

REPORT

Osteoporotic Re-fracture Prevention

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 by:

- *service redesign and evaluation* – applying redesign methodology to assist healthcare providers and consumers to review and improve the quality, effectiveness and efficiency of services
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Abbreviations and Glossary

Term	Definition
ACI	Agency for Clinical Innovation
CEC	Clinical Excellence Commission
ED	Emergency Department
FLC	Fracture Liaison Coordinator
GP	General Practitioner
HEET	Health Economics and Evaluation Team
IHI	Institute of Healthcare Improvement
LHD	Local Health District
LOS	Length of Stay
MoH	NSW Ministry of Health
MSK	Musculoskeletal
NWAU	National Weighted Activity Unit
ORP	Osteoporotic Refracture Prevention
PROM	Patient Reported Outcome Measures
M&E	Monitoring and Evaluation

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.

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).

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.

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 of Leading Better Value Care programs.

Table 1 Monitoring and evaluation cycle of Leading Better Value Care programs

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

Executive summary

Osteoporosis is a chronic condition characterised by low bone mineral density and deterioration of the bone tissue. Symptoms include decreased bone strength, increased bone fragility and an increased risk of bone fracture (minimal trauma fracture)¹. In Australia, approximately 3% of men and 13% of women between 50 and 69 years of age suffer from osteoporosis. These rates increase to 13% for men and 43% for women after age 70². Therefore, as the Australian population ages, the incidence of osteoporosis, minimal trauma fractures and refractures, is expected to rise.

Following the acute management of fractures, identification, clinical treatment and support for self-management for people sustaining minimal trauma fractures is poorly managed in Australia. To address this, the Agency for Clinical Innovation (ACI) Musculoskeletal Network has developed the *ACI Model of care for osteoporotic refracture prevention (ORP)*³. Key aspects of the model of care include:

- targeted efforts to identify people who require the service
- investigation of the underlying cause of the fracture
- medical treatment and conservative care
- ongoing follow-up to support optimal management of osteoporosis

The aims of the ORP model of care are to improve patient outcomes and increase health system efficiencies. Local and international evidence, including the formative evaluation of three New South Wales (NSW) ORP pilot sites, suggests that implementation of this model could improve quality of life for individuals and their families and reduce health system use.

In 2016, the NSW Ministry of Health (MoH) launched the Leading Better Value Care (LBVC) program. LBVC is aimed at changing the focus of the NSW public health system from volume to value based care. A key driver in achieving this is to align healthcare in NSW to the Institute of Healthcare Improvement (IHI) Triple Aim of improving patient and provider experience, population health outcomes, and system efficiency and effectiveness. The *ACI Model of Care for ORP* has been selected as one of the first programs in LBVC and will be implemented across all NSW local health districts in the 2017-18 financial year.

LBVC provides an opportunity to align measurement systems for ORP across roadmaps, service level agreements and impact evaluation. This will improve monitoring of program implementation and support the achievement of program milestones. This document provides the monitoring and evaluation plan for all aspects of the program.

Findings from monitoring and evaluation will be used to guide local level and statewide service improvements and contribute to investment decisions to improve the health of people in NSW.

¹ The Royal Australian College of General Practitioners and Osteoporosis Australia. Osteoporosis prevention, diagnosis and management in postmenopausal women and men over 50 years of age. 2nd edn. East Melbourne, Vic: RACGP, 2017

² Watts JJ, Abimanyi-Ochom J, Sanders K. Osteoporosis costing all Australians: A new burden of disease analysis – 2012 to 2022. Glebe, NSW: Osteoporosis Australia; 2013.

³ ACI Musculoskeletal Network. NSW Model of Care for Osteoporotic Refracture Prevention. Chatswood: Agency for Clinical Innovation; 2011 Jan. 36p.

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

Osteoporotic refracture prevention

Osteoporotic fractures are a source of significant, increasing and unnecessary, health system burden. Many of these fractures are sustained through minimal trauma and are often caused by one underlying chronic disease, osteoporosis. Osteoporosis is characterised by reduced bone density and strength that predisposes individuals to minimal trauma fractures.

