AUSTRALIAN DIABETES FOOT REGISTRY

Data Dictionary

version 1.1

ads Australian Diabetes Society
nadc National Association of Diabetes Centres
ST VINCENT'S HOSPITAL SYDNEY

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INTRODUCTION

DOCUMENT BACKGROUND

The Australian Diabetes Foot Registry is currently formed by the periodic centralisation of data from nationally standardised Australian Diabetes High Risk Foot Service Databases.[1] Australian clinical quality registries are required to update and maintain an accessible data dictionary to facilitate accurate data collection.[2]

The purpose of this Data Dictionary is thus to provide participating services with a quick reference document when greater clarity is needed in entering or utilising a data field. It is not expected that services read this document in its entirety, noting data collection instruments were designed to allow intuitive use. Further, this document may aid interpretation of reported data and compatibility with other diabetes-related foot disease datasets.

This project is supported by a national network of investigators and clinicians. This network shares the vision of improving care and outcomes for people with diabetes-related foot disease and building collaboration across High-Risk Foot Services. Harnessing this collective enthusiasm and expertise, the Data Dictionary is intended to be a living document. Updates are expected in real-time as we work to optimise the dataset and clarity of definitions. Maintaining relevance as guidelines are updated in response to new evidence is imperative.

Reference is made to several published data recommendations and standards. Compatibility of coding with the Australian Institute of Health and Welfare's Metadata Online Registry (METeOR) was prioritised where possible, noting no precedent had been set for the majority of fields.[3] Similarly, classifications set by the Australian Bureau of Statistics were employed where relevant.[4] The Diabetes Feet Australia 2016 'Australian Diabetic Foot Ulcer Minimum Dataset Dictionary' served as a valuable resource representing the first national attempt to standardise data capture, analysis and benchmarking by services managing diabetes-related foot complications.[5] Some field definitions were adopted or adapted from these sources.

The National Association of Diabetes Centres first introduced an accreditation program for Australian High Risk Foot Services in 2018, supported by the development of widely endorsed Standards of Care.[6] By design, the Australian Diabetes Foot Registry has become a key enabler for services to achieve the quality improvement Standard. Continued alignment of the standards with this Data Dictionary will build on the synergy between this project, quality improvement and service accreditation.

It is anticipated that many services will implement electronic medical records in the coming years. This transition carries the possibility of integrating data collection with routine clinical workflows. High Risk Foot Services are encouraged to advocate for adoption of a nationally standardised dataset. Careful and early consideration of data output from electronic medical records will be essential. The absence of a standardised 'data language' could see the return of siloed databases and negate our collaborative progress in enabling national audits and benchmarking.

DATA CONSTRUCT

Data is collected and managed using REDCap (Research Electronic Data Capture) hosted locally at the participating institution or centrally by the Sponsor.[7,8] REDCap is a secure, web-based software platform designed to support data capture for research studies, providing:

1. An intuitive interface for validated data capture
2. Audit trails for tracking data manipulation and export procedures
3. Automated export procedures for seamless data downloads to common statistical packages
4. Procedures for data integration and interoperability with external sources.

Each data collection instrument or form designed for this project is represented by a major heading in this document, namely:

- Demographics
- Service
- Clinical / Biomedical
- Ulcer assessment
- Active Charcot foot assessment
- Management
- Ulcer outcome
- Active Charcot foot outcome

The fields are numbered as minor headings.

Data collection instruments are further organised into Episodes of Care (or EOCs). An EOC commences when a participant attends the service with one or more active foot complications (i.e. foot ulcer and/or active Charcot foot). The EOC ends when each active foot complication has an outcome recorded and the participant has been discharged/transferred from the service. See relevant field definitions for more details on recording of outcomes and service separation.

Data collection instruments are repeated within an EOC or across EOCs, enabling longitudinal data entry. *Demographics* is only completed at baseline for the initial EOC. *Service* and *Clinical / Biomedical* are repeated at baseline for each EOC. *Management* is repeated for each EOC, however is considered a 'live' form. As such, *Management* is frequently updated throughout the EOC to build a summary of care complexity.

An *Ulcer assessment* and/or *Active Charcot foot assessment* is completed per active foot complication to record the initial characteristics. Any number of active foot complications can be added at commencement or throughout an EOC. Each active foot complication is allocated a numerical identifier. Corresponding to each assessment is an *Ulcer outcome* and/or *Active Charcot foot outcome*, similarly numbered.

Inbuilt features exist to optimise data quality at the time of data entry. 'Required fields' and 'Field validation' settings are noted in this document. Fields are preferentially in single-answer or multiple-answer format, with minimal free-text data entry. The nomenclature of including 'Not stated / inadequately described' as a choice for some fields was adopted from METeOR. This choice is used sparingly when a participant declines or is unable to provide an answer, or the data is otherwise unavailable. 'Form status' indicators alert the user to incomplete or unverified data collection instruments when the participant home page is accessed.

Descriptive fields have a supportive role, and as they are not data entry fields, they were omitted from this Data Dictionary. Descriptive fields are included on forms to enhance the user experience, provide quick access to clinically useful information, or improve data quality.

Data consistency, quality and completeness is further optimised by use of inbuilt REDCap applications, an online resource library and forum, periodic meetings, and on-demand audits. Processes continue to evolve and improve in response to feedback from investigators and clinicians involved in the project.

FEEDBACK / ENQUIRIES

Do you have feedback on the content of this Data Dictionary or on the data collected?

Click here or scan the QR code

For more information on this project visit https://nadc.net.au/hrfs-data-collection/. General enquiries and suggestions can be emailed to adfr@nadc.net.au.

DEMOGRAPHICS

The *Demographics* form includes the following 8 variables.

1. Record ID
2. Opt-out
3. Unique ID
4. Date of birth
5. Sex
6. Ethnicity
7. Aboriginal / Torres Strait Islander
8. Age

1. RECORD ID

REDCap field

Variable / field name:	record_ID
Field type:	text
Field label:	Record ID
Choices / calculations:	-
Field note:	-
Text validation:	-
Identifier:	N
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	Automatically and sequentially assigned by REDCap when a new record is created.
Data utility:	In combination with the *Group ID Number*, which is specific to each participating site, it signifies an individual participant and allows longitudinal data entry, even following deidentified data extraction for centralisation.

2. OPT-OUT

REDCap field

Variable / field name:	consent_optout
Field type:	radio
Field label:	Opt-out of the Australian Diabetes HRFS Database
Choices / calculations:	1, Yes 0, No
Field note:	De-identified data is contributed to the national database by default. Select 'Yes' to exclude this patient's data from the national database. Posters on display provide further information. Therefore, you are not required to raise this with the patient.
Text validation:	-
Identifier:	N
Branching logic:	-
Required field:	Y
Field annotation:	@DEFAULT='0'

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	Opt-out approach to consent in accordance with the National Statement on Ethical Conduct in Human Research[9] has National Mutual Acceptance ethics approval, and has been adopted by all states and territories except NT and WA. Waiver of consent is approved for NT and WA sites.
Data utility:	Records where consent_optout='1' will not be extracted at time of data centralisation.

3. UNIQUE ID

REDCap field

Variable / field name:	demographics_uid
Field type:	text
Field label:	Unique ID
Choices / calculations:	-
Field note:	-
Text validation:	integer (0-9999999999) * removed at sites where alphanumeric identifiers are used
Identifier:	Y
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Person – person identifier
Short name:	Person identifier
Identifier:	290046
Compatibility:	Y, without modification

Explanation

Definition/s: (adopted from METeOR)	Person identifier unique within an establishment or agency.
Data utility:	Signifies an individual participant and allows longitudinal data entry at a site level, however identifying fields are not extracted at time of data centralisation. It may ultimately allow linkage with other datasets provided ethics approval was obtained.

4. DATE OF BIRTH

REDCap field

Variable / field name:	demographics_dob
Field type:	text
Field label:	Date of birth
Choices / calculations:	-
Field note:	-
Text validation:	date_dmy (01-01-1900 to 01-01-2020)
Identifier:	Y
Branching logic:	-
Required field:	Y
Field annotation:	@HIDEBUTTON

METeOR item

Metadata item type:	Data Element
Official name:	Person – date of birth
Short name:	Date of birth
Identifier:	287007
Compatibility:	Y, format as DDMMYYYY

Explanation

Definition/s: (adopted from METeOR)	The date of birth of the person, expressed as DDMMYYYY.
Data utility:	Calculation of *Age* when used in combination with *Date of initial assessment* field. As identifying fields are not extracted at time of data centralisation only *Age* is retained on the central database.

5. SEX

REDCap field

Variable / field name:	demographics_gender
Field type:	radio
Field label:	Sex
Choices / calculations:	1, Male 2, Female 3, Intersex or indeterminate 99, Not stated / inadequately described
Field note:	-
Text validation:	-
Identifier:	N
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Person – sex
Short name:	Sex
Identifier:	635126
Compatibility:	Y, with ‘3’ now meaning ‘Other’ and ‘99’ recoded as ‘9’

Explanation

Definition/s: (adopted from METeOR)	The distinction between male, female, and others who do not have biological characteristics typically associated with either the male or female sex, as represented by a code.
Data utility:	Description of demography and stratification by sex in data analyses.

6. ETHNICITY

REDCap field

Variable / field name:	demographics_ethnicity
Field type:	radio
Field label:	Ethnicity
Choices / calculations:	1, Oceanian (Australia & New Zealand) 2, Oceanian (other) 3, North-West European 4, Southern and Eastern European 5, North African and Middle Eastern 6, South-East Asian 7, North-East Asian 8, Southern and Central Asian 9, People of the Americas (North America) 10, People of the Americas (Central & South America) 11, Sub-Saharan African 99, Not stated / inadequately described
Field note:	-
Text validation:	-
Identifier:	N
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note similarity to 'Country of origin' (Identifier 666464) based on Standard Australian Classification of Countries[10]

Explanation

Definition/s: (adopted from ABS)	Based on the Australian Standard Classification of Cultural and Ethnic Groups (ASCCEG),[11] the Australian statistical standard for classifying cultural and ethnic groups. The Australian Bureau of Statistics endorses the use of this classification for collecting, aggregating and disseminating data relating to the cultural and ethnic diversity of the Australian population.

For the purposes of the ASCCEG, ethnicity refers to the shared identity or similarity of a group of people on the basis of one or more distinguishing characteristics.

These characteristics include:

- A long shared history, the memory of which is kept alive
- A cultural tradition, including family and social customs, sometimes religiously based
- A common geographic origin
- A common language (but not necessarily limited to that group)
- A common literature (written or oral)
- A common religion
- Being a minority (often with a sense of being oppressed)
- Being racially conspicuous

Translation of REDCap field choices into ASCCEG codes:

REDCap field choice	ASCCEG code/s
1	11,12 (narrow groups)
2	13,14,15 (narrow groups)
3	2 (broad group)
4	3 (broad group)
5	4 (broad group)
6	5 (broad group)
7	6 (broad group)
8	7 (broad group)
9	81 (narrow group)
10	82,83,84 (narrow groups)
11	9 (broad group)

Data utility: Description of demography and stratification by ethnicity in data analyses. Allows comparability and compatibility with other datasets.

7. ABORIGINAL / TORRES STRAIT ISLANDER

REDCap field

Variable / field name:	demographics_atsi
Field type:	radio
Field label:	Aboriginal / Torres Strait Islander
Choices / calculations:	0, Neither Aboriginal nor Torres Strait Islander origin 1, Aboriginal but not Torres Strait Islander origin 2, Torres Strait Islander but not Aboriginal origin 3, Both Aboriginal and Torres Strait Islander origin 99, Not stated / inadequately described
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Person – indigenous status
Short name:	Sex
Identifier:	602543
Compatibility:	Y, with ‘0’ recoded as ‘4’ and ‘99’ recoded as ‘9’

Explanation

Definition/s: (adapted from METeOR)	Whether a person identifies as being of Aboriginal or Torres Strait Islander origin, as represented by a code. This is in accordance with the first two of three components of the Commonwealth definition, i.e. descent and self-identification.
Data utility:	Description of demography and stratification according to Aboriginal or Torres Strait Islander status in data analyses.

8. AGE

REDCap field

	Local field *	Central field *
Variable / field name:	demographics_age	demographics_age
Field type:	calc	text
Field label:	Age	Age
Choices / calculations:	round(datediff([first-event-name][demographics_dob],[event-name][service_initial_date],"y","dmy", true),1)	-
Field note:	years (calculated field)	years
Text validation:	-	number (0-120)
Identifier:	-	-
Branching logic:	-	-
Required field:	-	Y
Field annotation:	@HIDDEN	-

* field settings differ depending on whether the database is on a local versus central REDCap server, given identifiers are not permitted on the central REDCap server

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note could stratify according to ‘Age range’ (Identifier 635111)

Explanation

Definition/s: (adopted from METeOR)	The age of the person at commencement of each Episode of Care.
Data utility:	Description of demography and stratification by age in data analyses.

SERVICE

The *Service* form includes the following 9 variables.

