consider whether the measures could be identified in real-time with electronic health systems.

Criteria for inclusion and exclusion of studies

Table 1: Criteria for inclusion and exclusion of studies

	Included	Excluded
Population	Must focus on all three of the following: • Patients transferring between care settings (including between wards within a single organisation). • Patients taking anti-coagulants, insulin or high-risk medications in general.	• Focus on care in a single setting, e.g., Intensive Care Units with no reference to the transfer process. • Focus of study not on insulin, anticoagulants, or high-risk medications.
Construct of interest	Any measure used to describe the effectiveness of the safety intervention including: • Performance-based • Clinician-reported • Patient-reported	Studies that did not seek to determine whether intervention led to an improvement in safety or quality
Comparison	Comparison of patients who received the intervention compared with a control group, including randomised controlled trials, case-control and cohort studies.	Studies with no comparator groups, for example measures developed: • by expert opinion or Delphi consensus. • using population level data.
Outcomes	All measures used to assess whether the safety intervention had an impact will be identified from the studies and used for analysis to determine the comprehensiveness of the measures in terms of: • Whether they represent all the essential elements of transfer of care using the Key Components of an Ideal Transfer of Care framework. • Whether they provide insight into the work-system, processes and outcomes using the Systems Engineering Initiative for Patient Safety framework. • Whether they include lagging, leading and real-time measures. The potential for identifying the measure in real-time using electronic health systems will also be examined.	Measures where there is not enough description or detail to understand how these were obtained or calculated.
Study design	Primary research studies	Case reports, case reviews, review articles, unpublished studies, opinion pieces, cross-sectional studies.
Publication date	No limit	No limit
Language	English	Languages other than English

Search strategy for identification of studies

Four databases will be searched to identify relevant studies: Embase, Medline, Cinahl, and Cochrane databases. These are the prominent health and care related databases deemed most likely to contain studies relating to safety in healthcare.

Search terms will include:

- Transfer of care:
  - Transfer of care
  - Transition of care
  - Escalation
  - Medicine/medication discrepancies
  - Discharge
  - Admission
- Safety:
  - Safe
  - Harm
  - Hazard
  - Risk
  - Error
  - Resilience
- High-Risk Medications:
  - High-risk medication/medicine/drug
  - High-alert medicine/medication/drug
  - Insulin
  - Anticoagulants

Study Selection

An initial review of titles from the search results will identify any potentially meeting the inclusion criteria. A second review of the studies against the abstracts will identify any studies that do not meet the inclusion criteria. Where there is uncertainty, the full text of the article will be obtained to confirm. Any articles meeting the inclusion criteria will be selected, and the full text of the study will be obtained. Where articles are excluded, the reason for exclusion will be documented.

Assessment of methodological quality

The type of article will be identified and recorded, for example whether it was an article published in a journal, or an abstract presented at a conference. Methodological quality assessments will not be performed, as the aim of the study is to identify as many measures of improvement for medications during transfer of care as possible.

Method of data extraction

Each study included in the review will be listed in an excel spreadsheet. For each article, the full text will be read line-by-line and the following will be recorded:

- Citation (author and year of publication)
- Geographical location
- Type of study (design and publication type)
- Number of participants
- Intervention undertaken to improve safety
- Medication involved
- Type of transfer of care being investigated

- Measures used to evaluate the intervention
- Use of digital health systems in identifying, calculating or sharing the measurement data

Data synthesis

The author, CL, will review each measure and consider where they can be grouped together into a broader category, for example different types of adverse events. Each category of measure will then be mapped against three different frameworks in a table, using the framework synthesis approach.

The first framework is the Key Components of an ideal Transfer of Care.[4] This framework lists 10 stages of a discharge that must be completed for that transfer to be successful. By mapping against this framework, the measures will be assessed to understand whether they represent all the activities key to safe transfer. Each measure will be considered as to which component it best represents.

The second framework is the Systems Engineering Initiative for Patient Safety (SEIPS).[6–9] This conceptualises healthcare as taking place in a work system comprising of people, their environments, the tasks performed, and tools used. Processes are performed, and outcomes are influenced by the combination and interactions between the components of the work system and their impact on processes. The measures will be categorized as to whether they are providing insight into work systems, processes, or outcomes. Where possible, the author will use her knowledge and experience to consider what work system factors may influence the measure and list these.

Finally, the measures will be assessed to determine whether they measure past events (lagging indicators), provide an indication of whether an event may occur in the future (leading indicator), or provide real-time data about relevant measures.[10]

The results will be displayed in a table showing how the measures map across different frameworks, and where there are gaps and opportunities for new measures to be developed.

At each stage of data synthesis, the preliminary results will be shared and discussed with the co-authors (categorisation and mapping against each framework and consideration of digital use). The categorisation and mapping will be reviewed, and any ambiguities or challenges will be discussed and considered. The mapping and categorisation will then be agreed by all authors. This process will be repeated at regular intervals as the data synthesis progresses. The three authors are all healthcare professionals, two have a hospital-based background and one with a background in primary care. This provides insight into the context of the studies and measures identified and some aspects of the work-systems.

Results

The search results will use the PRISMA flowchart, detailing the review process and search results, how many articles were excluded and the reasons for exclusion for the exclusion for the articles where the full text was screened.

The included articles will be shared in a table listing the citation, type of study, intervention used, medication involved, the type of transfer of care studied and all the measures used to evaluate the intervention, and digital health system use. Descriptions of the geographical areas will be given in the text.

The measures mapped against the different frameworks will also be presented in a table, and a description of the gaps will be provided in the narrative text.

References:

1 World Health Organization. Medication Safety in Transitions of Care. 2019. http://apps.who.int/bookorders.

2 National Patient Safety Agency. Patient Safety Alert NPSA/2011/PSA003 The adult patient's passport to safer use of insulin. 2011.

3 NPSA. Patient Safety Alert 18: Actions that can make anticoagulant therapy safer (NPSA/2007/18). Published Online First: 2007.http://www.nrls.npsa.nhs.uk/resources/type/alerts/

4 Burke RE, Kripalani S, Vasilevskis EE, *et al.* Moving beyond readmission penalties: creating an ideal process to improve transitional care. *J Hosp Med* 2013;**8**:102–9. doi:10.1002/jhm.1990

5 Wiig S, Aase K, Billett S, *et al.* Defining the boundaries and operational concepts of resilience in the resilience in healthcare research program. *BMC Health Serv Res* 2020;**20**:1–9. doi:10.1186/s12913-020-05224-3

6 Holden RJ, Carayon P. SEIPS 101 and seven simple SEIPS tools. 2021;1–10. doi:10.1136/bmjqs-2020-012538

7 Carayon P, Schoofs Hundt A, Karsh BT, *et al.* Work system design for patient safety: The SEIPS model. *Qual Saf Health Care* 2006;**15**:i50. doi:10.1136/qshc.2005.015842

8 Holden RJ, Carayon P, Gurses AP, *et al.* SEIPS 2.0: a human factors framework for studying and improving the work of healthcare professionals and patients. *Ergonomics* 2013;**56**:1669–86. doi:10.1080/00140139.2013.838643

9 Carayon P, Wooldridge A, Hoonakker P, *et al.* SEIPS 3.0: Human-centered design of the patient journey for patient safety. *Appl Ergon* 2020;**84**:103033. doi:10.1016/j.apergo.2019.103033

10 Vincent C, Burnett S, Carthey J. Safety measurement and monitoring in healthcare: A framework to guide clinical teams and healthcare organisations in maintaining safety. *BMJ Qual Saf* 2014;**23**:670–7. doi:10.1136/bmjqs-2013-002757

Table 1: References and key information measures used

Year	Author and year	Article or abstract	Medication type	Intervention to improve safety	Care Transition	Electronic Health System Use	Measures used
2011	Avanzini et al.[1]	Article	Insulin	Standardised protocol	Intensive cardiac care unit to general ward	Not described	Percentage of blood glucose: • Within a narrow range on the first, second and third days after ToC • Within a wider range after meals on the first, second and third days after ToC Percentage of hypoglycaemia episodes on the first, second and third days after ToC Deaths Rates of main non-lethal cardiovascular complications
2011	Nordenholz et al.[2]	Abstract	Anticoagulant	Clinical care pathway	Emergency department to primary care	A standardized electronic order set	Laboratory ordering practices Readmission to an emergency department (ED) Readmission with deep vein thrombosis (DVT)
2011	Reger et al.[3]	Article	Anticoagulant	Discharge pathway	Hospital to primary care	Patients identified by scanning computer-based reports. Data collection.	Percentage patients with pharmacist coordination documented Pharmacist time spent per patient Recurrent venous thromboembolism (VTE) Major bleeding
2011	Schillig et al.[4]	Article	Anticoagulant	Pharmacist involvement	Hospital to primary care	Not described	Enrolment in anticoagulation clinic Documented inpatient-to-outpatient provider contact Documented inpatient provider-to-anticoagulation clinic communication Patient follow-up with the anticoagulation clinic within five days of discharge Composite of any INR[1] over 5, any episode of major bleeding or development of new

[1] INR stands for international normalised ratio, a blood test used to determine response to vitamin K antagonists (for example warfarin).

Year	Author and year	Article or abstract	Medication type	Intervention to improve safety	Care Transition	Electronic Health System Use	Measures used
							thromboembolic events within 30 days of hospital discharge
2011	Stafford et al.[5]	Article	Anticoagulant	Pharmacist involvement	Hospital to primary care	Not described	Major bleeding events within 90 days of discharge Thromboembolic events Rates of death Other adverse events (including minor bleeding) Unplanned hospital readmissions INR: • Control at eight days post-discharge and to day 90 • Rates of INR over 4 • Rates of INR within, below or above the therapeutic range Rates of persistence with warfarin therapy
2012	Falana et al.[6]	Abstract	Anticoagulant	Pharmacist involvement	Hospital to outpatient clinic	Not described	Major or minor bleeding Thromboembolic events INR greater than 5 Anticoagulation-related readmissions: • Emergency department (ED) visit • Readmission within 30 days of discharge Successful ToC to the next care provider at discharge.
2013	Martin III et al.[7]	Article	High-risk medications	Pharmacist involvement	Hospital to primary care	Pharmacy computer system produced a report identifying patients taking HRMs.	Percentage of discharge orders requiring resolution of: • Medication safety recommendations • Inadequate warfarin follow-up arrangements

Year	Author and year	Article or abstract	Medication type	Intervention to improve safety	Care Transition	Electronic Health System Use	Measures used
							• Unintentional medication changes Rate of physician acceptance of the team's clinical recommendations
2014	Falconieri et al.[8]	Article	Anticoagulant	TOC programme	Emergency Department to primary care	Not described	Follow up: • Percentage of patients who attended a follow-up appointment by 30 days • Time to follow-up appointment post-discharge Self-reported anticoagulation adherence Readmission rates Patient satisfaction
2014	Martins et al.[9]	Abstract	Anticoagulant	Outpatient clinic	Outpatient clinic to primary care	Not described	Time in therapeutic range Thromboembolic events Number of bleeding events
2015	Padron et al. [10]	Article	Anticoagulant	Anticoagulation stewardship program	Hospital to outpatient	Not described	Clinics: • Number of patients seen in clinic • Percentage of patients with therapeutic, subtherapeutic or supratherapeutic INR at clinic appointment • Appointment attendance Adverse events: • Bleeding • Thromboembolic events Readmissions to hospital or ED
2015	Dunn et al.[11]	Article	Anticoagulant	Information pack	Hospital to outpatient clinic	Retrospective administrative database review. Electronic health record use not	Change in the frequency of obtaining an INR value within 10 days of discharge Percentage patients attaining a therapeutic INR level within 10 days of discharge

Year	Author and year	Article or abstract	Medication type	Intervention to improve safety	Care Transition	Electronic Health System Use	Measures used
						described.	Clinician satisfaction
2015	Quach et al.[12]	Abstract	High-risk medications	Medication reconciliation	Primacy care to the Emergency Department	Not described	Potential for errors discovered to cause patient harm or discomfort
2015	Yilmaz et al.[13]	Abstract	High-risk medications	Medications reconciliation and discharge counselling	Hospital to primary care	Not described	Adherence Rate of medication reconciliation discrepancies Readmission rates Patient satisfaction
2016	Ha et al.[14]	Article	Anticoagulant	Standardised protocol	Hospital to primary care	Patient with medication interactions were identified retrospectively using electronic health record. Standardised data extraction form developed.	Time in therapeutic range Rates of the following during the time of interaction or within 30 days of antimicrobial discontinuation: • Thromboembolic events • Major bleeding events Documentation rates of significant antimicrobial-warfarin interactions
2017	Bryant et al.[15]	Abstract	Anticoagulant	Pharmacist involvement	Emergency department to primary care	Not described	Percentage of patients who received appropriate anticoagulation at time of discharge Number of patients with a pharmacist intervention Rates of patient education provided prior to discharge Time to outpatient follow-up

Year	Author and year	Article or abstract	Medication type	Intervention to improve safety	Care Transition	Electronic Health System Use	Measures used
2017	Castelli et al.[16]	Article	Anticoagulant	Information pack for patients	Hospital to primary care	A daily report generated to identify patients diagnosed with VTE prescribed rivaroxaban.	Percentage of patients who: • Transitioned to rivaroxaban 20 mg daily on day 22 • Had greater than 90% adherence • Stopped rivaroxaban for any reason Adherence Patient understanding of correct dose and timing of medication Overall satisfaction (patient) Rates of: • Minor bleeds • Events that required contacting physician or visiting an emergency department • Recurrent VTE • Death
2017	Chamoun et al.[17]	Article	Anticoagulant	Standardised protocol	Hospital to primary care	A report was generated from a patient database, and data collected from electronic healthcare records.	Bleeding: • Rates of bleeding events • INR on day bleeding occurred • Severity of bleeding event • Total number INR: • Composite of changes by 0.5 or more per day or INR greater than 4 during inpatient stay and follow up Percentage of patients achieving a therapeutic stable INR by day 7 and by day 14
2017	Wei et al.[18]	Article	Insulin	Remote glucose monitoring	Hospital to primary care	Remote monitoring of glycaemic control using a web-based communication portal.	Mean blood glucose level Exploratory outcomes of hypoglycaemia/hyperglycaemia Insulin titration frequency

Year	Author and year	Article or abstract	Medication type	Intervention to improve safety	Care Transition	Electronic Health System Use	Measures used
2017	Zdyb et al.[19]	Article	Anticoagulant	Counselling and education	Emergency department to primary care	Electronic health record used to identify patients requiring interventions. Standardised electronic form for documentation.	Appropriateness of medication dosing Rates of prescription collection If patient had contacted or seen their primary care provider Documented readmission or representation to a hospital within 90 days potentially related to anticoagulation
2018	Herges et al.[20]	Article	High-risk medications	Pharmacist involvement	Hospital to primary care	Electronic health record used to calculate risk of patient death or unplanned readmission. Used to calculate percentage of drug therapy problems and medication discrepancies metrics.	Readmission risk at 30, 60 and 180 days Number of drug therapy problem recommendations for all medications and HRMs Percentage of recommendations that were acted on by the clinician within 7 days Number of medication discrepancies for all medications and for HRMs
2019	Dempsey et al.[21]	Abstract	High-risk medications	Pharmacist involvement	Hospital to primary care	Not described	Average number of medication discrepancies per patient Number of medication access issues resolved 30-day medication related hospital readmissions
2019	Pyrlis et al.[22]	Article	Insulin	Transition diabetes team	Hospital to primary care	Not described	Hospital readmissions and emergency department presentations Patient satisfaction Change in HbA1c
2020	Kapoor et al.[23]	Article	Anticoagulant	Pharmacist involvement	Hospital to primary care	Nurse reviewed medication list and provided an up-to-date colour version with instructions to the patient by mail.	Quality of care transition using Coleman et al.'s Care Transition Measure (CTM) Patient knowledge regarding anticoagulation, interactions, risks, signs, and symptoms to report to prescriber Anticoagulant beliefs

Year	Author and year	Article or abstract	Medication type	Intervention to improve safety	Care Transition	Electronic Health System Use	Measures used
2020	Liang et al.[24]	Article	Anticoagulant	Pharmacist involvement	Hospital to primary care	Not described	Proportions of time within the target INR range during follow-up period Proportions of time within the expanded target range during follow-up period Time spent outside the critical INR range (≤1.5 or ≥ 5.0) Adverse events: • Bleeding • Recurrent thrombosis • Death Readmission Warfarin-related knowledge level
2020	Lim et al[25]	Article	Anticoagulant	Outpatient clinic	Emergency department to outpatient clinic	Guidance to clinicians via an electronic clinical decision support tool.	Readmissions Thromboembolic events Bleeding events
2020	Tyedin et al.[26]	Article	Anticoagulant	Pharmacist involvement	Hospital to primary care	Electronic health record used by pharmacists to chart and monitor warfarin. Electronic health records used for data collection.	Proportion of patients: • With an INR greater than 5.0 • Readmitted relating to anticoagulation • With a complete warfarin dose plan at discharge • With warfarin related errors during admission
2021	Andre et al.[27]	Abstract	Anticoagulant	Medication Reconciliation	Primary care to hospital	Not described	Frequency and type of reconciliation discrepancies at admission and discharge Patient knowledge Medication discrepancies rated for severity

Year	Author and year	Article or abstract	Medication type	Intervention to improve safety	Care Transition	Electronic Health System Use	Measures used
2021	Bakey et al.[28]	Article	Anticoagulant	Pharmacist involvement	Emergency department to primary care	EHS used to identify eligible patients and document pharmacist recommendations.	Rates of issues relating to care components: • Anticoagulation medication errors at discharge • Patient counselling on anticoagulation • Anticoagulation prescription at discharge Adverse events: • ED or hospital admission for bleeding within 30 days • ED or hospital admission for VTE within 30 days
2021	Bawazeer et al.[29]	Abstract	High-risk medications	Medication Reconciliation, counselling and follow up	Hospital to primary care	EHS used to identify patients on insulin and/or warfarin and for data collection	Adverse events: • Readmission rate within 30 days of discharge • Time to first unplanned health care utilization Time to the first outpatient clinic visit Disease-specific parameters (glycosylated haemoglobin (HbA1C) and INR Number of medication-related problems identified during the reconciliation stage Patient satisfaction with the service
2021	DeSancho et al.[30]	Journal	Anticoagulant	Counselling and education	Hospital to primary care	Not described	Scheduled follow up appointment Re-admission rates Adverse events: • Recurrent thrombosis • Bleeding events Adherence Anticoagulant recall errors: • Dose • Dose frequency

Year	Author and year	Article or abstract	Medication type	Intervention to improve safety	Care Transition	Electronic Health System Use	Measures used
2021	Gurwitz et al.[31]	Article	High-risk medications	Pharmacist involvement	Hospital to primary care	Communication with primary care team through the EHS relating to medication safety. Data collection.	Number of adverse drug-related incidents Clinically important medication errors
2021	Kane-Gill et al.[32]	Article	High-risk medications	Pharmacist involvement	Primary care to nursing home	Electronic clinical surveillance system highlighting medication risks.	Patient care recommendations evaluated by degree of harm prevented
2021	Magny-Normilus et al.[33]	Article	Insulin	Discharge intervention	Hospital to primary care	Patients identified by scanning EHS reports. Data collected using hospital's clinical data repository.	Adherence Monitoring: • Glycaemic control - change in A1c 60 to 120 days after discharge compared with the A1c in the 90 days before or at the time of index hospitalization • Proportion of monitored patient-days with severe hypoglycaemia (less than 40 mg/dL) within 30 days of discharge Readmissions
2021	Zabrosky et al.[34]	Abstract	High-risk medications	Standardised protocols for ToC	Hospital to primary care	Not described	Rate of referral to outpatient follow-up Readmissions Successful TOC protocol completion where evaluation/performed and documentation of following documented: • Baseline laboratory values • Therapeutic drug monitoring • Intravenous access • Drug-drug interactions • Medication availability • Patient counselling on medications • Pharmacist documentation in discharge

Year	Author and year	Article or abstract	Medication type	Intervention to improve safety	Care Transition	Electronic Health System Use	Measures used
							letter Pharmacist time Rate of inappropriate protocol initiation
2022	Lázaro Cebas et al.[35]	Article	High-risk medications	Pharmacist involvement	Hospital to primary care	Not described	Readmissions Cost of intervention

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Appendix II - Supplementary materials for research paper: Seeking systems-based facilitators of safety and healthcare resilience: a thematic review of incident reports

Supplementary Information: Incident reporting system search terms

Medication names included: apixaban, heparin, dalteparin, enoxaparin, rivaroxaban, edoxaban, dabigatran, warfarin, tinzaparin and fondaparinux (along with their associated trade names)

Key terms and abbreviations commonly associated with anticoagulation were: “INR”, “APTT”, “VKA”, “NOAC”, “DOAC”, “LMWH”, Vitamin K, Phytomen*, Anticoag*, Anti-coag*, PCC, Prothrombin and Octaplex.

Abbreviations were not written in full where the components were already included as search terms, for example, the term Low Molecular Weight Heparin (abbreviated as LMWH) would be identified by the term heparin.

