University of Glasgow
Institute of Health & Wellbeing

University of Glasgow

January 16 2016

IDSI Reference Case work stream Version 2.0

Eleanor Grieve
Andrew Briggs

Executive summary

This reports on the work undertaken by University of Glasgow and NICE International on each of the five objectives under the iDSI Reference Case (RC) work stream and on its future use by the BMGF.

Objectives 1 (RC templates) and 4 (RC piloting) are closely related, as are Objectives 2 (Technical Advisory Panel) and 3 (process of ongoing refinement).

The brief pilot studies' report gives an overview of each of the pilots and extracts key issues for further RC development under iDSI going forward. Some comments from the pilots are beyond the scope of this report but remain relevant to continued RC development going forward. The process of piloting the RC revealed that researchers found the RC challenging to fulfil every methodological and reporting standard, even those with substantial experience in economic evaluation in a low and middle income country (LMIC) context. Establishing a requirement that BMGF funded economic evaluation use of the RC ought to be accompanied by extensive efforts to build research capacity in modelling (mathematical, decision analytic) and cost-effectiveness analysis in LMICs. This would enable wider use of these approaches and closer adherence to the requirements of the RC.

Draft Terms of Reference for a Technical Advisory Panel (TAP) have been provided, and recommendations have been made as to how they could link into the process of ongoing refinement of the RC. This is combined with an outline of the process by which to bring together a suggested mix and representation of expertise and backgrounds as well as general considerations in putting together an advisory group. This report is subject to clarifications from BMGF on the TAP's envisaged role including how the panel would interface with BMGF and how it could interface with iDSI. The report is not meant to be overly comprehensive nor is it intended to be prescriptive but we hope it should be sufficient to be circulated internally at BMGF in order to gain initial buy-in and expedite the process of establishing a TAP to support the adoption and application of the RC.

Objective 5 (economic evaluation repository) ideally needs further co-ordination with Tufts Medical Center and their work on establishing a DALY database to be launched in 2016.

Finally, a key consideration to support the compliance and application of the RC going forward is establishing a Secretariat as IDSI continues to support its further development and use.

Contents

Acknowledgements

We acknowledge all the authors of the 5 studies who undertook piloting of the Reference Case, and generously gave of their time and sharing of their work in so doing.

We acknowledge in particular support from Tommy Wilkinson at NICE International who led on co-ordinating the RC piloting with the above studies.

Clarifications required

This report is intended to outline key areas and detail where clarification is needed as a key limitation is that the report cannot be very definitive as currently major factors such as how BMGF wants to use and fund the TAP is currently unknown. Here, we detail clarifications required especially with regard to the TAP's role, as well as how BMGF intends to incentivise the use of the RC as this will also drive the nature of the TAP.

Under objective 2, we propose a roster/membership of health economists to form an expert TAP. This would be run and convened by BMGF. Draft Terms of Reference (ToR) have been produced, however, this should be refined subject to the clarifications below.

Clarifications:

- What is the panel's envisaged role?
- How would TAP interface with Gates?
- Could TAP interface with iDSI?

Detailed feedback from BMGF on the details of the proposed ToR would be helpful to finalise them. An indication of the available budget going forward for the TAP will also be required as this will drive the functionality and output of the committee.

It would be helpful to address how the BMGF envisage incentivising use of the RC. Possible options discussed have included withholding funding and/or peer review with a rating or score. These issues are likely to drive the role and nature of the TAP.

Under objective 3, we propose a process of review building on existing Gates peer review process. We have made recommendations on employing a survey methodology to enable engagement with stakeholders to facilitate ongoing refinement of the RC.

Clarifications:

- What is Gates' existing peer review process?

Finally, the Gates RC is now referred to as the iDSI Reference Case. IDSI will continue to support its further development and use. There is, therefore, a need to establish a Secretariat to take forward the work proposed, and manage and co-ordinate the further refinement and development of the RC. For example, we would want to incorporate the work currently being undertaken by the Methods Working Groups on Evidence, Constraints and Thresholds to support the use of the RC. This would require resourcing. It also requires consideration of where this group would sit – within iDSI Secretariat, one of its partners, with BMGF?

