Diabetes High Risk Foot Services
Monitoring and evaluation plan

Health Economics and Evaluation Team
The Agency for Clinical Innovation (ACI) works with clinicians, consumers and managers to design and promote better healthcare for NSW. It does this through:

- **service redesign and evaluation** – applying redesign methodology to assist healthcare providers and consumers to review and improve the quality, effectiveness and efficiency of services
- **specialist advice on healthcare innovation** – advising on the development, evaluation and adoption of healthcare innovations from optimal use through to disinvestment
- **initiatives including guidelines and models of care** – developing a range of evidence-based healthcare improvement initiatives to benefit the NSW health system
- **implementation support** – working with ACI Networks, consumers and healthcare providers to assist delivery of healthcare innovations into practice across metropolitan and rural NSW
- **knowledge sharing** – partnering with healthcare providers to support collaboration, learning capability and knowledge sharing on healthcare innovation and improvement
- **continuous capability building** – working with healthcare providers to build capability in redesign, project management and change management through the Centre for Healthcare Redesign.

ACI Clinical Networks, Taskforces and Institutes provide a unique forum for people to collaborate across clinical specialties and regional and service boundaries to develop successful healthcare innovations.

A key priority for the ACI is identifying unwarranted variation in clinical practice. ACI teams work in partnership with healthcare providers to develop mechanisms aimed at reducing unwarranted variation and improving clinical practice and patient care.

www.aci.health.nsw.gov.au
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# Abbreviations

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<th>Abbreviation</th>
<th>Description</th>
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<td>ACI</td>
<td>Agency for Clinical Innovation</td>
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<td>LBVC</td>
<td>Leading Better Value Care</td>
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<td>HRFS</td>
<td>High Risk Foot Service</td>
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<td>IHI</td>
<td>Institute for Healthcare Improvement</td>
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<td>KEQs</td>
<td>Key evaluation questions</td>
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<td>LHD</td>
<td>Local Health District</td>
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<td>M&amp;E</td>
<td>Monitoring and Evaluation</td>
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<td>NSW</td>
<td>New South Wales</td>
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<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
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<td>MoH</td>
<td>NSW Ministry of Health</td>
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<td>The Standards</td>
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Glossary of evaluation terms

**Baseline** a pre-intervention assessment that is used to compare changes after implementation.

**Dose response** in this context is the examination of the link between dose and response as part of determining if a program caused the outcome and to what extent.

**Economic evaluation** is the process of systematic identification, measurement and valuation of inputs and outcomes of two alternative activities, and the subsequent comparative analysis of these. Economic evaluation methods provide a systematic way to identify, measure, value, and compare the costs and consequences of various programs, policies, or interventions.

**Efficiency** is a measure of how economic inputs (resources such as funds, expertise, time) are converted into results.

**Evaluability is** an assessment of the extent that an intervention can be evaluated in a reliable and credible fashion.

**Evaluand** is the subject of an evaluation, typically a program or system rather than a person.

**Focus group** is a group of people, selected for their relevance to an evaluation. Focus groups are facilitated by a trained facilitator in a series of discussions designed to share insights, ideas, and observations on a topic of concern.

**Evaluation domains**

- **Appropriateness** is the extent that program activities are appropriate for the outcomes in which it is to achieve.

- **Effectiveness** measures program effects in the target population/patient cohort by assessing the progress in the outcomes that the program is to achieve.

- **Impact** is the long-term, cumulative effect of programs/interventions over time on what they ultimately aim to change. It assesses program effectiveness in achieving its ultimate goals.

- **Sustainability** is the extent that the benefits of a program are maintained after formal support has ended.

- **Access and reach** measures how accessible the program is to the target population (access) and how many of the target population have accessed the program (reach).

**Formative and summative evaluation**

- **Formative evaluation (monitoring)** in formative (early) evaluation, programs or projects are typically assessed during their development or early implementation to provide information about how to revise and modify for improvement. In terms of the Leading Better Value Care program, there are two realms of formative evaluation. The first is the formative evaluation of the statewide program to indicate if programs are progressing towards goals and to define what improvements can be made to the overall program. The second realm is the assessment of the program at a site level to determine what is needed for local improvements.

- **Summative evaluation (impact)** the purpose of summative evaluation is to make value judgements on the worth, merit and significance of a program. This is typically assessed at the end of an operating cycle or once a program has been settled. Findings are used to help decide whether a program should be adopted, continued, or modified.

**Implementation fidelity** is the degree that an intervention has been delivered as intended and is critical to the successful translation of evidence-based interventions into practice.

**Implicit design** is a design with no formal control group and where measurement is made before and after exposure to the program.
**Indicator** is a specific, observable, and measurable characteristic or change that shows the progress a program is making toward achieving a specific outcome.

**Inferential statistical analysis** is statistical analysis using models to confirm relationships among variables of interest or to generalise findings to an overall population.

**Interrupted time series analysis** is a continuous sequence of observations on a population, taken repeatedly (normally at equal intervals) over time to measure changes and map trends.

**Interview guide** is a list of issues or questions that guide the discussion in an interview.

**Linear mixed models** are an extension to the linear model. It includes random effects in addition to the usual fixed effects.

**Longitudinal data or pre and post analysis** is collected over a period of time, sometimes involving a stream of data for particular persons or entities to show trends.

**Macro-meso-micro evaluation approach** refers to a three level approach to evaluation. In terms of Leading Better Value Care, this is:

- macro – statewide
- meso – LHD
- micro – local sites.

**Measuring tools or instruments** are devices used to collect data (such as questionnaires, interview guidelines, audits and observation record forms).

**Monitoring and evaluation (M&E)** is a process that helps improve performance and achieve results. Its goal is to improve current and future management of outputs, outcomes and impact.

**Multiple lines of evidence** is the use of several independent evaluation strategies to address the same evaluation issue, relying on different data sources, analytical methods, or both.

**Primary data** is collected by an evaluation team specifically for the evaluation study.

**Program** in terms of program evaluation, a program is a set of activities managed together over a sustained period of time that aims to achieve outcomes for a client or client group.

**Program evaluation** is a rigorous, systematic and objective process to assess a program’s effectiveness, efficiency, appropriateness and sustainability.

**Program theory and program logic**

- **Program theory** explains how and why the program is intended to work and the causal links between activities and consequences.
- **Program logic** is a pictorial depiction of the program theory.

**Qualitative data** are observations that are categorical rather than numerical, and often involve knowledge, attitudes, perceptions, and intentions.

**Quantitative data** are observations that are numerical.

**Secondary data** is collected and recorded by another person or organisation, usually for different purposes than the current evaluation.

**Stakeholders** are people or organisations that are invested in a program or that are interested in the results or what will be done with the results of an evaluation.

**Statistical analysis** is the manipulation of numerical or categorical data to predict phenomena, to draw conclusions about relationships among variables or to generalise results.

**Stratified sampling** is a probability sampling technique that divides a population into relatively homogeneous layers called strata, and selects appropriate samples independently in each of those layers.
**Surveys** are a data collection method that involves a planned effort to collect needed data from a sample (or a complete census) of the relevant population. The relevant population consists of people or entities affected by the program.