9. Date of initial assessment
10. Date of referral
11. Date of first appointment offered
12. Time from referral to initial assessment
13. Referral service
14. Referral from hospital
15. Referrer
16. Patient postcode
17. Telehealth

9. DATE OF INITIAL ASSESSMENT

REDCap field

Variable / field name:	service_initial_date
Field type:	text
Field label:	Date of initial assessment
Choices / calculations:	-
Field note:	-
Text validation:	date_dmy
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	@TODAY

METeOR item

Metadata item type:	Data Element
Official name:	Health service event – first service contact date
Short name:	First health service contact date
Identifier:	447930
Compatibility:	Y, format as DDMMYYYY

Explanation

Definition/s: (adapted from METeOR)	The date on which assessment, care, consultation and/or treatment is first delivered to the person by a health care provider from the High-Risk Foot Service, expressed as DDMMYYYY.
Data utility:	Calculation of *Age* when used in combination with *Date of birth* field. Analysis of time-based outcomes, including *Referral to initial review* and *Time in service*.

10. DATE OF REFERRAL

REDCap field

Variable / field name:	service_referral_date
Field type:	text
Field label:	Date of referral
Choices / calculations:	-
Field note:	Date of referral must occur on/before Date of initial assessment (i.e. [service_initial_date])
Text validation:	date_dmy (<[service_initial_date])
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Health service event – service request received date
Short name:	Health service request received date
Identifier:	447938
Compatibility:	Y, format as DDMMYYYY

Explanation

Definition/s: (adopted from METeOR)	The date on which a request for assessment, care, consultation and/or treatment is received by a High-Risk Foot Service health care provider or administrator, expressed as DDMMYYYY.
Data utility:	Analysis of time-based outcomes, including *Referral to initial review*, *Referral to first appointment offered* and *Referral to interdisciplinary review*.

11. DATE OF FIRST APPOINTMENT OFFERED

REDCap field

Variable / field name:	service_first_available
Field type:	text
Field label:	Date of first appointment offered
Choices / calculations:	-
Field note:	Relevant when delay unrelated to service availability (e.g. patient unavailable) If entered, Date of first appointment offered must occur between Date of referral & Date of initial assessment (i.e. [service_referral_date] to [service_initial_date])
Text validation:	date_dmy ([service_referral_date]-[service_initial_date])
Identifier:	-
Branching logic:	-
Required field:	N
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The date on which assessment, care, consultation and/or treatment is first *offered* to the person by a health care provider from the High-Risk Foot Service, expressed as DDMMYYYY.
Data utility:	Optional field as distinct from *Date of initial assessment*. Analysis of the time-based outcome *Referral to first appointment offered*, which may be a better reflection service availability than *Referral to initial review*.

12. TIME FROM REFERRAL TO INITIAL ASSESSMENT

REDCap field

Variable / field name:	service_waiting_time
Field type:	calc
Field label:	Time from referral to initial assessment
Choices / calculations:	datediff([service_referral_date],[service_initial_date],"d","dmy")
Field note:	days (calculated field)
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	-
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Computable as the difference between 'Service request received date' (Identifier 447938) and 'First service contact date' (Identifier 447930), expressed in days.

Explanation

Definition/s:	The time elapsed between *Date of referral* and *Date of initial assessment*, expressed in days.
Data utility:	Analogous to time-based outcome *Referral to initial review*. Included in database to inform user of 'waiting time' for real-time detection of outliers, correction of erroneous dates or completion of the *Date of first appointment offered* field where relevant.

13. REFERRAL SERVICE

REDCap field

Variable / field name:	service_referral_service
Field type:	radio
Field label:	Referral service
Choices / calculations:	1, Aboriginal health service 2, Community health service 3, General practice / medical centre 4, Hospital within area health service 5, Hospital external to area health service 6, Non-government organisation (including aged care, disability care & community services) 7, Private practice 97, Patient initiated 99, Not stated / inadequately described
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note similarity to ‘Service request source’ (Identifier 679552), which may be applied to non-admitted patient service requests.

Explanation

Definition/s:	The service or organisation that requested assessment, care, consultation and/or treatment of the person, as represented by a code. Patient initiated is chosen when the person self refers, without obtaining referral from another service or organisation prior to the *Initial Assessment*.
Data utility:	Description of service referral base and stratification by referral service in data analyses.

14. REFERRAL FROM HOSPITAL

REDCap field

Variable / field name:	service_referral_hospital
Field type:	radio
Field label:	Referral from hospital
Choices / calculations:	1, Outpatient clinic 2, Inpatient ward, foot complication primary reason for admission 3, Inpatient ward, foot complication secondary / incidental issue 4, Emergency department, not admitted to ward
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	[service_referral_service] = '4' or [service_referral_service] = '5'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The admission status of the person at time of referral from hospital within or external to area health service, as represented by a code.
Data utility:	Description of service referral base and stratification by admission status when referred in data analyses. Analysis of the time-based outcome *Referral to initial review* is separately reported for outpatients and inpatients.

15. REFERRER

REDCap field

Variable / field name:	service_referrer
Field type:	radio
Field label:	Referrer
Choices / calculations:	1, General practitioner 2, Endocrinologist 3, Orthopaedic surgeon 4, Vascular surgeon 5, Podiatrist 6, Nurse 7, Diabetes educator 97, Patient initiated 98, Other 99, Not stated / inadequately described
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note similarity to 'Provider occupation' (Identifier 523811) based on Australian and New Zealand Standard Classification of Occupations (ANZSCO)[12]

Explanation

Definition/s:	The occupation of the health care provider who requested assessment, care, consultation and/or treatment of the person, as represented by a code. While not directly compatible, a health care provider's occupation can be listed at any level of occupation specificity, as classified by ANZSCO.[12] Health professionals form sub-major group 25.

Translation of REDCap field choices into ANZSCO codes:

REDCap field choice	ANZSCO occupation code
1	253111
2	253315
3	253514
4	253521
5	252611
6	2544 (Registered Nurses Unit Group)
7	254211

Patient initiated is chosen when the person self refers, without obtaining referral from a health care provider prior to the *Initial Assessment*.

Data utility:	Description of service referral base and stratification by referrer in data analyses.

16. PATIENT POSTCODE

REDCap field

Variable / field name:	service_postcode
Field type:	text
Field label:	Patient postcode
Choices / calculations:	-
Field note:	(last recorded [previous-event-name][service_initial_date]: [previous-event-name][service_postcode])
Text validation:	integer (0800-9999)
Identifier:	-
Branching logic:	-
Required field:	N
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Address – Australian postcode
Short name:	Australian postcode
Identifier:	611398
Compatibility:	Y, without modification

Explanation

Definition/s:	The residential postcode of the person.
Data utility:	Description of service referral area and stratification on a geographic basis in data analyses. Geospatial information from postcodes has multiple applications, such as understanding the impact of remoteness. Categorisation is provided by the Australian Statistical Geography Standard.[13]

17. TELEHEALTH

REDCap field

Variable / field name:	service_telehealth
Field type:	radio
Field label:	Telehealth
Choices / calculations:	1, Yes 0, No
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	Assessment, care, consultation and/or treatment delivered via 'telehealth' in place of one or more face-to-face appointments during an Episode of Care. Physical attendance of the person to a HRFS was thus avoided on at least one occasion. Telehealth in this context means the person is: ○ In a location remote from the service (e.g. with another health care provider or at home) ○ In a regional/rural service with remote involvement of a HRFS (i.e. replace long-distance travel) Assessment must involve video call or telephone call in combination with photography (i.e. telephone call alone does not quality).
Data utility:	Description of service telehealth utilisation and stratification according to use of telehealth in data analyses. Increasing telehealth utilisation may prompt the simple binary input to be expanded with additional fields.

CLINICAL / BIOMEDICAL

The *Clinical / Biomedical* form includes the following 14 variables. The first 10 variables relate to diabetes mellitus, and the remaining 4 to other comorbidities.

18. Diabetes type
19. Diabetes duration
20. Macrovascular complications
21. Microvascular complications
22. History of previous foot ulceration
23. History of previous amputation
24. Extent of previous amputation
25. History of inactive Charcot foot
26. HbA1c
27. HbA1c (IFCC)
28. Common comorbidities
29. Smoking status
30. eGFR
31. Renal replacement therapy

18. DIABETES TYPE

REDCap field

Variable / field name:	diabetes_type
Field type:	radio
Field label:	Diabetes type
Choices / calculations:	1, Type 1 diabetes 2, Type 2 diabetes 3, Gestational diabetes mellitus (GDM) 4, Previous gestational diabetes mellitus (GDM) 5, Impaired fasting glucose (IFG) 6, Impaired glucose tolerance (IGT) 98, Other diabetes (secondary and genetic causes) 0, Not diagnosed with diabetes 99, Not stated / inadequately described
Field note:	(last recorded [previous-event-name][service_initial_date]: [previous-event-name][diabetes_type])
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Person – diabetes mellitus status
Short name:	Diabetes status
Identifier:	270194
Compatibility:	Y, with recoding as follows:

REDCap field choice	METeOR value
1	01
2	02
3	03
4	05
5	06
6	07
98	04
0	08
99	99

Note as a required field METeOR value ‘09’ meaning ‘Not assessed’ was not included.

Explanation

Definition/s: (adapted from METeOR)	Whether a person has or is at risk of diabetes, as represented by a code. Note where the current diagnosis (e.g. type 2 diabetes) differs from a past diagnosis (e.g. impaired fasting glucose) record the current diagnosis. Detailed definitions for each choice are available at: https://meteor.aihw.gov.au/content/270194
Data utility:	Characterisation of diabetes mellitus and stratification by diabetes type in data analyses.

19. DIABETES DURATION

REDCap field

Variable / field name:	diabetes_duration
Field type:	text
Field label:	Diabetes duration
Choices / calculations:	-
Field note:	years (last recorded [previous-event-name][service_initial_date]: [previous-event-name][diabetes_duration] years)
Text validation:	integer (0-100)
Identifier:	-
Branching logic:	[diabetes_type] = '1' or [diabetes_type] = '2' or [diabetes_type] = '3' or [diabetes_type] = '4' or [diabetes_type] = '5' or [diabetes_type] = '6' or [diabetes_type] = '98' or [diabetes_type] = '99'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note could use to calculate ‘Year of diagnosis of diabetes mellitus’ (Identifier 269930)

Explanation

Definition/s: (adopted from METeOR)	The time since diagnosis of diabetes mellitus at commencement of the Episode of Care, expressed in years.
Data utility:	Characterisation of diabetes mellitus and stratification by diabetes duration in data analyses.

20. MACROVASCULAR COMPLICATIONS

REDCap field

Variable / field name:	diabetes_macro_comp
Field type:	checkbox
Field label:	Macrovascular complications
Choices / calculations:	1, Peripheral arterial disease 2, Ischaemic heart disease 3, Cerebrovascular disease 0, None of the above 99, Not stated / inadequately described
Field note:	Select all that apply (last recorded [previous-event-name][service_initial_date]: [previous-event-name][diabetes_macro_comp])
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	@NONEOFTHEABOVE=0,99

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note overlap with Data Set Specification ‘Diabetes (clinical) NBPDS’ (Identifier 304865)

Explanation

Definition/s:	Whether a person has prior history of diabetes mellitus related macrovascular complications, as represented by a code. Note macrovascular complications may be documented on testing in a symptomatic or asymptomatic person, manifest as an acute ischaemic event, or inferred by documented cardiac or vascular procedures/surgery. To ensure accuracy, suggestive clinical features alone do not qualify and should be corroborated by objective evidence of arterial compromise on bedside tests or formal investigation.

	Examples of macrovascular complications: ○ Peripheral arterial disease – arterial compromise on bedside tests (e.g. doppler waveforms, toe pressures); significant arterial stenosis on duplex ultrasound or angiogram; lower limb vascular procedure (e.g. angioplasty, stent) or surgery (e.g. bypass); critical ischaemia necessitating amputation ○ Ischaemic heart disease – evidence of myocardial ischaemia on electrocardiogram or stress test; significant coronary artery stenosis on angiogram; cardiac procedure (e.g. angioplasty, stent) or surgery (e.g. bypass); acute myocardial infarction ○ Cerebrovascular disease – significant carotid artery stenosis; carotid endarterectomy; ischaemic stroke or transient ischaemic attack
Data utility:	Characterisation of diabetes mellitus and stratification by diabetes complications in data analyses.

21. MICROVASCULAR COMPLICATIONS

REDCap field

Variable / field name:	diabetes_micro_comp
Field type:	checkbox
Field label:	Microvascular complications
Choices / calculations:	1, Peripheral neuropathy 2, Retinopathy 3, Nephropathy 4, Autonomic dysfunction 5, Gastroparesis 6, Sexual dysfunction 0, None of the above 99, Not stated / inadequately described
Field note:	Select all that apply (last recorded [previous-event-name][service_initial_date]: [previous-event-name][diabetes_micro_comp])
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	@NONEOFTHEABOVE=0,99

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note overlap with Data Set Specification ‘Diabetes (clinical) NBPDS’ (Identifier 304865)

Explanation

Definition/s:	Whether a person has prior history of diabetes mellitus related microvascular complications, as represented by a code. Note microvascular complications may be documented on testing in a symptomatic or asymptomatic person or inferred by documented procedures/surgery. To ensure accuracy, suggestive clinical features alone do not qualify and should be corroborated by objective evidence on bedside tests or formal investigation (except for sexual dysfunction).