Appendix III – Topic Guides for semi-structured interviews

Topic Guide for Semi-structured interviews with patients and/or their caregivers

Introductory section:

- Introductions, welcome, thank participant for attending,
- Make sure participants are comfortable, technology working, what to do if call fails etc.
- Describe purpose of the interview (no right or wrong answers)
- To understand the interviewee's experiences of using insulin, particularly when moving between hospital and home.
- To find out whether there has been anything that helped with using insulin safely in their experience and also, what has made insulin use less safe.
- The interview should last up to an hour depending on how much you would like to share.
- I will take some notes, just to make sure that I don't miss anything that I might want to come back to later and to help me remember my thoughts

Confirm Consent

- Ensure participant understands the consent form
- Participation is completely voluntary, and participant can decide to stop at any time
- Participant does not have to answer all questions
- All responses will be confidential
- The interview will be recorded with permission and transcribed with no identifying details. Once the written account of the interview has been confirmed as correct, the original recording will be deleted.
- No identifying information will be in the transcript or contained in the report.

Confirm participant is happy for interview to be recorded, state that record button being pressed now.

Opening questions

Can you tell me about your recent hospital stay?

How was your insulin managed during this time?

Prompts for conversation:

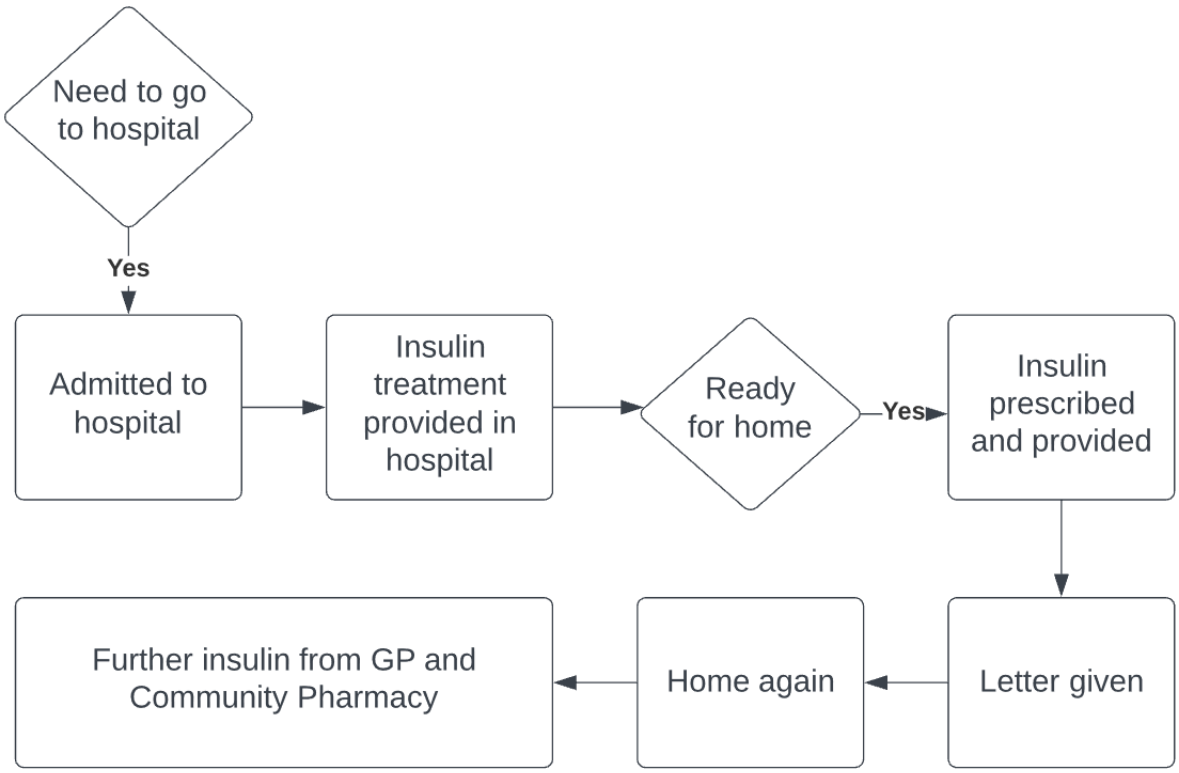
- Did you take your insulin with you?
- Were you able to administer it yourself?
- Did someone help you?
- Did the staff at the hospital know what to give you?
- Were there any changes to your insulin?
- Did you understand what was happening with your insulin?
- What information were you given about your insulin when it was time for you to go home?
- Did you have any issues with your insulin when you got back home? (enough supply, clear instructions)

Have you found anything that makes using insulin easier?

Process map:

This is a very basic map I've made trying to show the path that someone on insulin takes while they are in hospital and then returns home.

I would like to look at this map with you to find out whether you agree with the process of going to hospital and back home again. Are any gaps or parts that are not relevant or accurate?



(Anticipate person to have experienced some of the following: blood glucose monitoring, counselling, obtaining medicine, admission to hospital, clerking, discharge, communication of discharge with GP and pharmacy)

If you have experienced any of these steps, please could you describe the experience for you, we can compare it to this diagram and make changes to it so that it's more accurate.

We would like to speak to the healthcare professionals who were involved in managing your insulin. None of our conversation will be shared with them. We would like to understand how their role in helping you manage your insulin. Please could you tell me who they are?

Closing:

Do you have any other thoughts or concerns or issues about insulin that you want to raise?

Thank participant for taking part in the interview.

Topic Guide for Semi-structured interviews healthcare professionals

Introductory section:

- Introductions, welcome, thank participant for attending,
- Make sure participants are comfortable, technology working, what to do if call fails etc.
- Describe purpose of the interview (no right or wrong answers)
- To understand the interviewee's experiences of using insulin, particularly when moving between hospital and home.
- To find out whether there has been anything that helped with using insulin safely in their experience and also, what has made insulin use less safe.
- The interview should last up to an hour depending on how much you would like to share.
- I will take some notes, just to make sure that I don't miss anything that I might want to come back to later and to help me remember my thoughts

Confirm Consent

- Ensure participant understands the consent form
- Participation is completely voluntary, and participant can decide to stop at any time
- Participant does not have to answer all questions
- All responses will be confidential
- The interview will be recorded with permission and transcribed with no identifying details. Once the written account of the interview has been confirmed as correct, the original recording will be deleted.
- No identifying information will be in the transcript or contained in the report.

Confirm participant is happy for interview to be recorded, state that record button being pressed now.

Opening question

Please can you tell me a bit about your role, and how you are involved in supporting insulin use for people when they are admitted or discharged from hospital?

Prompts for conversation:

- Which health care setting do you work?
- In what ways have you had to manage or support someone to use insulin? (supply, prescribe, identify doses, medicine reconciliation, provide advice)

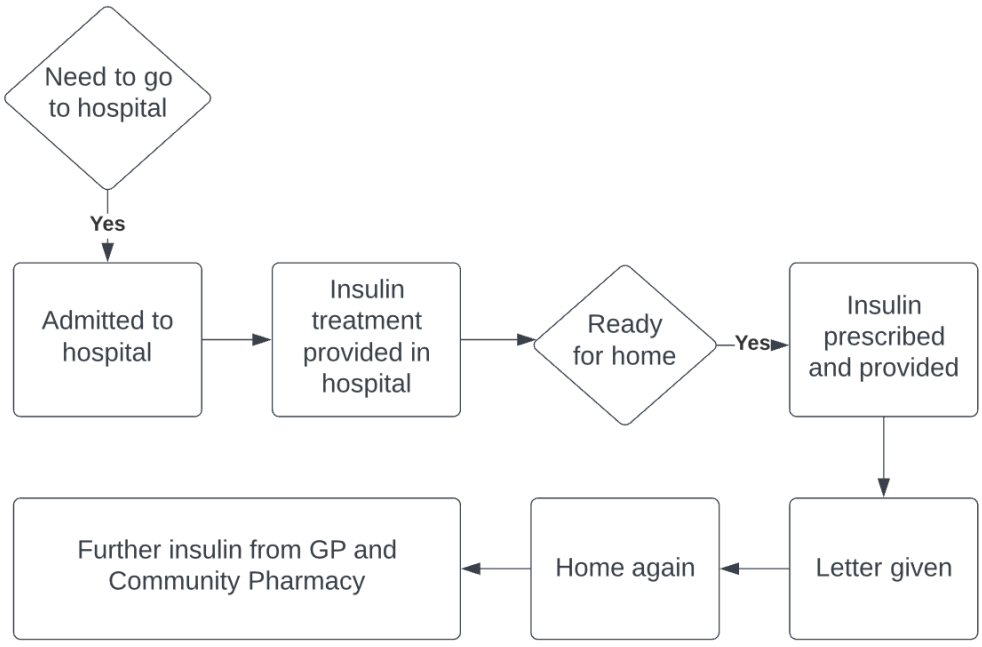
- What are some of the things that are/have been successful about insulin use in your experience?
- What are some of the challenges you have experienced in insulin use?
- What are the barriers to using insulin safely?

What experience have you had with insulin and electronic patient records?

- Can you order your insulin electronically
- Do you have to upload blood glucose tests or is this done automatically?
- Have you communicated with healthcare professionals in another setting using electronic records?
- How have electronic patient records helped to make insulin use safer?
- What are the challenges with insulin use and electronic patient records?

This is a very basic map I've made trying to show the path that someone on insulin takes while they are in hospital and then returns home.

I would like to look at this with you to find out whether you agree with the map, or if there are any gaps or parts that are not relevant or accurate. (Anticipate person to have experienced some of the following: blood glucose monitoring, counselling, obtaining medicine, admission to hospital, clerking, discharge, communication of discharge with GP and pharmacy).



If you have been involved with any of these steps, please could you describe the experience for you, we can compare it to this diagram and make changes to it so that it's more accurate.

Closing:

Do you have any other thoughts or concerns or issues about insulin that you want to raise?

Thank participant for taking part in the interview.

Topic Guide for Semi-structured interviews with digital health system professionals

Introductory section:

- Introductions, welcome, thank participant for attending,
- Make sure participants are comfortable, technology working, what to do if call fails etc.
- Describe purpose of the interview (no right or wrong answers)
- To understand how insulin is managed safely and monitored using digital health systems
- To find out whether there are additional opportunities for measuring and monitoring the safe use of insulin in digital health systems, and what the barriers and facilitators of these may be.
- The interview should last up to an hour depending on how much you would like to share.
- I will take some notes, just to make sure that I don't miss anything that I might want to come back to later and to help me remember my thoughts

Confirm Consent

- Ensure participant understands the consent form
- Participation is completely voluntary, and participant can decide to stop at any time
- Participant does not have to answer all questions
- All responses will be confidential
- The interview will be recorded with permission and transcribed with no identifying details. Once the written account of the interview has been confirmed as correct, the original recording will be deleted.
- No identifying information will be in the transcript or contained in the report.

Confirm participant is happy for interview to be recorded, state that record button being pressed now.

Opening question

Please can you tell me a bit about your role, and how you are involved in digital health systems?

Prompts for conversation:

- Which systems do you work with?
- Please could you describe your role?

In terms of insulin and/or diabetes in general, how are these managed in the digital health system you work with?

Prompts for conversation:

- What are the benefits of using digital systems for insulin management?
- What are some of the challenges?
- What opportunities are there?
- How is the safe use of insulin affected by the digital health system (challenges/difficulties, improvements, opportunities)

Are there any measures of safety in this electronic health systems? Could you describe this for me?

Prompts for conversation:

- For example, dashboards for diabetes, monitoring, highlighting people who need urgent attention
- Are there any ways that the safe use of insulin is monitored in this digital system?
- Are there any challenges with monitoring/measuring?
- What are the opportunities?

Closing:

Do you have any other thoughts or concerns or issues about insulin in digital health systems that you want to raise?

Thank participant for taking part in the interview.

Topic Guide for Focus Groups

Introductory section:

- Introductions, welcome, thank participant for attending.
- Make sure participants are comfortable, technology working, what to do if call fails etc.
- Describe purpose of the focus group.
- If meeting is virtual, use the raise hand function to let me know if you want to say anything and feel free to add comments into the chat box.
- To work as a group to agree what are the key activities that are needed to make sure insulin is used safely when people are admitted and discharged from hospital (no right or wrong answers).
- The focus group will last up to two hours.
- I will take some notes, just to make sure that I don't miss anything that I might want to come back to later and to help me remember my thoughts.

Confirm Consent

- Participation is completely voluntary, and participant can decide to stop at any time.
- All responses will be confidential.
- The focus group will be recorded with permission and transcribed with no identifying details. Once the written account of the interview has been confirmed as correct, the original recording will be deleted.
- No identifying information will be in the transcript or contained in the report.

Confirm participants are happy for interview to be recorded, state that record button being pressed now.

Introductions

Thank you all for coming. We have a mix of healthcare professionals from different settings and patients who use insulin and caregivers. Everybody will be given an opportunity to speak and contribute.

Please can we introduce ourselves, saying our names and what we like to best if given some free time.

This is a special type of map that you might not have come across together. Here's a simple one that shows how someone might do their washing. You can see the goal of the task is to have clean washing, but the steps are broken down into the different key activities that need to be done to wash clothes.

I've developed a map of activities that are done when patients who take insulin are admitted and discharged from hospital.

During this session, I'd like us to go through the map of insulin activities together, and make sure it's accurate, or if there are any gaps or parts that are not relevant.

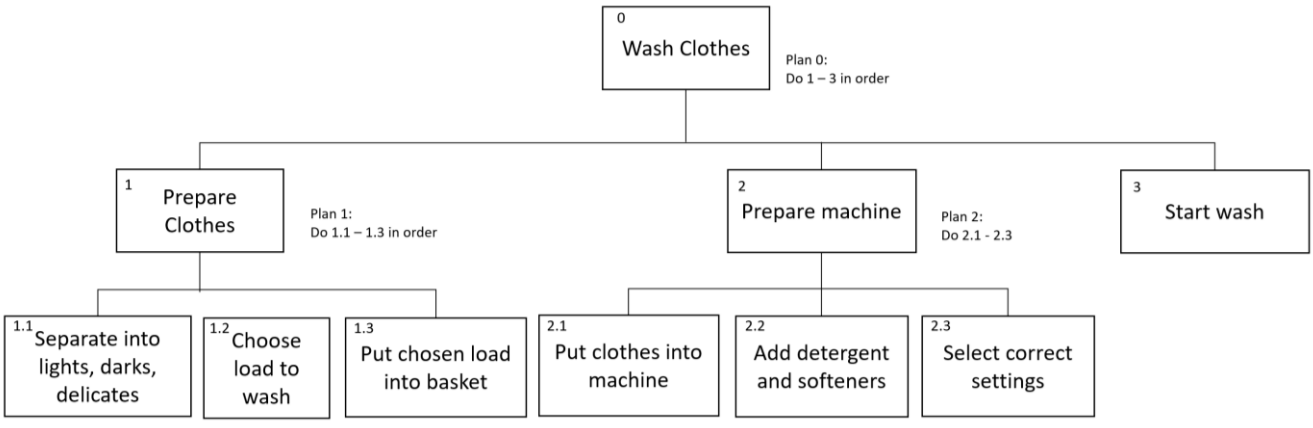
You've all been given some post-it notes that you can write any other activities you think of onto, or any comments. Feel free to attach these to the relevant step or part of the map. (If doing virtually, participants will be able to add post-it notes to a virtual whiteboard). I'll give you all some time to look at the map before we begin. Please ask me if you have any questions.

Let's go through the map systematically. For each step:

- Have we missed a key step that should have been done before this?
- Do you agree this is a key activity for insulin management during hospital admission/discharge? (why/why not?)
- Are there lots of steps involved in this activity? (what are they, do we need to describe them in detail?)
- What might impact this activity?

Closing:

Do you have any other thoughts or concerns or issues about insulin that you want to raise?



Thank participants for taking part in the focus group. There were some steps that we did not cover today. Would you be interested in meeting again to look at these? If yes, I will be in touch to confirm.

Appendix IV: Search terms used to identify national learning and response system incident reporting data

Search terms used:

Admission OR discharge OR transfer

AND

Any of the insulin terms in the table below:

Insulin	Aspart	Insuman	Xultophy	Novo	Solostar
Sliding scale	Glargine	Actrapid	Fiasp	Autopen	Innolet
	Glulisine	Humulin	Trurapi	Humapen	Optipen
	Determir	Apidra	Abasaglar	Kwikpen	Optiset
	Lispor	Humalog	Semglee	Tempo	Innovo
	Isophane	Levemir	Toujeo	Flexpen	
	Degludec	lantus	Sliqua	Penfill	
		Insulatard	Admelog	Flextouch	

Appendix V: Descriptions of ten journeys described in representative incident reports

The following incidents were selected from the NRLS data to represent different aspects of PWDI journeys across ToC.

1. A PWDI was admitted to hospital with gastroenteritis. Because he was eating and drinking less, his insulin doses were reduced. He was discharged home without being referred to the district nurses. He was already on the district nursing list of patients from before admission. When a district nurse visited him, the difference between the hospital doses and their records was identified. The GP was requested to update their prescription, and the district nurse monitored the PWDI's blood glucose levels. The GP reviewed blood glucose levels and discharge letter and decided that the PWDI should return to his previous insulin dose now that the gastroenteritis had resolved.
2. A person was started on insulin during a hospital admission, but no referral was made to the district nurses. The PWDI's daughter was not taught how to manage diabetes and insulin. The GP made a referral to the district nurses to provide training for diabetes management and to administer insulin.
3. A PWDI was admitted to hospital for surgery. Before the surgery she was fasting. The nurse administered her normal dose of insulin, despite the PWDI asking whether she should have this dose. The lady subsequently experienced hypoglycaemia and required an infusion of glucose. A referral was made to the hospital diabetes specialist nurses who advised on further management.
4. A PWDI was admitted to hospital. His usual insulin doses were prescribed to be given only "when required." He missed several doses of insulin before this was identified.
5. A PWDI was due to have surgery. Before he went into hospital, he was unable to source his normal insulin and missed about two doses. When he was admitted to hospital, the ward did not stock his normal insulin, and he missed further doses. He was not eating or drinking because he was due to have surgery, and when his blood glucose levels were checked, they were very high. This was treated with an insulin infusion. His normal insulins were supplied by the pharmacy, but there was a delay in administering them.
6. A PWDI attended the emergency department. His family were with him. When he was moved to the ward, a nurse tried to identify whether he was due to have his insulin dose. His family said that he had been given his insulin, but this had not been documented on the electronic health record.

7. Insulins and other medications were given to a PWDI ready to be discharged from the hospital. While waiting to go, his blood glucose levels were checked and were high. The PWDI took his insulins to manage the high levels. He was kept in hospital for three hours to monitor his blood glucose.
8. A PWDI started on insulin was discharged from hospital. He noticed that his blood glucose levels were high despite administering his insulin. He went to the GP who identified that he had been given a placebo insulin pen that had been used for training to take home and was therefore not getting any insulin.
9. A PWDI was admitted to hospital. He usually took a mixed insulin (Mix 50), however because this was not kept on the ward, a doctor prescribed a smaller dose of the same type of mixed insulin but with different proportions (Mix 25). His blood glucose levels were monitored regularly to review the impact of this change. The pharmacists identified the change and arranged a supply of his normal insulin the following morning.
10. A PWDI was discharged from hospital without a supply of any equipment, needles, sharps bin, lancets or monitoring strips. The PWDI was then unable to monitor his blood glucose levels or administer his insulin.