**Triangulation**, in the context of Leading Better Value Care, facilitates validation of data through cross verification from more than two sources.

**Utility** is the extent that an evaluation produces and disseminates reports that informs relevant audiences and have beneficial impact on their work.

The following table shows the monitoring and evaluation cycle for Leading Better Value Care programs.

**Table 1 Leading Better Value Care monitoring and evaluation cycle**

<table>
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<th>Evaluative perspectives</th>
<th>Expected economic benefits from the intervention – predicted</th>
<th>Evidence foundations of the intervention – program theory/logic model</th>
<th>Implementation evaluation – intervention coverage, fidelity of implementation and contributing factors</th>
<th>Outcomes evaluation – patient and provider experience and patient outcomes</th>
<th>Economic evaluation – benefits and return on investment</th>
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<td>Quantitative</td>
<td>Qualitative/quantitative</td>
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<td>Formative evaluation – early and ongoing alongside quarterly reporting</td>
<td>Qualitative/quantitative</td>
<td>Quantitative</td>
<td>.Qualitative/quantitative</td>
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<td>Quantitative</td>
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<td>Summative evaluation – at 12 months and 2 years</td>
<td>Qualitative/quantitative</td>
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Executive summary

Diabetes is a complex and chronic condition that affects an increasing number of Australians. It is a significant public health challenge, with a large impact on families, hospital activity and the cost of delivering hospital services. Complications of diabetes include heart disease, stroke, kidney damage, peripheral vascular disease, retinopathy, neuropathy, and diabetic foot disease.

Diabetic foot disease increases the risk of foot ulceration, infection, acute Charcot’s neuropathy and lower limb amputation. The risk is highest for those with a low socioeconomic status, Aboriginal and Torres Strait Islander Australians and those living in regional and remote areas. Across New South Wales (NSW), 17% of diabetes related hospitalisations were for diabetic foot-related conditions. However, there is significant variation in the management of diabetes-related foot complications and amputation rates across local health districts in NSW.

Variation may occur as a result of poor preventative care, inequity of access to appropriate care, and/or differences in amputation practices, standards and guidelines between regions. Where specialised care is available, a lack of clear referral pathways between specialised services and primary care, and a lack of specialised care early on admission often result in treatment for diabetes related foot conditions in acute care.

In response to challenges in care associated with advanced diabetic foot conditions, the Agency for Clinical Innovation (ACI) Endocrine Network developed High Risk Foot Standards (the Standards). The Standards are intended to be used by clinicians, health service managers, administrators and policy makers to guide planning and implementation of a multidisciplinary high risk foot service (HRFS).

In 2016, the NSW Ministry of Health (MoH) committed to improving the health status of people in NSW by changing the focus of health care to value rather than volume. This resulted in the establishment of the Leading Better Value Care (LBVC) initiative that aligns the provision of healthcare in NSW to the Institute of Healthcare Improvement Triple Aim – improving patient and provider experience, population health outcomes, and system efficiency and effectiveness.

Diabetes HRFS has been identified as one of the first tranche programs of the LBVC initiative to be implemented across NSW in 2017/18. This document provides the monitoring and evaluation (M&E) plan for HRFS, as part of LBVC. It outlines a mixed methods approach to answer key evaluation questions with a focus on patient and carer experience, efficiency and effectiveness of care.

The evaluation will assess the extent that the HRFS has led to the system changes required to achieve the intended outcomes. Findings will be used to guide local and statewide service improvements and contribute to investment decisions aimed at improving outcomes for the people of NSW.

ACI will lead the data collection, analyses and feedback process for the formative and summative evaluation components in collaboration with state-wide data custodians, local health districts implementation teams, other pillars and the Ministry.

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Introduction

Diabetes and diabetic foot disease

Diabetes is a chronic condition characterised by high blood glucose levels. The incidence of diabetes has grown considerably over the past two decades and has become a significant public health challenge in Australia\(^2\). It is associated with a range of complications including heart disease, stroke, kidney damage, peripheral vascular disease, retinopathy, neuropathy, and diabetic foot disease\(^2\).

Diabetic foot disease occurs as a result of diabetes-related conditions including microvascular disease and neuropathy that limit blood flow, alter sensation and impair wound healing. People with diabetes are at increased risk of lower limb amputation compared to people who do not have diabetes; minor wounds may develop into foot ulcers and infections that may eventually require amputation of the affected toes, feet or lower limbs.

Foot ulceration and lower limb amputations are a leading cause of non-fatal burden and hospitalisation for people with diabetes. In 2011, non-fatal burden due to lower limb amputations as a result of diabetes complications in Australia was three times as high for males as for females, and highest among people in the lowest socioeconomic group, Aboriginal and Torres Strait Islander Australians and those living in Very remote areas\(^1\). In 2014-15, the rate of amputations due to diabetes in New South Wales (NSW) was 13.8 per 100,000 population\(^3\). This rate is higher than many other Organisation for Economic Co-operation and Development (OECD) countries suggesting that there is significant room for improvement\(^4\).

Improvements in care include prevention and access to care, and specialised and coordinated multidisciplinary management of patients at high risk of foot complications and amputations in hospital and outpatient settings. Research demonstrates that increased use of podiatrists, multidisciplinary foot teams, clinical pathways, pressure offloading devices, and monitoring of amputation rates can reduce diabetic foot hospitalisations, amputations and costs by up to 90\%\(^5\).

These strategies have been implemented in other jurisdictions, but are yet to be adopted to the same extent in NSW.

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Need for change
Across NSW, 17% of all diabetes related hospitalisations in 2014-15 were for diabetic foot-related conditions. The management of diabetes-related foot complications and amputation rates across local health districts (LHDs) in NSW is inconsistent and variable. Variation may occur as a result of poor preventative care, inequity of access to appropriate care, and/or differences in amputation practices, standards and guidelines between regions.

Where specialised care is available, a lack of clear referral pathways between specialised services and primary care, and a lack of involvement of specialised care early on admission result in the majority of cases for diabetes-related foot disease receiving treatment within an acute setting.

In 2014-15, approximately 30,500 hospitalisations and 80% of the cost of diabetes-related foot complications in NSW were related to treating infections and ulcers. Over the next 10 years, it is projected that around 330,000 people in NSW will require hospitalisation for diabetes related foot infections and foot or lower limb ulcers. This is associated with a total cost of $2.8B (average of $276M per year) and an estimated 603,000 bed-days (equivalent to 1,652 hospital beds at full occupancy).

High risk foot standards
In 2014, the ACI Endocrine Network developed the High risk foot standards (the standards) to address challenges associated with treatment of advanced diabetic foot conditions, prevent or delay amputation, and guide the management of foot conditions earlier in the patient journey. The standards are in line with the recommendations of the National evidence based guidelines on the prevention, identification and management of foot complications in diabetes mellitus. They are intended to be used by clinicians, health service managers, administrators and policy makers to guide planning and implementation of a multidisciplinary high risk foot service (HRFS).