	Examples of microvascular complications: ○ Peripheral neuropathy – sensory impairment on bedside tests (e.g. monofilament, biothesiometry); characteristic findings on nerve conduction studies ○ Retinopathy – characteristic findings on ophthalmoscopy or retinal photography; ophthalmic procedure (e.g. intravitreal injection, laser) or surgery (e.g. vitrectomy) ○ Nephropathy – microalbuminuria and/or impaired kidney function on testing that persists at least 3 months; end-stage kidney disease requiring dialysis and/or kidney transplant ○ Autonomic dysfunction – characteristic findings on cardiovascular autonomic testing ○ Gastroparesis – characteristic findings on gastric emptying study ○ Sexual dysfunction – erectile dysfunction in men; vaginal dryness in women
Data utility:	Characterisation of diabetes mellitus and stratification by diabetes complications in data analyses.

22. HISTORY OF PREVIOUS FOOT ULCERATION

REDCap field

Variable / field name:	diabetes_foot_ulcer
Field type:	radio
Field label:	History of previous foot ulceration
Choices / calculations:	1, Yes 0, No 99, Not stated / inadequately described
Field note:	(last recorded [previous-event-name][service_initial_date]: [previous-event-name][diabetes_foot_ulcer])
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Person – foot ulcer indicator (history)
Short name:	Foot ulcer (history)
Identifier:	302819
Compatibility:	Y, '99' recoded as '9'

Explanation

Definition/s: (adapted from METeOR)	Whether a person has a previous history of healed ulceration on either foot, as represented by a code. The International Working Group on the Diabetic Foot defines ulceration as "a break of the skin of the foot that involves as a minimum the epidermis and part of the dermis."[14] Anatomically the foot is the part of the lower limb distal to the malleoli.
Data utility:	Characterisation of diabetes mellitus related foot complications and stratification by foot complications in data analyses.

23. HISTORY OF PREVIOUS AMPUTATION

REDCap field

Variable / field name:	diabetes_amputation
Field type:	radio
Field label:	History of previous amputation
Choices / calculations:	1, Yes 0, No 99, Not stated / inadequately described
Field note:	(last recorded [previous-event-name][service_initial_date]: [previous-event-name][diabetes_amputation])
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note similarity to 'Lower limb amputation due to vascular disease' (Identifier 270162)

Explanation

Definition/s:	Whether a person has undergone any level of lower limb amputation as represented by a code. The International Working Group on the Diabetic Foot defines amputation as "resection of a segment of a limb through a bone or through a joint".[14] Major amputation is "any resection proximal to the ankle" and minor amputation is "any resection through or distal to the ankle".
Data utility:	Characterisation of diabetes mellitus related foot complications and stratification by foot complications in data analyses.

24. EXTENT OF PREVIOUS AMPUTATION

REDCap field

Variable / field name:	diabetes_amputation_extent
Field type:	checkbox
Field label:	Extent of previous amputation
Choices / calculations:	1, Hallux 2, Other digit/s 3, First ray 4, Lesser ray/s 5, Transmetatarsal 6, Below knee 7, Above knee
Field note:	Select all that apply (last recorded [previous-event-name][service_initial_date]: [previous-event-name][diabetes_amputation_extent])
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The level/s at which previous lower limb amputations were performed as represented by a code. Note redundancy in sidedness and when multiple ‘other digit’ or ‘lesser ray’ amputations have occurred. Other digit/s refers to part or complete resection of phalanges of the second to fifth toes. Lesser ray/s refers to part or complete resection of the second to fifth metatarsals.
Data utility:	Characterisation of diabetes mellitus related foot complications and stratification by foot complications in data analyses.

25. HISTORY OF INACTIVE CHARCOT FOOT

REDCap field

Variable / field name:	diabetes_charcot
Field type:	radio
Field label:	History of inactive Charcot foot
Choices / calculations:	1, Yes 0, No 99, Not stated / inadequately described
Field note:	(last recorded [previous-event-name][service_initial_date]: [previous-event-name][diabetes_charcot])
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	Whether a person has a previous history of Charcot neuropathic osteoarthropathy involving one or both feet, as represented by a code. Charcot neuropathic osteoarthropathy, or Charcot foot, generally refers to a localised inflammatory condition affecting the soft tissues, joints and bone of the insensate foot and/or ankle, where several culminating factors lead to osteolysis, fracture, joint subluxation and destruction, and ultimately deformity. Inactive disease corresponds to Stage 3 of the Eichenholtz classification.[15] Clinically there is absence of inflammation and a more stable yet often deformed foot. Radiographical features include osteophytes, subchondral sclerosis and narrowing of joint spaces.
Data utility:	Characterisation of diabetes mellitus related foot complications and stratification by foot complications in data analyses.

26. HBA1C

REDCap field

Variable / field name:	diabetes_hba1c
Field type:	text
Field label:	HbA1c
Choices / calculations:	-
Field note:	%; within 3 months of <I>Date of initial assessment</i> (if unavailable leave blank)
Text validation:	number (1-30)
Identifier:	-
Branching logic:	-
Required field:	-
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Person – glycosylated haemoglobin level (measured)
Short name:	Glycosylated haemoglobin level (measured)
Identifier:	270325
Compatibility:	Y, without modification

Explanation

Definition/s: (adopted from METeOR)	A person's glycosylated haemoglobin (HbA1c) level, measured as percentage. Include the most recent value at Episode of Care commencement. The field is left blank if no value is available 3 months before or 3 months after Episode of Care commencement.
Data utility:	Characterisation of diabetes mellitus and stratification by initial glycaemic control in data analyses.

27. HBA1C (IFCC)

REDCap field

Variable / field name:	diabetes_hba1c_ifcc
Field type:	calc
Field label:	HbA1c (IFCC)
Choices / calculations:	round(53+(([diabetes_hba1c]-7)*11),0)
Field note:	mmol/mol (calculated field)
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	-
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Person – glycosylated haemoglobin level (measured)
Short name:	Glycosylated haemoglobin level (measured)
Identifier:	270325
Compatibility:	Y, with unit conversion

Explanation

Definition/s:	A person's glycosylated haemoglobin (HbA1c) level, measured in mmol of HbA1c per mol of haemoglobin (mmol/mol).
Data utility:	Characterisation of diabetes mellitus and stratification by initial glycaemic control in data analyses.

28. COMMON COMORBIDITIES

REDCap field

Variable / field name:	comorbidities_common
Field type:	checkbox
Field label:	Comorbidities
Choices / calculations:	1, Arthritis 2, Asthma 3, Back pain 4, Cancer 5, Chronic obstructive pulmonary disease 6, Congestive cardiac failure 7, Dementia 9, Dyslipidaemia 10, Hypertension 11, Mental health, depression 12, Mental health, other than depression 13, Osteoporosis 0, None of the above 99, Not stated / inadequately described
Field note:	Select all that apply, listed alphabetically (last recorded [previous-event-name][service_initial_date]: [previous-event-name][comorbidities_common])
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	@NONEOFTHEABOVE=0,99

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note similarity to ‘Type of chronic condition’ (Identifier 631845)

Explanation

Definition/s:	The type/s of chronic medical conditions with which a person has been diagnosed, as represented by a code. The Australian Institute of Health and Welfare commonly reports on 10 major chronic condition groups: arthritis, asthma, back pain, cancer, cardiovascular disease, chronic obstructive

	pulmonary disease, diabetes, chronic kidney disease, mental health conditions and osteoporosis.[16] Detailed inclusions for each choice are available in Table 1 at: https://www.aihw.gov.au/reports/chronic-disease/chronic-condition-multimorbidity/contents/chronic-conditions-and-multimorbidity Macrovascular disease, diabetes mellitus and chronic kidney disease were not included as choices as they are addressed by other fields. Congestive cardiac failure, dyslipidaemia and hypertension were deemed common and relevant to outcomes in this cohort and thus included. Mental health conditions were expanded to identify dementia and depression specifically.
Data utility:	Characterisation of comorbid disease and stratification by specific chronic conditions or multimorbidity in data analyses.

29. SMOKING STATUS

REDCap field

Variable / field name:	comorbidities_smoking
Field type:	radio
Field label:	Smoking status
Choices / calculations:	0, Never 1, Past 2, Current 99, Not stated / inadequately described
Field note:	(last recorded [previous-event-name][service_initial_date]: [previous-event-name][comorbidities_smoking])
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note similarity to ‘Tobacco smoking status’ (Identifier 270311)

Explanation

Definition/s: (adapted from METeOR)	A person's current and past smoking behaviour, as represented by a code. Never means the person does not smoke now and has smoked fewer than 100 cigarettes or similar amount of other tobacco products in their lifetime. Past means the person does not smoke at all now but has smoked at least 100 cigarettes or a similar amount of other tobacco products in their lifetime. Current means the person smokes any quantity or frequency of cigarettes or other tobacco products, irrespective of attempted cessation during the Episode of Care.
Data utility:	Characterisation of smoking status and stratification by cigarette/tobacco exposure in data analyses.

30. EGFR

REDCap field

Variable / field name:	comorbidities_egfr
Field type:	text
Field label:	eGFR
Choices / calculations:	-
Field note:	mL/min/1.73m²; within 3 months of <I>Date of initial assessment</i> (if >90 mL/min/1.73m² record as '99' or if unavailable leave blank)
Text validation:	integer (0-99)
Identifier:	-
Branching logic:	-
Required field:	-
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Person—estimated glomerular filtration rate (eGFR) result
Short name:	Estimated glomerular filtration rate result
Identifier:	503010
Compatibility:	Y, with recoding as follows:

REDCap field choice	METeOR value
99	1
60-89	2
45-59	3a
30-44	3b
15-29	4
0-14	5

Explanation

Definition/s:	A person's estimated glomerular filtration rate (eGFR) result, recorded in mL/min/1.73m^2 (i.e. the eGFR is estimated normalised for body surface area). Include the most recent value at Episode of Care commencement. The field is left blank if no value is available 3 months before or 3 months after Episode of Care commencement.

Data utility:	Characterisation of kidney function and stratification by initial kidney function in data analyses.

31. RENAL REPLACEMENT THERAPY

REDCap field

Variable / field name:	comorbidities_dialysis
Field type:	radio
Field label:	Renal replacement therapy
Choices / calculations:	0, None 1, Dialysis 2, Functioning renal transplant 99, Not stated / inadequately described
Field note:	(last recorded [previous-event-name][service_initial_date]: [previous-event-name][comorbidities_dialysis])
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note similarity to ‘Person – renal disease therapy’ (Identifier 270264)

Explanation

Definition/s: (adapted from METeOR)	The renal replacement therapy a person with end-stage kidney disease is receiving, including dialysis and functioning renal transplant, as represented by a code. Dialysis includes both chronic haemodialysis and chronic peritoneal dialysis, delivered at home, at a dialysis satellite centre or in hospital.
Data utility:	Characterisation of kidney function and stratification by requirement for renal replacement therapy in data analyses.

ULCER ASSESSMENT

The *Ulcer Assessment* form includes the following 26 variables. The last 7 variables relate to SINBAD classification and are automatically computed.

32. Date assessed
33. Side
34. Location
35. Aspect
36. Ulcer onset
37. Precipitant
38. Recurrent
39. Initial maximum diameter (a)
40. Initial perpendicular diameter (b)
41. Initial area estimate
42. Initial area measurement
43. Initial depth
44. Type
45. Ulcer classification system used *
46. WIfI depth grade
47. WIfI ischaemia grade
48. WIfI infection grade
49. Texas grade *
50. Texas stage *
51. SINBAD site
52. SINBAD ischaemia
53. SINBAD neuropathy
54. SINBAD infection
55. SINBAD area
56. SINBAD depth
57. SINBAD score

* Fields relating to The University of Texas Classification System have been retired. These fields are now hidden, however existing data has been retained and can still be extracted.

32. DATE ASSESSED

REDCap field

Variable / field name:	ulcer_date_assessed
Field type:	text
Field label:	Date assessed
Choices / calculations:	-
Field note:	-
Text validation:	date_dmy ([event-name][service_initial_date]-today)
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	@TODAY

METeOR item

Metadata item type:	Data Element
Official name:	Service contact – service contact date
Short name:	Service contact date
Identifier:	696285
Compatibility:	Y, format as DDMMYYYY

Explanation

Definition/s: (adapted from METeOR)	The date of service contact between a health care provider from the High-Risk Foot Service and the person undergoing assessment of a newly recorded foot ulceration, expressed as DDMMYYYY. The International Working Group on the Diabetic Foot defines ulceration as “a break of the skin of the foot that involves as a minimum the epidermis and part of the dermis.”[14] Anatomically the foot is the part of the lower limb distal to the malleoli.
Data utility:	Calculation of *Ulcer duration* when used in combination with *Ulcer onset* field. Analysis of time-based outcomes, including *Ulceration healing*, *Ulceration free* and *Ulceration recurrence* rates and intervals.

33. SIDE

REDCap field

Variable / field name:	ulcer_side
Field type:	radio
Field label:	Side
Choices / calculations:	1, Right 2, Left
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	Value Domain
Official name:	Laterality code A
Short name:	Laterality
Identifier:	270754
Compatibility:	Y, with recoding as follows:

REDCap field choice	METeOR value
1	R
2	L

Note as each foot ulceration entered discretely METeOR value ‘B’ meaning ‘Bilateral’ was not included.