Appendix VI: Functions identified and descriptions of their definition and aspects

Title	1. Decide hospital admission needed
Description	PWDI, informal caregiver (for example spouse, child, other relative or friend), a healthcare professional working in primary care, for example, district nurses, GP, primary care pharmacist, paramedic, 111 call handler, or staff in an outpatient clinic identify acute illness that requires assessment and/or treatment in an inpatient hospital setting. Person making decision for admission must be aware that symptoms are abnormal and concerning and PWDI must be seeking help or in obvious need of medical attention (e.g. collapse).
Input	Signs and symptoms of illness
Output	PWDI to attend hospital HCP refer to hospital for admission Ambulance to transport PWDI PWDI makes own way to hospital
Precondition	Acute illness
Resources	Staff available Task prioritisation Staff diabetes knowledge PWDI diabetes knowledge Caregiver diabetes knowledge Electronic health records IT available
Control	Admission pathways available Organisational handover guidelines
Time	

Title	2. Pack belongings for admission
Description	PWDI, caregiver and/or paramedic identify patient belongings needed for managing insulin during admission to hospital. This includes information about insulin, the insulin and device itself, carbohydrates, equipment for

	blood glucose and ketone monitoring (including phone and charger). Other belongings also gathered, but not relevant to this FRAM.
Input	PWDI makes own way to hospital Ambulance attends PWDI to provide transport
Output	Ready to attend hospital
Precondition	PWDI must be at home or have belongings with them
Resources	PWDI insulin supply available Access to and availability of insulin, equipment, and carbohydrates Access to and availability of insulin information (e.g. monitoring records, clinic letters) Knowledge of where to find insulin and equipment, e.g. general knowledge that unused insulin is stored in fridge Availability of PWDI and/or caregiver who can direct to specific locations of belongings Caregiver or paramedic who can gather items while PWDI acutely unwell
Control	Admission pathways available Organisational handover guidelines Preparing for hospital admission guidelines for PWDI (RPS Keeping patients safe when they transfer between care providers, Seven simple steps for keeping safe in hospital, Diabetes UK) Advice/instructions from 111 call handler or healthcare professional
Time	Ideally completed before transport to hospital Completed as quickly as possible, next function will start before completion if not done. Caregiver may complete after PWDI admitted to hospital

Title	**3. Travel to hospital**
Description	PWDI travels to hospital via ambulance or through own means (taxi, lift, walk) and attends a clinical area that deals with acute medical or surgical issues (can be ED, MAU, ambulatory unit, surgical emergency unit etc...). Where via ambulance, the input is PWDI to attend hospital, where own means, input is ready to attend hospital.
Input	PWDI to attend hospital Ready to attend hospital

	Ambulance attends PWDI to provide transport PWDI makes own way to hospital
Output	Arrival at hospital emergency unit
Precondition	Transportation available
Resources	Vehicle for transportation Person to drive vehicle Money for taxi Emergency unit available to attend Staff available (ambulance) Task prioritisation
Control	Admission pathways available
Time	Must occur before admission to hospital

Title	**4. Arrange ambulance**
Description	PWDI calls ambulance, or healthcare professional working in primary care or in NHS 111 recognises serious acute illness requiring urgent transport into hospital under supervision of paramedics. They arrange an ambulance either by phoning or using alternative system.
Input	Ambulance to transport PWDI
Output	Ambulance attends PWDI to provide transport
Precondition	
Resources	Telecommunication systems Staff available Electronic health records Task prioritisation Call handler Ambulances available
Control	Admission pathways available Organisational handover guidelines
Time	Before hospital admission

Title	**5. Refer PWDI to hospital**

Description	HCP working in primary care or NHS 111 assesses the patient and identifies that they require an assessment or treatment in an inpatient hospital setting. They either call an ambulance or advise patient to attend ambulatory or emergency unit using own transport.
Input	HCP refer to hospital for admission
Output	Ambulance to transport PWDI PWDI makes own way to hospital GP sends referral letter electronically GP prints referral letter to give to PWDI
Precondition	Decision made that assessment or treatment in a secondary care setting is required
Resources	Staff available Task prioritisation IT available Electronic health records Diabetes policy and guidelines Staff diabetes knowledge
Control	Admission pathways available Organisational handover guidelines
Time	Before admission to hospital Before travel to hospital

Title	**6. Handover diabetes care to hospital**
Description	Communication of information relating to the PWDI illness and medical history (particularly for this scenario, details about insulin management) shared by the paramedics or by the GP. This may be performed over the telephone, by email or by printed report. Insulin management includes what type of insulin, device, strength, dose, route and method of administration used, what CBG monitoring is done and what recent results have been, what other equipment has been used.
Input	GP prints referral letter to give to PWDI GP sends referral letter electronically Information about insulin management gathered
Output	Information about insulin management and medical history shared

Precondition	Insulin information identifiable
Resources	Electronic health records IT available PWDI diabetes knowledge PWDI insulin equipment available PWDI insulin supply available Caregiver diabetes knowledge Staff available PWDI CBG and insulin administration records Telephone for verbal handover Organisational handover guidelines
Control	National and local policies and guidelines for handing over patients (NICE guideline 94 structured handover) Information governance arrangements Diabetes policy and guidelines
Time	At time of admission if brought by ambulance At time of admission if PWDI brings printed letter from GP Before admission if GP phones/emails ahead

Title	**7. Gather insulin information**
Description	Identify all relevant information about insulin. This may vary depending on the location of the PWDI, person seeking information, the consciousness level of the PWDI and available resources.
Input	Insulin use identified Need to attend hospital Admitted to hospital GP prints referral letter to give to PWDI Ambulance attends PWDI to provide transport
Output	Information about insulin management gathered Ready to attend hospital Information about insulin management shared
Precondition	Awareness that PWD uses insulin
Resources	Communication mechanisms available

	PWDI insulin supply available PWDI insulin equipment available PWDI information leaflets and insulin passports PWDI diabetes knowledge PWDI CBG and insulin administration records Caregiver diabetes knowledge Electronic health records Diabetes clinic letters
Control	Ambulance guidelines GP referral practices Training and education Patient advice about hospital admissions
Time	Before hospital admission As early as possible after admission

Title	**8. Monitor blood glucose levels**
Description	Includes monitoring the PWDI for signs and symptoms of hypoglycaemia also performing blood glucose testing using finger prick testing or CGM. This is done by the PWDI themselves, caregivers or healthcare professionals, for example paramedics.
Input	Signs and symptoms of illness Signs or symptoms of hypoglycaemia identified Admission to hospital Treatment for hypoglycaemia given Treatment for hyperglycaemia given Monitor insulin dose for appropriateness
Output	Blood glucose levels taken Hypoglycaemia identified Blood glucose levels within desired range Hyperglycaemia identified Blood glucose levels reviewed
Precondition	Aware of need to monitor for low blood glucose levels
Resources	Knowledge of signs and symptoms of hypoglycaemia

	Skills to take sample and read glucose levels Glucose monitoring equipment Knowledge of target range and how to manage result outside this
Control	Instructions for glucometer/CGM use Skills and education of PWDI Skills and education of healthcare staff Assessment protocols for acute illness (paramedics, healthcare professionals) Hospital admission protocols
Time	Performed during assessment of acute illness Performed following admission to hospital Performed throughout pre-admission, admission, and discharge Repeated after treatment for hypoglycaemia or hyperglycaemia

Title	**9. Admit PWDI to hospital**
Description	Acutely unwell PWDI arrives at the Emergency unit and is registered onto the computer system, assigned a bedspace and listed for the relevant clinical team. For the purposes of this analysis registration to ED and admission to a ward are both considered admissions.
Input	Arrival at hospital emergency unit
Output	Admitted to hospital Hospital clinical team take over care Bed space assigned Hospital admission not required, sent home
Precondition	
Resources	Administrative staff trained and available Staff available Emergency unit available to go to Physical bed/chair space available to assign patient to Electronic health records Staff diabetes knowledge
Control	Admission pathways Instruction manuals for registering patients

	Clinical rotas for assigning clinical teams Acute Trust and Ambulance Trust emergency department booking-in policy where available
Time	Following arrival at hospital

Title	10. Provide orientation to clinical area
Description	Staff from clinical area show PWDI to their bed space/chair. Show where to store belongings, where toilets are, how to find help and assistance, where to find hypo treatments. Check whether there is anything they need. Check whether they have any insulin with them, help them to store this.
Input	Arrival at hospital emergency unit
Output	PWDI settled in clinical area PWDI own insulin stored according to guidelines
Precondition	Admitted to hospital
Resources	Bed space or chair must have been available and assigned to PWDI Staff available Lockable patient medicine cabinet Refrigerator available Treatments for hypoglycaemia available PWDI insulin equipment available Staff diabetes knowledge
Control	Diabetes policy and guidelines Staff available to undertake orientation Lockers and storage spaces
Time	Earliest starting time after bed space allocation

Title	11. Hospital based clinical team accept patient
Description	Surgical or medical team agree to manage patient's medical/surgical illness in hospital setting and take over responsibility for insulin and diabetes treatment. They add patient to list for clerking, review, ward rounds and are responsible for requesting tests and reviewing and responding to test results. Responsible for prescribing and adjusting medicines and managing acute illness.

Input	Information about insulin management shared
Output	Admitted to hospital
Precondition	Patient requires hospital-based treatment
Resources	Electronic health records Staff available Administrative staff trained and available Task prioritisation
Control	Admission pathways available
Time	Before admission to hospital

Title	**12. Confirm diabetes history**
Description	Part of initial history taking and triaging of illness, the clinical team looking after PWDI identifies past medical history, signs and symptoms of illness, medication history and makes a differential diagnosis and initial treatment plan.
Input	Hospital clinical team take over care Insulin use identified Information about insulin management shared Information about insulin management gathered
Output	Information about insulin documented Need for referral to Inpatient diabetes team identified
Precondition	
Resources	Staff available Electronic health records IT available Task prioritisation
Control	Staff diabetes knowledge Diabetes policy and guidelines
Time	As early as possible after admission to hospital After hospital based team accept patient

Title	**13. Develop diabetes inpatient treatment plan**

Description	Pre-admission diabetes management, lifestyle factors and current illness and medications reviewed, and an appropriate insulin regimen prescribed for current situation. This could include withholding insulin (for example if PWDI has hypoglycaemia), changing to intravenous insulin, or reducing the dose due to nil by mouth.
Input	Information about insulin known Information about insulin management shared
Output	Insulin and rescue treatments prescribed for inpatient administration Diabetes inpatient treatment plan documented
Precondition	Blood glucose levels identified Insulin use identified Ability to have food and drink assessed Impact of illness assessed Impact of other medications assessed
Resources	Electronic health records Staff available PWDI able to self-administer Specialist diabetes team available PWDI able to self-administer Prescriber available Staff diabetes knowledge PWDI insulin supply available PWDI diabetes knowledge Caregiver diabetes knowledge
Control	Diabetes policy and guidelines Diabetes training Insulin and equipment formulary
Time	After admission and before discharge

Title	**14. Prescribe insulin**
Description	Insulin is prescribed for inpatient administration along with rescue treatments using EHR. The dose is considered based on all available evidence and in accordance with available guidelines where known.

	May be prescribed by clinician, surgeon, or independent prescriber (for example pharmacist, specialist nurse). The treatment plan is developed to the best of the ability of the prescriber and should take into consideration previous dose, current requirements, and clinical situation.
Input	Insulin treatment plan developed Insulin and rescue treatments decided for inpatient administration
Output	Insulin and rescue treatments prescribed for inpatient administration Insulin and rescue treatment prescriptions adjusted
Precondition	
Resources	EPR configuration Prescriber available Staff diabetes knowledge Electronic health records
Control	Diabetes training Insulin and equipment formulary Diabetes policy and guidelines
Time	

Title	**15. Check baseline observations**
Description	Part of initial history taking and triaging of illness, baseline blood glucose levels and ketone levels are taken among other blood tests and clinical tests (such as BP, HT, respiratory rate etc). Part of the ABCDE approach of identifying and treating acute emergency illnesses.
Input	Admitted to hospital
Output	Blood glucose levels identified Blood ketone levels identified
Precondition	
Resources	Monitoring device connected through WiFi Insulin and equipment formulary Staff diabetes knowledge Staff available Electronic health records

Control	Hospital guidelines Manufacturer instructions Diabetes training
Time	After admitted to hospital

Title	**16. Treat presenting illness**
Description	Medical or surgical illness treated according to urgency.
Input	Admitted to hospital Paramedics identify medical emergency
Output	Medical or surgical treatment plan in place Acute medical/surgical emergencies resolved Acute medical/surgical emergencies managed
Precondition	
Resources	Admission pathways available Staff available Task prioritisation
Control	
Time	

Title	**17. Assess blood glucose levels**
Description	Review CBG or other blood glucose monitoring results to determine whether patient needs treatment. Safe glucose levels already defined for patient (vary depending on age and type of illness) - hypoglycaemia always when CBG below 4mmol/L.
Input	Blood glucose levels taken Hypoglycaemia identified Hyperglycaemia identified
Output	Blood glucose levels within desired range Blood glucose levels too low Blood glucose levels too high
Precondition	Blood glucose levels reported
Resources	Monitoring device connected through WiFi Equipment available

	Staff available Electronic health records Staff diabetes knowledge PWDI able to self-administer PWDI diabetes knowledge
Control	Glucose monitoring device instructions Diabetes policy and guidelines Diabetes training
Time	

Title	**18. Treat hypoglycaemia**
Description	PWDI to take food, glucose tablets, glucose gel, juice if able to. If not intravenous glucose or intramuscular glucagon to be given according to guidelines. Prescriber required for intravenous or intramuscular medicines, but not for food, glucose tablets, glucose gel or juice. Prescriptions for carbohydrates for hypoglycaemia automatically added alongside any prescription for insulin.
Input	Blood glucose levels too low
Output	Blood glucose levels within desired range Blood glucose above desired range Treatment for hypoglycaemia given
Precondition	Low blood glucose levels detected
Resources	Treatments for hypoglycaemia available Monitoring device connected through WiFi Staff available PWDI able to self-administer Staff diabetes knowledge Trained staff PWDI knowledge and skills Electronic health records Prescriber available
Control	Diabetes policy and guidelines Glucose monitoring device instructions

	EPR configuration Diabetes training
Time	

Title	19. Treat hyperglycaemia
Description	High blood glucose levels identified, cause diagnoses, emergency treatment prescribed, administered, and recorded on EPR, or administered by PWDI.
Input	Blood glucose levels too high Blood glucoses above desired range
Output	Blood glucose levels within desired range Blood glucose levels too low Need to check blood ketones Treatment for hyperglycaemia given Blood glucose levels taken
Precondition	High blood glucose levels detected Insulin available for administration
Resources	Insulin available and in date Staff available Monitoring device connected through WiFi Electronic health records Equipment available PWDI able to self-administer Specialist diabetes team available Prescriber available
Control	Diabetes policy and guidelines Diabetes training Glucose monitoring device instructions EPR configuration
Time	

Title	20. Arrange self-management of diabetes for PWDI

Description	Staff perform assessments, paperwork and organisational requirements to enable PWDI to administer their own insulin. This includes assessing capacity and understanding, signing consent and arranging suitable insulin and equipment to allow them to administer doses and monitor CBGs
Input	Insulin and rescue treatments prescribed for inpatient administration PWDI insulin supply available
Output	PWDI able to self-administer
Precondition	
Resources	Insulin available and in date Equipment available Refrigerator available Lockable patient medicine cabinet Staff available IT available Availability of monitoring devices Specialist diabetes team available
Control	Legislation Diabetes policy and guidelines Provider organisation diabetes strategy Diabetes training Insulin and equipment formulary
Time	

Title	**21. Source insulin for inpatient use**
Description	Nursing staff to review prescribed insulin and locate or arrange supply for use while admitted to clinical area. This involves checking the insulin brought in by the PWDI to confirm that it matches the prescription and is within 28 days of being opened, has been stored correctly and is in good condition according to relevant policies. The nurse must check whether the PWDI brought insulin with them and still has this among their belongings, whether it has been locked in the bedside locker or ward refgrigerator. If the PWDI does not have any of their own, or if it does not match the prescribed insulin, then ward stock

	should be checked to see if in-date and useable supply (and corresponding equipment is available, e.g. insulin syringe for insulin vial). If not available on ward, must be requested and supplied from pharmacy.
Input	Insulin and rescue treatments prescribed for inpatient administration Insulin and rescue treatment prescriptions adjusted
Output	Insulin available for administration
Precondition	
Resources	Staff diabetes knowledge Electronic health records Staff available Task prioritisation Insulin available and in date Refrigerator available Lockable patient medicine cabinet
Control	Diabetes training Insulin and equipment formulary Diabetes policy and guidelines Safe and secure storage of medicine policy
Time	Before treat hyperglycaemia Before insulin administration

Title	**22. Refer to Inpatient Diabetes team**
Description	Need for additional expertise or education and training identified by member of clinical team (either nursing, medical or pharmacy staff, physio/OT, discharge liaison team etc). Request made for advice on treatment or for input for training
Input	Need for referral to Inpatient diabetes team identified
Output	Insulin and rescue treatment prescriptions adjusted Insulin needs for discharge identified Training and education provided to PWDI
Precondition	
Resources	Trained staff

	Electronic health records Specialist diabetes team available Staff diabetes knowledge IT available
Control	Provider organisation diabetes strategy Diabetes training Diabetes policy and guidelines
Time	Diabetes inpatient team available during core working hours. Referral can be made any time, but only acted on during working hours.

Title	**23. Assess and treat high ketone levels**
Description	Ketone levels taken and reviewed. Where high according to clinical guidelines, the cause of this is identified, diagnosed and treatment is given. Monitoring is performed according to guidelines and the levels are checked and this step repeated until ketosis is resolved.
Input	Blood ketone levels taken Need to check blood ketones
Output	Ketone levels within normal range
Precondition	Ketone levels reported
Resources	Monitoring device connected through WiFi Equipment available Staff available Electronic health records Staff diabetes knowledge PWDI able to self-administer
Control	Glucose monitoring device instructions Diabetes policy and guidelines Diabetes training
Time	

Title	**24. Adjust insulin during acute illness**

Description	Impact of illness, current oral intake, other medicines being used, insulin treatments, hypoglycaemia episodes and hyperglycaemia episodes identified and considered
Input	Insulin and rescue treatments prescribed for inpatient administration Blood glucose levels too low Blood glucose levels too high Blood glucose levels reviewed Blood glucose levels within desired range Ketone levels within normal range Monitor insulin dose for appropriateness
Output	Insulin and rescue treatment prescriptions adjusted
Precondition	Monitoring performed
Resources	Staff available Staff diabetes knowledge Diabetes specialist team available Electronic health records PWDI knowledge of diabetes management Equipment available Prescriber available PWDI able to self-administer PWDI diabetes knowledge
Control	Diabetes policy and guidelines Diabetes training
Time	

Title	**25. Administer routine insulin**
Description	Routine doses of insulin administered according to prescription. This includes long acting basal insulins and other insulins prescribed to maintain insulins within a defined range. Also includes insulins to be given with meals (although this is less likely with Type 2 diabetes).
Input	Insulin and rescue treatments prescribed for inpatient administration
Output	Monitor insulin dose for appropriateness
Precondition	Insulin available for administration

Resources	Staff diabetes knowledge Electronic health records Staff available Task prioritisation Monitoring device connected through WiFi PWDI able to self-administer Specialist diabetes team available PWDI diabetes knowledge
Control	Diabetes training Insulin and equipment formulary Diabetes policy and guidelines
Time	Before treat hyperglycaemia Before insulin administration

Title	**26. Perform discharge assessment**
Description	Identify whether PWDI will continue to need insulin on discharge and whether any support is likely to be required. Consider social circumstances and potential impact of illness on ability to manage insulin. Consider how illness and concomitant medications may impact insulin needs and management. Set anticipated discharge date.
Input	Information about discharge known
Output	Insulin needs for discharge identified Referral to Inpatient diabetes team made Identified as medically fit for discharge
Precondition	Acute medical/surgical emergencies managed Medical or surgical treatment plan in place
Resources	Staff available Caregiver diabetes knowledge PWDI diabetes knowledge Specialist diabetes team available Electronic health records Discharge liaison team available Staff diabetes knowledge

Control	Diabetes policy and guidelines Diabetes training
Time	As soon as practical after medically stable, continued during admission

Title	**27. Identify insulin needs for discharge**
Description	Prescription must be written, checked by pharmacist, items required confirmed with the PWDI taking into consideration how much insulin is already on the ward for them and how much is at home.
Input	Insulin doses for discharge prescribed
Output	Insulin prescription processed by pharmacy
Precondition	
Resources	Staff available PWDI able to describe what insulin already available at home Prescriber available Electronic health records Specialist diabetes team
Control	Provider organisation diabetes strategy Insulin and equipment formulary National guidelines Staff diabetes knowledge
Time	Pharmacy department must be open or on-call pharmacist available

Title	**28. Create insulin plan for discharge**
Description	Review insulin requirements during admission, blood glucose levels, HbA1c, diet in hospital and likely diet following discharge and other medications and potential impact on insulin dosing along with discharge assessment and develop a plan for diabetes management and insulin dosing after discharge. This includes details about which insulin(s) and device(s) to use and at what doses, sick day rules, who will administer insulin, and monitoring requirements and how to adjust insulin.
Input	Insulin needs for discharge identified Insulin and rescue treatment prescriptions adjusted
Output	Insulin doses for discharge agreed

Precondition	
Resources	Staff available Electronic health records PWDI Caregiver Specialist diabetes team available Staff diabetes knowledge Diabetes inpatient treatment plan documented
Control	Diabetes policy and guidelines Diabetes training
Time	Must happen before discharge

Title	**29. Identify equipment needs for discharge**
Description	Nursing staff or diabetes specialist nurses must review and discuss with PWDI to determine what equipment is required and what is already available at home. This includes a sharps bin, CBG and ketone monitoring equipment (lancets, monitors, test strips) and insulin devices for pens that use cartridges. These items do not come from the inpatient pharmacy, but are usually supplied by either the diabetes team or from the ward stock.
Input	Insulin doses for discharge prescribed
Output	Equipment needs for discharge identified
Precondition	Insulin device must be decided Diabetes care plan agreed
Resources	Staff available PWDI able to describe what equipment already available Equipment available Telephone Courier
Control	Diabetes policy and guidelines Monitoring device instructions Commissioning arrangements (formulary) Diabetes training