Document outline
This plan outlines the monitoring and evaluation (M&E) approach to the Leading Better Value Care (LBVC) initiative for HRFS at a statewide level and is to be read in conjunction with the standards. It has been informed by key documents relating to HRFS in NSW. It draws heavily on the Evaluation Plan and Evaluation Tools for High Risk Foot Services Standards (Revised) that was developed in November 2015 by Deloitte Access Economics for the ACI. The plan comprises of:

- an overview of the NSW LBVC initiative
- an overview of the HRFS
- the purpose, parameters and limitations of the evaluation
- explanation of measurement alignment across the all levels of monitoring and evaluation
- a program logic showing the activities and change required to achieve the program outcomes

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- key evaluation questions
- the methods, data sources and analysis that will be conducted to answer the key questions
- risks associated with evaluation
- the governance, codes of behaviour and ethical framework that underpin the evaluation
- identification of relevant audiences and communication of findings.

**Background**

**Leading Better Value Healthcare**

In 2016, the NSW Ministry of Health (MoH) made a commitment to improving the health of people in NSW by shifting focus to value rather than volume. This resulted in the development of the NSW LBVC program, a statewide initiative incorporating specific programs aimed at improving the NSW health system performance against The Institute of Healthcare Improvement (IHI) Triple Aim of improving patient and provider experience, population health outcomes, and system efficiency and effectiveness.

Leading Better Value Care involves the implementation of eight selected clinical programs in the 2017-18 financial year, with a goal of delivering improved clinical outcomes, patient experience and cost benefits. One of these programs is the implementation of diabetes HRFS aligned with the standards across NSW.

**Figure 1: Triple aim of LBVC**

Leading Better Value Care initiatives will be implemented by each LHD and incorporated into LHD roadmaps and service level agreements for the purpose of monitoring and informing local quality improvements. A comprehensive impact evaluation will be undertaken after programs have been implemented within each LHD. The purpose of evaluation will be to assess the overall impact of each initiative and guide decision making around the value (worth, merit and significance) of the LBVC program.

**High risk foot services program overview**

**Aims of HRFS**

The goal of the diabetes HRFS program is to enhance access (including telehealth) to HRFS in order to reduce amputations and prevent unnecessary emergency department visits and admissions, reduce length of stay through better inpatient care and enhance patient confidence in accessing multi-disciplinary care after discharge. These strategies are anticipated to reduce unwarranted clinical variation across NSW for this patient cohort.

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9 Further information about the IHI triple aim can be found at [http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx](http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx)
The objectives of the Standards are to:

- provide a consistent definition of HRFS
- reduce clinical variation for the treatment of diabetes-related foot ulceration, infection and active Charcot’s neuroarthropathy
- ensure clinical practices are aligned to state, national and international guidelines
- guide the implementation of new HRFS
- facilitate equity of access to an appropriate level of foot care for all patients in NSW by supporting a basis for standardising clinical services
- strengthen HRFS referral pathways to improve interventions and efficiency and support secondary prevention
- improve care coordination and strengthen the multi-disciplinary approach to management of the HRFS.

After reading the Standards, LHDs are recommended to:

- undertake a gap analysis of existing services to identify current access to foot care for people with diabetic foot complications
- identify variation in service delivery and outcomes
- align existing services with the Standards
- explore local capacity to use Telehealth as one of the mechanisms to deliver equity of access to specialist services for those living in rural, remote and isolated communities across NSW.

The Standards outline best practice and indicators over 11 key components of a HRFS.

These components are:

1. a multidisciplinary team approach
2. clinical leadership and coordination
3. administrative support
4. Evidence based treatment guidelines
5. continuity of care across care settings
6. prompt access for urgent cases
7. co-located services within a health facility with access to on-site services
8. appropriate equipment
9. pressure offloading and medical grade footwear
10. access to wound care products
11. recording and monitoring of clinical outcomes.
The monitoring and evaluation framework

Purpose
The NSW Government is committed to evaluation to ensure a sound evidence base for program improvement and to contribute to decision making. The results of robust evaluations can significantly contribute to appropriate investment strategies and future policy and program directions to improve outcomes.

The purpose of this M&E plan is to clearly define the roles and responsibilities of the different aspects of monitoring and evaluation, support the development of roadmaps and service level agreements (SLAs) and to guide the evaluation of the impact of the program on the NSW health system.

The plan defines data sources and collection methods, both existing and required, to assess the program across the IHI Triple Aim including expected and unexpected outcomes, experience of care, efficiencies and effectiveness.

Parameters and limitations
This M&E plan is focussed on evaluating HRFS at a statewide level. Data at an LHD level will be necessary to enable comparison across the state and assess impact on the health system and variation.

Specific implementation measures will be collected through roadmaps and SLAs to monitor progress towards longer term HRFS program outcomes. These activities are not part of the impact evaluation. Rather, the evaluation will measure outcomes in two phases: early assessment of short term outcomes and a longer term impact evaluation to determine the overall impact.

Measurement alignment
This M&E plan will inform data requirements and collection systems. It is consistent with the Ministry’s LBVC measurement alignment framework, which focusses on creating shared priorities across the NSW health system.

There are three measurement levels aligned to guide HRFS from implementation milestones through to the achievement of end of program outcomes (Figure 2).

These three levels include:
- program/project roadmaps
- service level agreements
- impact evaluation

The measurement alignment within the M&E framework will enable:
- oversight of program delivery against anticipated milestones to identify and manage unexpected deviations (monitoring via roadmaps and service level agreements)
- a clear structure and methodology for the statewide end of program impact evaluation to guide investment, disinvestment and future improvements
• a consistent source of data collection that is integrated to avoid variation and duplication.

In the first year of operation, LBVC programs will have a fourth level of data collection. This will comprise of a quarterly indicator that shows the progression and/or improvement of program implementation. ACI will collect and analyse these indicators. After 12 months, ACI will use the results from the quarterly reporting data to assess outcomes achieved and apply these to a formative economic/fiscal analysis.

**Figure 2 Monitoring and evaluation of LBVC programs**

![Diagram of monitoring and evaluation processes]

**Methods**

**Design**

A mixed methods approach, including quantitative and qualitative components, will be used to evaluate HRFS as part of LBVC. Data will be collected at baseline and recollected over multiple time points to analyse changes. Triangulation of data from multiple sources and methods will be used to overcome limitations associated with a single data collection method and provide context and a broader understanding of the program impact\(^\text{10}\).

Evaluation will be used to determine implementation of *the standards* across NSW, and highlight key enablers, barriers and lessons for future improvements. It will be qualitative, with data from responses gathered in surveys, semi-structured interviews and/or focus groups. Consultations will be held with managers and executives who were involved in implementation of *the standards*, as well as clinicians. Analysis will be focused on drawing key themes out of the responses for each question, and identifying differences between sites.

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\(^{10}\) Patton MQ. Enhancing the quality and credibility of qualitative analysis. Health Serv Res. 1999 Dec;345(5 Pt 2): 1189-1208.
The impact evaluation will use a mix of qualitative and quantitative methods to assess whether the standards have achieved outcomes. Surveys, interviews and/or focus groups with providers will be combined with patient experience, patient outcome and systems-level outcome data.