Objective 1: Development of compliance templates including a submission/planning template to accompany applications + reporting template (s)

Depending on how RC adherence is to be monitored and encouraged, it is likely that both application and reporting templates will be required to ensure that researchers indicate how the RC is intended to be used in the planning stage of an economic evaluation, and also report using the RC framework after an economic evaluation has been completed. The reporting and application templates developed are annexed. These are the final versions used by the pilot studies. This involved a process of UoG and NI working with pilot studies for their feedback both before and after testing the reporting templates in their research.

A one-page 'How To' Note to accompany the templates has also been produced and is copied below.

The iDSI Reference Case

Economic Evaluation Application and Reporting Templates

Purpose of the iDSI Reference Case

The iDSI Reference Case (RC) is made up of eleven key principles to guide the planning, conduct and reporting of economic evaluations. Each of these eleven principles is supported by a set of methodological specifications and reporting standards that, taken together, make up a comprehensive framework for undertaking and presenting sound economic evaluations.

Components of the Reference Case – the 'building blocks'

The principles of the iDSI Reference Case inform corresponding methodological specifications, which in turn inform reporting standards. The principles describe how to undertake economic evaluations that are fit for purpose, outlining underlying concepts to guide methodological choice, without specifying particular metrics or parameter values. The methodological specifications are a non-exhaustive set of methodological options that are aligned with a corresponding principle. While some methodological specifications represent minimum standards of analytical quality (e.g. requiring a systematic evidence search to identify key parameters), many are decision and context dependent. Some methodological specification, such as discount rate and outcome measure, have been determined by BMGF in consultation with the research community. They are not necessarily the only methodological specification that represents adherence with the corresponding principle, and BMGF makes no representation that a particular stated methodological specification is superior to others available. However, BMGF requires adherence to stated methodological specifications for the purposes of consistency.

The Application Template

This Application Template requires researchers to outline how a planned economic evaluation achieves compliance with the Reference Case (RC). The Application Template is laid out in eleven sections reflecting the principles of the RC. In each section, the researcher is required to explain how the planned methods meet the requirements of the RC. Where deviation from the RC methodological specifications are proposed, researchers should explain why deviation is necessary, and how the corresponding principle would be met.

The Reporting Template

This Reporting Template allows researchers to report back to the BMGF following completion of an economic evaluation. The Reporting Template is laid out in eleven sections reflecting the principles of the RC. The main objective of the reporting template is to confirm compliance with the RC. In each section, the researcher is required to explain how the planned methods met the requirements of the RC or justify why they may have deviated from the RC. It is not primarily about reporting of results as this will necessarily be done in final manuscripts or reports (although some results will need to be reported on the template).

Objective 2: Propose roster/membership of health economists to form an expert Technical Assessment Panel to be run and convened by BMGF

The aim of any advisory group is to be a resource that brings together specialist knowledge, experience and skills. We provide draft ToR for a BMGF Technology Assessment Panel (TAP) – together with a suggested outline of the process by which to bring together a suggested mix and representation of expertise and backgrounds as well as general considerations in putting together an advisory group. These ToR are subject to clarifications from BMGF on the TAP's envisaged role including how the panel would interface with BMGF and how it could interface with iDSI. The report is not meant to be overly comprehensive nor is it intended to be prescriptive but we hope it should be sufficient to be circulated internally at BMGF in order to gain initial buy-in and expedite the process of establishing a TAP to support the adoption and application of the Reference Case.

Draft Terms of Reference

Name of group: BMGF Technical Advisory Panel – Reference Case

Purpose / role of the group:

BMGF has both a responsibility and a commitment to support and advocate for sound decision-making, the intelligent use of data, and the pursuit of allocative efficiency. As a major funder, BMGF is obliged to spend money ethically and wisely. As part of its mission, BMGF is a well-established funder of economic evaluations in LMICs utilising these not only in its own decision-making but also making these available for in-country decision makers. BMGF is also an advocate for supporting improved population health at the local level. In each of these roles, BMGF interests are furthered by improving the quality of health economic evaluations.