Time	Before discharge
	After discharge and couriered to PWDI

Title	30. Arrange discharge supply of insulin & equipment
Description	This step involves supplying relevant insulin(s) against a valid and pharmacist approved prescriptions. For equipment and devices, nursing staff must obtain supply of equipment that may be needed, for example needles and CBG monitors, if needed from the inpatient diabetes team. Insulin is prescribed, but other equipment is not prescribed but arranged by the diabetes or ward nurses.
Input	Insulin doses for discharge agreed Equipment needs for discharge identified
Output	Insulin and equipment given to PWDI
Precondition	Date of planned discharge must be confirmed
Resources	Staff available IT available Refrigerator Insulin available and in date Insulin doses for discharge prescribed Courier Electronic health records Telephone Specialist diabetes team available Equipment available
Control	Diabetes policy and guidelines Staff diabetes knowledge Commissioning contracts (e.g. 14 day supply in contract with commissioners)
Time	Before discharge ideally, or requires courier if occurs following discharge

Title	31. Provide discharge letter
Description	Diabetes management during admission, changes to therapy and care plan for discharge described in discharge letter. This includes list of

	medicines and insulin prescribed. Other equipment not routinely prescribed at most hospitals (although some do). Discharge letter written on electronic health records and sent to GP surgery email inbox by PDF. A copy is printed and given to the PWDI and/or caregiver.
Input	Insulin doses for discharge prescribed
Output	Electronic document shared
Precondition	PWDI must be discharged on Electronic Health Records
Resources	Electronic health records IT available Printer and paper Staff available Staff diabetes knowledge
Control	Diabetes policy and guidelines EPR configuration
Time	At point of leaving hospital

Title	**32. Discharge to primary care**
Description	PWDI ready to go home and discharged from hospital electronic health system and allowed to leave ward/clinical area.
Input	Identified as medically fit for discharge
Output	Medical care handed over to primary care PWDI back home
Precondition	
Resources	IT available Communication mechanisms available Organisational handover guidelines
Control	EPR configuration
Time	

Title	**33. Provide education to PWDI or carer**
Description	Provide PWDI or their caregiver an understanding of diabetes and insulin management evaluated, and education given on relevant areas including

	how to check CBGs, how to adjust insulin doses as needed, what to do when unwell, how to administer insulin, how to dispose of sharps etc.
Input	Diabetes management plan for discharge agreed PWDI back home Diabetes management plan agreed
Output	PWDI or caregiver aware of diabetes management plan Arrange follow up phone call from inpatient diabetes team PWDI insulin supply available PWDI insulin equipment available PWDI diabetes knowledge Caregiver diabetes knowledge Diabetes managed by PWDI Diabetes managed by caregiver PWDI CBG and insulin administration records PWDI or caregiver training PWDI carbohydrates available Information about insulin known
Precondition	PWDI or caregiver must be available to participate in training and education Staff member must be available and competent to provide training and education
Resources	Insulin available and in date Trained staff Equipment available Refrigerator available Specialist diabetes team available Patient information leaflets and insulin passports
Control	Provider organisation diabetes strategy Diabetes policy and guidelines Insulin and equipment formulary Diabetes training Commissioning contracts (e.g. 14 day supply in contract with commissioners)
Time	Before discharge ideally, or requires courier if occurs following discharge

Title	34. Make primary care referrals
Description	Referrals made to relevant outpatient teams, for example district nurses to help with insulin administration or community pharmacy for discharge medicine service consultation.
Input	Electronic document shared
Output	Referral sent to relevant services
Precondition	Need for referral identified during admission
Resources	IT available Electronic health records Communication mechanisms available Referral mechanisms available District nursing team available Community pharmacy available Staff diabetes knowledge Staff available
Control	Organisational handover guidelines Referral pathways available Referral mechanism available EPR configuration Provider organisation diabetes strategy
Time	Before discharge, after discharge letter written and finalised.

Title	35. Secondary care diabetes team make follow up phone call
Description	DSN calls patient after discharge to check patient management where they are on steroids or newly started on insulin.
Input	Arrange follow up phone call from inpatient diabetes team
Output	PWDI for routine follow-up
Precondition	Able to receive and participate in telephone call
Resources	Electronic health records Communication mechanisms available IT available Task prioritisation

	Staff diabetes knowledge Staff available Specialist diabetes team available
Control	Diabetes policy and guidelines Diabetes training
Time	Within a week following discharge

Title	**36. Travel home**
Description	PWDI travels home and resumes managing diabetes according to agreed care plan. Where required, district nurses come to support insulin administration and monitoring tasks.
Input	Insulin and equipment given to PWDI Electronic document shared
Output	PWDI back home
Precondition	Must be medically fit to go home
Resources	Transport
Control	
Time	May happen before or after discharge letter provided Happens after decision medically fit for discharge

Title	**37. Manage diabetes at home**
Description	The ongoing management of all aspects of diabetes care. This includes collaborating in the development of a diabetes plan, monitoring glucose levels, taking insulin, adjusting insulin based on test results and other factors such as carbohydrate intake. It also involves maintaining sufficient insulin and equipment supplies to continue to administer and monitor insulin. It includes treating hypoglycaemia and seeking help or advice where blood glucose levels are problematically outside of range (as per diabetes plan). It also includes ensuring that appointments are attended for review. It includes attending and undertaking training to understand how to manage diabetes according to plan. Includes storing insulin appropriately in fridge until bartridge/pen is in use.
Input	Diabetes management plan for discharge agreed PWDI back home

	Diabetes management plan agreed
Output	PWDI insulin supply available PWDI insulin equipment available PWDI diabetes knowledge Diabetes managed by PWDI Diabetes managed by caregiver Caregiver diabetes knowledge PWDI CBG and insulin administration records PWDI or Caregiver training PWDI carbohydrates available Information about insulin known
Precondition	PWDI or caregiver assessed as suitable to manage
Resources	Specialist diabetes team available Patient information leaflets and insulin passports Insulin available and in date Equipment available Refrigerator available
Control	Provider organisation diabetes strategy Diabetes training Diabetes policy and guidelines Insulin and equipment formulary
Time	

Title	**38. Primary Care team accept referral**
Description	Team who were sent referral agree see patient with PWDI for diabetes related issues/management/review. PWDI is added to caseload list and appointment is scheduled. Referrals include those directly from secondary care, e.g. to district nurses, or community pharmacies and could include those from primary care to outpatient diabetes team.
Input	Referral sent to relevant services
Output	Follow up arranged

Precondition	Team receives referral
Resources	Staff available Appointments available Electronic health records Administrative staff trained and available Task prioritisation IT available Staff diabetes knowledge
Control	Commissioning arrangements Provider organisation diabetes strategy Diabetes policy and guidelines
Time	Dependent on type of referral (District nurses, may be same day, community pharmacy, maybe in a week or two).

Title	**39. Identify hospital discharge**
Description	Administrative staff review discharge letter from primary care and assign to task list of relevant clinical staff (e.g. clinician for review of diabetes, pharmacist or Medicines Management Technician if medicines/insulin involved).
Input	Discharge letter reviewed
Output	Care needs documented Follow-up needs identified Follow up arranged PWDI for routine follow-up
Precondition	Staff member has access to discharge information
Resources	Electronic health records Discharge document Staff available Mechanism for referral to outpatient team (e.g. e-mail, online form) IT available Knowledge of referral processes Diabetes expertise
Control	Diabetes training

	Provider organisation diabetes strategy Diabetes policy and guidelines
Time	Time assigned to perform task as part of role Done within 48 – 72 hours of discharge

Title	40. Reconcile insulin in primary care
Description	Thorough check of insulin (usually pharmacist or pharmacy technician, could be GP) following potential changes during hospital admission. Any discrepancies with pre-admission insulin identified and confirmed that these were intentional. Confirm with hospital teams if documentation in discharge letter is unclear. Update of medical records to match.
Input	Changes to insulin identified
Output	Insulin updated in GP records
Precondition	Insulin information must be included in discharge letter
Resources	Telephone E-mail Electronic Health Records Staff available Staff diabetes knowledge IT available
Control	Guidelines (National med optimisation guidelines) Education and training
Time	Within 28 – 72 hours of discharge After changes to insulin identified

Title	41. GP surgery diabetes review
Description	Clinical member of staff reviews changes to diabetes plan, updates clinical records and decides patients ongoing care needs which may include referral to outpatient diabetes team.
Input	Need for diabetes clinical review
Output	Care needs documented Referral to local outpatient diabetes team
Precondition	Staff member has access to discharge information

Resources	Electronic health records Electronic document shared Trained staff available (clinical) Mechanism for referral to outpatient team (e.g. e-mail, online form) IT available Knowledge of referral processes Staff diabetes knowledge
Control	Training to use electronic health records Referral criteria
Time	Time assigned to perform task as part of role Done within 48 – 72 hours of discharge

Title	**42. PWDI follow up in primary care**
Description	Any healthcare professional follow up required is booked and communicated with PWDI who attends or is visited by the relevant person/team. This includes initial follow up with the community diabetes team, district nurses or community pharmacy. It also includes ongoing; routine follow up with the GP.
Input	Follow up arranged Follow-up needs identified PWDI for routine follow-up
Output	Diabetes care plan and insulin management reviewed and updated PWDI seen by relevant services Further follow up agreed and arranged
Precondition	Administrative tasks undertaken to ensure patient on caseload and scheduled for appointment
Resources	Administrative staff trained and available System to manage appointments Electronic health records Trained staff available to perform follow up appointments Transport Communication methods

	Capacity of service Specialist diabetes team Staff available IT available Staff diabetes knowledge
Control	Provider organisation diabetes strategy Commissioning arrangements Diabetes policy and guidelines
Time	Must occur after travel home Time to arrange appointment Time to travel to appointment Time to perform appointment

Title	**43. Review discharge letter in primary care**
Description	Member of staff assigned by admin reviews discharge information and identifies any changes to diabetes plan and need for referral to outpatient diabetes team.
Input	Staff member assigned to review discharge
Output	Changes to insulin identified Need for diabetes clinical review Follow-up needs identified Referral sent to relevant services
Precondition	Staff member has access to discharge information
Resources	Electronic health records Electronic document shared Trained staff available
Control	Training to use electronic health records Provider organisation diabetes strategy ? National strategy
Time	Time assigned to perform task as part of role
	Done within 48 – 72 hours of discharge

Title	44. Request insulin/equipment prescription in primary care
Description	Need for insulin/equipment identified and requested from relevant healthcare professional by PWDI or someone acting on their behalf.
Input	
Output	Prescription requested
Precondition	
Resources	IT available Communication methods Administrative staff trained and available Staff diabetes knowledge PWDI
Control	Diabetes policy and guidelines Local procedures
Time	Must happen before insulin/equipment prescribed

Title	45. Supply insulin and equipment in primary care
Description	Prescription received by pharmacy and sent electronically to PWDI nominated pharmacy who process the request, supply the medicines and store for collection or delivery to the PWDI.
Input	Prescription for insulin and/or equipment
Output	PWDI supplied/delivered with insulin and/or equipment
Precondition	IT available
Resources	Trained staff in pharmacy to process prescriptions (may include clinical review) Insulin and equipment in date and available Refrigerator Resources needed to deliver prescription Electronic health records Dispensing system and labelling equipment Staff diabetes knowledge Accountable pharmacist available
Control	Professional guidelines SOPs for dispensing

	Commissioning arrangements for pharmacy payment Provider organisation diabetes strategy
Time	Comes after prescribing insulin and equipment in primary care Time taken to perform tasks involved Electronic prescription needs to have been received

Title	46. Prescribe insulin and equipment in primary care
Description	Generate a prescription on EHR that is sent directly to a community pharmacy or printed and given to a person (e.g. PWDI, carer, relative, district nurse). The prescription is then taken/sent to a community pharmacy.
Input	Prescription requested
Output	Prescription for insulin and/or equipment produced
Precondition	IT available
Resources	Staff diabetes knowledge Staff available (GP, Community Diabetes) Prescriber available
Control	Prescribing legislation and standards Formulary Diabetes policy and guidelines
Time	Precedes supply insulin and equipment in primary care

Title	47. Seek assistance after discharge
Description	PWDI, caregiver, GP or other healthcare professional identifies new issue with diabetes and insulin and seeks help or advice to manage. Could be advice from primary or secondary care.
Input	PWDI back home
Output	Staff member assigned to review insulin
Precondition	
Resources	PWDI diabetes knowledge Caregiver diabetes knowledge Telecommunication systems
Control	Diabetes training
Time	After discharge

Title	48. Adjust insulin following discharge
Description	Healthcare professional in collaboration with PWDI or caregiver adjust insulin regimens to ensure blood glucose levels stay within desired range as much as possible.
Input	Insulin updated in GP records
	Staff member assigned to review insulin
Output	Diabetes management plan agreed Prescription for insulin and/or insulin produced Prescription requested
Precondition	
Resources	PWDI diabetes knowledge Caregiver diabetes knowledge Diabetes managed by PWDI Diabetes managed by caregiver PWDI CBG and insulin administration records Staff available Electronic health records
Control	Diabetes training Diabetes policy and guidelines
Time	

Title	49. Provide authority to administer insulin for district nurses
Description	GP identifies referral of PWDI to district nurses either through being copied into referral, or district nurses notifying of referral. The GP reviews the discharge letter and insulin doses and creates an agreed document that provides the district nurses with the authority to administer the PWDI's insulin at the doses listed.
Input	New or updated authority to administer required
Output	Follow up arranged Prescription for insulin and/or insulin produced
Precondition	
Resources	

Control	
Time	

Title	50. Review referral in primary care
Description	Agency receiving referral identifies it in their list, screens for appropriateness, and reviews any activities that need to be completed to add to caseload. Collaborates with GP to ensure paperwork in place.
Input	Referral sent to relevant services
Output	Medical care handed over to primary care New or updated authority to administer required
Precondition	
Resources	
Control	
Time	

Title	51. Provide diabetes framework
Description	Provider strategies for the provision of diabetes and insulin care. Includes staffing organisational policies, employ specialist team, training, equipment available and formulary, SOPs and guidelines. Includes pathway commissioning by ICB and their oversight and assurance.
Input	
Output	Provider organisation diabetes strategy Diabetes training Diabetes policy and guidelines Specialist diabetes team available Availability of monitoring devices EPR configuration Patient information leaflets and insulin passports Insulin and equipment formulary
Precondition	
Resources	
Control	NHS standard contract
Time	

Title	52. Empower PWDI management of diabetes
Description	Provide training and support for PWDI to perform ongoing management of all aspects of diabetes care and perform function manage diabetes at home.
Input	PWDI or Caregiver training
Output	PWDI diabetes knowledge Caregiver diabetes knowledge Diabetes managed by PWDI Diabetes managed by caregiver
Precondition	Diabetes management plan agreed
Resources	
Control	
Time	

Title	53. Healthcare organisational capacity
Description	
Input	
Output	Admission pathways available Emergency unit available to attend Hospital bed available District nursing capacity available Secondary care appointments available
Precondition	
Resources	Staff available Specialist diabetes team available Prescriber available Staff available (GP, Community diabetes) Ambulances available
Control	Task prioritisation
Time	

Title	54. Manage workload

Description	Prioritisation of staff member tasks that need to be performed for their patient cohort balancing the needs and urgency of the different patients on their list and constantly adjusting as circumstances change, e.g. new patients added to list, changes in illness. Managing the tasks within the resource they have available, e.g. time.
Input	
Output	Task prioritisation
Precondition	
Resources	Staff available Specialist diabetes team PWDI Travel time from remote locations to patient IT available *NB: glucose levels not part of NEWS scoring, therefore, do not automatically raise priority * Includes referrals
Control	Operational management of the hospital (includes Protected break time, location of teams e.g. diabetes team remote from ward, clinical team may be outlier and based elsewhere)
Time	

Title	**55. Provide ToC infrastructure**
Description	Integrated Care Boards and local organisations, including hospitals, primary care, NHS 111 and ambulance trusts develop mechanisms for referring unwell patients and determining where to either advise them to attend, or in the case of ambulance drivers, where to take the patients to be seen. It also includes discharge pathways, referral criteria and mechanisms for referring for primary care services.
Input	
Output	Admission pathways available Organisational handover guidelines Preparing for hospital admission guidelines for PWDI (RPS Keeping patients safe when they transfer between care providers, Seven simple steps for keeping safe in hospital, Diabetes UK)

	Referral mechanism available
Precondition	
Resources	Telecommunication systems IT available Electronic health records Internet and search directories Organisational websites
Control	Legislation NHS contractual requirements
Time	

Title	**56. Maintain IT infrastructure**
Description	Provide and maintain a functional IT system and associated software and hardware to enable healthcare provision, including access to healthcare records in different organisations, recording medical history, medications taken, appointment details, letters, pathology and laboratory results etc. Also includes the wireless connection between the CBG and ketone monitoring devices and the hospital EPR system.
Input	
Output	IT available Monitoring device connected through WiFi EPR configuration Electronic health records EHR interoperability
Precondition	
Resources	
Control	
Time	

Title	**57. Manage stock of insulin and equipment**
Description	Ordering system in place within hospital or primary care pharmacies to ensure that insulin is ordered, stocked and stored appropriately. This includes managing stock on wards to decide which areas should keep certain insulins as stock items, and when they should be ordered from the

	pharmacy. It also includes management and adjustment of guidelines where supply issues occur. Community pharmacy also manage insulin equipment that is prescribed by GPs. In hospital the diabetes specialist nurses manage insulin equipment ordering for providing to patients, and stock of needles, syringes, sharps bins, CBG devices etc are managed by the ward and ordered/topped up through procurement.
Input	
Output	Insulin available and in date Equipment available Refrigerator available Lockable patient medicine cabinet
Precondition	
Resources	Stock management system Staff available IT available
Control	Hospital policies and guidelines Legislation Diabetes policy and guidelines Provider organisation diabetes strategy
Time	

Title	**58. Provide appropriate competent staff**
Description	Supply adequate healthcare professionals with appropriate skills to match demand
Input	
Output	Staff available Specialist diabetes team available Administrative staff trained and available Prescriber available Staff available (GP, Community Diabetes) Discharge liaison team available
Precondition	
Resources	
Control	

Time	

Title	**59. Train staff around diabetes and insulin use**
Description	Training that non-specialist diabetes staff have to provide them with the competencies to care for PWDI using insulin.
Input	Diabetes training
Output	Staff diabetes knowledge
Precondition	
Resources	Training Specialist diabetes team Task prioritisation Staff available Diabetes expertise
Control	Curriculum undergraduate Curriculum postgraduate Professional training curriculum (e.g. for apprentice) Provider organisation diabetes strategy
Time	Time to undertake training Time to provide training Availability of staff released

Appendix VII: Detailed descriptions of functions and variability identified

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#1. Decide hospital admission is needed	PWDI, informal caregiver (for example spouse, child, other relative or friend), a healthcare professional working in primary care, for example, district nurses, GP, primary care pharmacist, paramedic, 111 call handler, or staff in an outpatient clinic identify acute illness that requires assessment and/or treatment in an inpatient hospital setting.	Missed opportunity to recognise the need for hospital assessment and deterioration in health. Incorrect decision for PWDI to attend hospital.	Function #9 Admit to hospital may be delayed or omitted
#2. Pack belongings for hospital admission	PWDI, caregiver and/or paramedic identify patient belongings needed for managing insulin during admission to hospital. This includes information about insulin, the insulin and device itself, carbohydrates, equipment for blood glucose and ketone monitoring (including phone and charger). Other belongings also gathered, but not relevant to this FRAM.	Insulin and equipment sent to hospital either: • Not taken • Incomplete • Incorrect	Information may not be available or may be incorrect when performing function #12 Confirm diabetes history

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#3. Travel to hospital	PWDI travels to hospital via ambulance or through own means (taxi, lift, walk) and attends a clinical area that deals with acute medical or surgical issues (can be ED, MAU, ambulatory unit, surgical emergency unit etc…). Where via ambulance, the input is PWDI to attend hospital, where own means, input is ready to attend hospital.	PWDI attends hospital: • Too late • When not required. PWDI doesn't attend hospital when required.	Function #9 Admit to hospital may be delayed or omitted.
#4. Arrange ambulance	PWDI calls ambulance, or healthcare professional working in primary care or in NHS 111 recognises serious acute illness requiring urgent transport into hospital under supervision of paramedics. They arrange an ambulance either by phoning or using alternative system.	Ambulance arranged: • Too late • Not done – PWDI makes own way to hospital.	Function #9 Admit to hospital may be delayed or omitted.
#5. Refer PWDI to hospital	HCP working in primary care or NHS 111 assesses the patient and identifies that they require an assessment or treatment in an inpatient hospital setting. They either call an ambulance, or advise patient to attend ambulatory or emergency unit using own transport.	Referral may be: • Too late • Not performed • Incorrect decision either to refer or not to refer	Referral information may not be available or may be incorrect when performing function #12 Confirm diabetes history