Minimal trauma fractures or 'fragility fractures' are those sustained from a trip, slip or fall from standing height. The majority of minimal trauma fractures occur in women. The residual lifetime risk of minimal trauma fracture is up to 45% for women older than 60 years of age⁴. After an initial fracture, the risk of refracture more than doubles. Initial fracture and subsequent refractures reduce independence and quality of life and increase the risk of hospitalisation, morbidity and mortality.

As the population ages, the incidence of osteoporotic fractures and refracture will place an increasing burden on individuals, communities and health systems. It is currently estimated that almost five million Australians live with osteoporosis⁵. This puts those affected at increased risk of fractures from minimal trauma, refracture and premature mortality. Many patients with osteoporosis are undertreated. In one Australian study only 28% of patients were receiving appropriate medical therapy following minimal trauma fracture⁶.

Clinical management to reduce the likelihood of refracture primarily involves:

- early identification of patients at risk of refracture
- early assessment and active treatment of osteoporosis
- long-term support to participate in reviews of and maintain best practice treatments.

Contemporary evidence suggests that this is the most effective way to manage the risk of future refractures and maximising the cost-effectiveness of healthcare delivery.

Document outline

This document outlines the monitoring and evaluation (M&E) plan for the *ACI Model of care for osteoporotic refracture prevention (ORP)* across NSW as an initiative of LBVC. The plan draws heavily on the original Aspex Consulting ORP evaluation plan and has been developed with significant input from the ACI Musculoskeletal Network and informed by key documents relevant to best practice care for people with minimal trauma fractures. It includes:

- overview of the NSW LBVC initiative
- background to the problem and ORP program design
- purpose, focus, limitations, design and methods for the evaluation
- program logic that illustrates how the model of care is expected to achieve the intended outcomes
- key evaluation questions
- methods, data sources and analysis that will be conducted to answer the key questions
- governance, codes of behaviour and ethical framework that underpin the evaluation.

⁴ Nguyen ND, Ahlborg HG, Center JR, Eisman JA, Nguyen TV. Residual lifetime risk of fractures in women and men. *J Bone Miner Res* 2007;22(6):781–88.

⁵ Aspex Consulting June 2014

⁶ Ibid

Background

Leading Better Value Care

In late 2016, the NSW Ministry of Health (MoH) introduced the LBVC initiative. LBVC is a comprehensive approach that aims to improve NSW Health system performance against the Institute of Healthcare Improvement (IHI) Triple Aim. The Triple Aim is based on a three pronged approach of:

- improving patient and provider experience
- population health outcomes
- system efficiency and effectiveness.

The initiative involves the implementation of eight programs across NSW in 2017-18. Statewide implementation of the Musculoskeletal Network's *NSW Model of care for osteoporotic refracture prevention* is one of the eight initiatives.

Figure 1: Triple aim of LBVC



Better Value Healthcare initiatives will be implemented by each Local Health District (LHD) and incorporated into roadmaps and service level agreements (SLAs) for the purpose of monitoring and informing local quality improvements. A comprehensive impact evaluation will be undertaken after programs have been implemented and settled 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 initiative.

ORP Program overview

Evidence underlying the ORP model of care

ORP models of care have been operating in a number of health services across Australia and internationally for many years. Recommendations to support key components of an ORP service are noted in a number of key documents including (but not limited to):

- clinical guidelines for *Osteoporosis prevention, diagnosis and management in postmenopausal women and men over 50 years of age (second edition)*, published in 2017 by the Royal Australian College of General Practitioners in collaboration with Osteoporosis Australia⁷
- a recently published meta-analysis of clinically effective components of international osteoporosis treatment programs⁸.

⁷ The Royal Australian College of General Practitioners and Osteoporosis Australia. *Osteoporosis prevention, diagnosis and management in postmenopausal women and men over 50 years of age*. 2nd edn. East Melbourne, Vic: RACGP, 2017.

⁸ Ganda K, Puech M, Chen JS, et al. Models of care for the secondary prevention of osteoporotic fractures: a systematic review and meta-analysis. *Osteoporosis International*. 2013; 24(2):393-406.