Economic appraisal methods will be used based on service utilisation and analysis of the National Weighted Activity Unit (NWAU) to determine effectiveness and return on investment.

Further information about specific data sources and analysis is included in the data and analysis matrix, later in this plan.

**Patient cohort**
The primary patient cohort for the HRFS is people over 15 years of age with diabetic foot related infections and/or ulcers of the foot or lower limb, including diabetes-related foot ulceration, infection and acute Charcot’s neuropathy.

The level of care required extends beyond that which can be readily provided in a podiatry (only) outpatient clinic and involves a coordinated multidisciplinary approach.

Specifically, the cohort includes hospitalisations that were assigned an ulcer and/or infection in category one below and a condition from at least one other of the following numbered categories (2-5).

International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (ICD-10 AM) codes relevant to this cohort include the following.

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<table>
<thead>
<tr>
<th>Category</th>
<th>Diagnosis code(s)</th>
</tr>
</thead>
</table>
| **Category 1: Infection and/or ulcer** | E10.69 Type 1 diabetes mellitus with other specified complication  
E11.69 Type 2 diabetes mellitus with other specified complication  
E13.69 Other specified diabetes mellitus with other specified complication  
E10.73 Type 1 diabetes mellitus with foot ulcer  
E11.73 Type 2 diabetes mellitus with foot ulcer  
E13.73 Other specified diabetes mellitus with foot ulcer  
E14.69 Unspecified diabetes mellitus with other specified complication  
L02.4 Cutaneous abscess, furuncle and carbuncle of limb  
L03.02 Cellulitis of toe  
L03.11 Cellulitis of lower limb  
L89 Decubitus ulcer  
L89.0 Decubitus [pressure] ulcer, stage I  
L89.1 Decubitus [pressure] ulcer, stage II  
L89.2 Decubitus [pressure] ulcer, stage III  
L89.3 Decubitus [pressure] ulcer, stage IV  
L89.9 Decubitus [pressure] ulcer, unspecified |
| **Category 2: Peripheral vascular disease** | E10.51 Type 1 diabetes mellitus with peripheral angiopathy, without gangrene  
E10.52 Type 1 diabetes mellitus with peripheral angiopathy, with gangrene  
E11.51 Type 2 diabetes mellitus with peripheral angiopathy, without gangrene  
E11.52 Type 2 diabetes mellitus with peripheral angiopathy, with gangrene  
E13.51 Other specified diabetes mellitus with peripheral angiopathy, without gangrene  
E13.52 Other specified diabetes mellitus with peripheral angiopathy, with gangrene  
E14.51 Unspecified diabetes mellitus with peripheral angiopathy, without gangrene  
E14.52 Unspecified diabetes mellitus with peripheral angiopathy, with gangrene |
| **Category 3: Peripheral neuropathy** | E10.42 Type 1 diabetes mellitus with diabetes polyneuropathy  
E11.42 Type 2 diabetes mellitus with diabetes polyneuropathy  
E13.42 Other specified diabetes mellitus with diabetes polyneuropathy  
E14.42 Unspecified diabetes mellitus with diabetes polyneuropathy  
E10.43 Type 1 diabetes mellitus with diabetes autonomic neuropathy  
E11.43 Type 2 diabetes mellitus with diabetes autonomic neuropathy  
E13.43 Other specified diabetes mellitus with diabetes autonomic neuropathy |
<table>
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<tr>
<th>Category</th>
<th>Diagnosis code(s)</th>
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</thead>
</table>
| Category 4: Conditions causing deformity and excessive ‘loading’ | E10.43 Type 1 diabetes mellitus with diabetes autonomic neuropathy  
E11.43 Type 2 diabetes mellitus with diabetes autonomic neuropathy  
E13.43 Other specified diabetes mellitus with diabetes autonomic neuropathy  
E14.43 Unspecified diabetes mellitus with diabetes autonomic neuropathy  
E10.61 Type 1 diabetes mellitus with diabetes musculoskeletal and connective tissue complication  
E11.61 Type 2 diabetes mellitus with diabetes musculoskeletal and connective tissue complication  
E13.61 Other specified diabetes mellitus with diabetes musculoskeletal and connective tissue complication  
E14.61 Unspecified diabetes mellitus with diabetes musculoskeletal and connective tissue complication  
L84 Corns and callosities  
M20.1 Hallux valgus (acquired)  
M20.2 Hallux rigidus  
M20.3 Other deformity of hallux (acquired)  
M20.4 Other hammer toe(s) (acquired)  
M20.5 Other deformities of toe(s) (acquired) |

**Category** | **Diagnosis code(s)** |
--- | --- |
**Diagnosis code(s)** | **Description** |
E14.43 | Unspecified diabetes mellitus with diabetes autonomic neuropathy |
E10.61 | Type 1 diabetes mellitus with diabetes musculoskeletal and connective tissue complication |
E11.61 | Type 2 diabetes mellitus with diabetes musculoskeletal and connective tissue complication |
E13.61 | Other specified diabetes mellitus with diabetes musculoskeletal and connective tissue complication |
E14.61 | Unspecified diabetes mellitus with diabetes musculoskeletal and connective tissue complication |
E10.71 | Type 1 diabetes mellitus with multiple microvascular complications |
E11.71 | Type 2 diabetes mellitus with multiple microvascular complications |
E12.71 | Malnutrition-related diabetes mellitus with multiple complications, stated as uncontrolled |
E13.71 | Other specified diabetes mellitus with multiple microvascular complications |
E14.71 | Unspecified diabetes mellitus with multiple microvascular complications |
E10.43 | Type 1 diabetes mellitus with diabetes autonomic neuropathy |
E11.43 | Type 2 diabetes mellitus with diabetes autonomic neuropathy |
E13.43 | Other specified diabetes mellitus with diabetes autonomic neuropathy |
E14.43 | Unspecified diabetes mellitus with diabetes autonomic neuropathy |
E10.61 | Type 1 diabetes mellitus with diabetes musculoskeletal and connective tissue complication |
E11.61 | Type 2 diabetes mellitus with diabetes musculoskeletal and connective tissue complication |
E13.61 | Other specified diabetes mellitus with diabetes musculoskeletal and connective tissue complication |
E14.61 | Unspecified diabetes mellitus with diabetes musculoskeletal and connective tissue complication |
L84 | Corns and callosities |
M20.1 | Hallux valgus (acquired) |
M20.2 | Hallux rigidus |
M20.3 | Other deformity of hallux (acquired) |
M20.4 | Other hammer toe(s) (acquired) |
M20.5 | Other deformities of toe(s) (acquired) |
<table>
<thead>
<tr>
<th>Category</th>
<th>Diagnosis code(s)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>M21.27 Flexion deformity, ankle and foot</td>
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<tr>
<td></td>
<td>M21.37 Wrist or foot drop (acquired), ankle and foot</td>
</tr>
<tr>
<td></td>
<td>M21.4 Flat foot [pes planus] (acquired)</td>
</tr>
<tr>
<td></td>
<td>M21.57 Acquired clawhand, clubhand, clawfoot and clubfoot, ankle and foot</td>
</tr>
<tr>
<td></td>
<td>M21.67 Other acquired deformities of ankle and foot, ankle and foot</td>
</tr>
<tr>
<td></td>
<td>M21.87 Other specified acquired deformities of limbs, ankle and foot</td>
</tr>
<tr>
<td>Category 5: Previous amputations</td>
<td>Z89.4 Acquired absence of foot and ankle</td>
</tr>
<tr>
<td></td>
<td>Z89.5 Acquired absence of leg at or below knee</td>
</tr>
<tr>
<td></td>
<td>Z89.6 Acquired absence of leg above knee</td>
</tr>
<tr>
<td></td>
<td>Z89.7 Acquired absence of both lower limbs [any level, except toes alone]</td>
</tr>
</tbody>
</table>

Source: ACI

**Baseline**

Baseline data will be collected in mid-2017. For LHDs that have not yet implemented HRFS, pre-implementation analysis will be an important component for guiding expected improvements.

