Development of Quality Indicators for Health in Mexico

Methods and process manual

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ABOUT THIS DOCUMENT

This guide defines core principles for developing and implementing evidence-informed quality indicators, and describes the processes and methods to be applied in Mexico. It is designed as a sustainable guide to help mandated health authorities in Mexico develop and implement robust and measurable criteria, derived from evidence-informed guidance, to improve the quality of patient care.

This manual covers both technical methods for developing indicators, from topic selection to implementation, and the processes to be followed to apply these methods consistently and with engagement from relevant groups. Stylised examples are given with reference to selected health conditions, but have been edited to remove data specific to a particular country or programme.

The methods for developing Quality Indicators may evolve over time, and the needs of the Mexican context may also change, so this guide is considered a 'live' document or work in progress. It should be reviewed regularly by the ultimate owners (the Mexican government) and, where possible, by the authors. We welcome constructive comments, suggestions or examples from users which will help improve the content of this draft document.

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CONTENTS

Inserts to the text

Glossary of acronyms and abbreviations

For Mexican institutions and terms, this guide will use the acronym or abbreviation used in Spanish (e.g. DGCES). For international institutions and terms, we use the English-language abbreviation (e.g. IADB for Inter-American Development Bank, not BID)

Acronym or abbreviation used	Term (English)	*Spanish term (if applicable)*
BIA	Budget impact analysis	*Análisis de impacto presupuestario*
CAUSES	Universal Catalogue of Health Services	*Catálogo Universal de Servicios de Salud*
CBCISS	Basic Table and Catalogue of Health Sector Supplies	*Cuadro Básico y Catálogo de Insumos del Sector Salud*
CCG	Clinical Commissioning Group (UK)	
CEA	Cost-effectiveness evaluation	*Evaluación costo-efectiva*
CENETEC	National Center for Health Technology Excellence (Mexico)	*Centro Nacional de Excelencia Tecnológica en Salud* (also known as CENETEC-Salud)
CNPSS	National Commission for Social Protection in Health (Mexico)	*Comisión Nacional de Protección Social en Salud*
COFEPRIS	Commission for Protection against Sanitary Risks (Mexico)	*Comisión Federal para la Protección contra Riesgos Sanitarios*
CONACAS	National Committee for Health Quality (Mexico)	*Comité Nacional por la Calidad en Salud*
CONAVE	National Committee for Epidemiological Surveillance (Mexico)	*Comité Nacional para la Vigilancia Epidemiológica*
CPG	Clinical practice guideline	*Guías de práctica clínica*
CQC	Care Quality Commission (UK)	
CSG	General Health Council (Mexico)	*Consejo de Salubridad General*
CURP	Unique Population Registry Code	*Clave Única de Registro de Población*
DGCES	General Directorate for Quality of Healthcare and Education (Mexico)	*Dirección General de Calidad y Educación en Salud* – Secretaría de Salud
DGE	General Directorate of Epidemiology (Mexico)	*Dirección General de Epidemiología* – Secretaría de Salud
DGED	General Directorate of Performance Evaluation (Mexico)	*Dirección General de Evaluación del Desempeño* – Secretaría de Salud
DGIS	General Directorate of Health Information (Mexico)	*Dirección General de Información en Salud* – Secretaría. de Salud
DGTI	General Directorate of Information Technology (Mexico)	*Dirección General de Tecnologías de la Información* – Secretaría. de Salud
DH	Department of Health (UK)	
DIF	National System for Integral Family Development (Mexico)	*Sistema Nacional para el Desarrollo Integral de la Familia*

DRG	Diagnostic related group	*Grupos relacionados diagnósiticos*
EHR	Electronic health records	*Expediente clínico electrónico*
Federal Commission for Care Regulation	Federal Commission for Regulation and Supervision of Health Care Establishments and Services	*Comisión Federal para la Regulación y Vigilancia de los Establecimientos y Servicios de Atención Médica*
FPGC	Catastrophic Health Expenditure Fund	*Fondo de Protección contra Gastos Catastróficos*
GP	General practice/practitioner	
HCQI	Health Care Quality Indicators	*Indicadores de Calidad en la atención a la salud*
HSCIC	Health and Social Care Information Centre (UK)	
HTA	Health technology assessment	*Evaluación de tecnologías en salud*
IADB	Inter-American Development Bank	*Banco Interamericano de Desarrollo (BID)*
ICD-10	International Classification of Diseases, Volume 10	*Código Internacional de Enfermedades*
IMSS	Mexican Institute of Social Security	*Instituto Mexicano del Seguro Social*
INDICAS	National System of Quality Indicators in Health	*Sistema Nacional de Indicadores de Calidad en Salud*
ISSFAM	Institute of Social Security for the Mexican Armed Forces	*Instituto de Seguridad Social para las Fuerzas Armadas Mexicanas*
ISSSTE	Institute of Social Security and Services for Government Workers	*Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado*
JCI	Joint Commission International (USA)	
MI	Myocardial infarction	*Infarto agudo al miocardio*
MoU	Memorandum of understanding	*Memorandum de entendimiento*
NCD	Non-communicable disease	*Enfermedades no transmitibles*
NHS	National Health Service (UK)	
NI	NICE International	
NICE	National Institute for Health and Care Excellence (UK)	
NOM		Norma(s) Oficial(es) Mexicana(s)
OECD	Organisation for Economic Co-operation and Development	*Organización para la Cooperación y Desarrollo Económicos (OCDE)*
PDSA	Plan-Do-Study-Act	
PEMEX	Mexican Petroleums	*Petróleos Mexicanos*
P4P	Pay for performance	*Pago por desempeño*
PGS	General Register of Health	*Padrón General de Salud*
PROM	Patient-reported outcome measure	
QALY	Quality-adjusted life year	
QOF	Quality and Outcomes Framework (UK)	

QS	Quality standard	
SAEH	Automated Hospital Discharge Sub-system	*Subsistema Automatizado de Egresos Hospitalarios*
SEDENA	Secretariat of National Defense (Mexico)	*Secretaría de la Defensa Nacional*
SEMAR	Naval Secretariat (Mexico)	*Secretaría de Marina*
SICALIDAD	Integrated Health Quality System	*Sistema Integral de Calidad en Salud*
SINAIS	National Health Information System	*Sistema Nacional de Información en Salud*
SINBA	National System of Basic Information on Health	*Sistema Nacional de Información Básica en Materia de Salud*
SINOS	Nominal Health System	*Sistema Nominal en Salud*
SMPG	Medical Security for a New Generation	*Seguro Médico para una Nueva Generación*
SNS	National Health System (Mexico)	*Sistema Nacional de Salud*
SPSS	Social Protection System in Health	*Sistema de Protección Social en Salud*
SS	Ministry of Health (Mexico)	*Secretaría de Salud*
SWG	Strategic working group	*Grupo estratégico de trabajo*
TWG	Technical working group	*Grupo técnico de trabajo*
UAE	Economic Analysis Unit (Mexico)	*Unidad de Análisis Económico* – Secretaría de Salud
UPI	Unique patient identifier	*Identificador único de paciente*
WHO	World Health Organisation	*Organización Mundial de Salud*

1   Introduction

> **Chapter objectives:**
>
> - Define essential terms and concepts when implementing a quality indicator scheme in health care
> - Introduce and give background to the proposed new core indicator scheme in Mexico
> - Explain the aspects of health care which can be measured, and the purposes of different types of indicators, according to international best practice
> - Describe in general terms how an indicator should be formulated and described
>
>
> ***Key terms and concepts:***
>
> | | Application in this manual |
> |---|---|
> | Clinical Guidelines | *Evidence-informed statements making recommendations on routine clinical care* |
> | Health Technology Assessment | *Use of evidence to inform decisions about financing and planning of health care, by evaluating the social, economic, ethical and organizational issues of a health intervention* |
> | Indicators | *Measurable aspects of performance which can be used to assess quality of health services* |
> | Target standard | *Level of care set prospectively which stipulates a level of care that providers should meet* |

1.1   What are quality indicators in health care?

Measuring and monitoring quality of care is increasingly recognised by healthcare payers and providers throughout the world as means of improving health services and outcomes (Campbell et al. 2015). Quality has been considered an overarching consideration of Universal Health Coverage (UHC) (Kieny 2015). Countries moving towards Universal Health Coverage (UHC) are especially concerned as they seek to provide services that are affordable and equitable while increasing the quality of care

patients receive (Mate et al. 2013), and to manage common challenges such as overcrowding and overuse of inappropriate treatments. Whilst there have been many initiatives worldwide around health financing and health systems reforms, questions of how to measure and improve quality, what to measure, and what all this means in clinical practice, are under-researched and under-addressed by the global development community. Likewise, the financial aspect of quality improvement initiatives is also little discussed, with health technology assessment (HTA) and health benefits plans (HBPs) not always explicitly addressing quality.

Indicators in general are defined as "*explicitly defined and measurable items which act as building blocks in the assessment of care*"[1]. They are a statement about the structure, process (interpersonal or clinical), or outcomes of care and are used to generate subsequent review. They:

- are derived from high quality evidence, and are developed in consultation with relevant parties

- provide explicit benchmarks for assessing actual care performance and improving practice

- inform payment mechanisms and incentives, in the context of health insurance, health benefits packages, and pay-for-performance frameworks

- interface closely with other quality improvement initiatives, including clinical audit.

Indicators may be used to help evaluate **the performance** of a clinical team, a healthcare institution[2], and/or health systems at the regional or national level[3]. They may also be used (separately or in conjunction) not to formally benchmark providers against each other, but to drive **quality improvement** at a practice or local level.

1.2   Why develop a core set of national indicators in Mexico?

The government of Mexico has already implemented several initiatives to create and use quality indicators for performance monitoring. The National Crusade for Quality

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[1] Campbell SM, Braspenning J, Hutchinson A, Marshall MN. Research methods used in developing and applying quality indicators in primary care. *British Medical Journal* 2003; **326:** 816-819

[2] For example, in the UK the QOF scores for each GP practice are available online: http://qof.hscic.gov.uk/

[3] For example, in the UK the NHS Outcomes Framework provides a high-level judgement on performance of the NHS: http://www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk/

was introduced under the National Health Programme of 2001-2006[4]. INDICAS (*Sistema Nacional de Indicadores de Calidad en Salu*d) was the indicator system initially developed as part of this initiative. This, along with SICALIDAD (*Sistema Integral de Calidad en Salud*), introduced later in 2006-12, has led to the development of a set of 33 indicators for medical and nursing care, across five dimensions:

- *Dignity in care*
- *Organization of services*
- *Effectiveness of care*
- *Nursing care in hospitalization*
- *Healthcare-acquired infections*

A key objective for the Mexican government in creating these initiatives is to support the integration and use of quality indicators within Mexican institutions responsible for the delivery and provision of health care. There are already multiple indicator sets of quality in multiple institutions of the Mexican health sector, but these are broadly not integrated nor comparable.

Aside from developing a comprehensive database of health system performance organized around an appropriately developed set of indicators, allowing for comparative analysis of different institutions, it is hoped that integration of these indicators will also support better decision-making locally, using the information generated to improve practice.

The Mexican government, through the leadership and coordinating role of the *Dirección General de Calidad y Educación en Salud* (DGCES), the focal point for the *national indicator programme*, is committed to work with multiple stakeholders within the system to address fragmentation, inefficiency and unnecessary duplication in the development of quality indicators. This manual sets out how a <u>core set of national indicators</u> will be developed, implemented and their impact assessed.

1.3 Quality indicators in the context of priority-setting, health technology assessment, and health benefits plans

Health technology assessment (HTA) and the development of clinical practice guidelines are important elements in supporting the effective prioritisation of health services, the design of health benefit plans, and improving the quality of care. A number of key elements have been identified in supporting the use of such evidence

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[4] OECD Reviews of Health Systems: Mexico. Organisation for Economic Co-operation and Development 2005

based products in actual policy[5]. These include having transparent processes in the development of such products, multi-stakeholder engagement, and clarity over how any recommendations can be taken up into actual policy and implemented in practice.

Any **implementation strategy** (or perhaps strategies) for evidence-informed products such as HTA findings and the guidance offered by clinical guidelines, will necessarily involve multiple elements. This will include for example, having effective mechanisms to **inspect and audit** providers against agreed standards (informed by evidence of clinical and cost-effectiveness as set out in HTAs and clinical guidelines). In that context, development of measurable quality indicators can be one tool to support the translation and implementation of evidence-informed outputs.

With a focus on key priority areas within pathways of care informed by epidemiological data and the views of providers and purchasers in the system, quality indicators generally measure outcomes that reflect the quality of care or more commonly, processes linked by evidence to improved outcomes. They can be used to monitor performance and be linked to rewards or penalties. Critically, the underpinning knowledge base for quality indicators will derive from a number of sources, but key among them will be robustly developed HTAs and in particular, clinical practice guidelines, with the latter also informed by and consistent with, any HTAs (see figure 1).

In brief, good quality indicator development will depend on effective input from and coordination with HTA, clinical guideline, and where appropriate, national formulary development processes and outputs. The design of individual indicators will also be informed by expertise in **routine health information collection** and **data management** to help ensure, for example, that data sources for any proposed indicators are feasible and appropriate. Coordinated action by a number of institutions and organisations within a health system will support the development of a coherent approach for integrating epidemiological and health service data, evidence-informed guidance, policy priorities and quality indicators.