Explanation

Definition/s: (adapted from METeOR)	The laterality of foot ulceration undergoing assessment, as represented by a code.
Data utility:	In combination with *Location* and *Aspect* it aids ulceration identification for outcome recording.

34. LOCATION

REDCap field

Variable / field name:	ulcer_location
Field type:	radio
Field label:	Location
Choices / calculations:	1, Hallux 2, Lesser toe 3, Forefoot (not toe) 4, Midfoot 5, Heel 6, Extensive (more than one region)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: The anatomical region of foot ulceration undergoing assessment, as represented by a code.

Hallux refers to the 1st phalange and associated soft tissue structures. Lesser toes refer to the 2nd-5th phalanges and associated soft tissue structures.
The International Working Group on the Diabetic Foot defines:[14]

- Forefoot as “the anterior (distal) part of the foot, that is composed of the metatarsal bones, the phalanges and associated soft tissue structures” noting phalanges are separately recorded field choices.
- Midfoot as “the part of the foot that is composed of the cuboid, navicular, and cuneiform bones, and associated soft tissue structures.”

	Heel refers to the calcaneus and associated soft tissue structures.
Data utility:	In combination with *Side* and *Aspect* it aids ulceration identification for outcome recording. Relevant to *WIfI* and imputation of *SINBAD site*, and thus stratification by ulceration severity in data analyses.

35. ASPECT

REDCap field

Variable / field name:	ulcer_aspect
Field type:	radio
Field label:	Aspect
Choices / calculations:	1, Plantar 2, Dorsal 3, Medial 4, Lateral 5, Apex of toe 6, Interdigital 7, Stump 9, Posterior 8, Extensive (more than one aspect)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The anatomical position of foot ulceration undergoing assessment, as represented by a code. Stump refers to soft tissue structures that remain at the site of partial bony resection.
Data utility:	In combination with *Side* and *Location* it aids ulceration identification for outcome recording. Relevant to *Pressure offloading* and *Footwear* selection, and thus stratification by management in data analyses.

36. ULCER ONSET

REDCap field

Variable / field name:	ulcer_date_onset
Field type:	text
Field label:	Ulcer onset
Choices / calculations:	-
Field note:	Approximate date first noticed by patient <I>Ulcer onset</i> must occur on/before <I>Date assessed</i> (i.e. [ulcer_date_assessed])
Text validation:	date_dmy (<[ulcer_date_assessed])
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The date of onset of the current active foot ulceration undergoing assessment, expressed as DDMMYYYY. Often precise date of onset is uncertain, in which case the best estimate by the person undergoing assessment, their carer or clinician is to be entered. For chronic ulceration defaulting to the 1st day of a month may be the best estimate.
Data utility:	Calculation of *Ulceration duration* when used in combination with *Date assessed* field. Stratification by *Ulceration duration* when assessed in data analyses, such as ulceration severity and outcomes.

37. PRECIPITANT

REDCap field

Variable / field name:	ulcer_precipitant
Field type:	radio
Field label:	Precipitant
Choices / calculations:	1, Acute trauma, footwear 2, Acute trauma, other (e.g. sharp) 3, Burn 4, Chronic trauma (e.g. deformity related, intrinsic) 5, Pressure injury 6, Surgical 98, Other or unknown
Field note:	Listed alphabetically
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The most likely and significant contributor to development of the foot ulceration undergoing assessment, as represented by a code. Surgical refers to a post-operative wound that is non-healing after primary closure (e.g. dehiscence, breakdown) or left open to heal by secondary intent. Most commonly the *Ulcer onset* field will be the surgical date (unless there was a period of healing). Note primary closure with expected wound healing trajectory is not ulceration. Other or unknown is to be used sparingly and accommodates rare aetiologies (e.g. vasculitis, neoplasm).
Data utility:	Characterisation of ulceration and stratification by ulceration precipitant / aetiology in data analyses.

38. RECURRENT

REDCap field

Variable / field name:	ulcer_recurrent
Field type:	radio
Field label:	Recurrent
Choices / calculations:	1, Yes 0, No
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	Whether the foot ulceration undergoing assessment is at the same site as a previous ulceration, with an intervening period of healing or complete re-epithelisation, as represented by a code.
Data utility:	Characterisation of ulceration and stratification by ulceration recurrence at the same site in data analyses. Note distinction from recurrent ulceration as a person-level outcome, i.e. a “new foot ulcer in a person who has a history of foot ulceration, irrespective of location and time, since previous foot ulcer.”[17]

39. INITIAL MAXIMUM DIAMETER

REDCap field

Variable / field name:	ulcer_max
Field type:	text
Field label:	Initial maximum diameter (a)
Choices / calculations:	-
Field note:	mm
Text validation:	number (>0)
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The greatest dimension of the foot ulceration undergoing assessment after debridement, measured as a straight line from side-to-side, recorded in mm. In the case of digital gangrene without discrete ulceration initial diameters are measured at the base of the necrotic toes, such that the area estimated will be the deficit left after auto-amputation.
Data utility:	Calculation of *Initial area estimate* when used in combination with *Initial perpendicular diameter (b)* field.

40. INITIAL PERPENDICULAR DIAMETER

REDCap field

Variable / field name:	ulcer_perp
Field type:	text
Field label:	Initial perpendicular diameter (b)
Choices / calculations:	-
Field note:	mm
Text validation:	number (>0)
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The greatest dimension of the foot ulceration undergoing assessment after debridement, measured perpendicular to *(a)* as a straight line from side-to-side, recorded in mm.
Data utility:	Calculation of *Initial area estimate* when used in combination with *Initial maximum diameter (a)* field.

41. INITIAL AREA ESTIMATE

REDCap field

Variable / field name:	ulcer_area
Field type:	calc
Field label:	Initial area estimate
Choices / calculations:	round(((3.14159265359/4)*[ulcer_max]*[ulcer_perp])/100,2)
Field note:	cm² (calculated field)
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	-
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The estimated area of foot ulceration undergoing assessment, recorded in cm^2, derived using the formula: $\frac{\pi * (a) * (b)}{4 * 100}$
Data utility:	Characterisation of ulceration, imputation of *SINBAD area* and stratification by ulceration size / severity in data analyses.

42. INITIAL AREA MEASUREMENT

REDCap field

Variable / field name:	ulcer_area_measure
Field type:	text
Field label:	Initial area measurement
Choices / calculations:	-
Field note:	cm² (i.e. by planimetry or imaging methods)
Text validation:	number (>0)
Identifier:	-
Branching logic:	-
Required field:	N
Field annotation *:	@HIDDEN * Omitted at sites that directly measure area

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The measured area of foot ulceration undergoing assessment, recorded in cm^2, obtained by validated planimetry or imaging methods.
Data utility:	Characterisation of ulceration, imputation of *SINBAD area* and stratification by ulceration size / severity in data analyses.

43. INITIAL DEPTH

REDCap field

Variable / field name:	ulcer_depth
Field type:	text
Field label:	Initial depth
Choices / calculations:	-
Field note:	mm
Text validation:	number (>0)
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The greatest depth of the foot ulceration undergoing assessment after debridement, measured by probe from skin surface to ulcer base (including any sinus), recorded in mm. In the case of digital gangrene without discrete ulceration initial depth is unlikely to be measurable and the field is left blank. Once auto-amputation occurs the depth is retrospectively added, thus providing an approximation of initial depth.
Data utility:	Characterisation of ulceration and stratification by ulceration size in data analyses.

44. TYPE

REDCap field

Variable / field name:	ulcer_type
Field type:	radio
Field label:	Type
Choices / calculations:	1, Neuropathic (loss of protective sensation) 2, Ischaemic (absence of pedal pulses) 3, Neuroischaemic 98, Other
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The type of foot ulceration undergoing assessment, as represented by a code. In considering presence of neuropathy and ischaemia the SINBAD system definitions were used.[18] Neuropathic ulceration refers to loss of protective sensation on the ipsilateral foot, typically determined by 10-g monofilament testing. Ischaemic ulceration refers to absence of pedal pulses (i.e. both dorsalis pedis and posterior tibial) with reduced tissue perfusion. Neuroischaemic refers to a combination of both findings. Other is to be used sparingly and accommodates rare aetiologies (e.g. vasculitis, neoplasm).
Data utility:	Characterisation of ulceration, imputation of *SINBAD ischaemia* and *SINBAD neuropathy*, and stratification by ulceration type / severity in data analyses.

45. ULCER CLASSIFICATION SYSTEM *

* Fields relating to The University of Texas Classification System have been retired. These fields are now hidden, however existing data has been retained and can still be extracted.

REDCap field

Variable / field name:	ulcer_system
Field type:	radio
Field label:	Ulcer classification system used
Choices / calculations:	1, WIfI (preferred) 2, Texas 3, Both
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	N
Field annotation:	@HIDDEN

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The standardised and validated classification system used for grading foot ulceration undergoing assessment, as represented by a code. WIfI refers to the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System.[19] Texas refers to the University of Texas Classification System.[20] WIfI (or both) is preferred to Texas alone given ischaemia and infection grading is more indepth.
Data utility:	Branching logic for WIfI and Texas Classification System fields.

46. WIFI DEPTH

REDCap field

Variable / field name:	ulcer_wifi_wound
Field type:	radio
Field label:	WIfI depth
Choices / calculations:	0, 0 (no ulcer or gangrene) 1, 1 (small/shallow ulcer, no bone exposed unless distal phalanx, no gangrene) 2, 2 (deep ulcer to bone/joint/tendon, shallow heel ulcer, gangrene limited to toes) 3, 3 (extensive ulcer, deep heel ulcer, extensive gangrene)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	[ulcer_system] <> '2'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: Classification of 'Wound/clinical category' with reference to the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System,[19] as represented by a code.

Grade	Ulcer	Gangrene
0	No ulcer	No gangrene
Clinical description: ischemic rest pain (requires typical symptoms + ischemia grade 3); no wound.		
1	Small, shallow ulcer(s) on distal leg or foot; no exposed bone, unless limited to distal phalanx	No gangrene
Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.		

2	Deeper ulcer with exposed bone, joint or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement	Gangrenous changes limited to digits
Clinical description: major tissue loss salvageable with multiple (≥3) digital amputations or standard TMA ± skin coverage.		
3	Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer ± calcaneal involvement	Extensive gangrene involving forefoot and /or midfoot; full thickness heel necrosis ± calcaneal involvement
Clinical description: extensive tissue loss salvageable only with a complex foot reconstruction or nontraditional TMA (Chopart or Lisfranc); flap coverage or complex wound management needed for large soft tissue defect		

TMA, Transmetatarsal amputation.

Data utility:	Characterisation of ulceration, imputation of *SINBAD depth* and stratification by ulceration classification / severity in data analyses.

47. WIFI ISCHAEMIA

REDCap field

Variable / field name:	ulcer_wifi_ischaemia
Field type:	radio
Field label:	WIfI ischaemia
Choices / calculations:	0, 0 (ABI >0.79, TP >59 mmHg) 1, 1 (ABI 0.60-0.79, TP 40-59 mmHg) 2, 2 (ABI 0.40-0.59, TP 30-39 mmHg) 3, 3 (ABI < 0.40, TP < 30 mmHg)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	[ulcer_system] <> '2'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: Classification of 'Ischaemia' with reference to the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System,[19] as represented by a code.

Grade	ABI	Ankle systolic pressure (mmHg)	TP, $TcPO_2$ (mmHg)
0	≥0.80	>100	≥60
1	0.6-0.79	70-100	40-59
2	0.4-0.59	50-70	30-39
3	≤0.39	<50	<30

ABI, ankle-brachial index; TP, toe pressure; $TcPO_2$, transcutaneous oximetry

Toe pressure measurement is recommended for people with diabetes.

Data utility: Characterisation of ulceration and stratification by ulceration classification / severity in data analyses.

48. WIFI INFECTION

REDCap field

Variable / field name:	ulcer_wifi_infection
Field type:	radio
Field label:	WIfI infection
Choices / calculations:	0, 0 (no symptoms/signs) 1, 1 (local infection of skin/subcutaneous tissue) 2, 2 (local infection deeper than skin/subcutaneous tissue) 3, 3 (systemic inflammatory response syndrome)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	[ulcer_system] <> '2'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: Classification of 'Infection' with reference to the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System,[19] as represented by a code.

Grade	Clinical manifestation of infection
0	No symptoms or signs of infection
1	Infection present, as defined by the presence of at least 2 of the following items: • Local swelling or induration • Erythema >0.5 to ≤2 cm around the ulcer • Local tenderness or pain • Local warmth • Purulent discharge (thick, opaque to white, or sanguineous secretion)

	Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as defined below). Exclude other causes of an inflammatory response of the skin (e.g. trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis)
2	Local infection (as defined above) with erythema >2 cm, or involving structures deeper than skin and subcutaneous tissues (e.g. abscess, osteomyelitis, septic arthritis, fasciitis), and No systemic inflammatory response signs (as defined below)
3	Local infection (as defined above) with the signs of SIRS, as manifested by 2 or more of the following: • Temperature >38° or <36°C • Heart rate >90 beats/min • Respiratory rate >20 breaths/min or $PaCO_2$ <32 mmHg • White blood cell count >12,000 or <4000 cu/mm or 10% immature (band) forms

$PaCO_2$, partial pressure of arterial carbon dioxide; SIRS, systemic inflammatory response syndrome

Data utility:	Characterisation of ulceration, imputation of *SINBAD infection* and stratification by ulceration classification / severity in data analyses.