**Program logic**

The program logic outlines how HRFS activities are organised to achieve the intended outcomes (Figure 3). It depicts the major components of the program, as well as the activities and changes required to achieve outcomes related to the Triple Aim: efficiency, experience and outcomes. The program logic guides M&E and is used to inform the selection of evaluation questions and subsequent data requirements for undertaking the evaluation. This program logic has been adapted from the initial model developed by Deloitte Access Economics in collaboration with the ACI and clinical stakeholders. It should be read from the bottom up.
Figure 3 program logic HRFS

**Telehealth initiatives**

**Telehealth initiatives**

**HRFS**

**Broader goals**

Health system resources are used efficiently

- High quality HRFS is provided for patients with serious foot complications in the outpatient setting
- HRFS procedures are performed consistently across NSW based on best practice relative to the patient’s condition

- High quality HRFS is provided for patients with serious foot complications in the outpatient setting
- HRFS procedures are performed consistently across NSW based on best practice relative to the patient’s condition

- Hospital based HRFS are available to patients with diabetic foot disease and complications in metro areas
- Referral pathways are in place to improve needs-based care and support secondary prevention

- Clinicians work in teams to provide coordinated care for people with serious foot complications
- Clinicians have the knowledge skills and confidence to deliver HRFS in line with best practice

- Patients in rural, remote, isolated and remote communities have equitable access to HRFS through augmentation of existing podiatry services
- Confidence in outpatient care is increased.

- Reduction in unnecessary (minor and major) amputations/increase in limb saving procedures
- Patients experience reduced ulcer severity and incidence of secondary prevention

- Patients access secondary treatment post-discharge from hospital
- Patients with a foot ulcer history are aware of and attending the HRFS in their area

- Patients with diabetes-related foot complications are identified early and referred to HRFS as appropriate

**End of program outcomes**

Clinical variation is reduced

- LHDs have processes in place to monitor safety and efficacy of clinical services, allocate resources and improve services
- LHDs have HRFS to meet the minimum standards

- Services, diabetes units and podiatrist clinics are aware of the Standards and best practice
- Telehealth is in place to support rural services
- Telehealth is in place to support rural services

- Clinicians receive training and education on HRFS
- Clinicians receive training and education on HRFS

- Clinicians are aware of local HRFS and how to refer
- Clinicians are aware of local HRFS and how to refer

- Care plans are developed with patients with diabetes-related foot complications
- Patients with diabetes-related foot complications are identified early and referred to HRFS as appropriate

**Intermediate outcomes**

- Services, diabetes units and podiatrist clinics are aware of the Standards and best practice
- Telehealth is in place to support rural services

- Clinicians receive training and education on HRFS
- Clinicians receive training and education on HRFS

- Clinicians are aware of local HRFS and how to refer
- Clinicians are aware of local HRFS and how to refer

- Care plans are developed with patients with diabetes-related foot complications
- Patients with diabetes-related foot complications are identified early and referred to HRFS as appropriate

**Immediate changes**

- Gap analysis to identify current access to foot care for people with serious foot complications
- Identify variation in service delivery and outcomes
- Align services with the Standards
- Explore capacity to use telehealth to improve equity of access across rural, remote and isolated communities

**Influencing activities**

**Foundation activities**

**ACI Standards for High Risk Foot Services in NSW**

**Problem definition:**
- Increasing rates of diabetes
- High rates of foot complications
- Inconsistent and variable management of diabetes-related foot complications
- Inequity of access
- Latent demand for HRFS: majority of patients bypass HRFS for acute care
- High cost of care in acute setting
- Management requires multidisciplinary, coordinated and continuity of care

**Objectives:**
1. Provide a consistent definition of HRFS
2. Reduce clinical variation for the treatment of diabetes-related foot complications
3. Ensure clinical practices are aligned with best practice
4. Guide the implementation of new HRFS
5. Facilitate equity of access for all patients in NSW
6. Strengthen HRFS referral pathways
7. Improve care coordination and a multidisciplinary approach to care
8. Form part of the overall NSW diabetes model of care

Diabetes-related foot complications: diabetes-related foot ulceration, infection and active Charcot’s neuroarthropathy
Key evaluation questions

Deriving from the program logic, key evaluation questions (KEQ) for the HRFS are contained in Table 1. This M&E plan includes questions relating to both monitoring and evaluation measures. The key questions are broken into the following categories:

The KEQ have been further categorised into specific evaluation domains and matched to the measurement alignment domains as shown in Table 2.

Table 2 key evaluation questions HRFS

<table>
<thead>
<tr>
<th>Evaluation domain</th>
<th>Measurement alignment domain</th>
<th>Key evaluation question</th>
<th>Sub questions</th>
</tr>
</thead>
</table>
| Appropriateness   | Implementation fidelity      | To what extent was the program implemented? | To what extent are LHDs and health practitioners aware of the HRFS standards?  
|                   |                             |                         | To what extent have the standards effectively supported implementation of HRFS?  
|                   |                             |                         | Are there any contextual facilitators or barriers to implementation?  
|                   |                             |                         | Do stakeholders understand their role in the implementation of the HRFS standards?  
|                   |                             |                         | Were governance structures clear?  
|                   |                             |                         | How accurately and fully were the standards implemented?  
|                   |                             |                         | To what extent does this vary between hospitals and locations (i.e. rural/regional and metropolitan)?  
|                   |                             | Has the implementation of the standards increased the consistency in treatment for diabetes-related foot conditions? | Has the implementation of the standards increased the consistency in treatment for diabetes-related foot conditions?  
|                   |                             |                         | Has the implementation of the standards increased the coordination of care, and facilitated a multi-disciplinary approach to management of treatment for diabetes-related foot conditions?  
<p>|                   |                             |                         | Has the implementation of the standards improved the |</p>
<table>
<thead>
<tr>
<th>Evaluation domain</th>
<th>Measurement alignment domain</th>
<th>Key evaluation question</th>
<th>Sub questions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>To what extent has the establishment of HRFS improved patient experience?</td>
<td>handover/referral and communication pathways for patients with diabetes-related foot conditions after treatment has begun? Has the implementation of the standards improved the patient experience for people who have received treatment for diabetes-related foot complications?</td>
</tr>
<tr>
<td>Impact</td>
<td>Improving healthcare of the public</td>
<td>To what extent has the establishment of HRFS had an impact on patient outcomes?</td>
<td>Has the implementation of the standards contributed to changes to the number of limb saving procedures (and potentially reducing the number of avoidable amputations and other procedures)?</td>
</tr>
<tr>
<td>Sustainability</td>
<td>Providing efficient and appropriate care</td>
<td>To what extent has the establishment of HRFS impacted service efficiency?</td>
<td>Has implementation of the standards improved the efficiency of resource utilisation in the health system in relation to diabetic foot services?</td>
</tr>
<tr>
<td>Access and reach</td>
<td>Improving healthcare of the public</td>
<td>Did the program reach its intended cohort? For whom did the program work and in what context?</td>
<td>Has the implementation of the standards enabled access to an appropriate level of services for all patients (specifically those in regional and rural areas and indigenous communities) requiring treatment for diabetes-related foot conditions in NSW?</td>
</tr>
</tbody>
</table>