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[5] Glassman A et al. Priority-setting institutions in health: recommendations from a center for global development working group. Glob Heart. 2012 Mar;7(1):13-34. doi: 10.1016

Figure 1: Translation of evidence into policy and practice
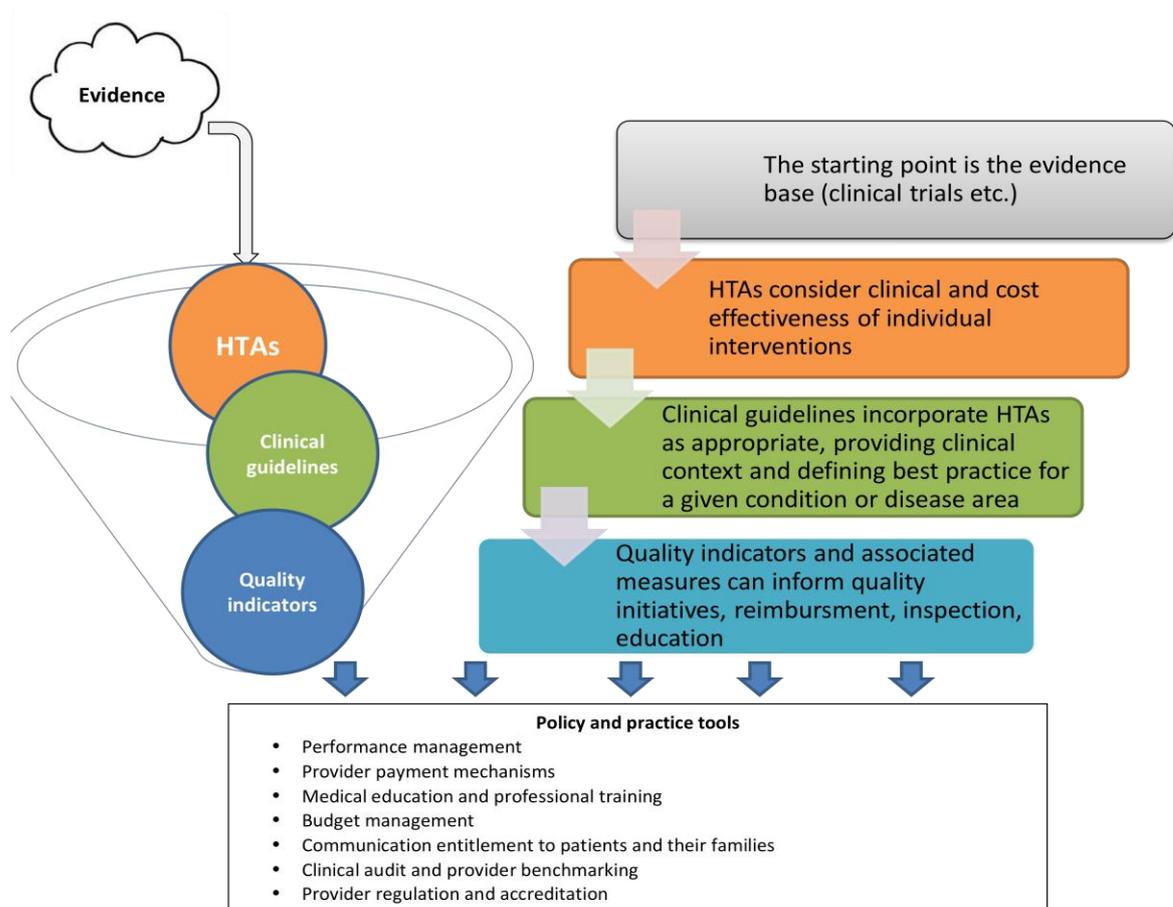
1.4 Overview of the institutions involved in the development and implementation of quality indicators in health care in Mexico

DGCES will work closely with many professional, insurer and other public sector organisations, including those representing patients, service users and carers. Key partners in the national indicator programme include the General Directorate of Health Information (DGIS), the General Directorate of Performance Evaluation (DGED), DGTI, DGE, CSG, Seguro Popular, IMSS, ISSSTE and CENETEC.

In Mexico, CENETEC, an agency of the Ministry of Health, is given the responsibility for the development of HTAs and national clinical practice guidelines for use by decision makers. Through the evidence-based information it provides, it seeks to ultimately "increase the quality and safety of health services" while at the same time improving resource allocation so that better value interventions are prioritised. As part of the development of a national, core set of quality indicators applicable to all institutions in Mexico, the DGCES-led national indicator programme will rely in large part on the evidence provided by CENETEC relating to clinical priority areas established by DGCES.

Additional data and evidence from national and international sources will be used address any gaps, but it is the aim of the indicator programme that CENETEC guidance ultimately provides the key recommendations underpinning the creation of quality indicators. The national indicator program will also interact with the General Health Council (CSG, *Consejo de Salubridad General*) since that body has a key role in establishing the *Cuadro Básico y Catálogo de Insumos del Sector Salud* (CBCISS). The work of the CSG is informed by HTAs and clinical guidelines and further highlights the need for institutional coordination to ensure that indicators are consistent with the underlying evidence base and benefit package design.

The DGIS and DGED will work with the DGCES to develop and test potential new indicators, develop technical specifications and business rules for new indicators. As part of the SINBA initiative (*Sistema Nacional de Información Básica en Materia de Salud; National System of Basic Health Information*) which aims to develop a functional technological framework which supports the convergence of information systems, DGIS is responsible for overseeing the General Health Register (PGS, *Padrón General de Salud*). The PGS represents the first major project to be implemented within SINBA, and seeks to consolidate basic information (including Unique Population Registry Code, name, and date and place of birth) on enrollees in the different health insurance schemes in a single nominal database.

DGCES will work with DGED, IMSS, ISSSTE and *Seguro Popular* to establish priority areas for national indicator development. In addition, they will also be involved in the development and design of the core set, building on their longstanding experience of developing and implementing quality indicators. It is recognized that while these institutions will be implementing the core set of national indicators, and the associated regulatory system, this does not mean that individual institutions should retire their own existing indicators. It is entirely reasonable for other bodies to develop indicators to serve their particular needs. However, this should be done in a manner that minimises duplication and redundancy, and does not in any way undermine the principle of effective and transparent reporting against a single set of core health indicators developed with cross-institutional support.

1.5   Basic definitions in indicator design

1.5.1   The nature of indicators

Quality indicators should be distinguished from guidelines, and from standards and targets (Baker et al[6], Campbell et al[7]).

Guidelines are systematically developed statements designed to help practitioners prospectively to 'do the right thing' in specific clinical circumstances.

Indicators are measurable aspects of performance for which there is evidence or consensus that what is measured can be used to assess quality.

A **target standard** is a level of care set prospectively which stipulates a level of care that providers should meet.

Box 1-1: Distinguishing between guidelines, indicators and standards – an example

> **Guideline**: If a patient's blood pressure is more than 160/90, the blood pressure should be measured again twice within three months.
>
> **Indicator**: The proportion of patients who, following a blood pressure reading of more than 160/90, have their blood pressure measured twice or more in the following three months.
>
> > *The numerator for the indicator is the number of patients with a blood pressure reading of more than 160/90 who have it measured twice or more in the following three months*
> >
> > *The denominator for the indicator is the number of patients with a blood pressure reading of more than 160/90.*
>
> **Target**: 90% of patients who, following a blood pressure reading of more than 160/90, have their blood pressure measured twice or more in the following three months.
>
> *Box: Examples of guidelines, indicators and standards (from Campbell et al 2002)*

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[6] Baker R, Fraser R. Development of review criteria: linking guidelines and assessment of quality. British Medical Journal 1995; 311: 370-373

[7] Campbell et al 2003 Research methods used in developing and applying quality indicators in primary care. BMJ 2003; 326: 816-9.

The example in Box 1-1 shows that indicators are defined very specifically. This indicator might be refined further with inclusion, exclusion and exception criteria (see Section 1.5.3 below).

As discussed in Section 1.1 por encima de, indicators can only *indicate* the 'true' underlying quality of a healthcare system, and will always reflect some random or unobserved variation. Overall, aberrant performance on an indicator should be a **reason to investigate further**, not a summative judgement[8].

1.5.2 Types of indicator

Different types of indicators have different purposes and can provide different insights:

- **Activity indicator**: measures the frequency with which an event occurred, such as blood pressure monitoring.
- **Performance indicator**: statistical devices for monitoring care provided to populations without any necessary inference about quality—for example, cost implications of BP monitoring.
- **Quality indicator**: infer a judgment about the quality of care provided based on evidence e.g. blood pressure monitoring and control for those diagnosed with diabetes.

Indicators of each of these types can also measure different aspects of care. These aspects include the **structure** of health care, actual care given (**process**), or the consequences of the interaction between individuals and a health care system (**outcome**)[9].

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[8] Association of Public Health Observatories and NHS Institute for Innovation and Improvement (2009)
The Good Indicators Guide: Understanding how to use and choose indicators

[9] Campbell SM, Roland M, Buetow S. Defining quality of care. Social Science & Medicine 2000; 51:1611-1625

Table 1: Aspects of care measured by indicators

Excerpted from NICE 2014 Indicators Process Guide[10]

Type	Characteristics	Example
Structure	May relate to the characteristics that enable the system's ability to meet care needs.	The **proportion** of patients who have had an acute stroke who spend 90% or more of their stay on a stroke unit.
Process	May relate to actions or activities that are undertaken.	The **proportion** of hip fracture patients who receive surgery on the day of, or the day after, admission.
Outcome	May relate to changes in health status or quality of life for individuals or populations, but may also relate to wider outcomes such as satisfaction or experience of people using services, changes in knowledge and changes in behaviour.	**Mortality rates** in the 12 months following admission to hospital for heart failure.

Examples of each of these aspects of care are given in Table 1 above. It is important for bodies developing indicators to distinguish clearly between the aspects of care being measured, and understand how they interact:

- Structure is the conduit through which care is delivered and received.
- Outcome is not a component of care but a consequence of care.

At the level of a *primary care facility*, process measures are often better indicators of quality of care if the purpose of measurement is to influence the behaviour of those providing care: processes are common, under the control of health professionals, and may be altered more rapidly. Outcome indicators can cover a range of different types of outcome. Changes in health status (including mortality or morbidity) or quality of life are the **'highest-level' outcome** which have the most direct relevance to the

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[10] National Institute for Health and Care Excellence (NICE), 2014. Indicators Process Guide

(see: http://www.nice.org.uk/media/default/Standards-and-indicators/CCG-OIS/Indicators-process-guide-2014.pdf)

ultimate goals of health system reform, but can be influenced by a range of outcomes outside the control of the healthcare services being assessed, such as patients' socio-economic mix[11]. For this reason, indicator sets often include **shorter-term outcomes** - such as healthcare-acquired infections, or emergency readmissions after hospital discharge – and **intermediate outcome** measures such as blood pressure or glucose level improvements/declines.

1.5.3   Specification of each indicator

Indicators are usually specified in the form of a **numerator** and a **denominator** describing the populations to be included in the indicator, which define a proportion (numerator/denominator) reported.

Indicators should also specify a description of **inclusions, exclusions and exceptions** from these populations. This is most effectively done through business rules for electronic records (see section 4.5.6 below), although it has been possible in schemes such as the US' Healthcare Effectiveness Data and Information Set (HEDIS) to draw data from paper-based records.

Table 2: Describing inclusions, exclusions and exceptions

Inclusions, exclusions and exceptions
• **Inclusions and exclusions** form part of the definition of populations to be included in the indicator.
• **Exceptions**[12] refer to patients who are on the disease register and who would ordinarily be included in the indicator denominator, but are removed from the denominator because they meet at least one of the exception criteria specified (e.g. terminally ill). The purpose of allowing exceptions is to avoid penalising practices for patient-specific clinical circumstances: patients excepted from the indicator calculation should receive an equal quality of care to those who are included. The overriding principle is that <u>blanket</u> exception reporting is not acceptable (for example, of all patients with a particular comorbidity) and individual decisions based on clinical judgment should be made. There is no 'ideal' level of exception reporting, although healthcare facilities with levels significantly outside the national averages may have this investigated[13].

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[11] Iezzoni L. Risk adjustment for performance measurement. In: Smith P, Mossialos E, Papanicolas I, Leatherman S (editors). Performance Measurement for Health System Improvement: Experiences, Challenges and Prospects. 2009. New York: Cambridge University Press

[12] See also 'Section 5: Exception reporting', in NHS Employers, Guidance for GMS contract 2015/16

[13] NICE, 2014. Indicators Process Guide

2 Developing a national core set of quality indicators in health care: overview

> **Chapter objectives:**
>
> - State the key principles for the national core quality indicator programme operated by DGCES
> - Describe the essential components and analyses to be conducted for each indicator in the core set
>
> ***Key terms and concepts:***
>
> | | Application in this manual |
> |---|---|
> | Budget/Cost impact analysis | *Estimate of the costs of implementing the changes required to achieve levels of quality as set out in the indicators* |
> | Cost-effectiveness analysis | *Assessment of whether the change in healthcare activity in order to comply with an indicator is good 'value for money'* |
> | Monetised benefits | *Value of the health improvements (calculated according to valuation of QALYs gained/DALYs averted) associated with achieving target levels for the indicator* |
> | Sensitivity analysis | *Estimate of the effect of uncertainty, or alternative modelling assumptions, upon the economic impact of a quality indicator* |

2.1 Key principles

DGCES' national indicator programme follows a number of high level strategic principles. These include using:

- A comprehensive evidence base
- Independence in the process of developing indicators (including independent advisory committees)
- Input from experts, patients, service users and carers
- Transparent processes and decision-making
- Public consultation
- Effective dissemination and implementation

- Regular review.

For the assessment of performance to be credible and acceptable, indicators selected should follow the general operating principles below:

- Based on **best available evidence** (ideally, evidence-based national guidance from CENETEC, and associated syntheses by DGCES of CENETEC's recommendations);
- Number of **indicators kept to the minimum** for each clinical condition, compatible with an accurate assessment of patient care;
- Data collected from practitioners should be **useful in patient care and minimally burdensome to collect**, never collected purely for audit purposes, and never collected twice (i.e. use routine patient data from electronic medical records where possible);
- The indicators selected should cover **all relevant aspects of quality** ('domains') as defined by the decision-maker.

2.2   Components of a quality indicator

The essential components of a quality indicator are those detailed in Section 1.5.3 above:

- **denominator**, describing the target population included in an indicator
- **numerator**, describing the number of people in the denominator who have the specified intervention, treatment or outcome
- description of **the inclusions, exclusions and exceptions**.

Developing the indicator will generally include defining:
- a short and long indicator title
- a detailed overview of the indicator, which includes:
    - a description of the purpose of the indicator
    - the reasoning for the indicator
    - reporting mechanisms
    - links to further information
- a cost-effectiveness and cost–impact analysis[14] (see below).

2.3   Incorporating financial incentives

It is intended that some indicators will be developed in the future to determine the quality of care <u>and</u> be linked with a financial incentive to a provider. Such indicators would need to be designed with care since there is a greater risk of unintended consequences (see also sections 5.4 and 6.2 debajo de). As with the indicator scheme

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[14] NICE 2014. Indicators Process Guide

in general, the provider and payment organisations are stakeholders in the process of creating financial incentives.

When considering a financial incentive, the basic questions determining how suitable a topic is for quality indicators (see also section 4.5.4 debajo de) are of even greater importance to answer in detail[15]. If the care recommended in an indicator is not adequately supported by evidence and local data, adding a pay-for-performance element only risks embedding errors and inconsistencies. When indicators are used as the basis for quality payments, there also needs to be a consideration of the cost-effectiveness (see below and section 4.6) of any attached quality payment. Note that this can be regarded as a separate exercise to any assessment of value for money (if available) that takes place when developing a clinical guideline recommendation or a relevant health technology assessment, where these represent the underpinning evidence to an indicator.