49. TEXAS GRADE *

* Fields relating to The University of Texas Classification System have been retired. These fields are now hidden, however existing data has been retained and can still be extracted.

REDCap field

Variable / field name:	ulcer_texas_grade
Field type:	radio
Field label:	Texas grade
Choices / calculations:	0, 0 (completely epithelialised) 1, 1 (superficial) 2, 2 (penetrating to tendon/capsule) 3, 3 (penetrating to bone/joint)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	[ulcer_system] = '2' or [ulcer_system] = '3'
Required field:	N
Field annotation:	@HIDDEN

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: Classification of ‘Grade’ with reference to the University of Texas Classification System,[20] as represented by a code. Grade in this context indicates ulceration depth and involvement of structures beneath the skin.

Grade	Depth
0	Pre- or postulcerative lesion completely epithelialised
1	Superficial wound, not involving tendon, capsule or bone
2	Wound penetrating to tendon or capsule
3	Wound penetrating to bone or joint

Data utility:	Characterisation of ulceration, imputation of *SINBAD depth* and stratification by ulceration classification / severity in data analyses.

50. TEXAS STAGE *

* Fields relating to The University of Texas Classification System have been retired. These fields are now hidden, however existing data has been retained and can still be extracted.

REDCap field

Variable / field name:	ulcer_texas_stage
Field type:	radio
Field label:	Texas stage
Choices / calculations:	0, A (no infection or ischaemia) 1, B (infection) 2, C (ischaemia) 3, D (infection and ischaemia)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	[ulcer_system] = '2' or [ulcer_system] = '3'
Required field:	N
Field annotation:	@HIDDEN

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: Classification of ‘Stage’ with reference to the University of Texas Classification System,[20] as represented by a code. Stage in this context indicates whether there is clinical and/or laboratory evidence of infection and/or ischaemia.

Stage	Criteria
0	No infection or ischaemia
1	Infection as defined by local and/or systemic signs, perhaps assisted by laboratory studies (e.g. inflammatory markers, tissue cultures). Local signs include frank purulence and/or 2 or more of the following: • Warmth • Erythema

	• Lymphangiitis • Lymphadenopathy • Oedema • Pain • Loss of function Systemic signs may include fever, chills, nausea, vomiting or generalized malaise.
2	Ischaemia as defined by a combination of 1 or more clinical signs / symptoms plus 1 or more non-invasive vascular studies. Clinical signs / symptoms may include claudication, rest pain, absent pulses, atrophic integument, absence of pedal hair, dependent rubor or pallor on elevation. Non-invasive criteria include: • transcutaneous oxygen ($TcPO_2$) measurements of <40 mmHg • Ankle-brachial index (ABI) of <0.80 • Absolute toe systolic pressure (TP) <45 mmHg
3	Both infection and ischaemia (as defined above)

Data utility: Characterisation of ulceration, imputation of *SINBAD infection* and stratification by ulceration classification / severity in data analyses.

51. SINBAD SITE

REDCap field

Variable / field name:	ulcer_sinbad_site
Field type:	calc
Field label:	SINBAD site
Choices / calculations:	if([ulcer_location]>3,1,0)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	-
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: Classification of 'Site' with reference to the SINBAD system for classifying and scoring foot ulcers,[18] as represented by a code. Site in this context is scored as follows:

Score	Definition
0	Forefoot (distal to tarso-metatarsal joint)
1	Midfoot and hindfoot

Data utility: Characterisation of ulceration, calculation of total *SINBAD score* and stratification by ulceration classification / severity in data analyses.

52. SINBAD ISCHAEMIA

REDCap field

Variable / field name:	ulcer_sinbad_ischaemia
Field type:	calc
Field label:	SINBAD ischaemia
Choices / calculations:	if([ulcer_type]=2,1,0)+if([ulcer_type]=3,1,0)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	-
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: Classification of 'Ischaemia' with reference to the SINBAD system for classifying and scoring foot ulcers,[18] as represented by a code. Ischaemia in this context is scored as follows:

Score	Definition
0	Blood flow relatively intact (at least one pulse palpable on the affected foot)
1	Evidence of ischaemia (neither pulse palpable with signs of reduced tissue perfusion, with or without gangrene)

Data utility: Characterisation of ulceration, calculation of total *SINBAD score* and stratification by ulceration classification / severity in data analyses.

53. SINBAD NEUROPATHY

REDCap field

Variable / field name:	ulcer_sinbad_neuropathy
Field type:	calc
Field label:	SINBAD neuropathy
Choices / calculations:	if([ulcer_type]=1,1,0)+if([ulcer_type]=3,1,0)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	-
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: Classification of 'neuropathy' with reference to the SINBAD system for classifying and scoring foot ulcers,[18] as represented by a code. Neuropathy in this context is scored as follows:

Score	Definition
0	Protective sensation intact
1	Protective sensation lost, on the basis of routine examination using either 10-g nylon monofilaments or Neurotips (Owen Mumford)

Data utility: Characterisation of ulceration, calculation of total *SINBAD score* and stratification by ulceration classification / severity in data analyses.

54. SINBAD INFECTION

REDCap field

Variable / field name:	ulcer_sinbad_infection
Field type:	calc
Field label:	SINBAD infection
Choices / calculations:	if((if([ulcer_wifi_infection]>0,1,0)+if([ulcer_texas_stage]=1,1,0)+ if([ulcer_texas_stage]=3,1,0))>0,1,0)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	-
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: Classification of 'infection' with reference to the SINBAD system for classifying and scoring foot ulcers,[18] as represented by a code. Infection in this context is scored as follows:

Score	Definition
0	Bacterial infection absent
1	Bacterial infection present, encompassing mild through to severe infection involving soft tissue and/or bone (as further defined by The International Working Group on the Diabetic Foot[21])

Data utility: Characterisation of ulceration, calculation of total *SINBAD score* and stratification by ulceration classification / severity in data analyses.

55. SINBAD AREA

REDCap field

Variable / field name:	ulcer_sinbad_area
Field type:	calc
Field label:	SINBAD area
Choices / calculations:	if([ulcer_area]>0.99,1,0)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	-
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: Classification of 'area' with reference to the SINBAD system for classifying and scoring foot ulcers,[18] as represented by a code. Area in this context is scored as follows:

Score	Definition
0	Ulcer < 1cm^2
1	Ulcer ≥ 1cm^2

Data utility: Characterisation of ulceration, calculation of total *SINBAD score* and stratification by ulceration classification / severity in data analyses.

56. SINBAD DEPTH

REDCap field

Variable / field name:	ulcer_sinbad_depth
Field type:	calc
Field label:	SINBAD depth
Choices / calculations:	if((if([ulcer_wifi_wound]>1,1,0)+if([ulcer_wifi_wound]>2,1,0)-if([ulcer_location]=5,1,0)+if([ulcer_texas_grade]>1,2,0))>0,1,0)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	-
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: Classification of 'depth' with reference to the SINBAD system for classifying and scoring foot ulcers,[18] as represented by a code. Depth in this context is scored as follows:

Score	Definition
0	Superficial (confined to skin and subcutaneous tissue)
1	Deep (reaching to tendon, periosteum, joint capsule or bone)

Data utility: Characterisation of ulceration, calculation of total *SINBAD score* and stratification by ulceration classification / severity in data analyses.

57. SINBAD SCORE

REDCap field

Variable / field name:	ulcer_sinbad_score
Field type:	calc
Field label:	SINBAD score
Choices / calculations:	[ulcer_sinbad_site]+[ulcer_sinbad_ischaemia]+ [ulcer_sinbad_neuropathy]+[ulcer_sinbad_infection]+ [ulcer_sinbad_area]+[ulcer_sinbad_depth]
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	-
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	Summation of all six aforementioned SINBAD categories to create a total score,[18] calculated as an integer (0-6).
Data utility:	Stratification by ulceration classification / severity in data analyses noting a *SINBAD score* of ≥3 has been associated with poorer healing outcomes.

ACTIVE CHARCOT FOOT ASSESSMENT

The *Active Charcot Foot Assessment* form includes the following 11 variables.

58. Date assessed
59. Side
60. Charcot foot onset
61. Precipitant
62. Recurrent
63. Deformity
64. Skin integrity
65. Temperature
66. Diagnostic imaging
67. Modified Eichenholtz Classification
68. Sanders & Frykberg Classification

58. DATE ASSESSED

REDCap field

Variable / field name:	charcot_date_assessed
Field type:	text
Field label:	Date assessed
Choices / calculations:	-
Field note:	-
Text validation:	date_dmy ([event-name][service_initial_date]-today)
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	@TODAY

METeOR item

Metadata item type:	Data Element
Official name:	Service contact – service contact date
Short name:	Service contact date
Identifier:	696285
Compatibility:	Y, format as DDMMYYYY

Explanation

Definition/s: (adapted from METeOR)	The date of service contact between a health care provider from the High-Risk Foot Service and the person undergoing assessment of a newly recorded active Charcot foot, expressed as DDMMYYYY. Charcot neuropathic osteoarthropathy, or Charcot foot, generally refers to a localised inflammatory condition affecting the soft tissues, joints and bone of the insensate foot and/or ankle, where several culminating factors lead to osteolysis, fracture, joint subluxation and destruction, and ultimately deformity. Active disease corresponds to Stage 0-2 of the Modified Eichenholtz classification.[15,22] Clinically there is evidence of inflammation and joint instability, which gradually subsides through the Stages. Radiographical features are absent in Stage 0, with subsequent development of fractures and deformity. Advanced imaging modalities are now commonly used in delineating disease activity and extent.

Data utility:	Calculation of active *Charcot foot duration* when used in combination with *Charcot foot onset* field. Analysis of time-based outcomes, including *Charcot foot consolidation* and *Charcot foot recurrence* rates and intervals.

59. SIDE

REDCap field

Variable / field name:	charcot_side
Field type:	radio
Field label:	Side
Choices / calculations:	1, Right 2, Left
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	Value Domain
Official name:	Laterality code A
Short name:	Laterality
Identifier:	270754
Compatibility:	Y, with recoding as follows: REDCap field choice / METeOR value 1 / R 2 / L Note as each active Charcot foot is entered discretely METeOR value 'B' meaning 'Bilateral' was not included.

Explanation

Definition/s: (adapted from METeOR)	The laterality of active Charcot foot undergoing assessment, as represented by a code.
Data utility:	Identification of active Charcot foot for outcome recording.

60. CHARCOT FOOT ONSET

REDCap field

Variable / field name:	charcot_date_onset
Field type:	text
Field label:	Charcot foot onset
Choices / calculations:	-
Field note:	Approximate date first noticed by patient <I>Charcot foot onset</i> must occur on/before <I>Date assessed</i> (i.e. [charcot_date_assessed])
Text validation:	date_dmy (<[charcot_date_assessed])
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The date of onset of the current active Charcot foot undergoing assessment, expressed as DDMMYYYY. Often precise date of onset is uncertain, in which case the best estimate by the person undergoing assessment, their carer or clinician is to be entered. Defaulting to the 1st day of a month may be the best estimate. Onset is to be ascertained by clinical history, particularly noting evolution of cardinal inflammatory signs (i.e. erythema, swelling and heat). Additionally, trauma and/or pain may be recalled.
Data utility:	Calculation of active *Charcot foot duration* when used in combination with *Date assessed* field. Stratification by active *Charcot foot duration* when assessed in data analyses, such as Charcot foot stage and outcomes.

61. PRECIPITANT

REDCap field

Variable / field name:	charcot_precipitant
Field type:	radio
Field label:	Precipitant
Choices / calculations:	0, None 1, Minimal trauma 2, Significant trauma 3, Surgical
Field note:	Minimal trauma = event not expected to fracture healthy bone (e.g. trip) Significant trauma = greater than 'minimal trauma'
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The most likely and significant contributor to development of the active Charcot foot undergoing assessment, as represented by a code. None is chosen when there is no recollection of a distinct injury that is temporarily related to the active *Charcot foot onset*. Minimal trauma (as annotated in the field note) refers to an event that would not be expected to fracture healthy bone (e.g. trip while walking, bodyweight lower limb strength training). In turn, significant trauma refers to an event of greater impact. Surgical infers temporal association with surgery on the ipsilateral foot (e.g. minor amputation). Importantly in this context it is often necessary to exclude an infective aetiology.
Data utility:	Characterisation of active Charcot foot and stratification by active Charcot foot precipitant / aetiology in data analyses.

62. RECURRENT

REDCap field

Variable / field name:	charcot_recurrent
Field type:	radio
Field label:	Recurrent
Choices / calculations:	1, Yes 0, No
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	Whether the active Charcot foot undergoing assessment is on the same side as a previous Charcot foot episode, with an intervening period of consolidation or inactive disease, as represented by a code. Inactive disease corresponds to Stage 3 of the Eichenholtz classification.[15] Clinically there is absence of inflammation and a more stable yet often deformed foot. Radiographical features include osteophytes, subchondral sclerosis and narrowing of joint spaces. Clinical judgement is required to differentiate true recurrence from inflammatory flare of the original active Charcot foot episode. Generally, return of inflammation within weeks of declared consolidation is more likely to represent incomplete treatment and continuation of the original episode.
Data utility:	Characterisation of active Charcot foot and stratification by Charcot foot recurrence on the same side in data analyses.