**Data and analysis matrix**

The data and analysis matrix outlines how the KEQs will be examined in the monitoring and evaluation of HRFS. ACI will lead the data collection, analyses and feedback process for the evaluation in collaboration with state-wide data custodians, local health districts implementation teams, other pillars and the Ministry.
<table>
<thead>
<tr>
<th>Sub-question/s</th>
<th>Reporting alignment and frequency</th>
<th>Measure/focus</th>
<th>Method/s</th>
<th>Data source</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>To what extent are LHDs and health practitioners aware of the HRFS Standards?</td>
<td>Service level agreements</td>
<td>→ The total number of non-admitted service units registered in HERO under the LBVC initiative to support services provided to targeted patients&lt;br&gt;→ Implementation stakeholder level of awareness of the Standards&lt;br&gt;→ Method for building awareness</td>
<td>MoH reporting mechanisms&lt;br&gt;Semi-structured interviews: HRFS teams&lt;br&gt;Semi-structured interviews: surgeons&lt;br&gt;Survey/questionnaire: allied health</td>
<td>HERO reports</td>
<td>Descriptive analysis&lt;br&gt;Assess level and variation in awareness and support of the standards amongst key stakeholders.&lt;br&gt;Explore mechanisms for building awareness.</td>
</tr>
<tr>
<td>To what extent have the standards effectively supported implementation of HRFS?</td>
<td>Roadmap</td>
<td>→ Assessment of standards underpinning the HRFS at each site</td>
<td>Local assessment reported through Roadmaps</td>
<td>LHD reporting mechanisms</td>
<td>LHD will assess the implementation of HRFS to ensure they incorporate the standards – used for improvement planning</td>
</tr>
<tr>
<td>Are there any contextual facilitators or barriers to implementation?</td>
<td>Roadmap</td>
<td>→ Key enablers and barriers to the implementation&lt;br&gt;→ HRFS aspects that were unable to be implemented</td>
<td>Semi-structured interviews: HRFS teams&lt;br&gt;Semi-structured interviews: surgeons</td>
<td>Primary data collection</td>
<td>Identify stakeholder perspectives on barriers and facilitators to implementation. Consider against aspects of the standards not yet implemented to guide ongoing strategies.</td>
</tr>
<tr>
<td>Sub-question/s</td>
<td>Reporting alignment and frequency</td>
<td>Measure/focus</td>
<td>Method/s</td>
<td>Data source</td>
<td>Analysis</td>
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</tr>
<tr>
<td>→ What health services for HRFS patients are not available</td>
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<td></td>
<td></td>
<td>Understand variation in resources/FTE for HRFS and alignment with HRFS as intended.</td>
</tr>
<tr>
<td>→ Equipment/IT and space availability</td>
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</tr>
<tr>
<td>Do stakeholders understand their role in the implementation of the HRFS Standards?</td>
<td>Roadmap</td>
<td>→ Description of resources to establish team and service/FTE</td>
<td>Semi-structured interviews: HRFS teams</td>
<td>Primary data collection</td>
<td></td>
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<td></td>
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<td></td>
<td>Semi-structured interviews: surgeons</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were governance structures clear?</td>
<td>Roadmap</td>
<td>→ Description of governance structures in place</td>
<td>Semi-structured interviews: HRFS teams</td>
<td>Primary data collection</td>
<td>Analysis of extent of variation in governance structures in different sites including maintaining current best practice guidelines.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>→ Assess stakeholder perceived effectiveness of governance structures in place</td>
<td>Semi-structured interviews: surgeons</td>
<td></td>
<td>Which governance structures are perceived to be more effective and why.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>→ # and % of allied health who believe treatment guidelines are continuously updated to reflect current best practice.</td>
<td></td>
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<tr>
<td>How accurately and fully</td>
<td>Roadmap</td>
<td>→ Gap analysis of</td>
<td>Semi-structured</td>
<td>Primary data</td>
<td>Analysis of extent of variation in</td>
</tr>
<tr>
<td>Sub-question/s</td>
<td>Reporting alignment and frequency</td>
<td>Measure/focus</td>
<td>Method/s</td>
<td>Data source</td>
<td>Analysis</td>
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<tr>
<td>were the Standards implemented?</td>
<td>Evaluation</td>
<td>HRFS against the standards to identify current access to HRF care</td>
<td>interviews: HRFS teams, Semi-structured interviews: surgeons</td>
<td>collection</td>
<td>implementation in different sites. Analysis by difference in location</td>
</tr>
<tr>
<td>To what extent does this vary between hospitals and locations (i.e. rural/regional and metropolitan)?</td>
<td></td>
<td>→ # and % of LHDs who develop an implementation plan for HRFS establishment aligned with the standards</td>
<td>Survey/questionnaire: allied health</td>
<td></td>
<td>(metropolitan/rural/remote)</td>
</tr>
<tr>
<td>Has the implementation of the Standards increased the coordination of care, and facilitated a multidisciplinary approach to management of treatment for diabetes-related foot conditions?</td>
<td>Evaluation</td>
<td>→ # and % of patients who report involvement in treatment discussion with HRFS team on referral and discharge</td>
<td>Patient survey</td>
<td>Patient reported experience measure (PREM) not yet developed.</td>
<td>Assess patient and allied health reports of referral and discharge/communication</td>
</tr>
<tr>
<td>Has the implementation of the Standards improved the handover/referral and communication pathways for patients with diabetes-related foot conditions after treatment has</td>
<td>Evaluation</td>
<td>→ # and % of allied Health who report timeliness and appropriateness of handover/referral of HRFS patients to</td>
<td>Quantitative data extraction and analysis</td>
<td>Admitted patient data collection</td>
<td>Assess patient and allied health reports of handover and referral pathways and compare with quantitative results</td>
</tr>
<tr>
<td>Sub-question/s</td>
<td>Reporting alignment and frequency</td>
<td>Measure/focus</td>
<td>Method/s</td>
<td>Data source</td>
<td>Analysis</td>
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<tr>
<td>begun?</td>
<td></td>
<td>GP/s</td>
<td></td>
<td>reported experience measure (PREM) not yet developed.</td>
<td></td>
</tr>
<tr>
<td>Has the implementation of the Standards improved the patient experience for people who have received treatment for diabetes-related foot complications?</td>
<td>Evaluation</td>
<td>→ # and % of patient satisfied with the treatment received</td>
<td>BHI patient survey pre and post comparisons</td>
<td>BHI survey.</td>
<td>ACI will work in collaboration with BHI to link data to patient cohort in for baseline patient experience and thereafter, oversample to gain adequate sample size where required</td>
</tr>
<tr>
<td>Sub-question/s</td>
<td>Reporting alignment and frequency</td>
<td>Measure/focus</td>
<td>Method/s</td>
<td>Data source</td>
<td>Analysis</td>
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<tr>
<td>Has the implementation of the Standards contributed to changes to the number of limb saving procedures (and potentially reducing the number of avoidable amputations and other procedures)?</td>
<td>Evaluation</td>
<td>➔ % of amputations in patient cohort</td>
<td>Quantitative data extraction and analysis</td>
<td>admitted patient data collection</td>
<td>Assess changes in rates of related procedures including; minor and major amputations and limb saving procedures. Amputation surgery occurs in 4 LHDs so patient address will be used to trace patient to LHD. Assess variation in amputation rate, LOS, hospitalisation rates, care in the last year of life and mortality across LHD populations. A matched or adjusted analysis will be used where possible.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>➔ % of limb saving procedures in patient cohort</td>
<td>Semi-structured interviews: surgeons</td>
<td>Primary data collection</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>➔ Surgeon perception of severity of conditions of patients referred for surgical consultation</td>
<td>Patient Reported outcome measure (data measures and tools not yet developed)</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>➔ Surgeon perception of proportion of patients who could have been identified and managed much earlier and potentially avoided or delayed the procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has the implementation of the Standards improved the efficiency of resource utilisation in the health system in relation to</td>
<td>Quarterly Monitoring indicators</td>
<td>➔ Inpatient utilisation (separations, beddays and NWAUs)*</td>
<td>Quantitative data extraction and analysis</td>
<td>Admitted patient data collection</td>
<td>Assess change over time in measures and potential relationship to implementation of HRFS.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>➔ Number of service</td>
<td>Analysis of benefits realised after 12 months.</td>
<td>Primary data collection EDWARD/Webnap</td>
<td></td>
</tr>
<tr>
<td>Sub-question/s</td>
<td>Reporting alignment and frequency</td>
<td>Measure/focus</td>
<td>Method/s</td>
<td>Data source</td>
<td>Analysis</td>
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</tr>
<tr>
<td>diabetic foot services?</td>
<td>events, telehealth services in the established (HERO) HRFS*</td>
<td>Benefits realised will be applied to economic/fiscal analysis through separations, beddays, NWAUs avoided</td>
<td>Assess timing of changes in non-admitted and admitted activity including use of telehealth</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>→ Foot ulcers/infections acute admissions as a proportion of HRF cohort</td>
<td>Economic/fiscal benefits applied to BaU to determine indicative benefits</td>
<td>Investigate for potential separations/beddays/NWAU avoided.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>→ Rate of growth in non-admitted service events of foot infection/ulcers</td>
<td>Summative economic evaluation (comparative economic analysis of pre and post implementation utilisation and fiscal results)</td>
<td>Pre-implementation Business as Usual base case to be used to as baseline for comparative economic analysis with post implementation results.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>→ Length of stay for admitted patient cohort</td>
<td>NSW Return on Investment for project</td>
<td>Summative assessment of net impact through comparison of quantifiable costs and benefits of the base case with the quantifiable costs and benefits of implementation of the model of care with the quantifiable costs and benefits of implementation of the HRFS. NSW return on investment for program</td>
<td></td>
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<tr>
<td></td>
<td>→ NWAU/average NWAU for patient cohort</td>
<td></td>
<td>The summative evaluation including economic analysis identifying return on investment,</td>
<td></td>
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</tr>
<tr>
<td>Sub-question/s</td>
<td>Reporting alignment and frequency</td>
<td>Measure/focus</td>
<td>Method/s</td>
<td>Data source</td>
<td>Analysis</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Has the implementation of the Standards enabled access to an appropriate level of services for all patients (specifically those in regional and rural areas and indigenous communities) requiring treatment for diabetes-related foot conditions in NSW?</td>
<td>Early and late impact</td>
<td>→ # and % of allied health who agree/disagree that HRFS patients in rural and remote locations have appropriate access to HRFS</td>
<td>Quantitative data extraction and analysis</td>
<td>EDWARD/We bnap</td>
<td>Assess HRFS access for rural and remote patients and use of telehealth via both qualitative and quantitative methods.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>→ Telehealth capacity and utilisation in HRFS in rural and remote areas</td>
<td>Survey/questionnaire: allied</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>→ Number of service events, telehealth services and NWAUs in the established (HERO) HRFS</td>
<td>Semi-structured interviews: HRFS teams</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Patient reported experience measure (PREM) not yet developed.</td>
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</table>