If a financial incentive is removed from use, the achievement of health facilities against the quality indicator should continue to be recorded, in order to monitor any possible drop in performance[16] (see Section 6.2 debajo de for more general recommendations on complete retirement of a quality indicator).

2.4 Economic impact of proposed indicators

In routine use, health economic analysis does not realistically need to be undertaken for all new potential new quality indicators. It can be assumed, if the process in chapter 4 (section 4.1 and 4.5 debajo de) is followed, that the interventions and activities recommended within the quality indicators are themselves cost-effective. However, the following factors suggest an assessment of economic impact is likely to add valuable new information[17]:

- The **costs and benefits of meeting the indicator target** are likely to be measurable
  - *Measurable indicator topics include:* diagnosis rates; patient experience scores

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[15] Lester, H and Campbell, S. (2010). Developing Quality and Outcomes Framework (QOF) indicators and the concept of 'QOFability'. *Quality in Primary Care* 2010;**18**:103–9

[16] Guthrie, B and Morales, D. (2014). What happens when pay for performance stops? *British Medical Journal*–Editorials **348**: g1413

Benzer, J. et al. (2014). Sustainability of quality improvement following removal of pay-for-performance incentives. *Journal of General Internal Medicine 29*(1): **127**-32 doi:10.1007/s11606-013-2572-4

[17] NICE (2014) Internal Draft document: Cost-effectiveness methodology

- - *Less measurable indicator topics include:* inclusion of patients on national registers
- Sufficient **data on costs** (**and benefits**, for cost-effectiveness analysis) can be sourced to support an economic analysis (*although see also section 4.6.2.2 on adapting to inadequate data*)
- The quality indicator is sufficiently **different to other indicators** that an existing economic analysis cannot be used.

2.4.1 Budget (or Cost) impact analysis

A proposed indicator (or set of indicators) may be accompanied by a budget impact analysis (BIA). This can be conducted directly by the organization creating the indicator set or a commissioned third-party (within the Ministry of Health/public sector, or a qualified external body such as an academic unit).

A BIA estimates the **costs of implementing the changes** required for achieving levels of quality as set out in the indicators at the national and sub-national (including local) levels. This analysis highlights potential savings if health facilities were to meet the target standard indicator, as well as areas where investment is needed upfront.

The overall aim is to assist planning and implementation, by policymakers as well as local hospital managers. The analysis would be available to both of these groups. Although the national BIA might not use evidence from each individual facility or district implementing the quality indicator, in order to plan sub-nationally, managers or commissioners can input local data a similar template to that used for the national core indicator set.

For further details on conducting a budget impact analysis, refer to Section 4.6.1 debajo de.

2.4.2 Cost-effectiveness analysis

Cost-effectiveness analysis assesses **whether something is good value for the amount of money invested**[18]. It compares the relative costs and outcomes (effects) of an intervention – in this case, the implementation of a proposed quality indicator (it can also be used in the evaluation of a set of indicators). It seeks to identify tangible benefits that could be produced when an indicator has an attached quality payment, in an *ex ante* analysis.

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[18] Campbell, S. M., Godman, B., Diogene, E., Fürst, J., Gustafsson, L. L., & Macbride-Stewart, S. (2014). Quality indicators as a tool in improving the introduction of new medicines. *Basic & Clinical Pharmacology & Toxicology , Jul 22. doi: 10.1111/bcpt.12295*.

As with BIA, appropriate sensitivity analyses should be undertaken. In addition, cost-effectiveness analysis can be applied when estimating the value of money of an indicator or set of indicators once implemented, if further evidence becomes available of 'actual' incremental costs and incremental benefits.

Cost effectiveness considers whether the costs associated with an indicator are outweighed by the benefits accrued by the health service. The cost-effectiveness of an indicator or a set of indicators is not the same as their budget impact, and as illustrated in Table 3, the two methodologies are slightly different. However, judgments of relative cost-effectiveness should reflect the appropriate budget constraint as captured by an appropriately set 'threshold' (see Section 4.6). It has been argued that such a threshold should be based on the benefits foregone associated with choosing between alternative priorities – in other words, the opportunity cost.[19]

Further details on cost-effectiveness analysis are in Section 4.6.2 debajo de. This discussion demonstrates that although BIA and CEA use some of the same data, and should be complementary, the objectives and focus of each is distinct.

Table 3: Distinguishing BIA from CEA

	Budget (cost) impact analysis	**Cost-effectiveness analysis**
Purpose	Assessing the costs of implementing the changes required for an indicator, to assist planning	Supporting a decision on whether an indicator represents good value for money
Type of costs used	Unit costs *(amounts paid by commissioners for activities and interventions in the health system)*	Reference costs *(overall economic costs to the health system of delivering the changes recommended)*
Typical time period reflected	Budget planning/allocation cycle	Medium to long term
Includes data on:		
(Monetised) health benefits	*N*	*Y*
Cost of incentive payments for meeting indicator standards (if applicable)	*N*	*Y*
Costs saved for the health system as a	*N*	*Y*

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[19] See: http://www.idsihealth.org/knowledge_base/cost-effectiveness-thresholds/

result of preventing illness		

2.4.3   Addressing uncertainty and gaps in data

Where there is significant uncertainty about the baseline position and impact of implementation or there is the potential to mislead people regarding the cost of implementation, it may be appropriate to highlight the issues but not to quantify the impact. Evidence on recommendations which cannot be quantified, but are considered likely by the technical teams to have an impact on costs or savings, should be presented to the Working Groups responsible for developing the indicators.

Even when there is sufficient data to make an estimate, there will always be uncertainty about the intervention's effect on health care over time. Each cost-impact estimate should be subject to **sensitivity analysis**, whereby inputs into the model are varied over plausible ranges. The plausible minimum and maximum values of each variable should be captured when collecting data[20]. One-way sensitivity analysis then shows how much (in absolute or percentage terms) the overall estimate varies when each of the inputs is allowed to fluctuate. In a mature indicator system, for those inputs which significantly affect the BIA/CEA result, local managers and commissioners should investigate whether their facility or region has sufficiently different values to require a secondary local analysis.

Sensitivity analysis may also be used to examine the impact of alternative modelling assumptions – for example, activity being undertaken as an outpatient rather than a day case.

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[20] NICE (2015) Draft: Assessing resource impact methods guide

3   Who is involved in developing the national core set of indicators?

Chapter objectives:

- Expand on the need for inter-institutional collaboration in indicator development
- Describe the roles and responsibilities of key stakeholder groups in the indicator development process
- Outline the skills needed by the secretariat

Key terms and concepts:

	Application in this manual
Declaration of interest	*Formal registration, by each individuals participating in indicator development, of any commercial or financial interests that might affect their objectivity*
Secretariat	*The team responsible for organising policy, clinical, technical and administrative inputs for development of the national core set of indicators*

3.1   Indicator development: A participatory, multi-disciplinary exercise

Several groups contribute to developing an indicator or indicator set, each with distinct areas of responsibility. Altogether these groups combine the inclusive participation of policy, clinical, technical and administrative inputs that the indicator scheme needs. Table 4 lists the different groups, their responsibilities, and how they interact.

Table 4: Groups involved in developing quality indicators, and core responsibilities

Group and composition	Responsibilities
Strategic Working Group, a decision-making committee convened by a policymaking/regulatory/payer body (such as the Ministry of Health, other relevant authorities/independent agencies including IMSS, ISSSTE).	• Determine priority conditions for indicator development • Oversee and direct work of the Technical Working Groups • Approve or ratify the indicators developed by TWG • Oversee and regulate implementation of the indicators

Technical Working Groups to develop the indicators in specified topic areas, led by a **Chair** and comprising topic experts (doctors, nurses, and clinicians from allied health professions), pharmacists, hospital managers, as well as a Technical Support Team (see below).	• Identify relevant source clinical guidance for the indicators • Discuss and select clinical recommendations to be included • Draft indicators and present to the Strategic Working Group • Lead consultation process and respond to consultation comments • Define data extraction rules and requirements from all health institutions, for each indicator agreed
Technical Support Teams in DGCES (and potentially with staff from DGIS, DGED, UAE and CENETEC) produces technical background and analysis to the Technical Working Groups. They may include specialists in: epidemiology, public health, evidence-based medicine, health economics, accountancy, clinical audit, implementation; alongside project managers and administrative staff	• Provide technical and administrative support to the Working Groups • Undertake epidemiological and routine data analysis, present results to the wider Strategic/Technical Working Groups • Assess quality of clinical guidance for indicators • Prepare meetings and documents for the Working Group • Undertake budget impact analysis/impact assessments. • Oversee piloting/testing of the indicators within the health information systems of each institution, to ensure data is reported accurately and consistently
Broader interested parties who may offer their input through consultation (but do not sit on committees or working groups). These can include healthcare professionals, patient groups, and other members from civil society.	• Review the indicators agreed by the Working Groups • Endorse and disseminate the indicators (for example, through events or publications by professional organisations)

The relationship between the various groups involved is illustrated in Figure 2[21]. Overall, any model for development of indicators and related tools requires a **close**

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[21] This is only one possible model for development of evidence-to-practice tools, adapted from successful approaches NICE International has supported in various settings.

working relationship between the decision-makers at policy level, and a **well-resourced advisory team** with the relevant technical and administrative expertise.

Establish the process, identify issues, convene Technical Working Groups

Final policy decision made to approve and publish indicators

Strategic Working Group

Assist in identifying recommendations from source documents, undertake routine analysis and support Technical Working Groups

Technical Support Team

Technical Working Groups

Agree quality indicators and data requirements

Draft Quality Indicators

Figure 2: Links between the different groups involved in indicator development

3.2   Strategic Working Group

Implementing quality improvement initiatives, including the core indicator set, has implications for the providers in Mexico responsible for planning and financing healthcare services, and the role of the *Secretaría de Salud* setting regulatory mechanisms.

The Government of Mexico will establish a dedicated ongoing mechanism to set high-level priority topic areas and direct the work of technical groups. This direction will include approving the published indicators, oversee their implementation, and measure performance.

3.3   Technical Working Groups

The Technical Working Groups will review and develop 'core' indicators for selected priority conditions, aligned with clinical practice guidelines where possible. Each group will have some members who are recruited for a specific clinical topic or indicator.

3.4   Technical Support Team

The Technical Support Team will prepare and present technical briefings that will inform the Working Groups in their decisions throughout development of indicators. The Technical Support Team is considered to be a supporting part of the Technical

Working Group and should be involved in all Working Group meetings and discussions. The team should work to job descriptions specifying their responsibilities and tasks as outlined in Table 4, and any associated Terms of Reference (TOR). Participation in the Working Groups and the Technical Support Team should also include a formal declaration of interests (See section 4.4.1)

This team would ideally include a range of technical skillsets such as:

- evidence-based medicine, including clinical guideline appraisal, development or adaptation

- health economics, including cost-effectiveness analysis and budget impact analysis

- clinical audit

- quality improvement and implementation

- impact evaluation

- administrative skills, including project management and logistical support.

4 Process for developing and approving quality indicators in health care

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Chapter objectives:

- State the key process steps involved when developing the core set of national indicators
- Outline the key methods to be applied at each step

Key terms and concepts:

	Application in this manual
Business rules	*Algorithms stating the denominator and numerator for each indicator, and data extraction requirements*
Prioritisation	*Assessment of potential indicators or topics against a standard set of criteria, to determine how far they meet strategic goals*
Threshold for cost effectiveness	*The point (or range) at which a health care activity or a quality indicator is considered as representing good 'value for money'*

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This section of the manual focusses on the detailed processes and methods for developing the core set of national indicators to ensure quality and consistency. This includes the clinical and economic evidence that underpin the recommendations, as well as processes for decision making.

Having a standardised and transparent process and methodology is important for two reasons: firstly, it enables multiple or successive technical support teams to work to a common and consistent framework. Secondly, it facilitates appropriate engagement from stakeholders. It will indicate clearly the opportunities for stakeholders to be involved and the timetable to be followed by all parties, and should be adhered to by all parties.

4.1 Overview

Developing and approving a set of indicators requires a number of distinct but interlinked activities with various parties involved. It can be thought of as an iterative process, particularly for the Technical Working Group which will engage in a number of meetings to agree on major decisions about the topic(s) and indicators, with technical and administrative work being carried out in the background between

meetings by the Technical Support Team. Throughout the process, the Technical Support Team will be working closely with key members of the Working Group (particularly its Chair). Figure 3 shows an overview of the whole process. Timelines may vary but should not usually take longer than 6-12 months.

The development of indicators and other quality improvement tools is also iterative in the sense that it begins with the broad context of the entire health system and all possible health conditions that could be covered; through topic selection to focus on one clinical topic, which then gets defined further into various clinical areas, each of which will have been covered by various relevant clinical guidelines with various recommendations, which will have to be further sifted, and so on. At each iteration, there is a process of prioritisation and deliberation. All this ideally results in an end product containing granular and focused quality indicators and measures, which will be implementable in clinical practice.