Key features of the model of care for ORP

The model of care for ORP is targeted at individuals who are at risk of osteoporotic refracture, and incorporates coordination of health services to deliver interventions to improve patient outcomes and health system efficiency. Key activities involve the appointment of a Fracture Liaison Co-ordinator (FLC) or coordinated services to streamline the following approaches:

- patient identification
- provision of bone health education for individual patients
- provision of early access to assessment, investigations and referrals as required
- ensuring each patient has access to a medical consultation and treatment commenced prior to handover to the patient's General Practitioner (GP) for ongoing care
- supporting access to community based conservative care
- supporting ongoing self-care
- performing bone health assessments to ensure treatment regimens are contemporary and individualised to patient's needs.

Learnings from the implementation of this model of care in NSW over the past six years have indicated that commencement of medical treatment within the LHD prior to referring patients back to their nominated GP provides benefits for patient care⁹.

The model of care recommends that ORP services undertake activities that:

- increase all local clinical staff awareness of the need for refracture prevention strategies regardless of the clinical setting; it is everyone's business
- increase local community awareness of the need for improved bone health and the impact of refracture prevention on quality of life for community members
- promote service co-ordination across hospital and community settings with primary and secondary care
- promote a quality improvement environment to maximise the impact of any local model of care on service delivery.

Evaluation purpose

Purpose

When done well, evaluation provides a sound evidence base for program improvement and information that can contribute to decision making on investment strategies and future policy and program directions to improve outcomes.

The monitoring approaches (formative evaluation) contained in this plan are focussed on defining to what extent the program has been implemented as planned¹⁰ and to assess progress towards the longer term outcomes.

Following implementation of the ORP model of care, an impact evaluation will be undertaken. This will be used to determine the overall effect of the ORP program at a statewide level, including intended and unintended outcomes.

⁹ MSK Network assessment

¹⁰ Referred to as implementation fidelity

The purpose of this plan is to guide monitoring and evaluation and:

- provide insight into the implementation of the ORP model of care across NSW, including the key enablers and barriers to adoption
- determine if the program has achieved its intended objectives
- assess the impact of ORP on the NSW health system
- define data sources and collection methods, both existing and required, to assess ORP across the IHI Triple Aim including expected and unexpected outcomes, experience of care, efficiencies and effectiveness.

Measurement alignment

A measurement alignment framework has been developed for LBVC to create shared priorities across the NSW health system and align data requirements and collection systems for implementation, outcome and impact measures.

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

These three levels include:

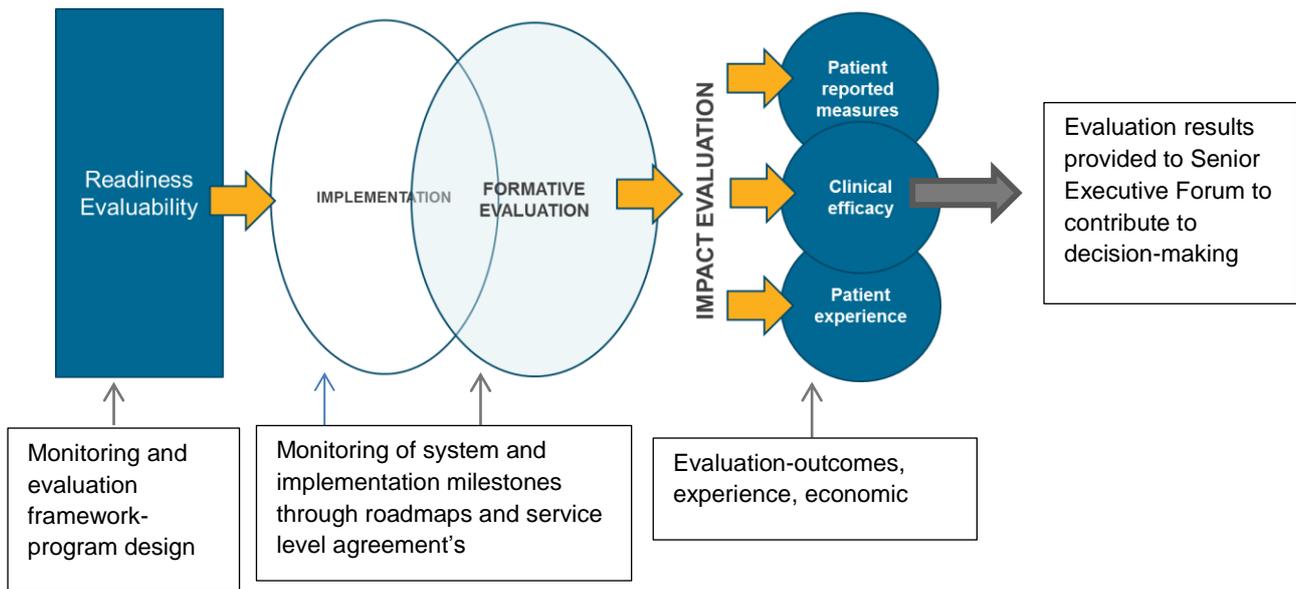
- program/project roadmaps
- service level agreements
- impact evaluation