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#6. Handover medical care to hospital	Communication of information relating to the PWDI illness and medical history (including details about insulin) shared by the paramedics or by the GP. This may be performed over the telephone, by email or by printed report.	Handover may be: • Performed too late • Omitted • Inaccurate • Incorrect	Information may not be available or may be incorrect when performing function #12 Confirm diabetes history. Required to accurately complete #13Develop diabetes inpatient treatment plan and #14 Prescribe insulin
#7. Gather insulin information	Identify all relevant information about insulin that is available. This may vary depending on the location of the PWDI, person seeking information, the consiousness level of the PWDI and available resources.	Information may be: • Not available • Not gathered and left behind. • Brought in following admission. • Incorrect (e.g. out of date or incomplete).	Information may not be available or may be incorrect when performing function #12 Confirm diabetes history. Required to accurately complete #13Develop diabetes inpatient treatment plan and #14 Prescribe insulin
#8. Monitor blood glucose levels	Includes monitoring the PWDI for signs and symptoms of hypoglycaemia also performing blood glucose testing using finger prick testing or CGM. This is done by the PWDI themselves, caregivers or healthcare professionals, for example paramedics.	Monitoring may be performed: • Too late • Not done • Performed incorrectly	Blood glucose levels are either not available or incorrect for function #16 Assess blood glucose levels

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#9. Admit PWDI to hospital	Acutely unwell PWDI arrives into the Emergency unit and is registered onto the computer system, assigned a bed-space and listed for the relevant clinical team. For the purposes of this analysis registration to ED and admission to a ward are both considered admissions.	Admission may be: • Too late • Not done when required • Inappropriate	May delay **#11 Hospital-based clinical team accept patient.**
#10. Provide orientation to clinical area	Staff from clinical area show PWDI to their bed space/chair. Show where to store belongings, where toilets are, how to find help and assistance, where to find hypo treatments. Check whether there is anything they need. Check whether they have any insulin with them, help them to store this.	Orientation may be: • Not performed. • Incompletely performed and key information not given, e.g. access to carbohydrates. • Provided late.	Delays or omissions in providing orientation may impact on PWDI ability to perform the following functions: #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #19 Arrange self-management of diabetes for PWDI.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#11. Hospital-based clinical team accept patient	Surgical or medical team agree to manage patient's medical/surgical illness in hospital setting and take over responsibility for insulin and diabetes treatment. They add patient to list for clerking, review, ward rounds and are responsible for requesting tests and reviewing and responding to test results. Responsible for prescribing and adjusting medicines and managing acute illness.	The clinical team may be: • Not accept the PWDI • Not the most appropriate clinical team • Delayed in accepting PWDI	May lead to delays in the following functions: #12 Confirm diabetes history. #13 Diabetes inpatient treatment plan developed. #14 Prescribe insulin. #15 Check baseline observations. #16 Assess blood glucose levels. #17 Treat hypoglycaemia. #18 Treat hyperglycaemia.
#12. Confirm diabetes history	Part of initial history taking and triaging of illness, the clinical team looking after PWDI identifies past medical history, signs and symptoms of illness, medication history and makes a differential diagnosis and initial treatment plan.	Where this is performed either too late or inaccurately, diabetes and insulin use may not be identified. If done incorrectly, wrong type of diabetes or insulin use may be identified and documented.	This may impact on the appropriateness of #13 Diabetes inpatient treatment plan developed. It may lead to omission of #14 Prescribe insulin and #16 Assess blood glucose levels, and consequently on #17 Treat hypoglycaemia & #18 Treat hyperglycaemia.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#13. Diabetes inpatient treatment plan developed	Pre-admission diabetes management, lifestyle factors and current illness and medications reviewed and an appropriate insulin regimen prescribed for current situation. This could include withholding insulin (for example if PWDI has hypoglycaemia), changing to intravenous insulin, or reducing the dose due to nil by mouth.	The diabetes plan may be: • Delayed • Not developed • Incorrect or incomplete	Variability in developing the diabetes plan may lead to omission of #14 Prescribe insulin and #20 Source insulin(s) for inpatient use. There may be delays in #23 Adjust insulin during acute illness or #24 Administer routine insulin. If a diabetes plan is not developed, it may impact on the ability of # 19 Arrange self-administration of insulin to be performed.
#14. Prescribe insulin	Insulin is prescribed for inpatient administration along with rescue treatments using EHR. The dose is considered based on all available evidence and in accordance with available guidelines where known. May be prescribed by clinician, surgeon, or independent prescriber (for example pharmacist, specialist nurse). The treatment plan is developed to the best of the ability of the prescriber and should take into consideration previous dose, current requirements and clinical situation.	Insulin prescription may be: • Delayed • Omitted • Incorrect • Incomplete (for example if only one of two insulins are prescribed, or if carbohydrates for managing hypoglycaemia are not co-prescribed).	Variability in prescribing insulin may lead to delays or omission of: #20 Source insulin(s) for inpatient use #24 Administer routine insulin. If insulin is not prescribed, it may lead to omission of #17 Treat hypoglycaemia.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#15. Check baseline observations	Part of initial history taking and triaging of illness, baseline blood glucose levels and ketone levels are taken among other blood tests and clinical tests (such as BP, HT, Resp rate etc). Part of the ABCDE approach of identifying and treating acute emergency illnesses.	Baseline observations of blood glucose levels and ketones may be omitted or performed and reviewed: • Too late • Incorrectly • Incompletely	Where baseline observations are omitted, incorrect or delayed, this may impact the following functions: #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #13 Diabetes inpatient treatment plan developed. #23 Adjust insulin during acute illness.
#16. Assess blood glucose levels	Safe glucose levels already defined for patient (vary depending on age and type of illness) - hypoglycaemia always when CBG below 4mmol/L.	Blood glucose level assessment may be omitted or performed: • Too late • Incorrectly • Incompletely	Where blood glucose assessments are omitted, incorrect or delayed, this may impact the following functions: #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #13 Diabetes inpatient treatment plan developed. #23 Adjust insulin during acute illness.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#17. Treat hypoglycaemia	PWDI to take food, glucose tablets, glucose gel, juice if able to. If not intravenous glucose or intramuscular glucagon to be given according to guidelines. Prescriber required for intravenous or intramuscular medicines, but not for food, glucose tablets, glucose gel or juice. Prescriptions for carbohydrates for hypoglycaemia automatically added alongside any prescription for insulin.	Treatment of hypoglycaemia may be: • Omitted • Given too late • Given incorrectly, for example incomplete dose of carbohydrates administered or the wrong treatment for hypoglycaemia administered	Incorrect, omitted or delayed treatment for hypoglycaemia may impact mean the need for #17 Treat hypoglycaemia to be repeated, or #18 Treat hyperglycaemia subsequently required. It may impact: #13 Diabetes inpatient treatment plan developed. #23 Adjust insulin during acute illness. It may prompt #21 Refer to inpatient diabetes team.
#18. Treat hyperglycaemia	High blood glucose levels identified, cause diagnoses, emergency treatment prescribed, administered and recorded on EPR.	Treatment of hyperglycaemia may be: • Omitted • Given too late • Given incorrectly (either too much, too little or wrong prescription)	Incorrect, omitted, or delayed treatment for hyperglycaemia may mean #17 Treat hypoglycaemia is required or, #18 Treat hyperglycaemia may need to be repeated. It may impact: #13 Diabetes inpatient treatment plan developed. #23 Adjust insulin during acute illness. It may prompt #21 Refer to inpatient diabetes team.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#19. Arrange self-management of diabetes for PWDI	Staff perform assessments, paperwork and organisational requirements to enable PWDI to administer their own insulin. This includes assessing capacity and understanding, signing consent and arranging suitable insulin and equipment to allow them to administer doses and monitor CBGs	Self-administration of insulin by PWDI may be omitted or arranged • Too late • Incorrectly (for example, if PWDI authorised to self-administer but unable to, or able to self-administer but not authorised to) • Incompletely (for example, authorised to self-administer but insulin, equipment and/or carbohydrates not available to PWDI)	This function requires #13 Diabetes inpatient treatment plan developed to have been completed. Where PWDI can and are authorised to self-administer, this can impact the following functions: #24 Administer routine insulin. #23 Adjust insulin during acute illness. #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #25 Perform discharge assessment. #26 Identify insulin needs for discharge. #27 Create insulin plan for discharge.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#20. Source insulin(s) for inpatient use	Nursing staff to review prescribed insulin and locate or arrange supply for use while admitted to clinical area. This involves checking the insulin brought in by the PWDI to confirm that it matches the prescription and is within 28 days of being opened, has been stored correctly and is in good condition according to relevant policies. The nurse must check whether the PWDI brought insulin with them and still has this among their belongings, whether it has been locked in the bedside locker or ward refrigerator. If the PWDI does not have any of their own, or if it does not match the prescribed insulin, then ward stock should be checked to see if in-date and useable supply (and corresponding equipment is available, e.g. insulin syringe for insulin vial). If not available on ward, must be requested and supplied from pharmacy.	Insulin may be either be omitted, sourced too late or the incorrectly (either the wrong insulin obtained, only one of multiple insulins obtained or insufficient insulin obtained).	If insulin for inpatient use varies, then this can impact: #24 Administer routine insulin. #18 Treat hyperglycaemia. #23 Adjust insulin during acute illness. #26 Identify insulin needs for discharge.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#21. Refer to inpatient diabetes team	Need for additional expertise or education and training identified by member of clinical team (either nursing, medical or pharmacy staff, physio/OT, discharge liaison team etc). Request made for advice on treatment or for input for training	Referral to the diabetes team may be omitted, performed too late, or performed incorrectly. Incorrect referrals could be: • Inappropriate • Made using the wrong method (e.g. email to incorrect address) • Incomplete (e.g. started but not sent)	Variability in referring to the diabetes team can impact the following functions: #23 Adjust insulin during acute illness. #18 Treat hyperglycaemia. #25 Perform discharge assessment. #26 Identify insulin needs for discharge. #27 Create insulin plan for discharge. #32 Provide education to PWDI or carer. #33 Make primary care referrals. #34 Secondary care diabetes team make follow-up phone call.
#22. Assess and treat high ketone levels	Ketone levels taken and reviewed. Where high according to clinical guidelines, the cause of this is identified, diagnosed and treatment is given. Monitoring is performed according to guidelines and the levels are checked and this step repeated until ketosis is resolved.	High ketone levels may be unrecognised, identified too late or incorrectly. Treatment may be omitted, delayed or incorrect.	Variability in assessing and treating high ketone levels may impact: #23 Adjust insulin during acute illness. #18 Treat hyperglycaemia. #27 Create insulin plan for discharge.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#23. Adjust insulin during acute illness	Impact of illness, current oral intake, other medicines being used, insulin treatments, hypoglycaemia episodes and hyperglycaemia episodes identified and considered	Insulin adjustments during acute illness may be: • Delayed • Omitted • Incorrect	Consequences of delayed, omitted or incorrect insulin adjustments may impact many functions. Consequences of incorrect doses may impact immediate diabetes treatment: #16 Assess blood glucose levels. #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #24 Administer routine insulin. Poorly managed diabetes during inpatient admission can impact discharge plans: #21 Refer to inpatient diabetes team. #25 Perform discharge assessment. #26 Identify insulin needs for discharge. #27 Create insulin plan for discharge.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#24. Administer routine insulin	Routine doses of insulin administered according to prescription. This includes long acting basal insulins and other insulins prescribed to maintain insulins within a defined range. Also includes insulins to be given with meals (although this is less likely with Type 2 diabetes).	Insulin administration may be: • Delayed • Omitted • Incorrect	Consequences of delayed, omitted or incorrect insulin administration may impact many functions. Consequences of incorrect doses may impact immediate diabetes treatment: #16 Assess blood glucose levels. #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #24 Administer routine insulin. Poorly managed diabetes during inpatient admission can impact discharge plans: #21 Refer to inpatient diabetes team. #25 Perform discharge assessment. #26 Identify insulin needs for discharge. #27 Create insulin plan for discharge.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#25. Perform discharge assessment	Identify whether PWDI will continue to need insulin on discharge and whether any support is likely to be required. Consider social circumstances and potential impact of illness on ability to manage insulin. Consider how illness and concomitant medications may impact insulin needs and management. Set anticipated discharge date.	Discharge assessment may be either omitted or performed: • Too late • Incorrectly	Variability in performing discharge assessment can impact: #26 Identify insulin needs for discharge. #28 Identify equipment needs for discharge #27 Create insulin plan for discharge. #33 Make primary care referrals. #34 Secondary care diabetes team make follow-up phone call.
#26. Identify insulin needs for discharge	Prescription must be written, checked by pharmacist, items required confirmed and supplied by the pharmacy and delivered to the ward.	Insulin needs for discharge may be either omitted, identified: • Too late • Incorrectly (wrong device, or insulin identified, support needs not identified, e.g. need for district nurse).	Variability in identifying insulin needs for discharge can impact: #27 Create insulin plan for discharge. #29 Arrange discharge supply of insulin & equipment. #30 Provide discharge letter. #33 Make primary care referrals. #34 Secondary care diabetes team make follow-up phone call.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#27. Create insulin plan for discharge	Review insulin requirements during admission, blood glucose levels, HbA1c, diet in hospital and likely diet following discharge and other medications and potential impact on insulin dosing along with discharge assessment and develop a plan for diabetes management and insulin dosing after discharge. This includes details about which insulin(s) and device(s) to use and at what doses, sick day rules, who will administer insulin, and monitoring requirements and how to adjust insulin.	The insulin plan for discharge may not be developed, or may be: • Delayed • Incorrect for the PWDI	Incorrect and delayed insulin plans for discharge will impact the following functions: #29 Arrange discharge supply of insulin & equipment. #30 Provide discharge letter. #32 Provide education to PWDI or carer. #33 Make primary care referrals. #26 Identify insulin needs for discharge. #28 Identify equipment needs for discharge

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#28. Identify equipment needs for discharge	Nursing staff or diabetes specialist nurses must review and discuss with PWDI to determine what equipment is required and what is already available at home. This includes a sharps bin, CBG and ketone monitoring equipment (lancets, monitors, test strips) and insulin devices for pens that use cartridges. These items do not come from the inpatient pharmacy, but are usually supplied by either the diabetes team or from the ward stock.	Equipment needs for discharge may be either omitted, or identified: • Too late • Incorrectly (wrong device, or insulin identified, support needs not identified, e.g. need for district nurse). • Incomplete (not enough equipment supplied on discharge)	Variability in identifying equipment could impact: #29 Arrange discharge supply of insulin & equipment. #30 Provide discharge letter. #32 Provide education to PWDI or carer. If this function is delayed, omitted or unsuccessful, it can impact: #8 Monitor blood glucose levels. #16 Assess blood glucose levels. #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #24 Administer routine insulin

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#29. Arrange discharge supply of insulin & equipment	This step involves prescribing relevant insulin(s) and devices, nursing staff identifying additional equipment that may be needed, for example needles and CBG monitors, if needed inpatient diabetes team to supply. Prescription must be written, checked by pharmacist, items required confirmed and supplied by the pharmacy and delivered to the ward. Insulin is prescribed, but other equipment is not prescribed but arranged by the diabetes or ward nurses. Insulin is prescribed, but other equipment is not prescribed but arranged by the diabetes or ward nurses.	Supply of insulin and equipment may be: • Too late (sent home after PWDI already left hospital) • Too early (needs may change before discharge) • Omitted (insulin and equipment not supplied) • Supplied incorrectly (wrong or incomplete)	If insulin and equipment supply does not occur as planned, this can impact: #24 Administer routine insulin. #32 Provide education to PWDI or carer. #36 Manage diabetes at home #43 Request insulin/equipment prescription in primary care.
#30. Provide discharge letter	Diabetes management during admission, changes to therapy and care plan for discharge described in discharge letter. This includes list of medicines and insulin prescribed. Other equipment not routinely prescribed at most hospitals (although some do). Discharge letter written on electronic health records and sent to GP surgery email inbox by PDF. A copy is printed and given to the PWDI and/or caregiver.	The discharge letter may be either: • Provided too late. • Not provided at all. • Incorrect with either inaccurate or incomplete information about diabetes and insulin.	If the discharge letter is delayed, omitted or incorrect, this can impact: # Primary care team accept referral. # Identify hospital discharge. # Reconcile insulin in primary care. # GP surgery diabetes review. # PWDI follow-up in primary care. # Review discharge letter in primary care. #36 Manage diabetes at home

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#31. Discharge to primary care	PWDI ready to go home and discharged from hospital electronic health system and allowed to leave ward/clinical area.	Discharge to primary care may be delayed or too early according to the PWDI clinical condition.	If the PWDI is discharged too early, the following functions may be affected: #23 Adjust insulin during acute illness. #27 Create insulin plan for discharge.
#32. Provide education to PWDI or carer	Provide PWDI or their caregiver an understanding of diabetes and insulin management evaluated, and education given on relevant areas including how to check CBGs, how to adjust insulin doses as needed, what to do when unwell, how to administer insulin, how to dispose of sharps etc.	Education may be provided too late, too early before final discharge plans are known, or not provided at all. It is also possible that the education could be incorrect or incomplete.	Providing education to the PWDI or carer is an opportunity to confirm that the correct insulin and devices have been provided. Therefore, variability in this function can impact: #26 Identify insulin needs for discharge. #28 Identify equipment needs for discharge. #36 Manage diabetes at home #8 Monitor blood glucose levels. #16 Assess blood glucose levels. #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #24 Administer routine insulin

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#33. Make primary care referrals	Referrals made to relevant outpatient teams, for example district nurses to help with insulin administration or community pharmacy for discharge medicine service consultation.	Referrals may either not be made, may be sent too late or be incorrect. For example, referrals may be for the wrong support needs, or not enough to support needs. Or the referral may be sent incorrectly, and the team does not receive the referral.	This can impact: #37 Primary care team accept referral. #47 Seek assistance after discharge.
#34. Secondary care diabetes team make follow-up phone call	DSN calls patient after discharge to check patient management where they are on steroids or newly started on insulin.	The phone call may either not be made or made too late. The conversation may not address all the issues or topics required for the PWDI to manage their diabetes.	Where secondary care referrals are delayed, omitted or incomplete, this may impact: #47 Adjust insulin following discharge. #36 Manage diabetes at home
#35. Travel home	PWDI travels home and resumes managing diabetes according to agreed care plan. Where required, district nurses come to support insulin administration and monitoring tasks.	Travel home may be delayed or too early according to the PWDI clinical condition.	