Figure 3: Process for developing and approving indicators in the core set

CEA – Cost-effectiveness analysis
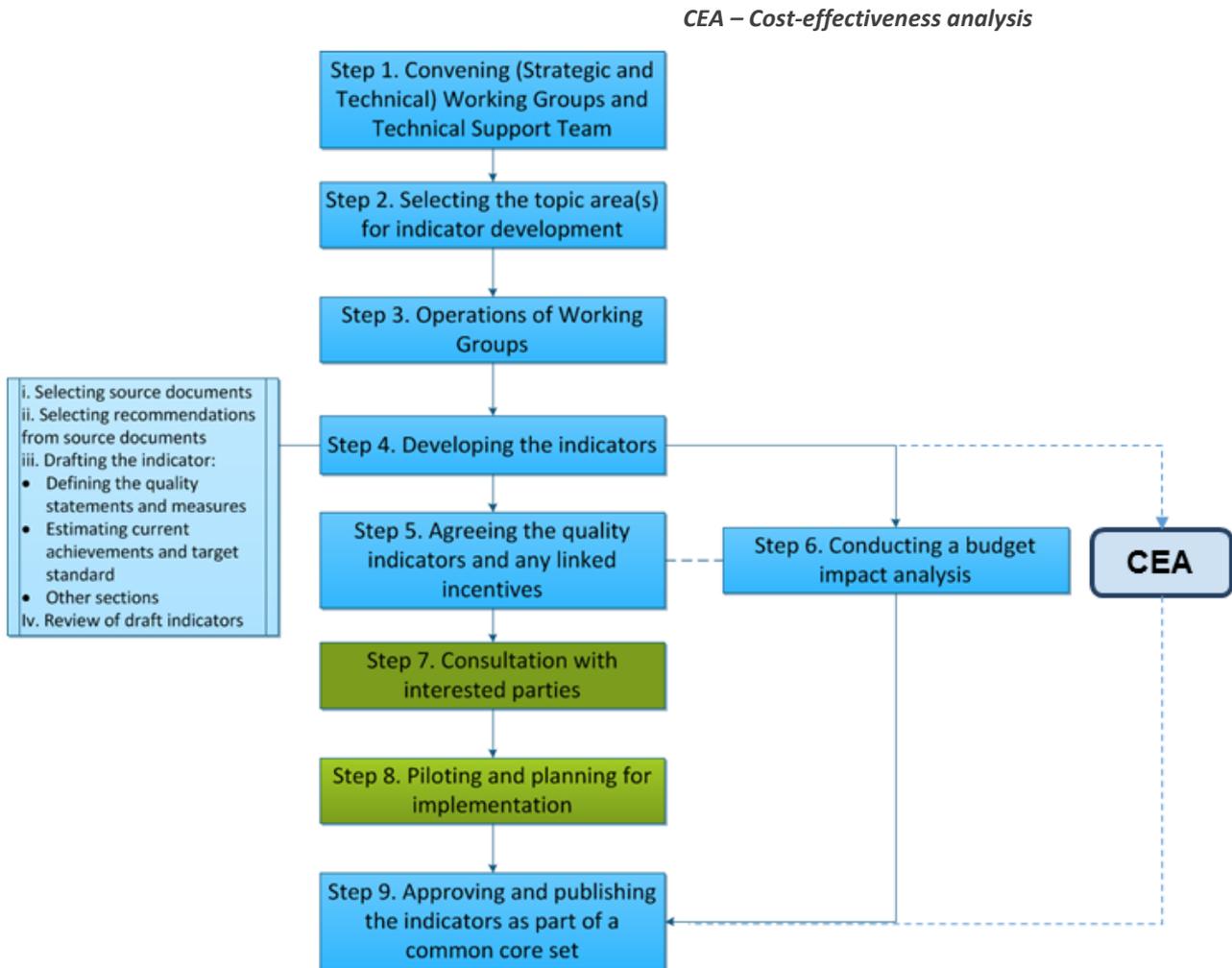
4.2 Convening Working Groups and Technical Support Team (Step 1)

DGCES, as leading body for the indicator programme, will convene the inter-agency Working Groups and the Technical Support Teams. As detailed in chapter 3 above, the Strategic Working Group will agree the process and methods, select the topic area for indicator development, approve the indicator sets, oversee and drive implementation.

A Technical Support Team should also be recruited on advice from the Strategic Working Group, to begin conducting the early technical and administrative work towards QI topic selection (see section 3.4 por encima de).

In addition to agreement on procedural matters (see Step 4), it is important for the Working Groups to agree a common statement of principles. This would be a generally applicable statement summarizing the high-level guiding values behind the indicator scheme. Such statements (a sample version in Appendix A) are useful both during the

early stages of a common core set, and in more mature schemes when new personnel are recruited and require familiarization with the principles.

4.3   Selecting the topic area(s) for indicator development (Step 2)

The topics for indicator development will be determined by a transparent process led by the Mexican government. Throughout the various steps of indicator development, prioritisation is important in order to maximise impact of the final set (See Figure 4) This may mean focusing on particular areas with evidence of or consensus on:

- high burden of disease

- high budget impact and associated problems of cost containment/cost escalation for payers; or high out-of-pocket payments and associated impoverishment for patients

- current poor quality, ineffective or highly variable care, particularly with regards to patient safety, clinical effectiveness, and patient experience

- significant regional variations in clinical practice, access to services, or health outcomes (especially in aspects of care that are not widely provided or not considered to be standard practice, but that are feasible)

- other social and ethical value considerations, for example favouring particular disadvantaged or marginalised population groups

- likelihood that changes to practice will be implementable and that quality improvement will be achievable.

Figure 4: Multiple sub-stages involved in prioritising topics for indicator development, following the principles of efficiency, effectiveness, and equity

Selecting broad topic area(s)	• Disease burden, budget impact, current quality of care, equity/ethical considerations
Defining the scope	• Relevance (to decision-making body), resources available for indicator development
Selecting source documents	• Relevance (to scope), methodological rigour
Identifying relevant recommendations	• Relevance (to scope), feasibility (of measurement), clinical/cost-effectiveness, impact on patient safety, budget impact, current quality of care, equity/ethical considerations
Prioritising recommendations to develop into indicators	• Feasibility (of implementation), clinical/cost-effectiveness, impact on patient safety, budget impact, current quality of care, equity/ethical considerations

The range and types of indicators used can be structured to reflect the strategic objectives of the decision-makers responsible for stewardship of the health system (for example, as in the Quality Management Model of DGCES). The processes and methods for developing indicators are in general the same across all conditions and clinical events. However, there are specific considerations relating to the disease path and treatment of chronic NCDs including diabetes, which the parties developing indicators should consider. Diabetes is often referred to as a 'tracer condition' for assessing health system performance as health outcomes are dependent on well-organised care spanning primary care (general practitioners/family doctors), specialist medical care, and paramedical services such as dietitians[22]. The indicators developed

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[22] McKee M, Nolte E. Chronic care. *In:* Smith P, Mossialos E, Papanicolas I, Leatherman S (editors). Performance Measurement for Health System Improvement: Experiences, Challenges and Prospects. 2009. New York: Cambridge University Press

will therefore ideally cover each of these levels of the health system and include prevention, treatment and management aspects of care.

Longitudinal information is essential, to track the disease course and the processes of care delivered, to assess the performance and quality of health services. Due to the expected lengthy disease course, particularly for NCDs, intermediate outcome indicators are likely to be more valuable than final outcomes, although rates of blindness or amputation among people with diabetes have been identified as an indicator of performance failings (although the source of these failings may not be specifically traceable)[23].

4.3.1 Data sources to inform high level topic selection

Local data and experience from experts should guide the topic selection process when possible, including reference to country-specific epidemiological studies including household surveys. Basic local epidemiological data (trends in mortality and morbidity) and other outcomes should be utilised, as well as routine data from regular reporting systems, audit and reviews collected by Ministry of Health authorities or health insurance bodies, hospitals, NGOs or other appropriate organisations in the country.

Data may also originate from global reports on major burden of disease from international agencies, for example WHO, World Bank, Organisation for Economic Co-operation and Development (OECD) reports, and the Disease Control Priorities project.

The Technical Support Team will collect and analyse the data, and summarise them in briefing papers that will be presented to the SWG for discussion. This can be conducted through a meeting or workshop to identify one or two key priority areas which are likely to meet the prioritisation criteria listed above.

4.3.2 Defining the scope of the indicator

As part of the topic selection process, it may be useful for the SWG (with support from the Technical Support Team) to draft and agree on a scope for the intended indicators. The scope will provide a direction on what the indicator, or indicators, will and will not cover specifically within the broad area of the selected clinical topic. This will provide clear guidance to the Technical Working Group in drafting the indicator, and ensure that the end product will be focused and fit-for-purpose for the specific needs of the

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[23] Armesto S, Labetra M, Wei L, Kelley E. *Health care quality indicators project*. 2006 data collection update report. 2007. Paris: OECD

Mexican health system. The scope can also include already existing indicators that are subject to review.

For example, if diabetes care is identified by the SWG as a priority clinical topic for indicator development, there will need to be decisions on whether the initial scope will be limited to hospital-based care for acute exacerbations or also include primary care services; and also whether prevention, routine management and treatment after exacerbation will both be covered.

A formal, well-defined scope will help to set clear expectations around the size of the work, reduce the likelihood of disagreements during indicator development, minimise the technical work required to search and manage irrelevant source documents and recommendations, and ensure that the indicators are sufficiently valid and feasible, and developed within the given time and resources.

4.4   Operations of Strategic and Technical Working Groups (Step 3)

The Strategic and Technical Working Groups will have long-term membership comprising a Chair and technically competent representatives from agreed institutions. These may be indefinite or fixed-term appointments. The TWGs will also include temporary members who have expertise on the clinical topic (whether by clinical, technical or policy experience on a day-to-day basis). All of these members should be recruited by the *Secretaría de Salud*, to develop the initial core indicators within each priority area.

The Working Groups will have standing orders appropriate to health sector governance bodies in Mexico[24], including standard provisions on matters such as:

- Eligibility for membership
- Quorum
- Decision-making process (e.g.: consensus or voting?)
- Confidentiality of meeting content
- Provisions for external observers and members of the public

4.4.1   Declaration of interests

All Working Group members should declare any interests they may have in becoming involved in the indicator development work, including funding from, employment in

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[24] As an example, the Terms of Reference and Standing Orders for NICE's Indicator Advisory Committee are available at: https://www.nice.org.uk/media/default/Get-involved/Meetings-In-Public/indicator-advisory-committee/ioc-standing-orders-and-terms-of-reference.pdf (November 2014)

or ownership of shares in the healthcare industry (including pharma companies, private healthcare providers and insurers). An open, universally applied declaration of interests helps to avoid public concern that links with the healthcare industry or other relevant interests might unduly influence the indicator sets[25]. The private healthcare industry plays an important role in many countries, including Mexico, and are hoped to be an end user of the indicator set *in the future*. It also enables the owners of the indicator set to source expertise from a range of individuals across the health sector, whilst managing any conflicts that arise as a result.

Declaring an interest will not necessarily preclude someone from being a Working Group member, but the person might be asked to leave the room during certain parts of a meeting where a significant conflict of interest exists. If a person's interest is so significant that it could affect their objectivity throughout the development of an indicator, it is unlikely that person would be invited to join the group. An example of a declaration of interest form can be found in Appendix B.

4.4.2   *Evidence to be provided by Technical Support Team*

The Technical Support Team (see Table 4 for full responsibilities) will be the primary source of evidence throughout the indicator development process, as synthesized from literature and national data sources.

Table 5: Typical evidence to be used when developing indicators

Document / evidence	Content
Initial briefing papers for priority health conditions	• Short overview of clinical features • Prevalence in Mexico and estimates of health service use (if known) • Estimates of resource impact (if known) • Existing indicators or guidance in Mexico • Discussion points: assessment of how feasible quality indicators would be (*with reference to core principles for quality indicator schemes, for example Section 2.1 por encima de*) • Clinical data system requirements to use a quality indicator

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[25] A useful discussion of more detailed issues behind declaring interests, including a sample decision process for managing declarations and conflicts of interest, is available from WHO.

'Declaration and management of interests'. In: World Health Organization. Handbook for guideline development. 2014. Geneva: WHO. See: http://www.who.int/kms/guidelines_review_committee/en/

Synthesis of **existing relevant recommendations**	*See Section 4.5.2 for details.*
Prospective impact assessment (including economic analysis, if possible) of proposed indicators	*See Section 2.4.1 (cost impact analysis) or 4.6 (economic analysis) for details.*
Reports from piloting and routine audit	*See Section 5.4 for details.*

An important area for the organisations responsible for creating the core indicator set to consider and communicate is the likely impact on implementation. This is the overall requirements in the health sector in order to successfully meet the indicator's target standard. A significant component of this assessment will be the budget impact analysis (Section 2.4.1 above), but the owners of the core indicator set should be aware of broader planning requirements in order to communicate effectively with health facility managers and other stakeholders. These include (a non-exhaustive list in Table 6) the time required to prepare for implementation, and links to stakeholders outside the health facilities themselves, such as training centres and professional unions.

Table 6: Potential drivers for impact on the health sector

Type of impact	Examples
Finance	• Initial costs of offering a new treatment, including dealing with any backlog of patient • Recurrent (e.g. annual) costs
Workforce	• Additional requirements for a particular specialism or cadre of health workers: for example, palliative care nurses
Infrastructure	• Information technology systems • Physical facilities • Equipment
Training and education	• One-off or routine training, for example, in a new procedure • Updates to the medical education syllabus

4.5   Developing the indicators (Step 4)

This will take place in several stages, requiring regular input from the Technical Working Groups, checking with expert interested parties, and input from the Strategic

Working Group for approval of the final product. The Technical Support Team will assist with managing the meeting and preparing briefings/papers for the group.

Quality indicators have been developed in a variety of different ways. One is for people to sit down around a table and come up with suggestions, usually based on readily available information. This approach has the advantages of simplicity but the disadvantage that the indicators may not be valid measures of quality. For example, in the UK Primary Care Trusts (and their predecessors) often focused on rates of hospital referral as measures of quality, when there is limited evidence to suggest a **consistent** relationship between rates of referral and quality of care.

A second approach is to base indicators on published evidence of effectiveness from randomised controlled trials – 'evidence based' quality indicators. It is important to understand what lies behind this notion. The evidence-based approach has the advantage of producing rigorous and scientifically acceptable indicators but may focus on a very limited part of primary care. Much of what is regarded as good quality care in primary and community-based care does not have (and probably never will have) experimental evidence to support it. Second, general practitioners (primary care physicians) often question the applicability to individual patients of evidence derived from scientific trials on selected populations – maybe not even including patients seen in primary care.

Different types of evidence can be used in constructing indicators, and there are formal ways of combining evidence with professional consensus, including consensus conferences and Delphi techniques[26]. These may start from existing clinical guidelines, which are usually based partly on evidence and partly on informal professional consensus.

One formal method of combining evidence with professional opinion is the RAND/UCLA appropriateness method[27], which has been extensively used in the US and increasingly in the UK. In this method, a panel is presented with a summary of evidence on the subject, and asked to score a large number of candidate indicators, usually in terms of whether they are valid measures of quality, whether they are clear, and whether it is feasible to collect the data. Scores are fed back to panel members so that they can see what their own scores were, and also what the average score for the whole group was on each indicator. Panel members then rescore the indicators (some

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[26] Campbell et al 2003 Research methods used in developing and applying quality indicators in primary care. BMJ 2003; 326: 816-9.

[27] Brook RH, Chassin MR, Fink A, Solomon DH, Kosekoff J, Park RE,. A method for the detailed assessment of the appropriateness of medical technologies. International Journal of Technology Assessment in Health Care 1986; 2: 53-63

of which may have been modified to make them clearer). This is best done following a face to face discussion, but can be done by post or online communication.

4.5.1 Selecting source documents

Relevant evidence-based clinical guidelines form the basis from which to build the indicator. These may be internationally produced clinical guidelines including those from reputable national guidelines' programmes, professional societies or national government programmes. For international guidelines, there are dedicated guidelines databases such as the US National Guidelines Clearinghouse (http://www.guideline.gov/).