For the first year of LBVC implementation, a set of indicators have been developed for each program to show progress towards implementation or program improvement. These are to be reported on a quarterly to the ACI. 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.

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 method 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 variations in data collection at many levels using different mechanisms.

Figure 2 Monitoring and evaluation approach for LBVC programs



Methods

Design

The M&E of the ORP program will take a macro, meso, micro approach consistent with the LBVC measurement alignment framework (figure 3). LHDs and the MoH will participate in monitoring through roadmaps and SLAs. The impact evaluation, including data collection and analysis and presentation of findings, will be the responsibility of relevant Pillars.

Figure 3 Micro, meso, macro approach



This evaluation will involve a mixed methods approach with both qualitative and quantitative data. A pre-post implementation design will test for changes that occur as a result of the program and dose response and linear mixed model analysis will test the extent that ORP is implemented and any association with patient outcomes (attribution).

Data sources for the evaluation will include:

- administrative patient data
- roadmap and SLA reports and supporting data
- patient reported outcome and experience data
- staff focus groups, interviews and surveys

- patient experience surveys.

Data specifications and patient cohort

Quantitative data analysis will be based on public health administrative data from two sources:

- NSW Admitted patient data collection, linked to identify refractures (from the MoH).
- HERO establishment type from the Non-admitted patient data collection (from the MoH)

The patient cohort is all people aged 50 years and over who present to a NSW public hospital with the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (ICD-10 AM) codes shown in Table 2.

Table 2 Patient cohort ORP

Code	Description
M80: 0,1,2,3,4,5,8,9	Osteoporosis with pathological fracture
M81: 0,1,2,3,4,5,6,8,9	Osteoporosis without pathological fracture
M82: 0,1,8	Osteoporosis in diseases classified elsewhere
S02: 0,1,2,3,4,5,6,7,8,9	Fracture of skull and facial bones
S12: 0,1,2,7,8,9	Fracture of neck
S22: 0,1,2,3,4,5,8,9	Fracture of rib(s), sternum and thoracic spine
S32: 0,1,2,3,4,5,7,8	Fracture of lumbar spine and thoracic spine
S42: 0,1,2,3,4,7,8,9	Fracture of shoulder and upper arm
S52: 0,5	Fracture of forearm
S62: 0,1,2,3,4,5,6,7,8	Fracture at wrist and hand level
S72: 0,1,2,3,4,7,8,9	Fracture of femur
S82: 0,1,2,3,4,5,6,8,9	Fracture of lower leg, including ankle
S92: (S92.0 fracture of calcaneus assumed not to be included) leaving only S92.1 (fracture of talus-astragalus)	Fracture of foot except ankle
T02: 0,1,2,3,4,5,6,7,8,9	Fractures involving multiple body regions
T08	Fracture of spine, level unspecified
T10	Fracture of upper limb, level unspecified
T12	Fracture of lower limb, level unspecified
T14.2	Fracture of unspecified body region
W: 0,1,3,4,5,6,7,8,10,18,19,22,50,51,54	Other external causes of accidental injury: Falls

Evaluation scope and timing

The statewide implementation of the ORP model of care will occur throughout the 2017-18 financial year, in two six-month phases: July to December 2017 and January to June 2018. It is anticipated that outcomes and impacts will be incrementally realised from July 2017 at phase one sites and December 2017 at phase two sites.