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#36. Manage diabetes at home		Self-management of insulin in primary care may be incorrect if needs not assessed correctly and required support not provided, if education inadequate or discharge information incorrect.	The following functions impact manage diabetes at home: #27 Create insulin plan for discharge. #26 Identify insulin needs for discharge. #28 Identify equipment needs for discharge. #29 Arrange discharge supply of insulin & equipment. #30 Provide discharge letter. #32 Provide education to PWDI or carer. Variability in this function can impact: #47 Adjust insulin following discharge. #47 Seek assistance after discharge. #8 Monitor blood glucose levels. #16 Assess blood glucose levels. #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #24 Administer routine insulin.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#37. Primary care team accept referral	Team who were sent referral agree to take on care for PWDI. PWDI is added to caseload list and appointment is scheduled.	Referral acceptance may be delayed, or the referral could be missed. A referral may be rejected if not completed correctly or does not meet referral criteria.	Where a primary care referral has not been actioned or is delayed #47 Adjust insulin following discharge. #36 Manage diabetes at home
#38. Identify hospital discharge	Administration staff identify PWDI has been discharged from hospital by identifying PDF of discharge letter in the surgery inbox.	The GP surgery may not identify the hospital discharge immediately, or not identify there has been a hospital admission at all.	Variability in this function can impact: #39 Reconcile insulin in primary care. #40 GP surgery diabetes review. #41 PWDI follow-up in primary care #42 Review discharge letter in primary care #44 Supply insulin and equipment in primary care #45 Prescribe insulin and equipment in primary care

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#39. Reconcile insulin in primary care	A thorough check of post-admission insulin following potential changes during hospital admission. Any discrepancies with pre-admission insulin are identified and confirmed that these were intentional. Confirm with hospital teams if the documentation in the discharge letter is unclear. Update of medical records to match.	Insulin needs may be identified too late, and changes to insulin may not be identified. The discharge letter may be incorrect with either inaccurate or incomplete information about diabetes and insulin. Changes to insulin may be documented incorrectly in GP records.	The following functions may be impacted by variability in reconciling insulin in primary care: #40 GP surgery diabetes review. #41 PWDI follow-up in primary care. #47 Adjust insulin following discharge. #42 Review discharge letter in primary care.
#40. GP surgery diabetes review	A clinical member of staff assigned by admin reviews discharge information and identifies any changes to the diabetes plan and need for referral to outpatient diabetes team.	Diabetes review may not be arranged and performed or may be delayed. Diabetes review may not cover all aspects of insulin management.	The following functions may be delayed or incorrect: #41 PWDI follow-up in primary care. #47 Adjust insulin following discharge. #42 Review discharge letter in primary care.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#41. PWDI follow-up in primary care	Referrals received by community pharmacy, outpatient diabetes team and/or district nurses and administrative activities undertaken to place PWDI on the list for appointment	May be omitted or delayed if referrals are either not sent, sent incorrectly, or not identified.	Requires the following functions to be completed: #33 Make primary care referrals #37 Primary care team accept referral #49 Review referral in primary care For district nurses, the following function must also be completed: #49 Provide authority to administer insulin for district nurses
#42. Review discharge letter in primary care	Administrative staff review discharge letter from primary care and assign to task list of relevant clinical staff (e.g. clinician for review of diabetes, pharmacist or Medicines Management Technician if medicines/insulin involved).	This review may be omitted or performed too late. It may be assigned to the incorrect healthcare professional to review. The review may not identify all the relevant insulin-related information in the discharge letter.	The following functions may be delayed or incorrect: #41 PWDI follow-up in primary care. #47 Adjust insulin following discharge. #40 GP surgery diabetes review may not be arranged as the need not identified.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#43. Request insulin/equipment prescription in primary care	Need for insulin/equipment identified and requested from relevant healthcare professional by PWDI or someone acting on their behalf.	If the insulin or equipment request is not made or delayed, the PWDI may run out. The wrong insulin or equipment may be requested (wrong insulin, equipment, or incomplete request).	If insulin or equipment not requested, may mean PWDI is unable to perform #36 Manage diabetes at home. Following functions unlikely to be performed: #44. Supply insulin and equipment in primary care. #45. Prescribe insulin and equipment in primary care.
#44. Supply insulin and equipment in primary care	Prescriptions generated by GP surgery and sent electronically to PWDI nominated pharmacy who process the request, supply the medicines and equipment and store for collection or delivery to the PWDI.	Insulin and equipment may not be supplied, or supply may be delayed. Incorrect insulin or equipment could be supplied.	Requires function #45 Prescribe insulin and equipment in primary care to be performed before this function can proceed. This function is a requirement for #36 Manage diabetes at home. If this function is delayed or omitted it can impact: #8 Monitor blood glucose levels. #16 Assess blood glucose levels. #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #24 Administer routine insulin

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
#45. Prescribe insulin and equipment in primary care	Generate a prescription on EHR that is sent directly to a community pharmacy or printed and given to a person (e.g. PWDI, carer, relative, district nurse). The prescription is then taken/sent to a community pharmacy.	Insulin and equipment may not be prescribed, or prescription may be delayed. Incorrect insulin or equipment could be prescribed.	This function is a requirement for #36 Manage diabetes at home. If this function is delayed or omitted it can impact: #8 Monitor blood glucose levels. #16 Assess blood glucose levels. #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #24 Administer routine insulin
#46. Seek assistance after discharge	PWDI, caregiver, GP or other healthcare professional identifies new issue with diabetes and insulin and seeks help or advice to manage. Could be advice from primary or secondary care.	Assistance may be sought too late or not sought at all. The request for assistance could be incorrectly directed, e.g. to a less appropriate healthcare professional.	If this function is not performed, then #47 Adjust insulin following discharge may be omitted.
#47. Adjust insulin following discharge	Healthcare professional in collaboration with PWDI or caregiver adjust insulin regimens to ensure blood glucose levels stay within the desired range as much as possible.	Insulin adjustments may not be made or may be delayed. Insulin may be adjusted incorrectly after discharge.	This function is a requirement for #36 Manage diabetes at home. It requires the following functions to have occurred or be performed to be accurate: #42 Review discharge letter in primary care. #39 Reconcile insulin in primary care.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
			It may both impact and be impacted by the following functions: #16 Assess blood glucose levels. #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #24 Administer routine insulin.
#48. Provide authority to administer insulin for district nurses	GP identifies referral of PWDI to district nurses either through being copied into referral, or district nurses notifying of referral. The GP reviews the discharge letter and insulin doses and creates an agreed document that provides the district nurses with the authority to administer the PWDI's insulin at the doses listed.	If this is delayed or omitted, district nurses may not be able to administer insulin when it is required. If it is done incorrectly, the district nurses may give incorrect doses of insulin.	The following functions must be completed for this function to be performed: #33 Make primary care referrals #37 Primary care team accept referral #49 Review referral in primary care #42 Review discharge letter in primary care. #39 Reconcile insulin in primary care #47 Adjust insulin following discharge. #42 Review discharge letter in primary care. If not performed it may impact the following functions: #16 Assess blood glucose levels.

Foreground functions	Function definition	Types of variability	Impact of or on other functions (functional coupling)
			#17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #24 Administer routine insulin.
#49. Review referral in primary care	Service receiving referral identifies it in their list, screens for appropriateness, and reviews any activities that need to be completed to add to caseload. Collaborates with GP to ensure paperwork in place.	If this is delayed or omitted, then the requirements of PWDI may not be identified and specific needs may not be addressed before follow-up occurs. For example, for district nurses, the authority to administer needs to be arranged with the GP.	If this function is delayed or omitted, then #48 Provide authority to administer insulin for district nurses may not occur. Therefore, #41 PWDI follow-up in primary care and #24 Administer Routine insulin may be omitted.

Appendix VIII: Functional resonance analysis method: Developing potential leading indicators – an illustrative example

Overview

The article presented in this appendix provides an illustrative example of using FRAM to develop potential targets for leading indicators. The methods used to develop the model and the findings are described. This study used FRAM to identify where variability can impact outcomes for safe insulin management during ToC. These areas were considered as targets for developing proactive indicators to highlight, in real-time, opportunities for safety interventions. Such indicators will complement traditional indicators in improving safety for this patient group.

A model for insulin management across ToC was developed using FRAM. Twenty-one key areas of variability were identified. Potential targets for leading indicators included six background functions for passive leading indicators and fifteen foreground functions for active leading indicators. These were presented at an online seminar with key stakeholders including PWDI, their caregivers and healthcare professionals from primary and secondary care. Seminar participants agreed that these represented key areas for safe insulin management during ToC.

Two example functions, 'Arrange self-management of diabetes in hospital' (a foreground function) and 'Empower PWDI to manage insulin' (a background function) were then chosen for further exploration during a seminar to gauge their potential as leading indicators. These two functions were chosen to be applicable to a wide range of attendees so all could contribute to the discussions. During the seminar the two functions were interrogated to explore what measures were already available, where there are gaps, and what measures would be required to understand the safety of these functions in real-time. A list of potential measures for each of the two leading indicators was developed by combining the findings from the seminar and the FRAM model.

The study findings provide a strong foundation for future development of Safety-II orientated indicators. FRAM provided a method to identify potential leading indicators based on understanding how work is performed and how variability can impact outcomes later in the pathway. Applying this method was challenging both because of the technical difficulty of the method and the complexity of the FRAM findings, given the extensive variation identified across almost all functions. It was pragmatic to focus on representative functions when considering indicator development as using the whole FRAM model would become overwhelming. Those

wishing to use this method would benefit from additional training materials and mentorship, including guidance for potential users how and when to use this method to get the most benefit.

Supplementary information is included in Appendix IX.

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SECTION A – Student Details

Student ID Number	LSH2005295	**Title**	Ms
First Name(s)	Catherine		
Surname/Family Name	Leon		
Thesis Title	A new approach to identifying safety measures across transfers of care for people who use insulin for Type 2 diabetes.		
Primary Supervisor	Helen Hogan		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?			
When was the work published?			
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Diabetic Medicine
Please list the paper's authors in the intended authorship order:	Catherine Leon, Helen Hogan, Yogini H Jani, Clare Crowley
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceptualised the study with the advice of my PhD supervisors. I performed the fieldwork and data analysis. I developed the FRAM model with advice and feedback from an expert mentor. I analysed the model and developed key findings. I wrote the initial draft of the paper, and amended and updated this following critical review from the co-authors.

SECTION E

Student Signature	Catherine Leon
Date	08/09/2024

Supervisor Signature	Helen Hogan
Date	08/09/2024

A new approach to identifying safety measures across transfers of care for people who use insulin for Type 2 diabetes

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Conflicts of interest

None to declare

Novelty Statement

- **What is already known?** Transfers of care for people with diabetes are known to be challenging for safe insulin management.
- **What has this study found?** The Functional Resonance Analysis Method (FRAM) was used to identify areas of variability as potential targets for proactive indicators of safe insulin management during ToC.
- **What are the implications of this study?** FRAM provides an inclusive approach to modelling complex pathways, allowing assessment of how variability can impact outcomes. Areas of variability can be targets for potential leading indicators. Training and mentoring opportunities would support new users to apply this method.

Funding and acknowledgements:

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Abstract:

Background

When people who use insulin for Type 2 diabetes have a hospital admission and discharge, they are at risk of harm from incorrect, delayed or missed insulin doses. Leading indicators can highlight potential areas of risk, providing opportunities to improve safety. Modelling the complex transfer of care pathway can provide insight into where leading indicators could be targeted to support improved outcomes.

Methods

Multiple qualitative methods were used, and a framework approach applied to identify activities (termed functions) involved in managing insulin during transfer of care, and how factors involving people, equipment and environments (local, organisational and external) impacted these. The Functional Resonance Analysis Method was used to map the transfer of care pathway, and key areas of variability were identified. These areas of variability and two example functions were validated and discussed with key/representative stakeholders in an online seminar.

Results

A total of 59 functions were mapped, and 21 were identified as key functions for potential new measures. These 21 functions were validated at a seminar, and two example functions, empowering people with diabetes who use insulin to manage their diabetes and arranging self-administration of insulin in hospital, were discussed in detail. A selection of potential measures were identified.

Conclusions

This study used the Functional Resonance Analysis Method to model safe insulin management during TOC and identify potential areas for new leading indicators. Examples of potential measures were described; however a coproduction approach is required to expand, define, and validate these.

Key words

Diabetes; drug safety; complications; insulin

Main text

Background

People with diabetes who use insulin (PWDI) face risks when they have a hospital admission and then return home.(51,108,182,183) The process of moving between care settings, such as home and hospital is called Transfer of Care (ToC). To manage insulin safely and avoid harm, it is important to communicate how insulin should be given and adjusted, and to consider the effects of illness, changes in diet and activity levels, and other medications. If insulin doses are incorrect, missed, or delayed, it can cause serious harm or even death.

Over the years, patient safety campaigns have tried to improve insulin management during ToC by creating patient-held insulin records,(51) developing guidelines for self-administration,(94) and introducing e-learning for patients and staff.(184,185) Despite these efforts, the same issues are still being addressed in a national campaign in England called the Get it Right First Time (GIRFT) Diabetes program.(55)

To improve insulin safety during ToC, it is essential to have measures that demonstrate how well insulin is being managed. Without this data, it's hard to prove the need for change, identify where to focus improvements, or see if interventions are working. Most traditional measures look at harm rates, like rates of hypo and hyperglycaemia, hospital readmissions, and deaths.(16) With increased digitisation of health records across health and care sectors, there is opportunity and a need for predictive measures, called leading indicators, that can identify risks in real-time and allow proactive safety improvements. These measures could help healthcare teams, organizations, and policymakers develop better systems for safe insulin management.

Creating proactive measures requires an understanding that healthcare is a complex system made up of people, tasks, equipment, and different environments.(14) These factors evolve, interact and change, requiring adjustments in care.(21) To measure safety effectively, it's important to understand and seek to predict these interactions, adjustments and how they combine to impact outcomes in detail.(38,97)

Leading indicators proactively highlight areas where adjustments may be required allowing those involved in healthcare to monitor for issues that may need to be addressed, and anticipate potential problems and seek to prevent them occurring or minimise their impact. There are two types of leading indicators, active and passive.(39) Active leading indicators for

use by people directly involved in providing and receiving care, such as the National Early Warning Sign scores, can highlight people at risk of deterioration in real time prompting timely review.(137) Passive leading indicators provide information to organisations about how well the systems and processes are designed.(39)

The Functional Resonance Analysis Method (FRAM) is a tool that models complex systems and examines how aspects of variability affect outcomes.(19) FRAM has been used to develop potential leading indicators for detecting sepsis.(38) FRAM models can represent both daily activities (termed functions) and the structural factors that support them (background functions). This study aimed to use FRAM to identify where variability can impact outcomes for safe insulin management during ToC. These areas were considered as targets for developing proactive indicators to highlight, in real-time, opportunities for safety interventions. Such indicators will complement traditional indicators in improving safety for this patient group.

Methods

Study design

Multiple qualitative methods were used to develop an understanding of insulin management for people with Type 2 diabetes during ToC. An overview of the components of the study are shown in Figure 39. ToC was defined as being from when the need for hospital admission was identified through to routine follow-up after discharge.

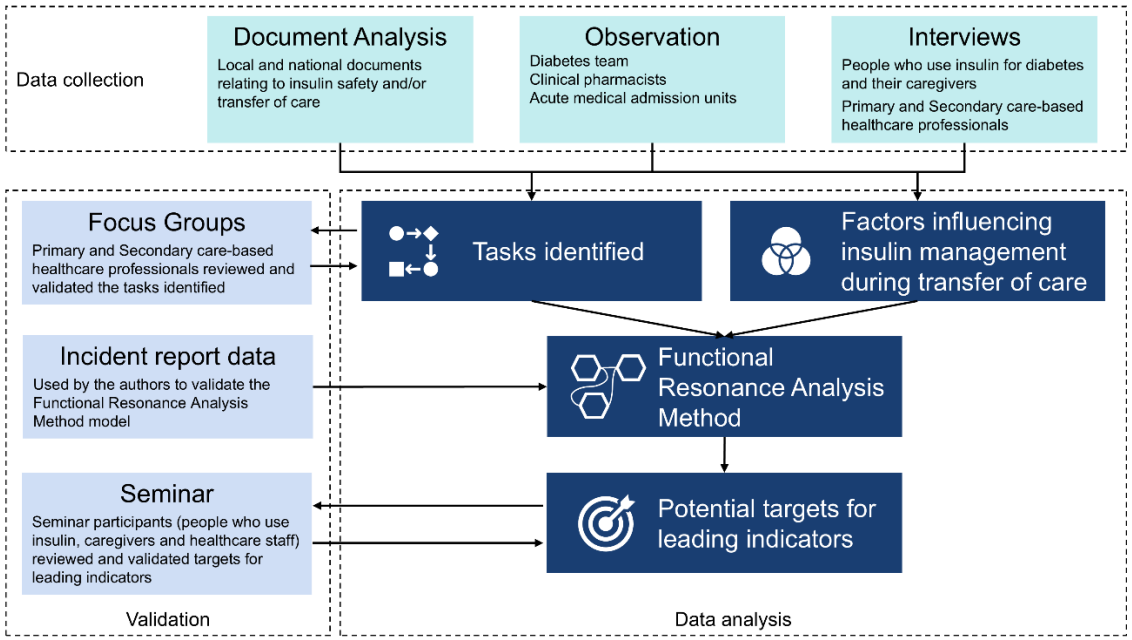

Figure 39: Data sources and components of research.

Setting and sample

Fieldwork was undertaken over 17 months between October 2022 and March 2024. The setting was initially within an integrated care system in England. To boost numbers, recruitment was widened to include participants for interviews, focus groups and the seminar from across England.

Data collection

Documentary analysis was undertaken on national and local documents relating to insulin safety and/or transfer of care. Documents were identified using hospital intranet searches and through exploration of relevant organisational websites, including the Joint British Diabetes Societies for Inpatient Care Group, the National Institute for Health and Care Excellence, the Royal College of General Practitioners, and the Royal Pharmaceutical Society.

Purposive observation was undertaken over 85 hours in a large, acute teaching hospital. The diabetes team and clinical pharmacists were observed managing diabetes and insulin and undertaking discharge preparations for PWDI who had been admitted to hospital. Care provision on acute medical admissions units was also observed to opportunistically identify PWDI recently admitted to hospital or about to be discharged home. Field notes were written during and immediately following the period of observation. The Systems Engineering Initiative for Patient Safety 101(SEIPS) work system categories were used to guide observations.(15) These categories define a work system as composing of people, tools and equipment, tasks and environments (local, organisational and external).

Semi-structured online interviews were undertaken with people involved in managing insulin during ToC, including PWDI over 18 years with Type 2 diabetes and a hospital admission within the last 5 years, or their caregivers and multiple professions across primary and secondary care. PWDI or caregivers were excluded if they could not participate in a telephone call or online video call or required an interpreter. Twenty interviewees were asked to describe their experiences with managing insulin during ToC, what goes well and where challenges are involved. Participants were identified by healthcare professionals during observation, and through invitations shared on national diabetes forums and on X (formerly Twitter). Purposive sampling of healthcare professionals known to the authors was used to invite participation in the interviews and online seminar.

Data analysis

Tasks required to manage insulin during ToC and the factors that influenced them were identified through a framework analysis of documents, field notes from observations and transcripts from interviews. SEIPS 101(15) work system categories were used to guide analysis. Factors that impacted insulin management were categorised according to whether they involved tasks, people, tools, or environments (local, organisational, or external). FRAM is a method that supports the identification of areas of variability which have potential to be developed as leading indicators. To best illustrate this application of this method, this paper focuses on the emergency admissions to hospital element of the ToC pathway, as this is a particularly high-risk time for safety.

The tasks identified during framework analysis were used as the basis for the FRAM functions, according to the method defined by Hollnagel,(19) and potential targets for leading indicators were identified using the method defined by Raben et al.(38) The functions were evaluated according to six aspects:

1. **Input** – the prompt for the function to begin.
2. **Output** – the outcome of the function.
3. **Pre-conditions** – anything that must be in place for the function to begin.
4. **Resources** – resources needed for the function, for example, skills, equipment, and guidelines.
5. **Controls** – the aspects of the system that control the output of the function, for example, IT programming or regulations.
6. **Time** – how time influences how the function is performed, for example, whether it needs to be before other functions, or how long the function may take to process.

See Figure 40 for an example function.

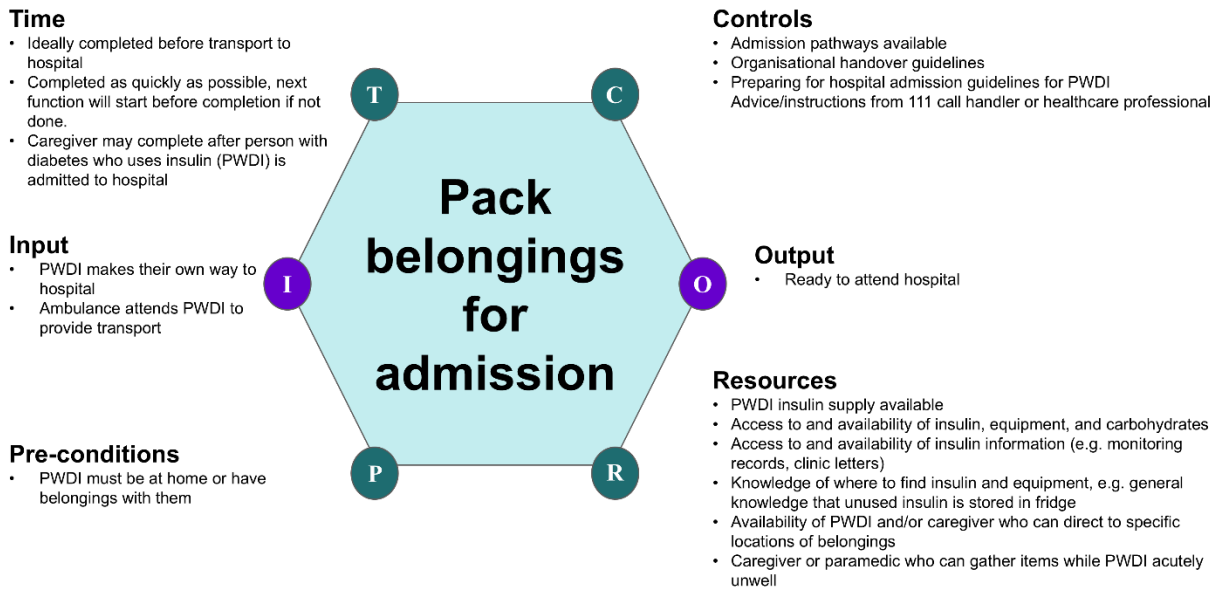

Figure 40: An example function demonstrating the aspects identified.

The model was built iteratively. During the process additional functions were identified and added, including background functions. Background functions are those that impact the success of other functions (foreground functions) but are not activities within the care pathway being studied. They include factors such as appropriately trained staff available and having organisational policies in place.

Once the functions were identified, each function was reviewed to explore how it varied and how this variation might impact the outcomes for insulin management during ToC. Variation could be due to the accuracy of the function, or the timing. For example, the function could be incomplete or incorrect, performed too early, too late or omitted. The potential variability and the consequences of this variability on other functions and ToC outcomes were then described and recorded in a spreadsheet. Supplementary Table 1 presents a sample of functions and their identified variability. Those functions where variability had the potential to impact outcomes were considered as potential targets for leading indicators.

Validation

Two focus groups were held with four healthcare professionals from primary and secondary care to agree the completeness and accuracy of the tasks involved in managing insulin safely during ToC identified through documentary analysis, observation, and qualitative interviews.