In the case of Mexican national indicator programme, a key source of evidence-based clinical guidelines will be those developed by CENETEC. Up-to-date CENETEC guidelines should be the starting point in any search for relevant evidence, although it needs to be recognised that CENETEC guidelines may not currently cover all priority areas of interest to indicator developers, or highlight key guideline recommendations that may serve as the basis of developing indicators. In those circumstances it may necessary to consider other clinical guidelines including those developed outside of Mexico. A key challenge when considering non-Mexican sources of evidence is its relevance to the Mexican context. Over time, through greater inter-institutional collaboration, it is expected that there will be better coordination between topic priority setting, guideline development and indicator creation. Nevertheless it may never be possible to completely remove the need to consider guidelines and other evidence from a variety of sources. All sources of evidence should be subject to quality assessment. **CENETEC guidelines should therefore be the starting point in any search for relevant evidence.**

A key principle of evidence-to-practice tools is that the quality indicator statements should be based on evidence-informed recommendations. The relevant guidelines or other guidance identified should comply with internationally recognised criteria for methodological rigour (for example the AGREE II criteria, http://www.agreetrust.org) to ensure that they are of sufficient quality and have addressed issues of applicability. It is preferable to use a **limited number of guidelines** to limit the burden of work and focus only on the documents that are most relevant to local practice.

Note that in the UK, NICE Quality Standards, and any derived quality indicators are largely based on clinical guideline recommendations that were (generally, though not always) made on the basis of cost-effectiveness in the NHS setting (NICE 2014a). Where UK or indeed international guidelines are adapted for use in other jurisdictions, cost-effectiveness cannot always be assumed as costs and resource use will vary across country settings.

4.5.2   Identifying relevant recommendations from source documents

Not all recommendations in the selected guidelines are relevant for developing the indicators. This depends on the breadth of the guidance and how much of the pathway of care they cover. For example, if the SWG has decided that the scope of the indicators should be restricted to the diagnosis of patients with suspected stroke in a hospital emergency department, then guidance on palliative care for stroke, or prevention of stroke in primary care will not be relevant.

The searching, assessment and sifting of guidelines, and the identification of relevant recommendations should be carried out by the Technical Support Team, with advice from the rest of the Working Group. DGCES is also developing algorithms with experts which synthesise the key recommendations of CENETEC guidelines, which will save time of these groups in reviewing the guidelines. A set of algorithms have already been developed and are being implemented on the topics of diabetes, heart attack, and depression. In the coming months algorithms will be developed in the areas of hypertension, leukaemia, overweight and obese children and adults. By the end of 2017, these will be further supplemented by algorithms on the topics of breast cancer, cervico-uterine cancer, and the prevention of maternal deaths during pregnancy.

There is no standard process for selecting recommendations, but again the overarching criteria for prioritising high impact recommendations, listed above can be used as a guide. It is advisable for the Technical Support Team to document the rationale and evidence sources for considering particular recommendations, and to present these to the Working Group and inform the prioritisation process.

4.5.3   Prioritising recommendations

Once the Technical Support Team has identified clinical recommendations that are relevant for the scope of the indicators, the relevant TWG will need to select a subset of recommendations which are suitable for developing as indicator. The prioritisation process should be based on broadly similar principles as before (see section 4.3), i.e. focusing on the recommendations that would have the most impact on area of poor current care or high variation, but also importantly considering practical implementation and feasibility issues, including feasibility of measuring the structure and process.

During the Working Group meeting, the Technical Support Team may present the relevant clinical recommendations, from various source documents, that span the various key clinical areas defined by the scope (for example, ranging diagnosis of acute stroke, acute management, early rehabilitation, to overall service organisation issues). The Working Group will then discuss these recommendations, with the objective of reaching a consensus on a shortlist of clinical recommendations that will be taken forward for development into indicators.

There are various possible models for consensus building, which may be employed flexibility depending on the circumstances, including the size, personal and cultural dynamics of the Working Group. Breakout sessions may work well for larger Working Groups in providing more opportunities for individual group members to contribute to the wider discussion.

4.5.4   Drafting the quality indicators based on recommendations

Drafting indicators will first require a judgement by the TWG on which recommendations within the guidelines represent genuinely high-quality care, and which have potential to be developed into indicators. These selected recommendations will therefore cover areas where quality can be improved, and where quality indicators could be used to support quality improvement initiatives.

Ahead of the TWG meeting, the Technical Support Team may start drafting the quality indicators, with advice from the TWG Chair. This will include drafting a detailed overview of each indicator (see section 2.2) together with briefing papers for consideration by the Working Group.

Each quality indicator should specify one requirement for high-quality care or service provision (for example, a single intervention, action or event). The indicator may also specify the timeframe in which the clinical activity is expected to be achieved and measured.

In some circumstances, a quality indicator may include more than one intervention or action when these activities are closely linked, or individual indicators describing these separately would lack clarity. For example, a quality indicator specifying high-quality post-diagnostic follow-up may simultaneously describe what is required of the diagnostic test as well as the various treatment options that follow depending on the outcome of the test; or a quality indicator around rehabilitation may describe both the requirements for a rehabilitation plan as well as the actual rehabilitation interventions.

Quality indicators are not verbatim restatements of the relevant source guideline recommendations. A quality indicator may map onto clinical guideline recommendations from one or more guidelines, and may be derived by rewording one or more recommendations into a single indicator statement.

Each proposed quality indicator will be accompanied by:

- Definitions of the terms used

- Implications of implementing the quality indicator nation-wide, for different audiences (service providers, healthcare professionals, payers, patients, service users, policy makers)

- Sources of data for measurement (for example registers, national and local databases)

- Guidance used to underpin the indicator (for example, guideline from which the recommendations were sourced)

- Specific considerations for individual groups, where relevant, for example equity impact upon socio-economic groups

A standardised pro-forma covering many of these questions (and others as relevant) for all proposed quality indicators, such as in Box 4-1, is essential to guide the deliberations of indicator Working Groups. An example of a related assessment from England is provided in Appendix C.

Box 4-1: Assessment of a proposed indicator

Clinical Disease Area	Suggested indicator wording	Suggested target standard *(and/or threshold to trigger payment if applicable)*
Are the relevant data being collected? If not, what would a new data collection system look like and how much would it cost?		
What is the underlying rationale for the selection of the indicator? For example, is there a published evidence base to support the activity in the indicator? *For example: published studies, consensus clinical view derived from a deliberative and independent process, local evidence of impact…*		
Can every *[primary care/inpatient treatment/etc]* facility in Mexico deliver the health care activity required by this indicator?		

ie: submit data, and be able to provide the care it details
Is the indicator and measurement clearly defined?
Can the indicator be influenced solely by activities in *[primary care/inpatient treatment/etc]* or does it depend on other factors/interventions?
What are the possible unintended consequences (e.g. for other parts of healthcare system or for non-health sectors across Mexico)

4.5.5   Defining the inclusions, exclusions and exemption criteria

The overriding principle is that blanket exception reporting is not acceptable (for example, of all patients with a particular comorbidity) and individual decisions based on clinical judgment should be made. There is no 'ideal' level of exception reporting, although healthcare facilities with levels significantly outside the national averages may have this investigated.

4.5.6   Setting business rules for data extraction

Business rules are algorithms that state clearly the denominator (all patients eligible for the care described in the indicator minus those who have been exception reported) and numerator (those patients who are reported to have received the care described in an indicator) requirements, as well as those patients, if applicable, who are eligible to be excepted to ensure accurate verification across providers when extracting and reporting data on indicators. These rules detail what should be recorded and the hierarchy of decisions that give effect to the extraction of the information required to calculate the numerator and denominator of the indicators. The Business rules for each indictor should be agreed by the Technical Working Group, *who will agree "all the information required to identify patients to be included in the disease register, indicator denominators and the indicator numerators. Each rule set is a series of logical statements which should be applied sequentially"*. As such, these rules will

constitute a standardised format for medical records and the ability to extract identical and comparable data across all providers. This will underpin the semantic interoperability of the Business Rules for each indicator. The most urgent requirements of Business Rules are to agree the codes or data that will be appropriate to meet the specific algorithms and specifications of the numerator and denominator for each indicator. These rule sets are produced to enable the clinical system suppliers of each organisation to extract these numbers from each organisation and to feed them to the central database against agreed timelines.

The UK Primary Care Commissioning QOF Management Guide: Volume 1 (2009, p4)[28] stated "*Each Dataset and Business Rule contains all the information required to identify patients to be included in the disease register, indicator denominators and the indicator numerators. Each rule set is a series of logical statements which should be applied sequentially*".

4.6   Conducting a prospective economic analysis (Steps 5 and 6)

Economic analyses should include a sensitivity analysis where possible, those variables for which the model is most sensitive to changes (approximately 3-4) should be discussed within the main document presented to the Working Group. As discussed in section 2.4.3 above, this sensitivity analysis helps individual health service providers and commissioners, to see how the impact on their budgets is likely to vary from the national estimate.

4.6.1   Budget (cost) impact analysis

As discussed in Section 2.4 por encima de, BIA estimates the costs of implementing the changes required for achieving levels of quality as set out in the indicators at the national and sub-national (including local) levels. This includes an analysis identifying the most significant drivers of cost.

The cost impact relates to the change required and can be estimated using the following formula:

(predicted activity x predicted cost) – (current activity x current cost)

One of the most important elements of any BIA is identifying the baseline and predicting how this might change. Changes could include either changes to the levels of service provided or changes in how services are provided, such as providing staff training or new items of equipment such as positron emission tomography (PET) scanners.

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[28] See: https://www.pcc-cic.org.uk/sites/default/files/articles/attachments/qof_volume_1_updated.pdf

4.6.2   Cost-effectiveness analysis

Indicators that relate directly to a change in treatment are most amenable to cost-effectiveness analysis, since there is an obvious link to clinical benefits, potentially supported by evidence. However, most indicators are not of this type.

When seeking to apply financial incentives, cost-effectiveness analysis involves consideration of two issues. The first determines whether the activity or intervention is cost effective and would result in benefits which are greater than the costs of undertaking the activity. Health benefits are measured in Quality Adjusted Life Years (QALYs). Estimates of the health benefits should ideally be obtained from evidence presented in related clinical guidelines and health technology assessments (where available).

In the UK primary care incentive scheme, the Quality and Outcomes Framework, two broad economic approaches have been applied when assessing the cost-effectiveness of indicators[29]. These approaches are:

- Net benefit analysis, which is used when there are <u>data on both incremental benefits and incremental costs</u>
- Threshold analysis, which is applied when <u>evidence is "thin" or unavailable</u>

These approaches value QALYs (the health benefits potentially associated with the indicator) in monetary terms. In the UK, this is the mid-point (£25,000) of the implicit "cost effectiveness threshold" of £20,000-£30,000 per QALY gained, which has been adopted by NICE.

4.6.2.1   Sufficient evidence is available about benefits: net benefit analysis

The net benefit calculation subtracts the delivery costs of implementation and the payments from the monetised health benefits:

$$\text{Net benefit} = (\text{monetised benefit} - \text{delivery cost}) - \textit{QOF payment},$$

where the *QOF payment* represents the financial incentive (an additional cost), which for any particular indicator would be triggered at an appropriate threshold level of achievement, with payments increasing up to a maximum performance threshold[30].

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[29] Based on work from researchers at the University of York and the University of East Anglia, for example:

Walker S et al. Value for money and the Quality and Outcomes Framework in primary care in the UK NHS. Br J Gen Pract. 2010 May;60(574):e213-20

[30] Quereshi N, Weng S, and Hex N. The role of cost-effectiveness analysis in the development of indicators to support incentive-based behaviour in primary care in England. J Health Serv Res Policy. 2016 May 20

Box 4-2: Worked example of net benefit analysisIndicator selection for analysis

In some cases, two closely related indicators will be developed. For example, a cost-effectiveness analysis can separately assess:

The percentage of patients with diabetes in whom the last IFCC-HbA1c is 53 mmol/mol or less in the preceding 12 months.

The percentage of patients with diabetes in whom the last IFCC-HbA1c is 58 mmol/mol or less in the preceding 12 months.

Sample calculation example

Input parameter	Value	*Description*
Registered population	*49.3 million*	
Prevalence (percentage)	*0.1%*	*Percentage of the population as defined by the indicator*
Prevalence (number of patients)	49,300	*The denominator of the indicator*
Current achievement	45%	
Minimum achievement	10%	*The lowest point at which health facilities can receive any incentive payment*
Maximum achievement	80%	*The point at which maximum points are awarded. This cap may be set below 100%, for example if there is a risk of incentivising over-treatment*
Costs to the health system		
Delivery cost per patient	£1,500	*Additional cost of health care per patient, <u>compared with current practice,</u> when complying with the indicator*
Total additional delivery cost	£25.9 million	*Additional cost to the health system to reach the maximum achievement from the baseline (ie an additional 35% of patients)*
Monetised benefit		
Incremental effect	0.10 QALY	*Additional DALYs averted/QALYs gained per patient, <u>compared with current practice,</u> when complying with the indicator.*

Monetised benefit	£2,500	*The value per patient of the health benefits gained from complying with the indicator (e.g. if policy-makers value a DALY averted at $25,000)*
Total monetised benefit	£43 million	*Additional value gained when maximum achievement reached from the baseline*
Costs of the incentive scheme		
Incentive payment	£5 million	*Total payment to health facilities if maximum achievement reached*
Net benefit	**£12.1 million**	*(monetised benefit – delivery cost) – cost of incentive*

***Figures** are inserted purely for demonstration purposes as a stylised example and are not taken from a specific analysis.*

When the net benefit is positive (monetised benefits outweigh the costs), then the indicator is considered to be cost-effective. The calculation and example above shows that there are several variables which can affect the overall net benefit result (and results of similar economic analyses), summarised in Table 7.

Table 7: Net benefit will increase if...

Input parameter	Direction	*Reason*
Incremental cost of intervention *per patient*	*Decreases*	*Reduces total delivery cost*
Incremental health benefit of intervention per patient	*Increases*	*Increases total monetized benefit*
Incentive value/'power' (payout to facilities for increasing compliance)	*Decreases*	*Reduces total cost of incentive payments*
Baseline achievement	*Decreases*	*Payment is allocated across <u>all</u> eligible patients*
Prevalence of condition (%)	*Increases*	*Larger eligible population (see above)*
Practice size (health facility catchment area)	*Increases*	*Larger eligible population*

When linking financial incentives to indicators, as is done with the QOF, there is the second issue of the level of payments that can be economically justified to increase the levels of desired activities whilst retaining net benefits to the health service. As the formula above shows any incentive payment is additional to the delivery cost. The level of the financial incentive could be varied in any analysis and linked with appropriate achievement thresholds.