63. DEFORMITY

REDCap field

Variable / field name:	charcot_deformity
Field type:	radio
Field label:	Deformity
Choices / calculations:	0, None 1, Forefoot 2, Midfoot bony prominence/partial collapse 3, Rocker bottom foot 4, Ankle/hindfoot
Field note:	Select predominant deformity on examination
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note ‘Person – foot deformity indicator’ (Identifier 302449) amalgamates any foot deformity in either foot using a binary code.

Explanation

Definition/s:	The presence of deformity on physical examination attributable to the current or a previous Charcot foot episode on the same foot undergoing assessment, as represented by a code. None is chosen if the foot appears symmetrical compared to the contralateral side. In the case that bilateral deformity is suspected the participant may be aware of a recent change in foot shape or historic clinical records may be consulted. When deformity is present choose the most predominant and clinically relevant feature. Forefoot includes abduction or adduction relative to the midfoot, and subluxation or dislocation of digits. Midfoot includes bony prominence and degrees of collapse of the longitudinal arch, with the most severe non-plantigrade deformity termed ‘rocker bottom foot’.

	Ankle/hindfoot includes varus or valgus deformity, typically with significant instability, or migration of the calcaneal tuberosity.
Data utility:	Characterisation of active Charcot foot and stratification by Charcot foot type / severity in data analyses.

64. SKIN INTEGRITY

REDCap field

Variable / field name:	charcot_skin
Field type:	radio
Field label:	Skin integrity
Choices / calculations:	0, Intact 1, Callus 2, Inflammation/cellulitis (no ulceration) 3, Pre-ulceration (e.g. blister, fissure, haemorrhage) 4, Ulceration with/without infection
Field note:	Select most appropriate option
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note ‘Person – foot ulcer indicator (current)’ (Identifier 302445) includes ulceration on either foot.

Explanation

Definition/s:

Condition of the skin on physical examination of the same foot undergoing active Charcot foot assessment, as represented by a code.

Intact is chosen if none of the subsequently listed choices apply. The International Working Group on the Diabetic Foot defines:[14]

- Callus as “increased thickness of the outer layer of the skin caused by excessive mechanical loading.”
- Cellulitis as “an infection of the skin (epidermis and dermis and hypodermis [subcutaneous fat and connective tissue]) manifested by one or more of the following: induration, erythema, warmth, pain or tenderness”, which thus overlaps with the cardinal inflammatory signs.

	• Pre-ulceration as a “lesion that has a high risk to develop into a foot ulcer, such as intra- or subcutaneous haemorrhage, blister, or skin fissure not penetrating into the dermis.” • Ulceration as “a break of the skin of the foot that involves as a minimum the epidermis and part of the dermis.” Anatomically the foot is the part of the lower limb distal to the malleoli. Note a corresponding *Ulcer Assessment* form is to be completed for each ulceration.
Data utility:	Characterisation of active Charcot foot and stratification by Charcot foot severity in data analyses. Additionally, branching logic to prompt completion of *Ulcer Assessment* form/s.

65. TEMPERATURE

REDCap field

Variable / field name:	charcot_max_temp
Field type:	text
Field label:	Temperature
Choices / calculations:	-
Field note:	^oC; maximum difference using dermal thermometer (if unavailable leave blank)
Text validation:	number (-20 to 20)
Identifier:	-
Branching logic:	-
Required field:	N
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:

The maximum foot temperature difference comparing like anatomical sites on the active Charcot foot to the contralateral side, measured in degrees Celsius.

Temperature measurements are obtained by a calibrated infrared dermal thermometer that has been validated in this clinical setting and is approved by the Therapeutic Goods Administration for medical use (e.g. DermaTemp DT-1001, Exergen Corporation).

A non-touch technique, where the sensor is held approximately half a centimetre from the skin surface, is preferred. A methodical approach should be taken in measuring and calculating the temperature difference at each anatomical site. The optional embedded algorithm prompts temperature measurement at 11 points on each foot: 7 points on plantar surface (i.e. distal hallux, 1st, 3rd and 5th metatarsal heads, medial and lateral longitudinal arch, and heel), 2 points on the dorsal surface (i.e. midfoot and anterior ankle), and the medial

	and lateral malleoli. Positive values imply the temperature is higher in the active Charcot foot. Only the greatest positive value is recorded.
Data utility:	Characterisation of active Charcot foot and validation of disease stage.

66. DIAGNOSTIC IMAGING

REDCap field

Variable / field name:	ix_charcot_radio
Field type:	checkbox
Field label:	Diagnostic imaging
Choices / calculations:	1, X-ray 2, CT without contrast 3, CT with contrast 4, MRI without contrast 5, MRI with contrast 6, Bone scan 7, White cell scan
Field note:	Select all that apply
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note relationship to Data Element Concept ‘Person – diagnostic imaging type’ (Identifier 431752) implemented for other diseases.

Explanation

Definition/s: (adapted from METeOR)	The type of medical imaging performed to confirm the diagnosis and determine the nature of active Charcot foot in a person, as represented by a code.
Data utility:	Access to / utilisation of advanced imaging for active Charcot foot and validation of disease diagnosis.

67. MODIFIED EICHENHOLTZ CLASSIFICATION

REDCap field

Variable / field name:	charcot_stage
Field type:	radio
Field label:	Modified Eichenholtz Classification (stage)
Choices / calculations:	0, 0 (inflammation, normal radiographs) 1, 1 (inflammation, fracture/subluxation) 2, 2 (less inflammation, absorption/fusion) 3, 3 (no inflammation, sclerosis/joint narrowing)
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:

The stage of Charcot foot undergoing assessment according to clinical and radiographical findings, as represented by a code.

Eichenholtz defined three stages with Stage 0 subsequently added by Shibata et al. to recognise clinical signs may manifest before radiographic changes are evident.[15,22] The stages are as follows:

Stage	Clinical	Radiographical
0	Loss of protective sensation, swelling and erythema, instability	Normal radiographs
1 Fragmentation Dissolution Development	Warm oedematous foot, laxity of ligaments	Osteopenia, periarticular fragmentation, fracture,

		subluxation of joints
2 Coalescence	Healing phase, less oedema and warmth	Absorption of debris, fusion of bony fragments, early sclerosis
3 Reconstruction Remodelling	Absence of inflammation, more stable but deformed foot	Osteophytes, subchondral sclerosis, narrowing of joint spaces

Data utility:	Characterisation of active Charcot foot and stratification by Charcot foot classification / severity in data analyses.

68. SANDERS & FRYKBERG CLASSIFICATION

REDCap field

Variable / field name:	charcot_site
Field type:	checkbox
Field label:	Sanders & Frykberg Classification (site/s)
Choices / calculations:	1, 1 (metatarsophalangeal & interphalangeal joints) 2, 2 (tarsometatarsal joints) 3, 3 (midtarsal joints) 4, 4 (ankle and subtalar joints) 5, 5 (posterior calcaneus)
Field note:	Select all that apply
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: The anatomical site/s of disease involvement in the active Charcot foot undergoing assessment, as represented by a code.

Sanders and Frykberg defined five ‘types’, however they can occur in combination.[23] The types are as follows:

Type	Localisation
1	Metatarsophalangeal and interphalangeal joints
2	Tarsometatarsal joints (Lisfranc)
3	Midtarsal joints – cuneonavicular, talonavicular, calcaneocuboid (Chopart)
4	Ankle joint and subtalar joint
5	Posterior calcaneus

Data utility:	Characterisation of active Charcot foot and stratification by Charcot foot classification / severity in data analyses noting the type has clinical utility in predicting the likely disease course.

MANAGEMENT

The *Management* form includes the following 18 variables. The first 14 variables relate to all episodes of care, and the remaining 4 to those involved active Charcot foot.

69. Inter-disciplinary team input
70. Date of first interdisciplinary assessment
71. Date of first vascular surgical input
72. Pressure offloading
73. Offloading best practice
74. Footwear
75. Systemic antibiotics
76. Hospitalisation required
77. Cumulative length of stay
78. HITH length of stay
79. Extent of amputation
80. Patient disposition
81. Date of separation
82. Date deceased
83. Antiresorptive therapy
84. Corrective/offloading surgery
85. Surgery type
86. Surgery timing

69. INTER-DISCIPLINARY TEAM INPUT

REDCap field

Variable / field name:	management_input
Field type:	checkbox
Field label:	Inter-disciplinary team input
Choices / calculations:	1, Endocrinologist 2, Podiatrist 3, Orthopaedic surgeon 4, Vascular surgeon 5, Pedorthist 6, Orthotist 7, Diabetes educator 8, Dietitian 9, Wound nurse 10, Infectious diseases 11, Rehabilitation 12, Aboriginal health 13, Psychologist 96, Other physician 97, Other surgeon 98, Other allied health
Field note:	Select all that apply
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note similarity to 'Provider occupation' (Identifier 523811) based on Australian and New Zealand Standard Classification of Occupations (ANZSCO)[12]

Explanation

Definition/s: (adapted from METeOR)	The occupation of each health care provider who delivered assessment, care, consultation and/or treatment of the person, and is recognised as a member of the interdisciplinary High-Risk Foot Service team, as represented by a code.

Note, as distinct from the *Date of first interdisciplinary assessment* field, this field documents contact of health care providers at any timepoint during the Episode of Care. The National Association of Diabetes Centres (NADC) Standards require co-location of the 'core team', including a senior consulting diabetologist / endocrinologist / physician, a senior podiatrist, and a credentialled diabetes educator.[6] For other health care providers that are not available on-site formalised rapid access referral pathways are permitted. In this case care coordination should involve direct communication between the on-site interdisciplinary High-Risk Foot Service team and off-site health care provider.

While not directly compatible, a health care provider's occupation can be listed at any level of occupation specificity, as defined in the ANZSCO.[12] Health professionals form sub-major group 25.

Translation of REDCap field choices into ANZSCO codes:

REDCap field choice	ANZSCO occupation code
1	253315
2	252611
3	253514
4	253521
5	N/A (Pedorthist not indexed)
6	251912
7	254211
8	251111
9	2544 (Registered Nurses Unit Group)
10	253399
11	253399
12	411511
13	272311

Data utility: Description of management complexity, stratification by interdisciplinary input in data analyses, and benchmarking of sites with reference to the NADC Standards.[6]

70. DATE OF FIRST INTERDISCIPLINARY ASSESSMENT

REDCap field

Variable / field name:	service_interdisc_date
Field type:	text
Field label:	Date of first interdisciplinary assessment
Choices / calculations:	-
Field note:	Date of first interdisciplinary assessment must occur on/after Date of initial assessment (i.e. [event-name][service_initial_date])
Text validation:	date_dmy (>[event-name][service_initial_date])
Identifier:	-

Branching logic:	(if([management_input(1)]=1,1,0)+
	if([management_input(2)]=1,1,0)+
	if([management_input(3)]=1,1,0)+
	if([management_input(4)]=1,1,0)+
	if([management_input(5)]=1,1,0)+
	if([management_input(6)]=1,1,0)+
	if([management_input(7)]=1,1,0)+
	if([management_input(8)]=1,1,0)+
	if([management_input(9)]=1,1,0)+
	if([management_input(10)]=1,1,0)+
	if([management_input(11)]=1,1,0)+
	if([management_input(12)]=1,1,0)+
	if([management_input(13)]=1,1,0)+
	if([management_input(96)]=1,1,0)+
	if([management_input(97)]=1,1,0)+
	if([management_input(98)]=1,1,0))>1

Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The date on which assessment, care, consultation and/or treatment is first delivered to the person by an interdisciplinary High-Risk Foot Service team, expressed as DDMMYYYY.

	Interdisciplinary means two or more health care providers with different occupations are co-located. Note staffing to meet NADC iHRFS Standards indicators is captured by the *Interdisciplinary team input* field.
Data utility:	Analysis of the time-based outcome *Referral to interdisciplinary review*.

71. DATE OF FIRST VASCULAR SURGICAL ASSESSMENT

REDCap field

Variable / field name:	service_vascular_date
Field type:	text
Field label:	Date of first vascular surgical assessment
Choices / calculations:	-
Field note:	Date of first vascular surgical assessment must occur on/after Date of initial assessment (i.e. [event-name][service_initial_date])
Text validation:	date_dmy (>[event-name][service_initial_date])
Identifier:	-
Branching logic:	[management_input(4)] = '1'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The date on which assessment, care, consultation and/or treatment is first delivered to the person by a vascular surgeon as part of the interdisciplinary High-Risk Foot Service team, expressed as DDMMYYYY. Vascular surgical input may be obtained off-site if facilitated by formalised referral pathways and direct communication with the High-Risk Foot Service team.
Data utility:	Analysis of the time-based outcome *Referral to vascular surgical input*.