Once developed, the FRAM model was tested for completeness using incident reports from the National Reporting and Learning System (NRLS). A structured search was performed of the NRLS database to identify incidents relating to insulin and related terms, admission, discharge,

and transfer of care. A random sample of 100 incident reports were accessed, covering both primary and secondary care. From these reports, ten incidents that provided the most comprehensive narratives and represented different sections of the patient journey were selected and used to check the completeness of the model (a summary of these incidents is included in the supplementary information). A further online seminar was held with PWDI, caregivers and primary and secondary health professionals and managers to present the findings of the analysis and to gauge consensus on the key background and foreground functions associated with safe insulin management during ToC. Suggestions for missing functions or factors and comments were requested and discussed. Additional functions identified during validation processes were added to the model as functions.

Identification of potential areas for safety indicator development

In the online seminar with twelve PWDI, caregivers and health professionals, two representative functions where variability impacted outcomes were interrogated in detail. The potential for these functions as areas for development of new safety leading indicators was explored. The chosen functions represented one background function (empower PWDI to manage diabetes) related to the structural factors required for successful outcomes and one foreground function (arrange self-management of diabetes while in hospital) related to supporting PWDI as care is being provided. The seminar identified the limits of current safety measures and measurement gaps before focusing on potential new measures related to the two functions and data collection requirements.

Reflexivity and author contributions

Data collection and analysis was performed by the lead researcher (CL), a medication safety pharmacist by background. This allowed the author to understand the clinical context of the terms and aspects of care being observed and described. The qualitative findings were reviewed on a regular basis by the study team (YJ and HH with backgrounds in safety, pharmacy, and primary care) following which areas for further exploration and data collection were identified.

The FRAM was performed by CL with advice and feedback given by CC, a pharmacist and a Chartered Ergonomist experienced in using FRAM. Any identified need for additional functions, and any differences of opinion about the model, were discussed to reach consensus and the model updated.

Ethics

Ethics approval was obtained from the United Kingdom NHS Health Research Authority and Ethics Committee (22/EE/0155) and the University Ethics committee (28148). Amendments were obtained from both ethics committees to widen the recruitment of patients, healthcare professionals and to extend the deadline. All participants provided informed consent for participation.

Results

Documentary analysis was used to explore how work was prescribed while observation and interviews provided insight into how work was performed in an everyday setting. This allowed a detailed understanding of the ToC care pathways and the factors that influence how they are performed. This information was used to identify and define the FRAM functions, and consider where variation in function output impacts outcomes for insulin management during ToC.

Fifty-nine functions were identified spanning ToC pathways, including nine background functions and 50 foreground functions. A list of the functions identified is included in Table 6. Analysis of incident data led to the inclusion of an additional two functions, 'Provide authority to administer insulin for district nurses,' and 'Review referral in primary care'.

Table 6: *Functions identified for the Functional Resonance Analysis Method, with proposed key functions impacting outcomes highlighted.*

	Name of function	Type of function	Proposed target for leading indicators?
1	Decide hospital admission is needed	Foreground	No
2	Pack belongings for hospital admission	Foreground	No
3	Travel to hospital	Foreground	No
4	Arrange ambulance	Foreground	No
5	Refer the person with diabetes who uses insulin (PWDI) to hospital	Foreground	No
6	Handover diabetes care to hospital	Foreground	Yes
7	Gather insulin information	Foreground	Yes
8	Monitor blood glucose levels	Foreground	No
9	Admit PWDI to hospital	Foreground	No
10	Provide orientation to clinical area	Foreground	No

11	Hospital-based clinical team accept patient	Foreground	No
12	Confirm diabetes history	Foreground	Yes
13	Develop diabetes inpatient treatment plan	Foreground	Yes
14	Prescribe insulin	Foreground	Yes
15	Check baseline observations	Foreground	No
16	Assess blood glucose levels	Foreground	No
17	Treat hypoglycaemia	Foreground	No
18	Treat hyperglycaemia	Foreground	No
19	Arrange self-management of diabetes for PWDI while in hospital	Foreground	Yes
20	Source insulin(s) for inpatient use	Foreground	No
21	Refer to inpatient diabetes team	Foreground	No
22	Assess and treat high ketone levels	Foreground	No
23	Adjust insulin during acute illness	Foreground	No
24	Administer routine insulin	Foreground	No
25	Perform discharge assessment	Foreground	Yes
26	Identify insulin needs for discharge	Foreground	No
27	Create insulin plan for discharge	Foreground	Yes
28	Identify equipment needs for discharge	Foreground	No
29	Arrange discharge supply of insulin & equipment	Foreground	No
30	Provide discharge letter	Foreground	Yes
31	Discharge to primary care	Foreground	No
32	Provide education to PWDI or carer	Foreground	Yes
33	Make primary care referrals	Foreground	Yes
34	Secondary care diabetes team make follow-up phone call	Foreground	No
35	Travel home	Foreground	No
36	Manage diabetes at home	Foreground	Yes
37	Primary care team accept referral	Foreground	No
38	Identify hospital discharge	Foreground	No
39	Reconcile insulin in primary care	Foreground	No
40	GP surgery diabetes review	Foreground	No

41	PWDI follow-up in primary care	Foreground	No
42	Review discharge letter in primary care	Foreground	Yes
43	Request insulin/equipment prescription in primary care	Foreground	No
44	Supply insulin and equipment in primary care	Foreground	No
45	Prescribe insulin and equipment in primary care	Foreground	No
46	Seek assistance after discharge	Foreground	Yes
47	Adjust insulin following discharge	Foreground	Yes
48	Provide authority to administer insulin for district nurses	Foreground	No
49	Review referral in primary care	Foreground	No
50	Treat presenting illness	Foreground	No
51	Provide diabetes framework	Background	Yes
52	Empower PWDI management of diabetes	Background	Yes
53	Healthcare organisational capacity	Background	No
54	Manage workload	Background	No
55	Provide transfer of care infrastructure	Background	No
56	Maintain IT infrastructure	Background	Yes
57	Manage stock of insulin and equipment	Background	Yes
58	Provide appropriate competent staff	Background	Yes
59	Train staff around diabetes and insulin use	Background	Yes

Key targets for potential indicators

Six background functions and fifteen foreground functions were associated with the greatest variability impacting insulin management across ToC. This variability was due to the potential for inaccuracy, incorrect timing or through interactions with other functions. These functions are highlighted in Table 6. These were considered as potential targets for developing leading indicators, see Table 7 for a list of these functions and their definitions. The FRAM model with targets for potential indicators is shown in Figure 41. An example of a function demonstrating the potential causes and consequences of variability is demonstrated in Figure 42.

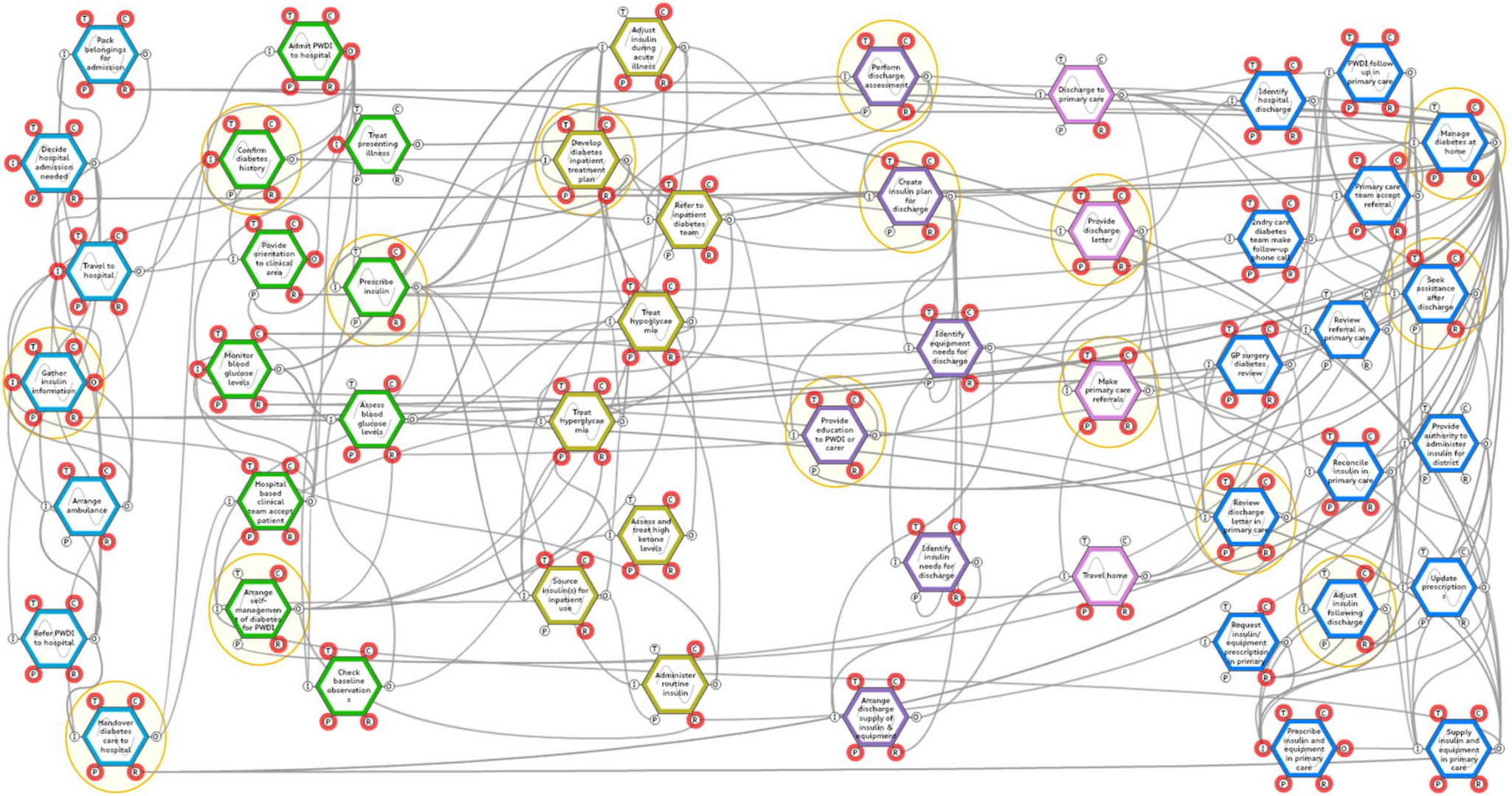

Figure 41: Functional Resonance Analysis Method (FRAM) model of foreground functions. Targets for potential leading indicators are highlighted in yellow.

Table 7: Functions considered as potential leading indicators and their definitions

Type of function	Name of function	Definition
Foreground	Manage diabetes at home	Managing all aspects of diabetes care including: • Collaborating to develop and update diabetes plan • Monitoring glucose levels and identifying and treating hypoglycaemia • Seeking advice if blood glucose levels are problematically outside of range (as per diabetes plan) • Administering insulin and adjusting doses • Maintaining sufficient insulin and equipment supplies • Attending appointments for review • Undertaking training to understand how to manage diabetes according to plan • Storing insulin appropriately in fridge until cartridge/pen is in use
	Handover diabetes care to hospital	Communication of information: • Includes the person with diabetes who uses insulin (PWDI)s current illness, medical and diabetes history and insulin information • May be shared by the paramedics or by the general practitioner (GP) • May be performed over the telephone, by email or by printed report
	Gather insulin information	Identify all relevant information about insulin that is available at the time depending on: • The location of the PWDI • The consciousness level of the PWDI • Available resources (e.g. pen device and record book availability)
	Confirm diabetes history	Identify presence of diabetes: • Identify past medical history and presence of diabetes • Consider diabetes and glucose levels alongside signs and symptoms of illness • Medication history and identify insulin use
	Develop diabetes inpatient treatment plan	Plan should describe an appropriate insulin regimen prescribed for current situation based on: • Pre-admission diabetes management • Lifestyle factors • Impact of current illness and concurrent medications reviewed Plan may include withholding insulin (for example if PWDI has hypoglycaemia), changing to intravenous insulin, or reducing the dose if unable to eat.
	Prescribe insulin	Insulin is prescribed for inpatient administration along with rescue treatments using Electronic Health Record (EHR).

	Arrange self-management of diabetes for PWDI while in hospital	Staff perform assessments, paperwork, and organisational requirements to enable PWDI to administer their own insulin. This includes:
		• Assessing capacity and understanding
		• Obtaining written consent
		• Arranging suitable insulin and equipment to allow them to:
		  ○ Administer insulin doses
		  ○ Monitor blood glucose levels

Type of function	Name of function	Definition
		○ Manage hypo or hyperglycaemia.
Foreground	Perform discharge assessment	Evaluate PWDI's insulin needs for discharge and consider: • Whether any support is likely to be required given social circumstances and potential impact of illness on ability to manage insulin. • Impact of illness and concomitant medications
	Create insulin plan for discharge	Develop plan with PWDI for managing diabetes after discharge considering: • Insulin requirements during admission and blood glucose levels • Diet in hospital and likely diet following discharge • Other medications and their potential impact on insulin dosing • Discharge assessment for social and other support needs • Develop a plan that includes all the above plus: ○ Details about which insulin(s) and device(s) to use ○ What to do when unwell (sick day rules) ○ Plan for who will administer insulin ○ Monitoring requirements
	Provide discharge letter	Letter from hospital to GP including details of: • Diabetes management during admission • Changes to diabetes management and diabetes care plan for discharge • List of medicines and insulin prescribed • Other equipment not routinely prescribed at most hospitals (although some do) Discharge letters are written on electronic health records (EHR) and: • Sent electronically to GP surgery email inbox • A printed copy is given to the PWDI and/or caregiver
	Provide education to PWDI or carer	Provide education to PWDI or their caregiver including: • How to monitor blood glucose levels • How to administer insulin • How to adjust insulin doses as needed • What to do when unwell • How to dispose of sharps • Implications for driving
	Make primary care referrals	Referrals made to relevant outpatient teams where needed including: • District nurses to help with insulin administration • Community pharmacy for review of discharge medications
	Review discharge letter in primary care	Administrative staff in GP surgery: • Identify hospital discharge letter • Assign to task list of relevant clinical staff for review (e.g. clinician for review of diabetes, pharmacist, or Medicines Management Technician if medicines/insulin involved).

Type of function	Name of function	Definition
	Seek assistance after discharge	If an issue with diabetes or insulin occurs after discharge: • PWDI, caregiver, GP or other healthcare professional seek help or advice to manage • Advice could be sought from primary or secondary care
	Adjust insulin following discharge	Healthcare professional in collaboration with PWDI or caregiver: • Review blood glucose levels and insulin doses • Adjust insulin to ensure blood glucose levels stay within desired range as much as possible • Update diabetes plan
Background	Provide diabetes framework	Provider strategies include organisational: • Staffing policies including specialist teams • Training provision • Equipment and medication formulary • Standard operating procedures and guidelines • Commissioned pathways, their oversight and assurance.
	Empower people who use insulin to manage their diabetes	Providing the training and support to enable PWDI (or their caregivers) to manage diabetes at home (see foreground function for included components).
	Maintain IT infrastructure	Provide and maintain a functional IT system and associated software and hardware that: • Allows access to healthcare records across organisations • Enables recording of and access to medical history, medications, appointment details, clinical letters, pathology, and laboratory results etc. • Includes the wireless connection between the monitoring devices and the hospital EHR system

	Manage stock of insulin and equipment	Ordering system in place within hospital or primary care pharmacies to:
		• Ensure that insulin is ordered, stocked and stored appropriately
		• Manage stock on wards
		• Management and adjustment of guidelines where supply issues occur
		Insulin equipment is managed by:
		• Community pharmacy when prescribed by GPs in primary care
		• In hospital the manage provision of:
		  ○ Diabetes specialist nurses provide insulin equipment for the PWDI
		  ○ Hospital stock systems provide a supply of needles, syringes, sharps bins and monitoring devices etc

	Provide appropriate competent staff	Organisations provide adequate healthcare professionals with appropriate skills to match demand of patient population.
	Train staff around diabetes and insulin use	Training for staff enables non-specialist diabetes staff to be equipped with the competencies to care for PWDI using insulin.

*PWDI = people with diabetes who use insulin

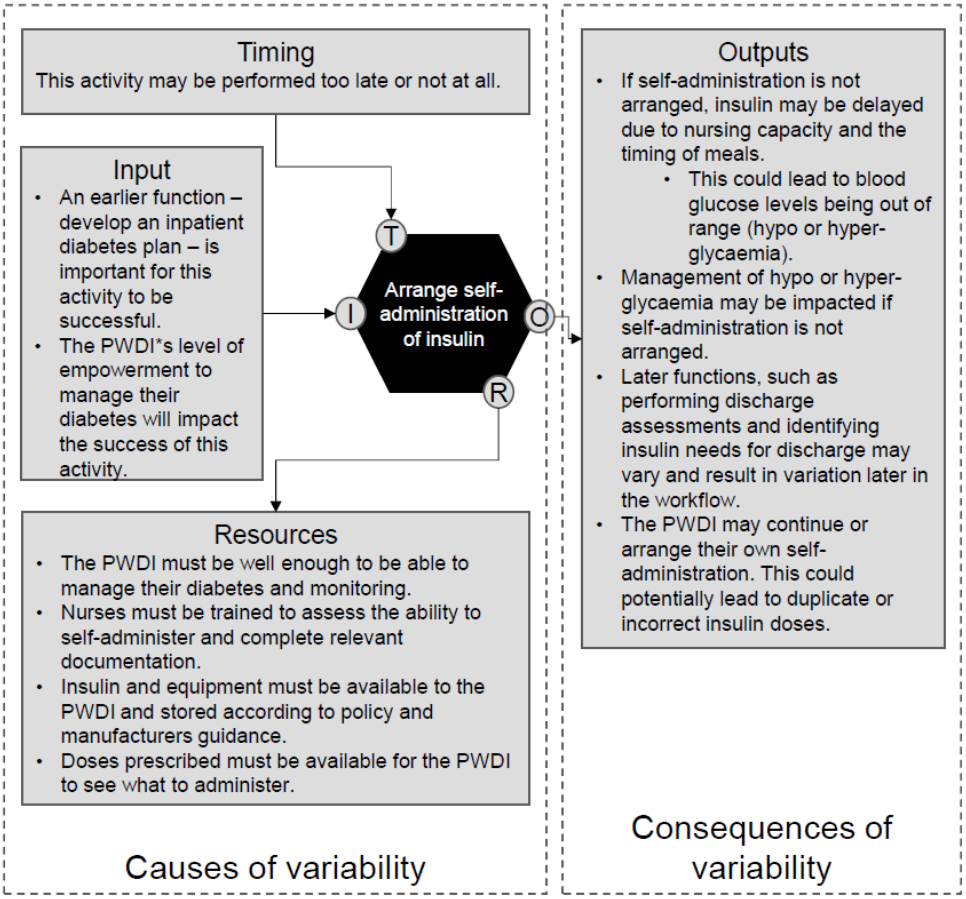

Figure 42: Potential causes and consequences of variation for the function 'Arrange self-administration of insulin (during hospital admission).

Two representative functions were used as examples to consider possible measures at the Seminar and are presented below. These were 'Arrange self-management of diabetes for PWDI,' and 'Empower PWDI to manage diabetes.'

Types of variability identified

Potential variability was identified in functions spanning the whole ToC care pathway. Very few functions were automated or had systems in place to support performance. Functions required many resources to be completed successfully. Empowered PWDI were key to providing safety information and could support staff by managing diabetes, however other factors influenced how successfully their contributions were received. For example, the PWDI may be too unwell to contribute to their care during their acute illness and hospital policies around the storage of medicines could interfere with enabling self-administration. Alternatively, the formal function may not be completed, and self-administration happens informally, but this can introduce variability through inaccurate documentation, and potentially insufficient access to insulin,

carbohydrates and equipment needed. The availability of skilled staff with knowledge to understand insulin and diabetes management during acute illness was a key resource required for almost all functions. Policies and guidelines provide detailed guidance about many aspects of ToC, however these were not always programmed into the EHR and required staff to know or access and act on the information within the guidelines. The consequences of unsuccessful functions across ToC included incorrect doses of insulin being administered, which led to hypo or hyperglycaemia. Unsuccessful functions also impacted later functions in the care pathway, and therefore the successful management of insulin across ToC.