Net present value and utilisation analysis results will inform decisions regarding ongoing investment.
Risks

The key risks to conducting an effective impact evaluation for HRFS are:
- available data may be insufficient to conduct a thorough evaluation
- available data may be insufficient to control for the impact of factors outside of the implementation of the standards
- available data quality may be poor
- available data may be inconsistent between data sources.

In the absence of a randomised evaluation design, a key challenge will be accounting for the impact of factors outside the implementation of HRFS including changes in demographics over time, changes in funding, process and clinical service delivery unrelated to HRFS and uncertainty regarding the extent and variability of implementation at each site.

The risk that the outcomes of the implementation of the standards will not be able to be accurately controlled for is perhaps the greatest risk for this project. The availability of comprehensive hospital activity data, patient experience and outcomes data and qualitative data directly from clinicians should ensure that there is a sufficient amount of high quality and consistent data to assess most of the intended outcomes of the standards.

Governance

Consistent with the *NSW Program Evaluation Guidelines* and the *ACI Framework: Understanding Program Evaluation*, the evaluation of the diabetes HRFS program within the LBVC initiative will be conducted by ACI Health Economics and Evaluation Team and include an Evaluation Steering Committee. The Steering Committee will comprise content area experts (clinicians) and evaluation expertise with representation from LHDs, the Endocrine Network and independent experts at a minimum. The Steering Committee will be responsible for ensuring that the evaluation is conducted in accordance with this M&E plan and to ensure findings are communicated to relevant stakeholders and audiences. A checklist against the NSW Program Evaluation Guidelines is attached at Appendix I and is to be used to guide the evaluation activities.

Terms of Reference for the evaluation will be developed at the time of establishing the Steering Committee.

Communication and reporting plan

The dissemination of evaluation findings will be critical to inform future planning and investment decisions related to the improving the outcomes and experience for people with osteoporosis. Communication of evaluation findings will be provided in an appropriate form to each audience and stakeholder group identified. Forums for feedback and discussion of results will be important for reflection and learning. The ORP evaluation governance committee will define a communication plan.
**Audience and stakeholders**

Key audiences and stakeholders include the following.