4.6.2.2 Insufficient evidence is available: threshold analysis

Threshold analysis is potentially useful when source evidence (for example from HTAs or guidelines) is not available. This can occur when, for example, costs are known or can be reasonably estimated, but the health benefit (in terms of QALYs gained or DALYs averted) is unknown. Under these circumstances it is possible to identify the level of effectiveness for an indicator to be considered "cost-effective" (that is, when the net benefit becomes positive before financial incentivisation could be considered). Expert judgement must be used to assess the most likely degree of health benefit.

Threshold analyses are most likely to be used in the case of process indicators, involving a change in information available to the treating clinicians in a disease area where there is an appropriate therapy available. A link is hypothesized with improved patient outcomes and a net benefit analysis would only be possible where robust evidence to support the hypothesis is available. In reality, this evidence is often not available or reliable (Campbell et al 2014).

Clearly, judgement has to be applied on whether a range of QALY gains/DALYs averted could be achieved. This would also inform the level of financial incentive that would be appropriate on economic grounds. However, since the specific health benefit likely to be achieved is unknown, the range of QALYs/DALYs and the number of different payment levels to choose from for a given indicator may be quite large.

4.6.3 Application in Mexico

Similar methods to those used in the UK could be adopted in Mexico to check whether an indicator is likely to represent cost-effective practice, *even if there is no desire to link with a quality payment*. When applying the net benefit analytical approach, the relevant official cost-effectiveness threshold is based on GDP per capita as indicated in current guidelines specified by the CSG[31]. The World Bank has indicated that Mexican GDP per capita as expressed in international dollars, is 17,277 (2015). If for example an indicator is expected to generate health benefits of the order of 0.1 QALY per person, then the monetised benefit under these circumstances (and assuming that

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[31] Guía de Evaluación de Insumos para la Salud, Febrero 2015. Dirección General Adjunta de Priorización, Comisión Interinstitucional del Cuadro Básico y Catálogo de Insumos del Sector Salud.

GDP per capita represents the relevant cost-effectiveness threshold to use) would be estimated as:

$$0.1 \text{ QALY} \times 17{,}277 = \text{approximately } \$ 1{,}728$$

$$(\text{international } \$)$$

Note that the CSG guidelines allow for benefits to be expressed in either QALYs or Disability Adjusted Life Years (DALYs). Whether health benefit is expressed in QALYs or DALYs, the broad approach is the same. However, it is important that existing guidelines for the conduct of economic evaluation in support of HTAs and clinical guidelines is consistent with any approach adopted for assessing the cost-effectiveness of quality indicators. The approach could in principle capture productivity losses or other costs, such as out-of-pocket expenditure. The approach used in the UK does not include these additional costs because of pre-existing guidelines that limits the perspective taken.

An economics subgroup of the TWG, with relevant expertise, could coordinate with the Technical Support Team to focus on defining the rationale of the economic approach to be applied (cost-effectiveness analysis and budget impact), and assessing the quality of any analyses. Additional expertise from Mexico may sought: for example the Economic Analysis Unit (*Unidad de Análisis Económico,* UAE) has a track record of developing cost-effectiveness evaluations for benefit package development. Pilot testing of the indicators should include an attempt to capture additional data on likely costs and health benefits of implementing the indicator, including identifying more accurately the eligible patient population and its size. These can be used to refine any analyses which are reported to the sub-group for discussion and agreement. Both cost-effectiveness and budget (or cost) impact analysis rely on the same core data. With cost impact analysis, the aim is to extrapolate evidence of costs and savings (and monetised benefits) at an individual patient level to national and or subnational (regional) levels (see section 2.4). At the very minimum, a cost impact analysis should be attempted, as this will assist in planning and implementation by local policy makers and managers.

4.7   Consultation with interested parties (Step 7)

The TWG may ask for comments from wider stakeholders (including patient organisations and professional groups) on potential new indicators during a public consultation period. The duration of this consultation should not be significantly longer than 4-6 weeks. Stakeholders are asked to comment on, for example, potential unintended consequences, barriers to implementation, differential impact or

inequalities. Stakeholders may also be asked specifically about any important areas for consideration that have been identified and not resolved within the TWG or SWG.

DGCES may be able to inform stakeholders in advance about the public consultation by email and on the website, in a similar fashion to the NICE consultation process[32]. Once consultation begins stakeholders can see the proposed indicators on the DGCES website and submit comments on a comments proforma.

An example illustrating the core questions for each proposed indicator is shown below (Table 8). It may be advisable in the early years of the indicator programme to ask more general, less technical questions as stakeholders get used to the process of submitting comments. There may be additional topic-specific or indicator-specific questions for particular proposed indicators. These would likely be generated through discussions in the Working Groups; for example where members are aware of disagreement over the clinical necessity of a recommendation, or where there is current wide variation in the healthcare delivered which would make it difficult to deliver or monitor the care indicated. Examples of indicator-specific questions asked of stakeholders in recent NICE consultations were:

- *[Topic: Identifying undiagnosed atrial fibrillation (people with comorbidities)]* "People with chronic conditions were identified as an appropriate population for manual pulse palpation. Do stakeholders consider the range of the conditions covered in the indicator suitable?"
- *[Topic: Identifying undiagnosed atrial fibrillation (people aged 65 years and over)]* "Can respondents comment on access to ECG services?"
- *[Topic: Anticoagulation to prevent stroke]* "To what extent would this already happen as routine practice during consultations with this population?"
- *[Topic: Diabetes in children and young people]* "If the data are available should this indicator be broken down into age bands of perhaps 5 years – i.e., 0 – 5 years, 5 – 10 years, and 10 – 15 years etc."

Table 8: Example proforma questions for receiving stakeholder comments

Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly.	
Organisation name – stakeholder or respondent *(if you are responding as an individual rather than a registered stakeholder please leave blank):*	[**Insert organisation name**]
Disclosure *Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.[33]*	[**Insert disclosure here**]

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[32] For example, including previously filled in forms, see Consultation on NICE Indicators: https://www.nice.org.uk/about/what-we-do/our-programmes/standards-and-indicators/consultation-on-nice-indicators

[33] Other disclosures, e.g. to particular food and drink manufacturers, may be added as appropriate to align with the Government of Mexico's disclosures and ethics policies.

Name of person completing form:		[**Insert your name here**]	
Topic	**Indicator ID and draft wording**	**Questions**	**Comments** Insert each comment in a new row.
Broad clinical area and type of care *eg: Diabetes – diagnosis and early management in primary care*	**IND DM001**[34]: In all patients with identified prediabetes, other components of metabolic syndrome and cardiovascular risk should be investigated. [*with examples*]	Do you think there are any barriers to implementing the care described by this indicator?	
		Do you think there are potential unintended consequences to implementing / using this indicator?	
		Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.	
		Do you have any general comments on this indicator?	
		To what extent would this already happen as routine practice during consultations with this population?	

Checklist for submitting comments

- Use this comment form and submit it as a Word document (not a PDF).
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 response from each organisation.
- Do not paste other tables into this table – type directly into the table.
- Underline and highlight any confidential information or other material that you do not wish to be made public.
- Do not include medical information about yourself or another person from which you or the person could be identified.
- Spell out any abbreviations you use
- For copyright reasons, comment forms do not include attachments such as research articles, letters or leaflets (for copyright reasons).We return comments forms that have attachments without reading them. The stakeholder may resubmit the form without attachments, but it must be received by the deadline.

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[34] An existing recommendation from CENETEC guidance (IMSS-718-14) is chosen as an example.

> **Note:** We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.
>
> Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by the Ministry of Health, its officers or advisory Committees.

The Technical Support Team would prepare summary reports analyzing and responding to all the consultation comments, which are presented to the TWG for review.

4.8 Piloting draft indicators (Step 8)

Piloting new indicators recognizes the importance of learning from the experiences of staff in addressing the potential new indicators and of asking staff what they think of them. This process seeks to highlight potential problems that can be addressed prior to the indicator being implemented on a national level. Further details can be found in section 5.4.

It is recommended strongly that piloting should be against an indicator testing protocol[35]. Quality indicators should be subjected to a testing protocol before being used in practice using key attributes such as **acceptability, feasibility and reliability**, as well as identifying issues derived from actual implementation and **unintended consequences**.

4.9 Approving and publishing the indicators (Step 9)

Once approved by the Strategic Working Group after consultation, the indicator menus will be taken forward for piloting. Indicators should be accompanied by:

- An overview or summary for health service providers, which includes descriptions of the reasoning for the indicator, reporting mechanisms, inclusions, exclusions and exceptions and links to further information
- Cost-effectiveness and cost–impact analysis (when undertaken)
- Methodological specifications of how the indicator was developed

Publishing summaries of the analyses conducted (with sensitive data removed) helps to ensure acceptability of the overall core indicator set if it is seen as being developed to consistent standards. As discussed in earlier sections (e.g. 2.4.1 por encima de), this

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[35] Campbell SM, Kontopantelis E, Hannon KL, Barber A, Burke M, Lester HE. Framework and indicator testing protocol for developing and piloting quality indicators for the UK Quality and Outcomes Framework. BMC Fam Pract. 2011 Aug 10;12(1):85.

publication also helps health service providers and commissioners to build on the analyses and make more detailed local plans for implementation.

5   Preparing for implementation and piloting of the indicators

Chapter objectives:

- Highlight the importance of a preparing adequately for implementation
- Set out the key components of implementation, including the role of piloting

Key terms and concepts:

<u>Application in this manual</u>

Baseline assessment	*Detailed prospective capture of data on how far the activities recommended in a quality indicator are being performed in current care*
Piloting	*A proof-of-concept implementation in a selection of health facilities to test the indicator's feasibility in practice and fitness for purpose*

5.1   General principles of implementation

Implementing the indicator set will require changes in how practice is structured and delivered. This will need detailed planning and preparation, with appropriate budgetary planning. It is critical that a phased approach is taken to implementation, with careful selection of pilot sites. A key issue that will need to be addressed during planning and piloting is feasibility – the design and roll-out of any indicator set will need to take into account existing system constraints and any needs for capacity strengthening where possible. For example, it is important to consider the existing burdens on data collection faced by provider units, and the availability (and acceptability) of electronically submitted data.

There will be different implementation models that are workable, depending on the local circumstances. These will include whether existing quality strategies and quality initiatives could be leveraged, and the readiness or capacity of the local health system (in terms of available financial, structural and human resources) to initiate change.

Regardless of the model, there are some general principles of good practice that should maximise the likelihood of a successful implementation:

- Start small, and aim for **incremental progress;**
- **Prioritise** to maximise impact;
- **Engage and involve all relevant interested parties** with a role to play in implementation (including policymakers, hospital managers, and clinicians on

the ground) as early as possible in the process, to maximise all parties' ownership of quality improvement

- **Monitor, measure, and record** practice and outcomes, including a baseline measurement of current practice, as well as throughout implementation, in order to test and understand the impact of quality improvement activities, and to provide lessons for further improvement.

In this section, we outline a general approach to implementation. It includes the following elements:

1. Planning
2. Inception (pre-implementation)
3. Pilot implementation
4. Post-implementation and wider rollout

Following the **Plan-Do-Study-Act** (PDSA) framework (NHS Institute for Innovation and Improvement 2008)[36], a pilot is a proof-of-concept to test the indicator's **feasibility in practice**, and to learn lessons that would facilitate its scaling up.

5.2 Planning for implementation

During indicator development, the TWGs will have discussed practical issues of implementation, as will have the SWG in approving the final version. The Technical Support Team may have explored the potential feasibility of each of the quality indicators. Consultation with interested parties (see section 4.7) should also have highlighted potential challenges in applying the indicator in practice. Finally, the BIA will have highlighted resource implications. As indicated in Chapter 4 above, piloting is the last stage of creating a quality indicator (or set) before they are published and rolled out.

5.2.1 Phased implementation

A phased implementation may be envisaged, starting with a pilot in a small number of hospitals within a province before a full roll out across the state or country. Selecting suitable pilot sites will be an important activity during this planning stage, and feasibility will be a major consideration here. However, random assignation of pilot sites within a prospectively defined set allows for far more powerful analysis of data, and the potential to draw early lessons on impact.

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[36] See:
http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/plan_do_study_act.html

Implementation could also be phased in the sense that the pilot could start with the most impactful and feasible subset of the indicators, before the remaining indicators developed are adopted incrementally. Again this could be determined locally using some of the prioritisation criteria mentioned above, whether through a formal gap analysis or audit, or through consensus involving the local interested parties. For example, implementation could in the short term focus on the quality measures and indicators that are relatively easily achievable through staff training and one-off procurement of equipment and materials, with likely sustained impact. In the medium and longer term, the focus could shift to quality measures and indicators requiring system reorganisation.

5.3 Inception (pre-implementation) activities

A number of activities will need to take place in preparation for the indicator pilots and implementation. These may include:

- Any necessarily policy or administrative steps; for instance, a circular from the Ministry of Health, or contractual arrangements with the pilot hospitals
- Developing standard operating procedures (SOPs, i.e. specifications for each quality indicator), training materials and protocols, clinical protocols and tools (such as screening instruments)
- Developing data collection tools, and conducting baseline assessments
- Developing tools for local BIA/impact assessment (such as Excel spreadsheet templates for use at the hospital level), and conducting local BIA using locally relevant cost and resource use estimates
- Identifying local priorities for implementation
- Staff recruitment, training, and procurement to enable implementation of quality indicators

5.3.1 Baseline assessment

Since a key objective of indicators is to measure and drive improvement, a reliable and valid baseline assessment will be absolutely crucial to successful implementation. Possible approaches could include:

- general organisational audit; for example, a snapshot of each hospital's stroke service structure, patient caseload, and staffing levels and competencies
- tailored organisational audit, specific to the quality measures defined in the indicators, and;
- patient-level audit, through case review.

Such an assessment can form the basis of a formal gap analysis at each implementation site to determine local priorities for implementation, whether for the

purposes of the pilot or were the indicators to be subsequently more widely implemented. It will also strengthen the cost and resource use estimates for updating the BIA.

Depending on the needs of interested parties, available resources (time, financial, and human resources) and information systems, not all of audit approaches may be useful or feasible in this initial pilot stage. For example, for a small-scale indicator pilot, it may not be necessary to conduct a case review of individual patient notes, although any data gaps in the baseline organisational audit may inform future improvements to address data collection and monitoring needs at the patient-level.