Parameters and limitations

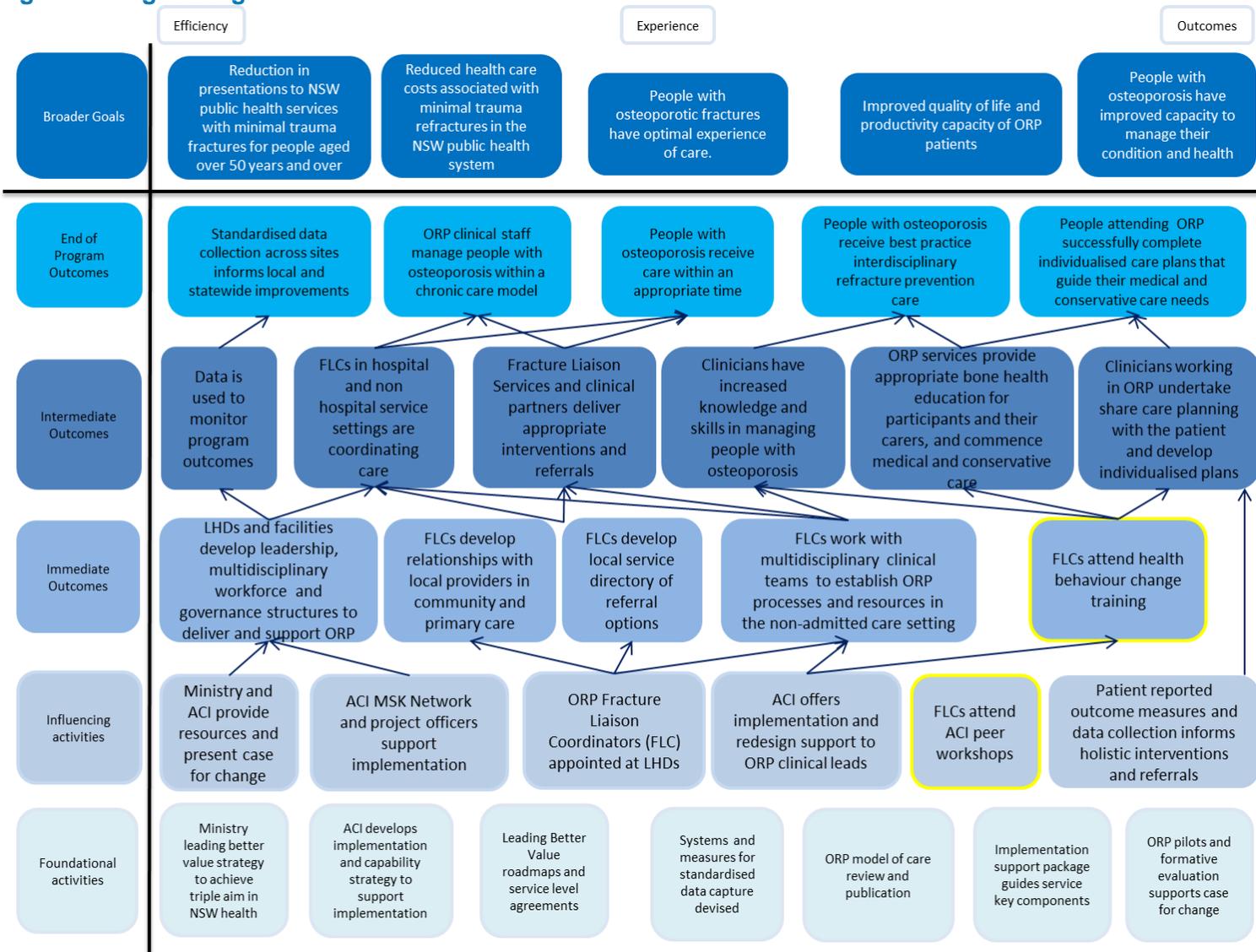
This M&E plan is focussed on evaluating the ORP model of care at a statewide level. Data will be accessed at an LHD level necessary to enable comparison across the state. Specific implementation indicators at site level will be collected as monitoring measures for roadmaps and SLAs to show that LHDs are progressing towards longer term program outcomes.

Several data limitations are inherent in this M&E plan. This includes the current lack of standardised collection systems for patient reported outcomes and quality of life data. It is considered essential that this data is collected to assess patient and clinical outcomes and measure value. Systems to collect required data will be investigated over the coming year.