- The NSW Ministry Senior Executive Forum membership; NSW Health Executive and Chief Executives, including the LBVC leadership team: interest in overall impact and future investment or disinvestment decisions.
- The ACI Executive and Network Managers: to understand program effectiveness, impact and directions for this and future programs. To understand, explain factors affecting clinical variation.
- The ACI Endocrine Network: to assess program effectiveness and provide feedback loop for ongoing improvement in the care of people with diabetes-related foot complications.
- LHD clinicians, service managers and executive: to understand factors affecting local performance and comparison with state and/or peer group equivalents, and to implement local quality improvement initiatives.
- People with diabetes and their carers: as partners in the care provided.

**Codes of behaviour and ethics**

This M&E plan comprises the delivery of human services and potentially confidential information. The evaluation will be conducted in an ethical manner and all individual records will be destroyed at the end of the evaluation.

The evaluation will be conducted in compliance with:

- *ACI Responsible governance, management and conduct of research: An ACI framework*¹²
- Australasian Evaluation Society (AES) Guidelines for the ethical conduct of evaluations¹³
- National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct of Human Research*¹⁴.

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References

Appendices

Evaluation of programs in ACI checklist

Compliance with the NSW Government Program Evaluation Guidelines (January 2016)
This checklist is designed to assist people involved in evaluations in ACI ensure that evaluations are consistent with the NSW Government Program Evaluation Guidelines. A full copy of the Guidelines and the corresponding Toolkit can be accessed here: https://www.treasury.nsw.gov.au/projects-initiatives/centre-program-evaluation

Definitions
Program evaluation builds evidence to contribute to decision making that can assist programs to operate at their optimal and to deliver good outcomes to end users.
In terms of evaluation in NSW, program refers to “A set of activities managed together over a sustained period of time that aim to achieve an outcome for a client or client group.” Program evaluation refers to “A rigorous, systematic and objective process to assess a program’s effectiveness, efficiency, appropriateness and sustainability.”

Principles (quick check)
The Guidelines take a principles based approach using nine principles that underpin best practice in program evaluation. These are noted below for quick assessment. The principles and associated activities form the remainder of this checklist under a series of focus areas.

<table>
<thead>
<tr>
<th>Principle</th>
<th>Check (✓)</th>
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<tbody>
<tr>
<td>Evaluation has been built into the program design</td>
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<tr>
<td>Evaluation is based on sound methods</td>
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<tr>
<td>Resources and adequate time to evaluate is included in the program</td>
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<tr>
<td>The right mix of expertise and independence has been used to develop and</td>
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<tr>
<td>undertake the evaluation</td>
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<tr>
<td>Proper governance and oversight has been established</td>
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<tr>
<td>The evaluation design and conduct in its undertaking meets ethical</td>
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<tr>
<td>standards</td>
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<tr>
<td>Relevant stakeholders have informed and guided the evaluation</td>
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<tr>
<td>Evaluation data has been used meaningfully</td>
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<tr>
<td>The evaluation is transparent and open to scrutiny</td>
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</table>
### Planning evaluation

<table>
<thead>
<tr>
<th>Assessment of key processes underpinning good practice</th>
<th>Check (✓)</th>
<th>Corresponding page # in guidelines</th>
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</thead>
<tbody>
<tr>
<td>Has the subject of the evaluation been clearly defined?</td>
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<tr>
<td>Is there a clearly defined scope?</td>
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<tr>
<td>Is the purpose of the evaluation clear (i.e. what decisions will the evaluation be used to inform – continuing, expanding or discontinuing)?</td>
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<tr>
<td>Are key roles and responsibilities for the evaluation allocated (who will manage, who will commission, who will conduct, who will implement findings)?</td>
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<tr>
<td>Are key evaluation questions defined?</td>
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<tr>
<td>Is there an authorising environment for the evaluation (i.e: authorisation to access data, interview end users/staff)?</td>
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</table>

### Governance

Use governance processes to ensure oversight of evaluation design, implementation and reporting.

<table>
<thead>
<tr>
<th>Assessment of key processes underpinning good practice</th>
<th>Check (✓)</th>
<th>Corresponding page # in guidelines</th>
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</thead>
<tbody>
<tr>
<td>Is there a governance structure in place to oversight the evaluation?</td>
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<tr>
<td>Does the governance structure include staff with appropriate seniority and understanding of evaluation?</td>
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<tr>
<td>Does the governance structure include staff/stakeholders with expertise in the content area?</td>
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<tr>
<td>Does the governance structure include staff/stakeholders with expertise in evaluation methods?</td>
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<tr>
<td>Does the governance structure include processes to disseminate information?</td>
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</table>
### Audience and stakeholders

<table>
<thead>
<tr>
<th>Assessment of key processes underpinning good practice</th>
<th>Check (✓)</th>
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<tbody>
<tr>
<td>Do stakeholders include program participants, senior decision makers, government and non-government staff involved in managing and delivering the program?</td>
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<tr>
<td>Has audience (those that will receive and use the evaluation findings) been identified (ie executive funders, Cabinet, Network)?</td>
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<tr>
<td>Has a stakeholder communication strategy been developed as part of the evaluation plan?</td>
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<tr>
<td>Are stakeholders involved in all aspects of the evaluation – planning, design, conducting and understanding of the results?</td>
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</table>

### Undertaking the evaluation

<table>
<thead>
<tr>
<th>Assessment of key processes underpinning good practice</th>
<th>Check (✓)</th>
<th>Corresponding page # in guidelines</th>
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</thead>
<tbody>
<tr>
<td>Have good project management principles, practice and tools been established to manage the evaluation?</td>
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<tr>
<td>Have sound methods been established to answer each of the key evaluation questions and any sub questions?</td>
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<tr>
<td>Have data sources and analysis approaches been defined for each question/method?</td>
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</tr>
<tr>
<td>Are data sources (both primary and secondary) valid and robust?</td>
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<tr>
<td>Has data been used meaningfully to report clear statements of findings for consideration?</td>
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<td>11</td>
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<tr>
<td>Is the evaluation plan, conduct and findings (methods, assumptions and analyses) transparent and open to scrutiny?</td>
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<tr>
<td>Have the ethical implications of the evaluation activities been considered and addressed adequately where personal data and impacts on vulnerable groups is potential?</td>
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<tr>
<td>Are privacy safeguards in place for end users, staff and vulnerable populations?</td>
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<tr>
<td>Is ethics approval required and if so, sought prior to commencing data collection?</td>
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</table>
**Using key findings**

<table>
<thead>
<tr>
<th>Assessment of key processes underpinning good practice</th>
<th>Check (✓)</th>
<th>Corresponding page # in guidelines</th>
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<tbody>
<tr>
<td>Is there a plan for communicating findings to decision makers, service providers and other stakeholders?</td>
<td></td>
<td>16</td>
</tr>
<tr>
<td>Is there a plan for how the key findings will be used?</td>
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<td>16</td>
</tr>
</tbody>
</table>

The Health Economics and Evaluation Team can be contacted for further advice.

Further appendices will comprise instruments developed for data collection and will be attached in due course.