Seminar findings

Seminar participants agreed that the six background functions and fifteen foreground functions proposed were strong potential targets for developing indicators of safe insulin management across ToC. The twelve participants highlighted the challenges of safety measurement in general, including the many different pathways PWDI take to hospital admission and the fact that data is currently stored in multiple systems and formats. Central access to key information is not available to all who need it and changes in information governance arrangements will be required especially to ensure data can be viewed across the whole care pathways and that PWDI have appropriate access and ability to input relevant data. Minimal real-time data is collected in the NHS and mechanisms to allow such collection will need to be developed. These digital systems would need both the PWDI and healthcare staff to see inclusion of data items such as glucose levels, insulin doses administered, diet and any treatments taken for hypo or hyperglycaemia across the care pathway to allow proactive intervention. Participants identified there was a gap in measures reflecting 'Empower PWDI to manage diabetes' (background function). Currently the blood test glycated haemoglobin (HbA1c) is used to understand diabetes management over time acting as a proxy for PWDI empowerment, but this is a retrospective measure as it represents average glucose control over previous months. It was agreed that proactive measures should be a target for development and that qualitative data would be essential to capture performance in these areas. Indicators that capture PWDI knowledge, belief and attitudes would be important and that indicators were person centric. A key challenge would be facilitating access for PWDI to shared systems such as EHR to allow recording of real-time information around hypoglycaemia, diet and side effects which could be shared proactively with the healthcare team. Participants identified the need for accurate recording of insulin self-administration on hospital records to support measurement of the function 'Arrange self-management of diabetes while in hospital' (foreground function). No routine measures exist to capture the number of PWDI who self-administer insulin and

methods to collect these data require development. At present, PWDI have no way to enter relevant information themselves into the hospital EHR and rely on staff transcribing on their behalf.

For both functions, participants felt that data on blood glucose levels and dosing information from continuous glucose monitors (CGM) and pen device recordings urgently need to be integrated into electronic patient records across the healthcare system. Findings from the seminar and the FRAM model were combined to produce a list of potential leading indicators for each of the two functions (Table 8).

Table 8: Example measures for Empowering People with diabetes who use insulin (PWDI) to self-manage and arranging self-management of diabetes in hospital

Potential leading indicator	Activities involved	Potential measures	Target audience	Indicator type
Empowering People With Diabetes who use Insulin (PWDI) to self-manage	Collaborate to develop and update diabetes plans.	• Number of organisations with shared, co-produced, documented diabetes plans in place.	Integrated Care System	Passive
	PWDI attend appointments for review.	• Percentage of appointments scheduled. • Percentage of appointments attended. • Timing of follow-up after admission.	Organisation PWDI Healthcare teams	Passive (Active for PWDI and healthcare teams)

	Undertake training to understand how to manage diabetes according to plan.	• Number of PWDI undertaking commissioned training.
		• Qualitative data from PWDI describing:
		  ○ Usefulness of training.
		  ○ How well it met their needs.
		  ○ Their understanding of diabetes management and motivation to manage diabetes and use insulin.
			Organisation and Integrated Care System	Passive

	Monitor glucose levels	• Percentage of PWDI with diabetes regular prescriptions for monitoring equipment. • Population level HbA1c data (percentages of population within different ranges).	Organisation	Passive
	Take insulin and adjust doses based on test results and other factors such as carbohydrate intake.	• Percentage of PWDI with a documented, up-to-date, co-produced, shared diabetes plan.	Organisation	Passive
	Treat hypoglycaemia and seek help or advice where blood glucose levels are problematically outside of range (as per diabetes plan).	• Number of documented diabetes plans with directions for when to seek help or advice. • Number of contacts to diabetes teams or GP surgeries seeking advice for blood glucose levels.	Organisation	Passive
	Maintain sufficient insulin and equipment supplies to continue to administer and monitor insulin	• Insulin and equipment formularies agreed across region. • Regularly reviewed and updated. • Escalation plans and alternative options defined in case of supply shortages.	Organisation	Passive

Potential leading indicator	Activities involved	Potential measures	Target audience	Indicator type
	Store insulin appropriately in fridge until cartridge/pen is in use.	• Evidence that insulin initiation guidelines and education programmes review and consider PWDI's ability to store insulin according to manufacturer directions.	Organisation	Passive
	PWDI knowledge, belief and attitudes around diabetes and insulin management	• Qualitative surveys and responses	Organisation Healthcare teams	Passive (Active for teams)
Arranging self-management of diabetes in hospital	Recognition person uses insulin and should self-administer unless there is a reason not to.	• PWDI and diabetes self-management status highlighted on Electronic Health Records (EHR). ○ Measure percentage of PWDI who are self-managing their diabetes.	Healthcare professional, teams and Organisation	Active (Passive for the organisation)
	Risk assessments performed to ensure self-administration appropriate	• The number of task(s) outstanding for completion highlighted on EHR.	Healthcare professional and teams	Active
	Paperwork and other organisational requirements completed including: • Assessment of insulin administration technique • Arranging informed consent with PWDI • Completing forms and documentation	• The number of task(s) outstanding for completion highlighted on EHR.	Healthcare professional and teams	Active
	Insulin and equipment provided to allow: • Insulin administration • Blood glucose monitoring • Carbohydrates to treat hypoglycaemia	• The number of task(s) outstanding for completion highlighted on EHR.	Healthcare professional and teams	Active
	Identification and documentation of insulin doses taken on electronic health record	• Number of doses documented on EHR. • Real-time data for blood glucose levels. • Insulin doses or blood glucose levels outside normal range highlighted on EHR.	PWDI, Healthcare professional and teams	Active
	Identification and documentation of any blood glucose levels outside desired range	• Real-time data for blood glucose levels.	PWDI, Healthcare	Active

Potential leading indicator	Activities involved	Potential measures	Target audience	Indicator type
	and any carbohydrates taken to treat hypoglycaemia	• Insulin doses or blood glucose levels outside normal range highlighted on EHR. • Carbohydrates consumed by PWDI documented on EHR. • Carbohydrates consumed by PWDI to manage hypoglycaemia highlighted on EHR.	professional and teams	
	PWDI highlighting any issues to nurses or doctors	• Number of queries from PWDI about diabetes or insulin management	Healthcare professional and teams	Active
	Insulin doses adjusted in agreement with PWDI	• Number of dose changes highlighted in EHR. • Number of PWDI signatures highlighting agreement for dose change. • Real-time data on accuracy of dose documented compared with dose prescribed on EHR.	PWDI, Healthcare professional and teams	Active

Discussion

A new approach, the Functional Resonance Analysis Method (FRAM) was applied successfully to model insulin management across ToC. We found potential areas for developing proactive indicators to highlight risks in real-time, providing key opportunities for safety improvement. Analysis of the FRAM model identified fifteen highly variable foreground functions as potential targets for the development of active leading indicators, and six background functions as targets for passive leading indicator development. These functions had the greatest impact on outcomes. Examples of potential measures for further development were identified. Safe insulin management across ToC relies on the inclusion and empowerment of PWDI and their caregivers.(55) Therefore, co-developing new leading indicators for safe insulin management with this community is essential. We demonstrated how the FRAM model can be used in a collaborative way as a basis to work with PWDI, caregivers and healthcare professionals to identify gaps in safety measurement, potential new measures and means of data collection to identify challenges to overcome. These findings can be fed into the next stage of indicator development of defining the measures, ensuring their purpose is clear, what the units of measurement will be, how the data will be collected and calculated and how such data will enable people involved to monitor and anticipate potential safety issues.(32) The application of FRAM provided a method to identify potential indicators based on understanding how work is performed and how variability can impact outcomes later in the pathway. It contrasts with other approaches to indicator development that rely on analysis of past harm. Applying this method is challenging without the input of an experienced practitioner, and given the extensive variation identified across almost all functions, it was necessary to focus on representative functions or the model would become overwhelming. Those wishing to use this method would benefit from the development of training materials and mentorship models which should support potential users to understand how and when to use this method to get the most benefit.

For safety improvement interventions to be effective, the causes of variability influencing successful outcomes must be understood. Leading indicators can highlight this variability, providing opportunities to intervene and evaluate improvement. Potential real-time measurement is limited by the technology and integration of current systems. As EHR and wearable technologies such as continuous glucose monitors (CGM) become more compatible and connected within and across care settings, the opportunities for active leading indicators and real-time measures will expand. Insulin management is undergoing significant transformation with the advent of CGM. CGM allows glucose levels to be monitored through a

device attached to the skin, and results are sent to an application automatically. Such devices are not currently routinely integrated into electronic health records (EHR) and are not universally used for all people with diabetes who use insulin, however researchers are exploring the safety and potential benefits of this approach.(186,187) As such technology becomes more widely used and more integrated across health care systems, the FRAM model developed in this process will require adaptation.

Using FRAM to develop leading indicators across ToC allows a proactive perspective of safety improvement that provides a strong foundation for indicator development. This method meets many of the Global Principles for Measuring Patient Safety(146): It seeks to target key areas for improvement, the process requires full involvement of PWDI and their caregivers, it considers the whole journey across different care settings and it aims to identify real-time data. Further work to develop specific measures should strive to meet the other aims of ensuring equity, and that they can be continuously adapted to changes in care pathways. In addition, the burden of data collection for staff must be minimised.

A FRAM model allows potential outcomes in a care pathway to be anticipated. It can demonstrate how functions promote successful outcomes (for example enabling self-administration in hospital) and how others can cause adverse outcomes if omitted or delayed (create insulin plan). Several challenges limit the opportunities for FRAM to be used more widely within the NHS and other healthcare systems. The first is the limited training opportunities to learn how to use and apply FRAM. There are currently few (if any) courses available to learn how to develop a FRAM model in England. Guidance is based on written materials and/or ad hoc peer support from those who have already used the method. Given the lengthy process and multiple steps involved, opportunities for training and formal mentoring would support those who wish to use FRAM to develop the skills and knowledge to get the most out of the process. In England, the NHS has introduced the role of the Patient Safety Specialist,(9) who may be a suitable target audience for such training. Another practical challenge is the resource implications for gathering and analysing data, then performing and validating the FRAM. Each of these steps requires input from stakeholders to ensure that findings represent how work is performed in real-life settings. Given the financial, workforce and workload pressures facing the NHS and other healthcare systems, the use of FRAM will need to be carefully targeted to care pathways that will obtain the most benefit. Finally, FRAM models may be large and difficult to interpret, and therefore presenting information meaningfully to influence change may be challenging.(147,148)

Strengths and limitations

This study used multiple methods to model insulin management across ToC. PWDI and healthcare professionals across different care settings contributed to the development and validation of the model. Due to the high level of detail involved in a FRAM analysis, the model produced is specific to the study. As interview, focus group and seminar participants were recruited from across England, the model produced is likely to apply to many integrated care systems in England. Although many of the principles will be similar in other healthcare settings, the detailed results may not be generalisable to other healthcare systems.

Due to the pressures on clinical staff, it was challenging to get engagement, and it was not possible to perform observation in primary care. Using the NRLS data to validate the FRAM model allowed primary care settings to be represented but identified the need to perform additional work with district nurses to fully map the functions that occur in this part of insulin management during ToC.

Conclusion

This study used FRAM to identify potential areas to target active and passive leading indicators for safe insulin management during TOC. The method provided valuable insight into how and where variability occurs, and how safety is maintained despite variability, but was lengthy and specific to context in which it was developed. Some example potential measures were described, however a co-production approach to expanding, defining, and validating these is required.

Appendix IX: Supplementary information for Functional Resilience Analysis Method: Developing potential leading indicators – an illustrative example

Supplementary Table 1: Sample of functions and variability

Function	Causes of variability	Impact of or on other functions	Resources required	What is controlling the function?
Confirm diabetes history	The ability to confirm that someone has diabetes and how they manage this relies on the PWDI or their caregiver being able to provide this information. Some details are available in the GP record, for example the type of insulin and the device used, sometimes dosing information may be included. Information about how insulin is adjusted based on diet and exercise is known only to those managing this, usually the PWDI or their caregiver. Insulin dosing information for people who have insulin administered by district nurses is held in the district nursing records which may not be available to the hospital staff. If staff are unaware or do not identify that someone has diabetes and requires insulin, there may be delays to prescribing and administration of doses, and consequently unstable blood glucose levels. If staff are unable to identify previous doses of insulin, the PWDI may be administered an intravenous insulin infusion.	This may impact on the appropriateness of #13 Diabetes inpatient treatment plan developed. It may lead to omission of #14 Prescribe insulin and #16 Assess blood glucose levels, and consequently on #17 Treat hypoglycaemia & #18 Treat hyperglycaemia. If diabetes history is not confirmed, it may impact the ability to # 19 Arrange self-administration of insulin.	Staff available to seek information and discuss medical and diabetes history with PWDI or their caregiver, Electronic health records (EHR) containing details of diagnosis of diabetes (including type and prescribed treatments) IT equipment, such as functioning computer stations, smartcard readers (allowing access to EHR), keyboards available Staff available must have the skills to identify the tasks required, for example confirming diabetes history, and prioritise these according to the needs of all the patients on their caseload.	Staff diabetes knowledge is essential to understand the need to identify the PWDI usual diabetes management and consider how their current circumstances require adjustments. Diabetes policy and guidelines provide information to staff about how to manage insulin and diabetes in different situations.

Function	Causes of variability	Impact of or on other functions	Resources required	What is controlling the function?
Arrange self-administration for PWDI	Self-administration of insulin may not be arranged. PWDI insulin may be locked away or stored in the fridge in the clinical area where they are unable to access it to administer doses at the time needed. The PWDI also requires access to equipment to check blood glucose levels and treat hypoglycaemia. Manufacturers require insulin cartridges and pre-filled pens to be stored in the fridge until they are used, after which they can be kept at room temperature for 28 days. To arrange self-administration, nursing staff must feel confident that the PWDI is able to manage the tasks involved in the context of their skills and knowledge, but particularly in the context of their often fluctuating health, where illness may temporarily prevent their ability to manage. Where there are delays in providing and administering insulin in hospital, PWDI may arrange and source their own supply of insulin and administer doses to themselves. There is the potential risk of duplicate doses being administered, or EHR records not being accurate if doses administered by PWDI are not recorded.	This function requires #13 Diabetes inpatient treatment plan developed to have been completed. Where PWDI can and are authorised to self-administer, this can impact the following functions: #24 Administer routine insulin. #23 Adjust insulin during acute illness. #17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #25 Perform discharge assessment.	The correct insulin and a suitable administration device must be available for the PWDI to use, and must be in date. Equipment available to administer insulin, monitor blood glucose levels and dispose of sharps are required. A lockable patient medicine cabinet that can be accessed by the PWDI is required to allow organisations to meet legislative and hospital requirements for safe storage of medications. Staff must be available to complete the required assessments, documentation and activities involved in sourcing insulin, assessing ability and capacity to self-manage, and transcribe and document doses administered. The specialist diabetes team available are required to provide expert advice where ward staff are unsure or are facing a complex situation.	Diabetes policy and guidelines provide information to staff about how to manage insulin and diabetes in different situations. Provider organisation diabetes strategies will provide guidelines and authority for how to assess and authorise a PWDI to self-manage their insulin and diabetes. Legislation and relevant organisational policies impacts how insulin should be stored and how PWDI can have access to it in order to self-manage their diabetes. Diabetes training for PWDI and staff enables understanding of how diabetes should be managed, and how doses should be adjusted based on varying glucose levels. The local insulin and equipment formulary

Function	Causes of variability	Impact of or on other functions	Resources required	What is controlling the function?
		#26 Identify insulin needs for discharge. #27 Create insulin plan for discharge.		defines what insulins and equipment are available for PWDI to use while in hospital.
Provide education to PWDI or carer	Variation in providing education to the PWDI or caregiver can occur where the need for education is not identified, for example someone who has previously been using insulin, but either had a pre-existing need for additional information, or where changes to insulin management have occurred during the hospital admission and the need to provide education around these was not recognised. The provision of education is dependent on timing and the availability of trained staff. The Specialist Diabetes Team did not have capacity to provide training outside core working ours, for example over night and sometimes over weekends. Where team members were unavailable due to industrial action or illness, remaining staff members had to prioritise education for those newly started on insulin or where a specific referral had been made. The specialist diabetes team had a structured method of providing education that ward staff did not have access to, therefore the depth and comprehensiveness of training varied depending on who was providing the information. Some PWDI may require additional education sessions due to the large amount of information shared, the ability to provide this relied on staff recognising the	Providing education to the PWDI or carer is an opportunity to confirm that the correct insulin and devices have been provided. Therefore, variability in this function can impact: #26 Identify insulin needs for discharge. #28 Identify equipment needs for discharge. #36 Self-management of insulin in primary care #8 Monitor blood sugar levels. #16 Assess blood glucose levels.	To provide education to the PWDI and/or their carer, this requires staff trained to identify the need for such education, and to provide the training. Training around insulin requires teaching about monitoring blood glucose levels, understanding the results and how to manage insulin based on blood glucose levels. PWDI must be trained to understand the signs and symptoms of hypo and hyperglycaemia and how to manage these conditions. It is important to explain how to use insulin when unwell, and when to seek extra help. The PWDI must also be able to use their insulin device to deliver the correct dose and dispose of the sharps correctly. Due to the breadth of the information and education required, the diabetes specialist teams are usually the team who provide this education. Leaflets may be used to support the education, usually provided by manufacturers. Placebos and equipment are available to support the clinical staff to demonstrate techniques and provide education. Electronic health records allow healthcare	Diabetes policy and guidelines Formularies Diabetes training Commissioning contracts (e.g. 14 day supply in contract with commissioners)

Function	Causes of variability	Impact of or on other functions	Resources required	What is controlling the function?
	additional need, the timing of discharge and the availability of staff able to provide the education.	#17 Treat hypoglycaemia. #18 Treat hyperglycaemia. #24 Administer routine insulin	professionals to document details of training that has been provided. Telephones are required to request training and are used to contact the PWDI after discharge to follow-up if required. Insulin passports are available to allow PWDI to document their insulin details, however these were not observed in use during this study.	
Train staff around diabetes and insulin use	Staff training around diabetes and insulin use is provided during undergraduate education, by specialist diabetes teams and through an electronic learning module. Despite this training, many staff remained under-confident in managing and adjusting insulin. The diabetes specialist team were often consulted for advice on how to manage and adjust insulin for PWDI during their admission. Undergraduate training could vary in terms of content, and staff may have graduated ad different times, meaning that it was variably recent and memorable. Staff have access to a nationally available e-learning package, but different organisations mandate this in different ways, leading to variability in completion. Training provided by the diabetes specialist teams is managed by that team and varies by organisation. Evaluation of the impact of training requires assessment of competency.	The availability of staff who were trained, competent and confident in managing insulin and diabetes impacted most functions in the FRAM model.	The content of training is informed by national and local policies and guidelines. Provision of training requires staff time to complete, and where provide by the local diabetes team, time to prepare and deliver the sessions.	The provision of training is controlled by the organisational priority setting, and their local diabetes strategy. National training and competency standards govern undergraduate training.

Supplementary information 2: Incident data

The following incidents were selected from the NRLS data to represent different aspects of PWDI journeys across ToC.

1. A PWDI was admitted to hospital with gastroenteritis. Because he was eating and drinking less, his insulin doses were reduced. He was discharged home without being referred to the district nurses. He was already on the district nursing list of patients from before admission. When a district nurse visited him, the difference between the hospital doses and their records was identified. The GP was requested to update their prescription, and the district nurse monitored the PWDI's blood sugars. The GP reviewed blood sugars and discharge letter and decided that the PWDI should return to his previous insulin dose now that the gastroenteritis had resolved.
2. A person was started on insulin during a hospital admission, but no referral was made to the district nurses. The PWDI's daughter was not taught how to manage diabetes and insulin. The GP made a referral to the district nurses to provide training for diabetes management and to administer insulin.
3. A PWDI was admitted to hospital for surgery. Before the surgery she was fasting. The nurse administered her normal dose of insulin, despite the PWDI asking whether she should have this dose. The lady subsequently experienced hypoglycaemia and required an infusion of glucose. A referral was made to the hospital diabetes specialist nurses who advised on further management.
4. A PWDI was admitted to hospital. His usual insulin doses were prescribed to be given only "when required." He missed several doses of insulin before this was identified.
5. A PWDI was due to have surgery. Before he went into hospital, he was unable to source his normal insulin and missed about two doses. When he was admitted to hospital, the ward did not stock his normal insulin, and he missed further doses. He was not eating or drinking because he was due to have surgery, and when his blood sugars were checked, they were very high. This was treated with an insulin infusion. His normal insulins were supplied by the pharmacy, but there was a delay in administering them.
6. A PWDI attended the emergency department. His family were with him. When he was moved to the ward, a nurse tried to identify whether he was due to have his insulin dose. His family said that he had been given his insulin, but this had not been documented on the electronic health record.
7. Insulins and other medications were given to a PWDI ready to be discharged from the hospital. While waiting to go, his blood glucose levels were checked and were high. The PWDI took his insulins to manage the high levels. He was kept in hospital for three hours to monitor his blood glucose.
8. A PWDI started on insulin was discharged from hospital. He noticed that his blood glucose levels were high despite administering his insulin. He went to the GP who identified that he had been given a placebo insulin pen that had been used for training to take home and was therefore not getting any insulin.
9. A PWDI was admitted to hospital. He usually took a mixed insulin (Mix 50), however because this was not kept on the ward, a doctor prescribed a smaller dose of the same type of mixed insulin but with different proportions (Mix 25). His blood glucose levels were monitored regularly to review the impact of this change. The pharmacists identified the change and arranged a supply of his normal insulin the following morning

10. A PWDI was discharged from hospital without a supply of any equipment, needles, sharps bin, lancets or monitoring strips. The PWDI was then unable to monitor his blood glucose levels or administer his insulin.