Program Logic

The program logic outlines how the ORP program will work to achieve its intended outcomes. It provides a foundation to guide M&E and track progress towards milestones. The logic should be viewed from bottom to top. Figure 4 presents the program logic for the ORP program.

Figure 4 Program logic for ORP



Assumptions within the program logic

All programs (and program logics) include assumptions. These assumptions are tested during the monitoring and evaluation to understand the potential facilitators and barriers to anticipated changes. The assumptions for ORP include that:

- LHD executive, facility service managers and clinicians agree that there is a case for change and that improvements are required
- LHDs will identify clinical leaders and review workforce required to drive local practice changes
- governance processes will be established to support local accountability for improvements
- all people presenting with minimal trauma fractures will respond to the care delivered as expected and outlined in the broader goals
- delivery of the model of care will improve patient and carer experience across the health system
- system factors will support the implementation and sustainability of the ORP model of care.

Key evaluation questions

Key evaluation questions are used to guide the focus of monitoring and evaluation. The key questions are determined based on the program logic and in particular the immediate, intermediate and end of program outcomes (Table 3). This M&E plan includes questions related to monitoring (roadmaps and SLAs) and impact evaluation.

Table 3 Key evaluation questions

Evaluation domain	Measurement alignment domain	Key evaluation question
Appropriateness	Implementation fidelity	To what extent was the program implemented as intended?
Effectiveness	Improving experience of care	What LHD clinical processes changed and to what extent to improve health care for people with osteoporosis who present with a minimal trauma fracture?
		What were the facilitators and constraints to the program being embedded?
		To what extent has the program been implemented state-wide and is further investment required?
		To what extent does the workforce feel knowledgeable and confident to apply best practice management for people with osteoporosis who present with a minimal trauma fracture?
		To what extent has the program had an impact on the experience of people with osteoporosis who present with a minimal trauma fracture?
Impact	Improving healthcare of the public	To what extent has the program prevented the rate of refracture for people with osteoporosis?
		To what extent has the program impacted

Evaluation domain	Measurement alignment domain	Key evaluation question
		the outcomes of people with osteoporosis who present with a minimal fracture?
Sustainability	Providing efficient and appropriate care	To what extent has the program been implemented statewide and is further investment required?
Access and reach	Improving healthcare of the public	<p>Did the program reach its intended cohort?</p> <p>For whom did the program work and in what context?</p>

Data and analysis matrix

The following data matrix outlines the data sources, collection and analysis methods that will be used to answer the key evaluation questions. Further indicators may be included in the specific LHD Roadmaps.

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.

Table 4 Data and analysis matrix

Key evaluation question	Reporting alignment and frequency	Measure	Method	Data source	Analysis
To what extent was the program implemented as intended?	Roadmaps	<ul style="list-style-type: none"> → Number and which sites implementing → Executive sponsor and governance established → Coordinated approach established → Pathway for coordinated approach established 	Descriptive analysis reported through Roadmaps	LHD/Facility reporting mechanism	Descriptive reports
	Service level agreements	<ul style="list-style-type: none"> → The total number of non-admitted service units registered in HERO under the LBVC initiative to support services provided to targeted patient cohorts 	HSIPR report	HSIPR report	Descriptive reports
	Roadmaps	<ul style="list-style-type: none"> → Numbers/proportion of people participating in the ORP who have a DXA scan within the last 12 months 	ORP data collection	Data collection system to be developed	Descriptive reports
	Evaluation	<ul style="list-style-type: none"> → Numbers/proportion of people participating in the ORP who have had measurement of their serum Vitamin D levels within the last six months → Numbers/proportion of people participating in the ORP who are prescribed specific osteoporosis pharmacotherapy → Number/proportion of people who report medicating with their prescribed specific osteoporotic pharmacotherapy 			