If resources allow, it is also helpful to conduct baseline assessments at both pilot and non-pilot sites, as to allow more robust analysis of the effect of implementing the indicators on process and clinical outcomes, even if a randomised controlled trial of implementation were not possible. As a rule of thumb, baseline data should span at least 3 months prior to the start of implementation, though longer is preferable. For example, for more sophisticated analytic techniques such as interrupted time series regression, data spanning at least 12 months pre-intervention is the generally accepted requirement[37].

5.4   Piloting

Piloting indicators provides valuable information about its applicability in practice, allowing identification of problems not previously recognised.

Regular auditing and reporting from pilot sites and regular follow-up will therefore be essential, including a record of reported challenges and suggestions for improvement from staff at pilot sites.

The following broad options are available for piloting and testing indicators; a protocol (See Appendix D) can be followed according to which option is the most appropriate for each draft indicator[38]:

1.   A full piloting process in which the indicator is used in practice for a period of time to assess clarity, feasibility, impact, acceptability and any unintended consequences. This may include face-to-face semi-structured interviews with staff and, if appropriate, patients or service users. In the UK, the piloting period for the QOF is 6 months.
2.   Convening a workshop of experts, patients, service users or lay members to advise on feasibility, impact, acceptability and any unintended consequences.

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[37] Wagner et al. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther. 2002 Aug;27(4):299-309

[38] NICE, 2014. Indicators Process Guide.

3. Working with sources and QA bodies for health system data, to assess data sources for the indicator to ensure they are feasible and the methods are appropriate.

Box 5-1: Case study – indicator piloting in the UK

> **CASE STUDY: Piloting**
>
> As part of the NICE-managed Quality and Outcomes Framework (QOF) process, all clinical and health improvement indicators are piloted, using an agreed methodology, in a representative sample of GP practices across England, Scotland, Wales and Northern Ireland. The National Collaborating Centre for Indicator Development (University of Birmingham) currently works with NICE to develop and test indicators[39].
>
> As the QOF scheme has been running for many years, the participating facilities pilot 5-10 indicators per round. Approximately 20-30 practices participate in each sample.
>
> **Quantitative assessment**
>
> **Implementation data** is reported throughout the pilot period [baseline, mid-term and final] on each indicator:
>
> - Numbers of practices reporting data
> - Percentage of patients achieving indicator standard (by practice and in total)
> - Numbers of patients excluded from indicator
> - Changes in outcomes from baseline
>
> This pilot can be accompanied by a health economic report, which uses the actual levels of achievement for each indicator to make an estimate of its value for money. This expands on any prospective analysis conducted at the indicator design stage.
>
> **Qualitative assessment**
>
> The piloting process includes interviews with health facility staff of all cadres on the experience of piloting the indicators.
>
> | Topic | Sample questions of interest |
> |---|---|

---

[39] See: http://www.birmingham.ac.uk/research/activity/applied-health/research/quality-safety/index.aspx

Clarity	• Is the indicator understood and followed in a consistent way by all staff?
Feasibility	• Can appropriate business rules be developed? • Is the practice equipped to collect data and deliver on this indicator? • Is the target appropriate for all people with the health condition in question?
Acceptability	• Do the practices support inclusion of this indicator in the core set? *Eg: is the health condition perceived as a priority? Do staff anticipate patient resistance?*
Unintended consequences	• Is there an associated potential for over-medicalisation, side effects, etc?

The results of these interviews can be summarised to group the results into bands: ie, for example, 80-99% of practices supporting implementation, versus 70-79%, 60-69%, etc.

This produces a summary judgement on whether the indicator is recommended for implementation, and if not, whether the problems identified in piloting can be resolved by returning to the earlier indicator development steps.

The more formal the judgements in an indicator scheme, the more detailed a pilot is advisable

The protocol to be followed will depend in part upon the purpose for which the indicator will be used, and how 'high-powered' any attached financial or reputational incentives are. Some indicators are intended to be used to make explicit judgements and to formally hold organisations to account. For example, a commissioner may use indicators to determine the quality of care and award a financial incentive to a provider. In this scenario, the increased focus on the particular aspect of care may also bring unintended consequences. These indicators therefore require a high degree of accuracy and quality assurance and their development therefore usually requires in-depth methods such as full piloting.

The framework within which an indicator is to be used usually determines its purpose. Occasionally the Strategic Working Group may agree that an indicator is intended for judgement but that there is such a low risk of problems with feasibility, acceptability or unintended consequences that a less intensive form of indicator testing is more appropriate.

Other indicators may be intended to be used in softer ways, for example to guide quality improvement. These indicators may therefore need less precision as long as they are appropriate for comparative assessment. Developing these indicators therefore usually requires a testing process in which checks are undertaken to ensure that the data set used for an indicator is reliable and the design and construct of the indicator is appropriate, but a period of piloting is not necessary. The impact, acceptability and unintended consequences of indicators are also tested by less intensive means than piloting, for example through consultation.

6   Reviewing and retiring indicators

6.1   Regular review of the indicator set

Technical criteria and methodologies for reviewing existing indicators will be based on a set of underpinning principles[40] for indicator replacement and key issues that need to be considered by any organization or country planning to remove indicators. These principles are established in a clinical performance framework developed at the University of Manchester, as part of a wider protocol for developing new, and reviewing existing indicators[41] that addresses the key dimensions of acceptability, feasibility, reliability and implementation. The performance of an existing indicator should be assessed in at least five ways:

1.   Average rate of achievement, which should be high
2.   Recent trend in achievement rate, to identify indicators that have reached the limits of achievement.
3.   Extent and trend in variation of achievement rate
4.   Average rate and trend in exception reporting (exclusions)
5.   Extent and trend in variation of exception rate (exclusions)

6.2   Retirement of indicators

There are two main reasons for retiring an existing indicator from an indicator set:

- The activity that is measured in the indicator results in significant harm or unintended consequences
- There is limited potential for further improvement on the indicator for the substantial majority of practices

The first reason reflects the need to respond to emerging evidence that an activity measured by an indicator might be causing harm to patients. The second reason reflects the need to maximise health gain from a core set of indicators. Assuming a limited number of activities will be included in the national core set at any one time, all existing and potential indicators should be prioritised – at least in part – on the

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[40] Reeves D, Doran T, Valderas JM, Kontopantelis E, Trueman P, Sutton M, Campbell SM, Lester H. Updating clinical performance frameworks: developing a rationale for removing indicators. *British Medical Journal*. 2010 Apr 6;**340**:c1717. doi: 10.1136/bmj.c1717

[41] Campbell SM, Kontopantelis E, Hannon KL, Barber A, Burke M, Lester HE. Framework and indicator testing protocol for developing and piloting quality indicators for the UK Quality and Outcomes Framework. BMC Fam Pract. 2011 Aug 10;12(1):85.

basis of potential benefit to patients. Where there is evidence that achievement for a particular indicator has reached a ceiling, that indicator should therefore be considered for retirement.

The decision to retire an indicator will be based on intrinsic and contextual factors. Intrinsic factors relate to the issues raise above, for example: the potential for further improvement for the particular activity or new evidence for the validity of the indicator. Contextual factors consider the wider framework in which the indicator is operating, including relevant policy considerations. Potential candidates for removal can be identified using intrinsic factors, with the final decision to remove reflecting the wider context.

In the absence of changes to the evidence base, intrinsic factors can be assessed statistically in terms of trends in performance for each indicator and the predicted net benefit of continuing to incentivise. Assessment of net benefit is particularly suited to indicators relating to therapeutic interventions – e.g. prescribing ACE inhibitors – but less so to 'process' indicators – e.g. measuring and reviewing – where it may be difficult to quantify health benefits.

7   Impact assessment

7.1   Planning for impact assessment

Implementation and impact evaluation can be conducted in numerous ways. These include experimental evaluation using randomised or quasi-experimental designs; observational evaluation using audit and monitoring, descriptive case-studies and comparative case-studies; and process evaluation, which aims to look at the "Black Box" of the intervention to identify potential determinants of success and failure. The method chosen is often pragmatic to meet the needs and timetable of the intervention. However, if quantitative data evaluation is to be used, randomisation is recommended strongly where possible. However, alongside any such experimental design, it is recommended that parallel qualitative or process evaluations take place to understand the determinants to *take into account the context for implementation; what is important is not what works, but where and why it works.*

7.2   Quantitative impact assessment

As is the case when piloting draft indicators, when agreed indicators are finally rolled out it is important that systems are enabled to routinely collect data on resource use and outcomes that will allow for formal impact assessment and indicator review following a period of implementation.

Depending on the availability of data, especially longitudinal information, and the aims of any impact assessment, a number of quantitative methods may be available to researchers when assessing the impact on cost or indeed other outcomes of interest following roll-out of a set of national indicators in the absence of any experimental evaluation. These include time series based approaches[42] or more formal econometric techniques[43]. These methods have been applied when evaluating the UK Quality and Outcomes Framework as the examples show. The key aim is to ensure that the specific impact of the indicators can be isolated from other possible determinants on the outcomes of interest. Therefore, any quantitative analysis will need to be designed carefully and involve expert input.

7.3   Qualitative impact assessment

A process evaluation seeks to describe the improvement initiative and the outcome, process and balancing measures that form the measurement strategy i.e. the exact nature of the strategy and what resource investments (including time investments)

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[42] Doran T, Kontopantelis E, Valderas JM, Campbell S, Roland M, Salisbury C et al. Effect of financial incentives on incentivised and non-incentivised clinical activities: longitudinal analysis of data from the UK Quality and Outcomes Framework. BMJ (Clinical research ed.). 2011 Jul 9;342(7814). d3590. Available from: 10.1136/bmj.d3590

[43] Martin S, Smith PC, Dusheiko M, Gravelle H, Rice N (2010). Do Quality Improvements in Primary Care Reduce Secondary Care Costs? London: The Health Foundation. Available at: www.health.org.uk/

are required. For example, it could include evaluating each Pilot site or each State's actual exposure to the national core set of indicators; for example, was the programme implemented as planned.

A process evaluation evaluates the experiences of people participating, identifies the problems that arose while implementing the changes and describe what barriers and/or unintended consequences teams experienced and how they overcame them. This is conducted normally using semi-structured interviews or focus groups.

8   Review of this manual

The methods for developing Quality Indicators may evolve over time, and the needs of the Mexican context may also change, so this guide is considered a 'live' document or work in progress. It should be reviewed regularly by the ultimate owners (the Mexican government) and, where possible, by the original authors.

Ideally, the review period would coincide with the frequency of topic selection to develop new indicators. This may be annual, or less frequently.

9   APPENDICES

Appendix A. Standing document for participants: Core principles
Core principles of Quality Indicator development in Mexico

Agreed and adapted from materials originally provided by NICE International and the University of Manchester [draft date: May 2016]

This document provides a summary of the core principles for quality indicator development, for use by all those involved in their production. It should particularly be understood by members of the coordinating Strategic Working Group, and Technical Working Groups developing specific indicators.

 This summary should be read alongside the relevant Methods and Process Manual, which describes the indicator development process in greater detail and provides links to relevant literature.

Indicators should measure changes in clinical behaviour or outcomes – directly or indirectly

1. **End outcomes** (such as mortality or patient satisfaction) can be difficult to measure or attribute directly to healthcare quality, for a number of reasons.

2. Indirect or **intermediate clinical outcomes** (e.g. blood pressure, cholesterol level) can be used as a proxy for end outcomes. Indirect outcomes can reflect changes in end outcomes – for example, lowering cholesterol levels is expected to result in fewer cardiac deaths. However, some intermediate outcomes may still be dependent on factors outside the control of the individual health professional, such as wider socio-economic factors.

3. **Process** measures (e.g. number and appropriateness of blood tests) may be a more suitable subject for indicator development, if the purpose of measurement is to influence the behaviour of those providing care: processes are common, under the control of health professionals, and may more rapidly be altered. Process indicators can relate to outcomes either directly (for example, by measuring delivery of a therapeutic intervention) or indirectly (for example, referral to a service or provision

of an annual review). However, it can be difficult to identify what actions have had a direct causal link to the end outcome.

4. When prioritising indicators, consideration needs to be given to the extent to which they measure improved outcomes for patients. The Working Groups should be confident that the set of indicators which they prioritise, overall, reflect both a) true and valued health improvements, and b) improved behaviour by health professionals. However, not all indicators will be able to achieve <u>both</u> of these: for example, patients do not usually value reducing their cholesterol level as an end in itself. However, this would still be important for an indicator set to measure.

Indicators indicate, rather than make definitive judgements about performance

5. Quality indicators are only one part of a broader quality improvement strategy and framework, which will include accreditation, audit processes and support for provider quality improvement. Indicators should not just be associated with fault-finding, unless <u>specifically designed</u> to do so.

6. Even in the limited domain of measuring quality, indicators are not the only policy tool available. Indicators usually rely on numbers and numerical techniques, but other forms of evidence such as (protection of) clinical 'whistleblowers' are also valuable.

7. Definitions of key criteria for an indicator set are given below; some of these are expanded on in this document.

Developing quality indicators

- **Face/content validity**: *To what extent to the indicators accurately represent the concept being assessed? Is the indicator underpinned by evidence (content validity) and/or consensus (face validity)?*
- **Reproducibility**: *would the same indicators be developed if the same method of development was repeated?*
- **Clarity:** *Are the indicators are described in clear and unambiguous terms? Are the variables to be measured defined? Is the patient population or clinical setting in which the indicators are intended to be used described?*

Applying quality indicators

- **Acceptability**: *Is the indicator acceptable to both those being assessed and those undertaking the assessment?*
- **Feasibility:** *Are valid, reliable, and consistent data available and can they be collected within the resources available?*
- **Reliability**: *Are the findings reproducible when administered by different raters (inter-rater reliability).*
- **Sensitivity to change**: *Does the indicator have the capacity to detect changes in quality of care?*
- **Predictive validity:** *Does the indicator have the capacity to predict the outcome of care?*

Indicators are based on evidence based guideline recommendations

8. The national core set of quality indicators are derived from the best available evidence, such as CENETEC guidelines; expert syntheses by DGCES of CENETEC's recommendations; other international accredited sources and Quality Standards.

9. The Working Groups should not review nor re-appraise the underlying primary evidence base, although they may consider additional credible sources of information if these were not reviewed by the CENETEC guideline, or if the guideline has not been updated.

10. In cases where there are no pre-selected Quality Standards (high-priority recommendations representing excellent care) in the source guidelines, the Working Group would use their expertise to select specific recommendations which can be developed into indicators.

Indicators should be feasible

11. Ideally, indicators should use existing data collections. However, some indicators may require new data collections, new clinical codes (e.g. Read codes) in an existing

data set or there may be a need for better recording of data in existing systems, for example, outcomes from secondary care in primary care systems.