72. PRESSURE OFFLOADING

REDCap field

Variable / field name:	management_offloading
Field type:	checkbox
Field label:	Pressure offloading
Choices / calculations:	0, None 1, Non-removable knee-high device, total contact cast 2, Non-removable knee-high device, other 3, Removable knee-high device 4, Removable ankle-high device 5, Therapeutic footwear 6, Surgical offloading 7, Foot orthoses 8, Felted foam 98, Other 99, Not stated / inadequately described
Field note:	Select all that apply
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	@NONEOFTHEABOVE=0,99

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: (adapted from DFA)	Whether a person with active foot ulceration and/or active Charcot foot is using or is being prescribed an offloading intervention, as represented by a code. Field choices are amalgamated over the Episode of Care. This field was adapted from the Australian Diabetic Foot Ulcer Minimum Dataset Dictionary.[5] Definitions for offloading devices have been published by the International Working Group on the Diabetic Foot:[24]

- Non-removable knee-high device, total contact cast – “a custom-made, well-moulded, minimally padded, knee-high non-removable fiberglass or plaster cast that maintains total contact with the entire plantar surface and lower leg. The cast is often worn with an attachable sole that protects the cast and facilitates walking.”
- Non-removable knee-high device, other – “prefabricated removable, mostly knee-high, walker rendered non-removable to the patient, by a healthcare professional circumferentially wrapping with a layer(s) of fiberglass cast material or other closure technique such as a tie wrap. Such a device is also known as “instant total contact cast”. Manufacturers may also provide means to make the walker non-removable such as incorporating locking mechanisms into the walker.”
- Removable knee-high device – “offloading device that extends up the leg to a level just below the knee”, including prefabricated, knee-high, removable cast walkers, such as CAM walkers, moonboots or air cast walkers, or custom-made bi-valved knee-high total contact casts.
- Removable ankle-high device – “an offloading device that extends no higher up the leg than just above the ankle and can be further sub-grouped into above ankle-high and below ankle-high offloading devices. Includes ankle-high walker, forefoot offloading shoe, cast shoe, healing sandal, post-operative healing shoe, and custom-made temporary shoe.”
- Therapeutic footwear – “generic term for footwear designed to have a therapeutic effect that cannot be provided by or in a conventional shoe. Custom-made shoes or sandals, custom-made insoles, extra- depth shoes, and custom-made or prefabricated medical grade footwear are examples of therapeutic footwear.” Although not recommended for offloading of active foot ulceration and/or active Charcot foot it may be unavoidable in some circumstances or used as a step-down approach.
- Foot orthoses – a “device put inside the shoe to achieve pressure reduction or alteration in the function of the foot”, which can be prefabricated or custom-made.

Felted foam has different densities and an adherent backing that enables it to be cut, contoured and fixed to a surface, typically the pressure offloading insole of an existing offloading device or footwear, or the foot.[25]

Surgical offloading refers to adjunctive procedures that aim to reduce plantar pressure and thereby facilitate healing or reduce risk of (re-)ulceration (e.g. Achilles tendon lengthening, gastrocnemius muscle release, exostectomy).

Data utility:	Description of management complexity, stratification by offloading utilisation in data analyses, and benchmarking of sites with reference to evidence-based guidelines.

73. OFFLOADING BEST PRACTICE

REDCap field

Variable / field name:	management_offloading_bp
Field type:	checkbox
Field label:	Offloading best practice
Choices / calculations:	1, Yes, adhered to guideline recommendations 2, No, due to contraindication factors 3, No, due to patient intolerance factors 4, No, due to lack of service resource / skill factors 99, Not applicable
Field note:	Select all that apply See Guidelines / Data Dictionary for specific factors
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	@NONEOFTHEABOVE=99

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:

Whether a person is using or is being prescribed a best practice offloading intervention/s, and rationale for the offloading employed otherwise, as represented by a code. Field choices are amalgamated over the Episode of Care.

Best practice implies the offloading intervention aligns with national and international guidelines.[24,25] Offloading may not be optimised due to one or more contraindication-, patient- or service-dependant factors.[25] Specific factors include:

- Contraindication – infection presence and severity, ischaemia presence and severity, high risk of falls
- Patient – occupation, family requirement, driving requirement, climate, follow-up attendance, cultural practices, personal preference
- Service – resources, skills

Data utility:	Understanding rationale for offloading utilisation with reference to evidence-based guidelines.

74. FOOTWEAR

REDCap field

Variable / field name:	management_footwear
Field type:	radio
Field label:	Footwear
Choices / calculations:	1, Off-the-shelf 2, Pre-fabricated medical grade 3, Custom-made medical grade 99, Not applicable
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:

Whether a person with active foot ulceration and/or active Charcot foot is using or is being prescribed footwear, as represented by a code. Field choices are amalgamated over the Episode of Care.

Footwear may be prescribed synchronously with offloading (i.e. for the contralateral foot), consecutively with offloading (i.e. step-down transition), or therapeutically in place of another offloading intervention (seldom best practice).

Definitions for footwear have been published by Diabetes Feet Australia:[26]

- Off-the-shelf – “Readily available footwear that has not been modified and has no intended therapeutic functions.”
- Pre-fabricated medical grade – “Pre-fabricated footwear that meets the specific needs of a person, on the basis of footwear that provides extra depth, multiple width

	fittings and features designed to accommodate a broader range of foot types. Other features may include modified soles, fastenings and smooth internal linings. This type of footwear is usually available at specialty shoe shops." ○ Custom-made medical grade – "Footwear uniquely manufactured for one person, when this person cannot be safely accommodated in pre-fabricated medical grade footwear. It is made to accommodate deformity and relieve pressure over at-risk sites on the plantar and dorsal surfaces of the foot. In-depth assessment, multiple measurements, impressions or a mould, and a positive model of a person's foot and ankle are generally required for manufacture."
Data utility:	Description of management complexity and therapeutic footwear utilisation, and benchmarking of sites with reference to evidence-based guidelines.

75. SYSTEMIC ANTIBIOTICS

REDCap field

Variable / field name:	management_antibiotics
Field type:	checkbox
Field label:	Systemic antibiotics
Choices / calculations:	0, None 1, Oral 2, Outpatient parenteral 3, Inpatient parenteral 99, Not stated / inadequately described
Field note:	Select all that apply
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	@NONEOFTHEABOVE=0,99

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	Whether a person with active foot ulceration and/or active Charcot foot is using or is being prescribed antimicrobial therapy for the treatment of suspected or diagnosed infection involving either foot, as represented by a code. Field choices are amalgamated over the Episode of Care. Oral antibiotics are typically formulated as tablets, capsule or suspensions. Parenteral antibiotics are typically administered intravenously. In accordance with the Infectious Diseases Society of America Clinical Practice Guideline for the Management of Outpatient Parenteral Antimicrobial Therapy,[27] outpatient parenteral refers to administration of parenteral antimicrobial therapy in at least 2 doses on different days without intervening hospitalisation. A person may receive this therapy at their home (i.e. regular

	health care provider visits or self-administration after training), or by regular attendance to a hospital/clinic. Inpatient parenteral refers to administration of parenteral antimicrobial therapy while admitted to a hospital ward, whether or not that stay is overnight.
Data utility:	Description of management complexity, antimicrobial therapy utilisation and outpatient parenteral service availability, and benchmarking of sites with reference to evidence-based guidelines.

76. HOSPITALISATION REQUIRED

REDCap field

Variable / field name:	management_hospitalisation
Field type:	checkbox
Field label:	Hospitalisation required
Choices / calculations:	0, None 1, Yes, for antibiotics 2, Yes, for revascularisation 3, Yes, for surgical debridement 4, Yes, for minor amputation (below ankle) 5, Yes, for major amputation (above ankle) 6, Yes, for surgical offloading procedure 7, Yes, Hospital-in-the-Home 98, Yes, for other procedures / investigations 99, Not stated / inadequately described
Field note:	Select all that apply
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	@NONEOFTHEABOVE=0,99

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s: (adapted from DFA)	Whether a person with active foot ulceration and/or active Charcot foot required hospital admission/s for management of the foot complication/s, and the reason/s for those admission/s, as represented by a code. Field choices are amalgamated over the Episode of Care. This field was adapted from the Australian Diabetic Foot Ulcer Minimum Dataset Dictionary.[5] Admission for antibiotics would typically align with a choice of inpatient parental or outpatient parenteral *Systemic antibiotics* (i.e. the previous field). Where applicable, admission for

	outpatient parenteral antibiotics should be further clarified by additionally choosing Hospital-in-the-Home (HITH). A person may receive HITH care for reasons other than antibiotic therapy. The Australian Institute of Health and Welfare defines HITH as provision of care to hospital admitted patients in their place of residence (permanent or temporary) as a substitute for hospital accommodation.[28] Greater clarification is available at: https://meteor.aihw.gov.au/content/327308 Revascularisation encompasses both endovascular interventions and open surgical procedures. Surgical debridement refers to removal of infected and/or nonviable tissue often combined with wound irrigation performed by a surgeon in an operating theatre. The International Working Group on the Diabetic Foot defines: ○ Surgical offloading as “a surgical procedure or technique undertaken with the intention of relieving mechanical stress from a specific region of the foot, and includes Achilles tendon lengthening, metatarsal head resection, osteotomy, arthroplasty, arthrodesis, ostectomy, exostectomy, external fixation, flexor tendon transfer or tenotomy, silicone injections, tissue augmentation.”[24] ○ Amputation as “resection of a segment of a limb through a bone or through a joint”. Major amputation is “any resection proximal to the ankle” and minor amputation is “any resection through or distal to the ankle”.[14]
Data utility:	Description of management complexity and hospital resource utilisation, and benchmarking of sites with reference to evidence-based guidelines.

77. CUMULATIVE LENGTH OF STAY

REDCap field

Variable / field name:	management_los
Field type:	text
Field label:	Cumulative length of stay
Choices / calculations:	-
Field note:	days (summate <u>all</u> admitted days, both inpatient and HITH, during this episode of care)
Text validation:	number (>[management_los_hith])
Identifier:	-
Branching logic:	[management_hospitilisation(1)] = '1' or [management_hospitilisation(2)] = '1' or [management_hospitilisation(3)] = '1' or [management_hospitilisation(4)] = '1' or [management_hospitilisation(5)] = '1' or [management_hospitilisation(6)] = '1' or [management_hospitilisation(7)] = '1' or [management_hospitilisation(98)] = '1'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Episode of admitted patient care – length of stay (excluding leave days)
Short name:	Length of stay
Identifier:	269982
Compatibility:	Y, by summation across the Episode of Care

Explanation

Definition/s: (adapted from METeOR)	The cumulative length of stay of a person, excluding leave days, measured in days and summated across the Episode of Care. Length of stay per admission is calculated as: [separation date] - [admission date] - [total leave days] inclusive of admission and separation dates. This metric encompasses days admitted to a hospital ward and days admitted under Hospital-in-the-Home (HITH). If relevant, the latter is then entered in the *HITH length of stay* field.

Data utility:	Description of management complexity and hospital resource utilisation.

78. HITH CUMULATIVE LENGTH OF STAY

REDCap field

Variable / field name:	management_los_hith
Field type:	text
Field label:	HITH cumulative length of stay
Choices / calculations:	-
Field note:	days (summate <u>only HITH</u> admitted days during this episode of care)
Text validation:	number (0-[management_los])
Identifier:	-
Branching logic:	[management_hospitilisation(7)] = '1'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Episode of admitted patient care – number of days of hospital-in-the-home care
Short name:	Number of days of hospital-in-the-home care
Identifier:	686115
Compatibility:	Y, by summation across the Episode of Care

Explanation

Definition/s: (adapted from METeOR)	The total number of hospital-in-the-home (HITH) days occurring for an admitted patient, summated across the Episode of Care. Number of HITH days is calculated as: [separation date] - [admission date] - [total leave days] inclusive of admission (or change between hospital and home accomodation) date if person home at end of day, and exclusive of separation date. Note, as distinct from the *Cumulative length of stay* field, this field only includes days admitted under HITH.
Data utility:	Description of management complexity and hospital resource utilisation.

79. EXTENT OF AMPUTATION

REDCap field

Variable / field name:	management_amputation
Field type:	checkbox
Field label:	Extent of amputation
Choices / calculations:	1, Hallux 2, Other digit/s 3, First ray 4, Lesser ray/s 5, Transmetatarsal 6, Below knee 7, Above knee
Field note:	(performed during this episode of care)
Text validation:	-
Identifier:	-
Branching logic:	[management_hospitilisation(4)] = '1' or [management_hospitilisation(5)] = '1'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The level/s at which lower limb amputations were required for management of the foot complication/s as represented by a code. Field choices are amalgamated over the Episode of Care. Note redundancy in sidedness and when multiple ‘other digit’ or ‘lesser ray’ amputations have occurred. Other digit/s refers to part or complete resection of phalanges of the second to fifth toes. Lesser ray/s refers to part or complete resection of the second to fifth metatarsals.
Data utility:	Description of management complexity and hospital resource utilisation, and analysis of foot complication outcomes.