Key evaluation question	Reporting alignment and frequency	Measure	Method	Data source	Analysis
		<ul style="list-style-type: none"> → Numbers/proportion of people participating in the ORP, who are engaging in recommended lifestyle behaviours such as exercise, dietary habits, falls prevention, quit smoking, calcium and vitamin D supplementation if required. → Numbers/proportion and percent of people sustaining a minimal trauma fracture after commencing participation in the ORP. 			
What LHD clinical processes changed and to what extent to improve health care for people with osteoporosis who present with a minimal trauma fracture?	Quarterly monitoring	<ul style="list-style-type: none"> → # & % of referrals to hospital and community services for patients at risk of ORP (and referral source) → # and % of patients having assessment for refracture prevention and osteoporosis → # & % of patients that have received a personalised management plan for fracture prevention that includes dietary advice, medical treatments and falls prevention strategies → # and % of patients followed up 6 months after initial assessment → Inpatient utilisation (NWAUs, separations, beddays) → Non-admitted utilisations (NWAUs, service events) 	<p>ORP data collection</p> <p>Admitted Patient Data Collection</p> <p>Economic/fiscal analysis</p>	Data collection system to be developed	<p>Pre and post analysis using linear mixed models</p> <p>Analysis of benefits realised after 12 months.</p> <p>Benefits realised will be applied to economic/fiscal analysis through separations, beddays, NWAUs avoided</p> <p>Economic/fiscal benefits applied to BaU to determine indicative benefits</p>
What were the facilitators and constraints to the program being embedded?	Evaluation	Facilitators and barriers to achieving end of program outcomes	Semi-structured interviews from sample LHD, ACI and Ministry staff.	Primary data collection	Pre and post comparisons
To what extent does	Evaluation	→ Knowledge and attitude change	Pre and post training	Primary data collection	Pre -post HCA

Key evaluation question	Reporting alignment and frequency	Measure	Method	Data source	Analysis
the workforce feel knowledgeable and confident to apply best practice management for people with osteoporosis who present with a minimal trauma fracture?		<ul style="list-style-type: none"> → Practice changes resulting from knowledge and attitude change → Uptake of training in Behaviour Change (HCA two-day workshop) 	questionnaire repeated again 12 months after training		training survey at six and 12 months.
To what extent has the program had an impact on the experience of people with osteoporosis who present with a minimal trauma fracture?	Evaluation	Patient experience of care including: <ul style="list-style-type: none"> → shared decision making → disease literacy → confidence in bone health and refracture prevention self-managed care → referral for individualised support as required 	BHI patient survey linked to patient cohort as baseline and sampling for post assessments (oversampling where necessary)	BHI patient survey	Impact of changes in care processes on patient and carer experience. Pre and post comparisons
To what extent has the program prevented the rate of refracture for people with osteoporosis?	Evaluation	<ul style="list-style-type: none"> → Knowledge and attitude change → Practice changes resulting from knowledge and attitude change → Uptake of training in Behaviour Change (HCA two-day workshop) 	Pre and post comparison	Questionnaires	Pre and post analysis to identify trends
To what extent has the program impacted the outcomes of people with osteoporosis who present with a minimal fracture?	Evaluation	<ul style="list-style-type: none"> → Quality of life indicators including change in morbidity e.g pain and function identified through PROMIS 29 	Data collection: method under development (PROMIS 29)	PROMIS 29	PRMs analysed to measure value – this won't be available until adequate sample of responses available.
To what extent has the program been implemented statewide and is further investment required?	Evaluation	<ul style="list-style-type: none"> → # Refracture presentations to NSW Public Health facility → Volume of refracture presentations to emergency department avoided → NWAU per emergency department presentation avoided → Economic comparison of BaU base case with post implementation results (fiscal and utilisation) 	Pre and post analysis	Admitted Patient Data Collection	Pre-implementation Business as Usual base case to be used to as baseline for comparative economic analysis with post implementation results.

Key evaluation question	Reporting alignment and frequency	Measure	Method	Data source	Analysis
		<ul style="list-style-type: none"> → Summative economic evaluation (comparative economic analysis of pre and post implementation utilisation and fiscal results) → NSW Return on Investment for project 			<p>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</p> <p>The summative evaluation including economic analysis identifying return on investment, net present value and utilisation analysis results will inform decisions regarding ongoing investment</p>
<p>Did the program reach its intended cohort?</p> <p>For whom did the program work and in what context?</p>	Evaluation	<p># patients accessing program as % of total cohort</p> <p>Patient characteristics</p>	<p>ORP data collection Pre and post analysis</p> <p>Outcomes by sub group</p>	<p>Data collection to be developed</p> <p>Admitted Patient data Collection</p>	<p>Descriptive analysis</p> <p>Comparison of patient outcomes against patient characteristics (age groups, rural, metro)</p>