12. The Working Groups may recommend an indicator for further development and testing that cannot be implemented straight away and may not be ready for a period of time. In the early stages, in particular, of developing a national core indicator set, piloting of indicators in a selection of health facilities is essential to ensure their acceptability among health professionals and check for unintended consequences.

Appendix B. Sample declaration of interests form

Before joining the Strategic or Technical Working Groups, or Technical Support Team, you should declare any interests you have that could affect your membership

What is a 'declaration of interests'?

It is the process by which a Working Group member registers any commercial or financial interests that might affect their objectivity (for instance if they carry out work for, or their organisation receives funding from the healthcare industry). These might create a conflict of interest and could affect the independence of any quality indicator, and related tools, to which the person contributed.

Why is this important?

Declaring interests helps to avoid public concern that links with the healthcare industry or other relevant interests might unduly influence the work of the quality indicator. It ensures that such interests are openly and publicly declared. Declaring such an interest wouldn't necessarily preclude someone from being a Working Group member, but the person might be asked to leave the room during certain parts of a meeting where there might be a conflict of interest.

If a person's interest is so significant that it could affect their objectivity throughout the development of a quality indicator (for instance if they work for or have a significant number of shares in a drug company, or their organisation receives funding from a drug company), then even if he or she receive no personal benefit from such interest, it is unlikely that person would be invited to join the group.

Definitions

Healthcare industry: Any companies, partnerships or individuals involved with the manufacture, sale or supply of health technologies (medicines, equipment etc.) that are, or may be used by the healthcare service in the country.

Personal interest: Payments directly to an individual from the healthcare industry or related trade associations (e.g. through consultancy work, fee-paid work or direct share-holdings).

Non-personal interest: Payment which benefits a department or organisation for which a person has managerial responsibility, but is not received by the person themselves. For example, charitable organsisation might receive sponsorship or educational grants from drug companies, which might be considered as affecting the objectivity of people working for the organisation.

Name:…………………………………………………..

Do you have any interest to declare: Yes ☐   No ☐

If 'Yes' Please list below any interests you want to declare:

……..

Appendix C. Example of assessment of a potential quality indicator

> *Note for reference by DGCES:*
>
> This is a full worked example from the English QOF.

This was a **real assessment** carried out to inform the updating of a <u>process</u> indicator on the diabetes patient register. The indicator suggested by NICE was incorporated into the QOF (currently listed as DM indicator 012). The wording of the QOF indicator specifies the risk classification, taken from the NICE clinical guideline on type 2 diabetes:

*The percentage of patients with diabetes, on the register, with a record of
foot examination and risk classification: 1) low risk (normal sensation,
palpable pulses), 2) increased risk (neuropathy or absent pulses), 3) high
risk (neuropathy or absent pulses plus deformity or skin changes in previous
ulcer) or 4) ulcerated foot, within the preceding 15 months*

Clinical Disease Area	Suggested indicator wording	Suggested threshold to trigger payment
DIABETES MELLITUS	The percentage of patients with diabetes aged 17 or over with a record of the findings of testing of foot sensation using a 10 g monofilament or vibration (using biothesiometer or calibrated tuning fork), palpation of foot pulses and inspection for any foot deformity in the previous 15 months.	N/A

Are the relevant data being collected? If not, what would a new data collection system look like and how much would it cost?

Local data: **Revising these indicators will require revisions to clinical systems and the QMAS software. To satisfy the indicator, the records should include the findings of all three aspects of foot health: – sensation (present, reduced or absent), pulses (present, reduced or absent) and inspection: (normal, past ulcer or deformity, current ulcer). These findings should be recorded for both feet, independently.**

Furthermore, the indicator will also be included in the *National Diabetes Footcare Audit* from 2013 onwards.

Finally, the *National Centre for Health Outcomes Development* measures admissions to hospital of patients with diabetes where a lower limb amputation is undertaken.

What is the underlying rationale for the selection of the indicator? For example, is there a published evidence base to support the activity in the indicator?

Yes, there is significant evidence in support of the indicator:

1. A Joint Initiative from Foot in Diabetes UK, Diabetes UK, The Association of British Clinical Diabetologists, The Primary Care Diabetes Society & The Society of Chiropodists and Podiatrists. The National Minimum Skills Framework for Commissioning of Foot Care Services for People with Diabetes. November 2006

2. NICE Clinical Guidelines; Type 2 diabetes - footcare. January 2004. page 31 onwards; NICE Guideline 10 (Type 2 diabetes: Prevention and management of foot problems) and NICE guideline 119 (Diabetic foot - inpatient management of people with diabetic foot ulcers and infection).

Can every primary care practice in England and Wales deliver on this indicator?

Yes – they have the relevant software and are already collecting data on patients with DM in relation to diabetic foot.

Is the indicator and measurement clearly defined?

Yes – three aspects of foot care, namely, inspection, pulse and sensation

Can the indicator be influenced solely by activities in primary care or does it depend on other factors/interventions?

The former is the case – this is a process of assessment of 'diabetic feet' during regular visits to the GP practice

What are the possible unintended consequences (e.g. for other parts of healthcare system or for non-health sectors)

No major ones identified – The NICE guidance already recommends that everyone with diabetes should have an annual assessment of the risk of foot ulceration. Including this in the QOF is achievable and will encourage practitioners to consider what further action is needed for those with increased risk of ulceration in order to prevent incidence of foot ulceration and lower limb amputation rates (*outcomes reached through achieving the output indicator*).

Appendix D. Proposed indicator piloting protocol

Contact details for queries:

Xxxxxxxxx

Xxxxxxxxx

xxxxxxxxx

Date: xx/xx/xxxx

This protocol was produced as part of a project on the "Evaluation, Design and Implementation of the National System for Quality Care Monitoring" funded by the Inter-American Development Bank (www.iadb.org).

This piloting protocol describes the piloting process, which will involve 2 main elements: 1) working on the piloted indicators, 2) interviews with staff at pilot organisations. The piloting process is explained in Section 2 of this protocol.

This pilot represents the 6-month pilot period from xx/xx/xxxx to xx/xx/xxxx. We are asking you to Pilot xx indicators across xx clinical areas, as described in Section 3.

Information about IT support and the Business Rules for these pilot indicators is in Section 4. However, we shall also send you more information on the IT arrangements in a separate IT handbook in xx/xxxx.

What happens after the 6-month piloting period is described in Section 5 of this protocol.

Contents

- Brief overview of the piloting process
- Aims of Piloting

- How were the organisations selected?

- Confidentiality agreement
- Pilot indicators
- Interviews

- Introduction
  - List of indicators
  - Heart Failure / Myocardial Infarction

- Guidance for the indicators
- Data extraction

- Timeline
- Interviews and organisation feedback

Guide to using this protocol

The protocol is set out in 5 sections:

Section 1:   Contains a summary of the background to the pilot and its aims.

Section 2:   Contains a summary of the States and organisations taking part and what you are being asked to do

Section 3:   Provides information about the indicators you will be piloting

Section 4:   Provides brief guidance about the available IT support for the indicators, working with xxxx, data extraction and overall information requirements. There will be a separate IT handbook in xxxx that will explain the Business Rules and recommend which ICD10 codes to use for the piloted indicators.

Section 5:   Provides an overview of what will happen after the pilot

Section 1: Background, Aims and Objectives of the Piloting Scheme

Background

Since September 2015, the General Directorate of Quality and Health Education (DGCES) is working with multiple partners to evaluate, design and implement a National System for Quality Care Monitoring. Partners include: DGTI, DGIS, DGED, CENETEC, IMSS, SSSTE, Seguro Popular and SIDSS.

This protocol is about how to test pilot draft indicators on a sample of organisations and patients before inclusion in any final indicator set. The pilot will evaluate the performance of these draft indicators in terms of their feasibility, acceptability, reliability, validity and implementation issues including the potential for unintended consequences if they were implemented nationally.

The value of piloting is akin to a 'reality check', and is a learning process highlighting potential problems that can be addressed prior to the indicator being implemented on a national level.

We shall want to find out what staff in participating organisations think of the indicators being piloted and what is involved in addressing the aspects of care necessary to implement each piloted indicator. We shall visit the organisation after the piloting period to find out what you think of the indicators.

After the development/piloting process the indicators will be subject to review by a Strategic Working Group (SWG) composed of representatives of the organisations listed above.

Aims of Piloting

Piloting new indicators recognises the importance of learning from the experiences of staff in addressing the potential new indicators and of asking staff what they think of them. We aim to ensure that the learning process is a two-way street and is as open and transparent as possible. This is a pilot and we want to know what you think of the indicators.

Pilot timelines

Each participating organisation in this piloting period will have received a copy of this handbook by xx/xx/xxxx.

- **This Pilot starts on xx/xx/xxxx**

After having sent you this protocol and the details of the indicators to be piloted, we shall wait a few weeks (approximately 4-6 weeks) before visiting the organisation. This is in order to give you time to think about the indicators and the Business Rules as an organisation and how you want to go about addressing them.

We shall then aim to visit each organisation xxxxxx

At this visit, we shall talk through the Piloting process, the indicators being Piloted and the Business Rules. We shall also explain the workload diaries and what will happen throughout the duration of the Pilot and afterwards.

However, if you have any queries or comments before we visit the practice please contact us (details on page ?).

- **This Pilot ends on xx/xx/xxxx**

Summary of Key Action/Timelines during QOF Pilot: xxxx

Action	Date/Time
Each participating organisation to receive and review the *'Pilot Information and Indicator Pack'* and identify any queries	By xx/xx/xxxx
Each participating organisation to receive and review the '*IT handbook'*	By xx/xx/xxxx.
Reflection	Reflection period for the organisation staff to consider the indicators and Business Rules
Pilot starts	xx/xx/xxxx
Organisation visit by research team	During xx/xx/xxxx
Pilot ends	xx/xx/xxxx
Interview visit (please see below)	During Month xx, 20xx

Section 2: Practices taking part

How were the States and organisations selected?

xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

<div style="border:1px solid black;">

Note for reference by DGCES:

For DGCES to complete and update as criteria for pilot practices are agreed.

This is usually a key part of the testing protocol as organisations will want to know why they are taking part.

</div>

What you are being asked to do

Confidentiality agreement

You have already signed a confidentiality agreement. Thank you.

Pilot indicators

We are asking you to pilot xx indicators across xx clinical areas. Please see Sections 3 and 4 respectively for details.

Questionnaire (Organisation Profile Questionnaire)

A manager in each participating organisation will have been asked to complete a Profile Questionnaire. This questionnaire includes questions that will create a detailed profile of each organisation in terms of numbers (whole time equivalent and head count) and types of staff (doctors, nurses, admin staff, reception staff and others) that work in the organisation, as well as the types of services offered in the organisation.

Interviews

Interviews with staff will take place at the organisation's premises after the pilot period. We anticipate that we shall interview a senior manager and clinician most involved in piloting in each organisation. Interviews will follow an open-ended approach to explore each interviewee's experience of the pilot. Interviews would be anticipated to last 45 minutes and will be organised at a time convenient to the organisation's staff.

Section 3: The indicators

The purpose of this section is to provide your practice with a brief overview of the rationale behind the pilot indicators and to set them in a clinical context.

There are three sections and each one follows the same lay out, giving you information about the clinical area, current management, recent policy guidance and then the evidence base underpinning the indicator(s). Web links have been given to the CENETEC guidance where relevant.

The Pilot indicators

EXAMPLE Heart Failure / Myocardial Infarction

Indicators that you are being asked to pilot

1. The percentage of patients with heart failure (diagnosed after 1/4/2011) with a record of referral for an exercise based rehabilitation programme.
2. The percentage of patients with an MI within the last 15 months with a record of a referral to a cardiac rehabilitation programme.

Cardiac rehabilitation has been shown to increase physical health and decrease subsequent morbidity and mortality in people with Coronary Heart Disease. Evidence suggests that cardiac rehabilitation could potentially lead to a reduction in recurrent myocardial infarctions and subsequent unplanned admissions to secondary care as well as fewer hospital admissions for heart failure.

These indicators do not specify who refers for rehabilitation, recognising that the referral may have been actioned by secondary care.

Please note that the heart failure indicator is prospective.

You can access the relevant NICE guidance at:

http://www.nice.org.uk/nicemedia/live/13099/50514/50514.pdf (heart failure)

and

http://www.nice.org.uk/nicemedia/pdf/CG48NICEGuidance.pdf (myocardial infarction)

The particular clinical issues we'd like you to think about during this pilot are

1. Who should refer for rehabilitation?
2. Should you refer a second time if someone has a second MI and if so, in what timeframe?

3. What if someone was referred for cardiac rehab after an MI and then develops heart failure-should you then refer them to an exercise based rehabilitation programme?

Section 4: The IT guidance for the indicators

Data will be extracted from each organisation to assess reliability and feasibility.

Feasibility relates to evidence about whether accurate data are available and collectable in current family practice information systems, and supported by current methods of data extraction. The assessment of reliability focuses on quality assuring reproducibility. A specification for each indicator will be written by xxxxx, detailing how data will be extracted from patient electronic medical records. Piloting enables these data extraction rules to be tested and for any errors to be identified and rectified.

In xx/xxxx, you will receive more information about the IT elements of the Piloting. This will include:

- A summary of the processes used to develop the Business Rulesets for the indicators that are being piloted

- Information about the Business Rulesets and ICD-10 Codes for each Piloted condition/ indicator

- Information on data entry and recommendations on which ICD-10 codes to use

As part of the pilot, there will be two data extractions planned of summary data from your organisation: These will be the baseline data extraction on xx/xx/xxxx and also the final extraction in xx/xxxx

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Note for reference by DGCES:

The example here is from a UK QOF pilot.

The protocol for Mexico should include relevant information: for example, whether the data will be extracted and submitted electronically, or extracted manually on a form, etc.

Data extraction process steps:

xxxxxxxxxxxxxx

Data extraction timelines

1st data extraction   xx/xx/xxxx

Final data extraction   xx/xx/xxxx

Section 5: What happens after the 6 month Pilot?

<u>Interviews</u>

Acceptability and implementation of indicators will be assessed through semi-structured interviews with doctors, nurses and administrative staff involved in piloting.

Interviews with staff will take place either by telephone or at the organisation's premises after the pilot period that is, in the weeks following the end of the relevant pilot period. Interviews will follow an open-ended approach to explore each interviewee's experience of the pilot. But we shall also have some structured questions about specific aspects of the piloted indicators. Interviews will last about 45 minutes. We should hope to interview a senior manager and clinician involved in the piloting, as well as nursing staff as appropriate. We shall talk more about the interviews when we visit the practice in a few weeks' time.