80. PATIENT DISPOSITION

REDCap field

Variable / field name:	discharge_disposition
Field type:	radio
Field label:	Patient disposition
Choices / calculations:	0, Not discharged / transferred / deceased 1, Discharged / transferred to other acute hospital 2, Discharged to a residential aged care service 3, Discharged / transferred to palliative care 4, Discharged / transferred to other High Risk Foot Service 5, Discharged as healed to prevention service 9, Discharged before healing to prevention service 6, Discharged / transferred to other health care providers 7, Left against medical advice / discharged at own risk 8, Deceased 97, Lost to follow-up 98, Other
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	Note similarity to ‘Mode of separation’ (Identifier 722644)

Explanation

Definition/s: (adapted from DFA)	Status at separation of the person from the HRFS and/or place to which the person’s foot care is released, as represented by a code. Generally, if the person were to return to the HRFS after separation a new Episode of Care would be commenced. This field was adapted from the Australian Diabetic Foot Ulcer Minimum Dataset Dictionary.[5] While an Episode of Care is ongoing, ‘Not discharged / transferred / deceased’ is chosen or assumed to be the status

	if the field is incomplete. Discharged / transferred to other services (e.g. acute hospital, residential aged care, palliative care, HRFS) implies ongoing foot care is to be provided by that service, unless another referral is made back to the current HRFS. Commonly HRFS have a de-escalation pathway within their health service when healing has occurred or is imminent. The person is deemed to be at sufficiently high risk of recurrent ulceration that podiatric care is provided in-house or within the health service. Either 'Discharged *as healed* to prevention service' or 'Discharged *before healing* to prevention service' may be the appropriate choice in this circumstance. Another common scenario is that the HRFS transfers foot care back to a community or private podiatrist external to their health service, in which case 'Discharged / transferred to other health care providers' is chosen. 'Lost to follow-up' is used sparingly where attempts to contact the person have repeatedly failed and outcome data is otherwise not obtainable from other services.
Data utility:	Description of separations for Episodes of Care completed, including escalation and de-escalation of care, and mortality rates. Indicating the possibility of incomplete outcome data in the case of loss to follow-up.

81. DATE OF SEPARATION

REDCap field

Variable / field name:	discharge_date
Field type:	text
Field label:	Date of separation
Choices / calculations:	-
Field note:	Date of separation must occur on/after Date of initial assessment (i.e. [event-name][service_initial_date])
Text validation:	date_dmy (>[event-name][service_initial_date])
Identifier:	-
Branching logic:	[discharge_disposition] = '1' or [discharge_disposition] = '2' or [discharge_disposition] = '3' or [discharge_disposition] = '4' or [discharge_disposition] = '5' or [discharge_disposition] = '6' or [discharge_disposition] = '7' or [discharge_disposition] = '8' or [discharge_disposition] = '9' or [discharge_disposition] = '97' or [discharge_disposition] = '98'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The date on which last contact is made between a health care provider from the High-Risk Foot Service and the person for assessment, care, consultation and/or treatment, expressed as DDMMYYYY. This corresponds to the change in *Patient disposition* (i.e. the previous field) and concludes the current Episode of Care.
Data utility:	Analysis time-based outcome *Time in service*, and timing of ulceration and active Charcot foot outcomes relative to separation. If relevant, calculation of age at death when used in combination with *Date of birth* or *Age* fields.

82. DATE DECEASED

REDCap field

Variable / field name:	discharge_deceased_date
Field type:	text
Field label:	Date deceased if post-dates separation
Choices / calculations:	-
Field note:	If not relevant or unavailable leave blank If entered, Date deceased must occur after Date of separation (i.e. [discharge_date]). Otherwise change Patient disposition to 'deceased'.
Text validation:	date_dmy (>[discharge_date])
Identifier:	-
Branching logic:	[discharge_disposition] = '1' or [discharge_disposition] = '2' or [discharge_disposition] = '3' or [discharge_disposition] = '4' or [discharge_disposition] = '5' or [discharge_disposition] = '6' or [discharge_disposition] = '7' or [discharge_disposition] = '9' or [discharge_disposition] = '97' or [discharge_disposition] = '98'
Required field:	N
Field annotation:	-

METeOR item

Metadata item type:	Data Element
Official name:	Person – date of death
Short name:	Date of death
Identifier:	646025
Compatibility:	Y, without modification

Explanation

Definition/s: (adapted from METeOR)	The date upon which a person ceases to live, expressed as DDMMYYYY. This may be used to record a deceased date if occurring between Episodes of Care. Note if the person ceases to live during an Episode of Care, the *Patient disposition* is recorded as deceased and the *Date of separation* denotes the deceased date.
Data utility:	If relevant, indication in the database that a person has died and rudimentary mortality analysis (in the absence of data linkage). Calculation of age at death when used in combination with *Date of birth* or *Age* fields.

83. ANTIRESORPTIVE THERAPY

REDCap field

Variable / field name:	management_antiresorptive
Field type:	radio
Field label:	Antiresorptive therapy
Choices / calculations:	0, None 1, Yes 99, Not stated / inadequately described
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	[charcot_date_assessed][first-instance]<>""
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	Whether a person with active Charcot foot is using or is being prescribed antiresorptive therapy whilst in the active stage of disease, as represented by a code. The Modified Eichenholtz Criteria defines active stages of disease as Stage 0, 1 or 2.[15,22] Antiresorptive therapy includes bisphosphonates (e.g. alendronate, pamidronate, risedronate, zoledronate) and denosumab.
Data utility:	Description of therapeutic adjuncts in the management of active Charcot foot and stratification by antiresorptive use in data analyses.

84. CORRECTIVE/OFFLOADING SURGERY

REDCap field

Variable / field name:	management_ortho
Field type:	radio
Field label:	Corrective/offloading surgery
Choices / calculations:	0, None 1, Yes 99, Not stated / inadequately described
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	[charcot_date_assessed][first-instance]<>""
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	Whether a person treated for an active Charcot foot episode undergoes surgical intervention, as represented by a code. Surgical intervention in this context may have goals of stabilising the foot, correcting deformity or redistributing pressure. Note *Surgery Type* and *Surgery Timing* (with respect to date of consolidation) are clarified by fields that follow.
Data utility:	Description of therapeutic adjuncts in the management of Charcot foot and stratification by surgical intervention in data analyses.

85. SURGERY TYPE

REDCap field

Variable / field name:	management_ortho_surgery
Field type:	checkbox
Field label:	Surgery type
Choices / calculations:	1, Exostectomy 2, Arthrodesis 3, Internal fixation 4, External fixation 5, Achilles tendon lengthening 6, Gastrocnemius recession 98, Other 99, Not stated / inadequately described
Field note:	Select all that apply
Text validation:	-
Identifier:	-
Branching logic:	[management_ortho]='1'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The surgical procedure/s employed in a person treated for an active Charcot foot episode, as represented by a code. Exostectomy is the removal of a bony prominence or outgrowth. Arthrodesis is the fusion of a joint. Fixation is the use of hardware to stabilise, realign or join bone, with hardware located internal and/or external to the foot. Achilles tendon lengthening is achieved by a series of cuts or punctures to the tendon, and subsequent casting. Gastrocnemius recession is the lengthening of the gastrocnemius muscle, typically by division of the fascia.

Data utility:	Description of therapeutic adjuncts in the management of Charcot foot and stratification by surgical intervention in data analyses.

86. SURGERY TIMING

REDCap field

Variable / field name:	management_ortho_time
Field type:	radio
Field label:	Surgery timing
Choices / calculations:	1, After consolidation 2, Before consolidation 99, Not stated / inadequately described
Field note:	Consolidation phase = modified Eichenholtz stage III
Text validation:	-
Identifier:	-
Branching logic:	[management_ortho]='1'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The timing of surgical procedure/s employed in a person treated for an active Charcot foot episode, as represented by a code. Timing is recorded with respect to date of consolidation. Consolidated or inactive disease corresponds to Stage 3 of the Eichenholtz classification.[15] Clinically there is absence of inflammation and a more stable yet often deformed foot. Radiographical features include osteophytes, subchondral sclerosis and narrowing of joint spaces.
Data utility:	Description of therapeutic adjuncts in the management of Charcot foot and stratification by surgical intervention in data analyses.

ULCER OUTCOME

The *Ulcer Outcome* form includes the following 3 variables. Response to the first variable determines applicability of subsequent date fields.

87. Ulceration status
88. Date healed
89. Date amputated

87. ULCERATION STATUS

REDCap field

Variable / field name:	outcome_ulcer
Field type:	radio
Field label:	Ulceration status
Choices / calculations:	1, Healed 0, Not healed 2, Amputated
Field note:	-
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The status of each foot ulceration recorded in the current Episode of Care, as represented by a code. The International Working Group on the Diabetic Foot defines ulceration healing as “complete epithelialisation without any drainage.”[14] Amputated refers to surgical removal of the ulceration as a result of amputation at a more proximal level. On selection of this field choice the user should ensure *Hospitalisation required* and *Extent of amputation* fields are completed on the Management form.
Data utility:	Description of ulceration outcomes and branching logic for *Date healed* and *Date amputated* fields. A status of not healed is assumed if this form is incomplete. Ulceration outcomes can be corelated with factors of interest, at the participant, clinical or service level.

Ulceration recurrence at the participant level can be calculated when combined with *Date healed* and *Date amputated* fields, and future *Ulceration onset* dates.

88. DATE HEALED

REDCap field

Variable / field name:	outcome_healed_date
Field type:	text
Field label:	Date healed
Choices / calculations:	-
Field note:	Date healed must occur on/after <I>Date assessed (i.e. [ulcer_date_assessed][current-instance])
Text validation:	date_dmy (>[ulcer_date_assessed][current-instance])
Identifier:	-
Branching logic:	[outcome_ulcer] = '1'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The date of foot ulceration healing, expressed as DDMMYYYY.
Data utility:	Analysis of ulceration outcomes, including *Ulceration healing at [timepoint]* and *Ulceration free at [timepoint]*. The latter is a participant level outcome. See *Ulceration status* for other data utilisation options.

89. DATE AMPUTATED

REDCap field

Variable / field name:	outcome_amputation_date
Field type:	text
Field label:	Date amputated
Choices / calculations:	-
Field note:	Date amputated must occur on/after <I>Date assessed (i.e. [ulcer_date_assessed][current-instance])
Text validation:	date_dmy (>[ulcer_date_assessed][current-instance])
Identifier:	-
Branching logic:	[outcome_ulcer] = '2'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The date of foot ulceration amputation, expressed as DDMMYYYY.
Data utility:	Analysis of ulceration outcomes, including *Ulceration amputation at [timepoint]* and *Ulceration free at [timepoint]*. The latter is a participant level outcome. See *Ulceration status* for other data utilisation options.

ACTIVE CHARCOT FOOT OUTCOME

The *Active Charcot Foot Outcome* form includes the following 3 variables. Response to the first variable determines applicability of subsequent date fields.

90. Charcot foot status
91. Date consolidated
92. Date amputated

90. CHARCOT FOOT STATUS

REDCap field

Variable / field name:	outcome_charcot
Field type:	radio
Field label:	Charcot foot status
Choices / calculations:	1, Consolidated 0, Not consolidated 2, Amputated
Field note:	Consolidation phase = modified Eichenholtz stage III
Text validation:	-
Identifier:	-
Branching logic:	-
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The status of each active Charcot foot recorded in the current Episode of Care, as represented by a code. Consolidation is synonymous with 'clinical remission' or 'inactive' disease. The International Working Group on the Diabetic Foot defines clinical remission as "The absence of clinical signs of inflammation, with or without deformity, and radiographic consolidation of fractures, if present, on plain X-ray."[29] Amputated refers to surgical removal of the Charcot foot as a result of major amputation. On selection of this field choice the user should ensure *Hospitalisation required* and *Extent of amputation* fields are completed on the Management form.
Data utility:	Description of active Charcot foot outcomes and branching logic for *Date consolidated* and *Date amputated* fields. A status of not consolidated is assumed if this form is incomplete. Active Charcot foot outcomes can be corelated with factors of interest, at the participant, clinical or service level.

Charcot foot reactivation at the participant level can be calculated when combined with *Date consolidated* and *Date amputated* fields, and future *Charcot foot onset* dates.

91. DATE CONSOLIDATED

REDCap field

Variable / field name:	outcome_cn_resolved_date
Field type:	text
Field label:	Date consolidated
Choices / calculations:	-
Field note:	Date consolidated must occur on/after <I>Date assessed (i.e. [charcot_date_assessed][current-instance])
Text validation:	date_dmy (>[charcot_date_assessed][current-instance])
Identifier:	-
Branching logic:	[outcome_charcot] = '1'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The date of Charcot foot consolidation, expressed as DDMMYYYY.
Data utility:	Analysis of active Charcot foot outcomes, including *Charcot foot consolidation at [timepoint]*. See *Charcot foot status* for other data utilisation options.

92. DATE AMPUTATED

REDCap field

Variable / field name:	outcome_cn_amputation_date
Field type:	text
Field label:	Date amputated
Choices / calculations:	-
Field note:	Date amputated must occur on/after <I>Date assessed (i.e. [charcot_date_assessed][current-instance])
Text validation:	date_dmy (>[charcot_date_assessed][current-instance])
Identifier:	-
Branching logic:	[outcome_charcot] = '2'
Required field:	Y
Field annotation:	-

METeOR item

Metadata item type:	-
Official name:	-
Short name:	-
Identifier:	-
Compatibility:	-

Explanation

Definition/s:	The date of Charcot foot amputation, expressed as DDMMYYYY.
Data utility:	Analysis of ulceration outcomes, including *Charcot foot amputation at [timepoint]*. See *Charcot foot status* for other data utilisation options.

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