Risks

Inherent to any program evaluation is a set of risks that need to be monitored and managed and, if necessary, escalated to the attention of relevant decision makers. A risk register will be established once the ORP M&E process begins. In the interim, the following potential risks have been identified:

- The expected variability and breadth of responses to the model of care across LHDs will be difficult to capture to measure service fidelity and attribution.
- Standardised collection of clinical processes and other data measures within the data plan is under development and availability for evaluation is not assured.

Governance

Consistent with the *NSW Program Evaluation Guidelines* and the *ACI Framework: Understanding Program Evaluation*, the evaluation of the ORP 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 Musculoskeletal 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 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 Musculoskeletal Network: to assess program effectiveness and provide feedback loop for ongoing improvement in the care of people with osteoporotic minimal trauma fractures.
- 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 osteoporosis who experience a minimal trauma fracture 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*¹¹
- Australasian Evaluation Society (AES) Guidelines for the ethical conduct of evaluations¹²
- National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct of Human Research*¹³.

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9. The National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellors' Committee. National statement on ethical conduct in human research. Canberra: Commonwealth of Australia: 2007 [updated May 2015; cited 2017 Mar 20]. Available from:
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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.

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

Planning evaluation

Assessment of key processes underpinning good practice	Check (✓)	Corresponding page # in Guidelines
Has the subject of the evaluation been clearly defined?		11
Is there a clearly defined scope?		11
Is the purpose of the evaluation clear (ie what decisions will the evaluation be used to inform – continuing, expanding or discontinuing)?		11
Are key roles and responsibilities for the evaluation allocated (who will manage, who will commission, who will conduct, who will implement findings)?		11

Assessment of key processes underpinning good practice	Check (✓)	Corresponding page # in Guidelines
Are key evaluation questions defined?		11
Is there an authorising environment for the evaluation (ie: authorisation to access data, interview end users/staff)?		15

Governance

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

Assessment of key processes underpinning good practice	Check (✓)	Corresponding page # in Guidelines
Is there a governance structure in place to oversight the evaluation?		11
Does the governance structure include staff with appropriate seniority and understanding of evaluation?		11
Does the governance structure include staff/stakeholders with expertise in the content area?		11
Does the governance structure include staff/stakeholders with expertise in evaluation methods?		11
Does the governance structure include processes to disseminate information?		11

Audience and stakeholders

Assessment of key processes underpinning good practice	Check (✓)	Corresponding page # in Guidelines
Do stakeholders include program participants, senior decision makers, government and non-government staff involved in managing and delivering the program?		15
Has audience (those that will receive and use the evaluation findings) been identified (ie executive funders, Cabinet, Network)?		11
Has a stakeholder communication strategy been developed as part of the evaluation plan?		12
Are stakeholders involved in all aspects of the evaluation – planning, design, conducting and understanding of the results?		12

Undertaking the evaluation

Assessment of key processes underpinning good practice	Check (✓)	Corresponding page # in Guidelines
Have good project management principles, practice		15

Assessment of key processes underpinning good practice	Check (✓)	Corresponding page # in Guidelines
and tools been established to manage the evaluation?		
Have sound methods been established to answer each of the key evaluation questions and any sub questions?		11
Have data sources and analysis approaches been defined for each question/method?		11
Are data sources (both primary and secondary) valid and robust?		11
Has data been used meaningfully to report clear statements of findings for consideration?		11
Is the evaluation plan, conduct and findings (methods, assumptions and analyses) transparent and open to scrutiny?		12
Have the ethical implications of the evaluation activities been considered and addressed adequately where personal data and impacts on vulnerable groups is potential?		12
Are privacy safeguards in place for end users, staff and vulnerable populations?		12
Is ethics approval required and if so, sought prior to commencing data collection?		12

Using key findings

Assessment of key processes underpinning good practice	Check (✓)	Corresponding page # in Guidelines
Is there a plan for communicating findings to decision makers, service providers and other stakeholders?		16
Is there a plan for how the key findings will be used?		16

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.