By using a refererence case developed with BMGF-funded economic evaluations in mind, BMGF has the opportunity to introduce a methodological framework for economic evaluation that reflects its own social and scientific value judgements but does so transparently and explicitly. It is also important to BMGF that economic evaluations are generalizable across different contexts and settings so that they can inform its own decisions across multiple contexts while also being useful to other decision makers. This means that the reference case must support as much generalisability as possible while maintaining a fundamental usefulness or ability to inform good decisions about health and health care on a local level.

The role of the Technical Advisory Panel (TAP) is to promote the adoption and application of the RC in order to improve the quality of economic evaluations and inform better decision-making. The TAP would operate on a continuous basis (as distinct from a time-limited role). It would have no direct decision making powers within BMGF but provide advisory support. The TAP will comprise of a broad representation of thematic and geographical sectors, organisations and individuals

from academia, policy making, global health including LMIC representatives, and methodological experts working in both high, and low and middle-income settings. The TAP may operate virtually and will meet in person annually. Members will be required to declare any conflicts of interest.

Responsibilities are likely to include:

- Receive funding applications and grant reports for periodic review (in line with BMGF's funding cycles) and assessment for RC compliance against the RC Principles, Methodological Specifications and Reporting Standards.
- Attend one face-to-face meeting per year and virtual meetings as required.
- Provide feedback, technical advice and guidance to Programme Officers on the quality and compliance of grantees' reports and applications for funding for economic evaluations – who, in turn, will use this information in their decision-making and communications with partners/grantees (see Figure 1: Workflow).
- To identify areas of concern regarding non-compliance issues.
- To identify opportunities for providing practical capacity building support to partners and researchers to advance compliance of the RC.
- Develop and implement a process for ongoing refinement of the RC as required *(see objective 3).*
- Provide a mechanism by which examples of good practice can be shared within and outside the foundation to promote ongoing learning and improvement.
- To ensure all economic evaluations are recorded in the foundation's evaluation registry.
- To assess the need for an update of the RC every 3-4 years. Envisage this would focus on the methodological specifications.
- Help ensure BMGF work is informed by the best available evidence.
- To support any other activities that enables the promotion of Gates RC Compliance to become a recognised indicator of economic evaluations that are methodologically robust and able to inform sound decisions.
- To annually review the relevance and value of the TAP's work.

Membership:

Recruitment of such a panel would be based on the envisaged role of the group regarding who would be involved, what skills, where advertised and whether there is a need for a recruitment panel. A TAP would bring together a pool of exerts in health economics, including international experts who are leaders in their field, representatives from low- and middle-income countries, HICs and those working in LMICs. We envisage that it would be comprised of individuals from academia, HTA, policy-making and global health.

The TAP may recruit from existing networks but also keen to move 'beyond the usual suspects'. In particular, one issue is how best to attract and identify researchers from LMICs – possibly via the RC reporting process or IDSI connections.

The terms, application process (CV, referees), skill base and sector mix, how many academics, practitioners need to be considered as well as how the TAP would chaired.

Job description would cover:

Essential skills: TAP members need to demonstrate they have the skills necessary to help fulfil the responsibilities described above – with, for example, experience relevant to international development, recognised intellectual leadership and academic record, experience in working in LMICs, demonstrated track record of research and peer reviewed publications, understanding of BMGF work, experience and knowledge of research capacity building activities in LMICs.

Desirable skills could include experience and leadership in management, experience of multi-disciplinary advisory groups, familiarity with funding environment, knowledge of academic and scientific institutions in LMICs, demonstrate commitment to supporting capacity and proven ability to work with diverse teams of researchers.

Numbers would be restricted to X. Period of membership might revolve every 2/3 years – though could be extended.

Members would be selected against a JD by the BMGF committees (see below) and /or a Secretariat managing the RC (see Objective 4). This would likely take the form of an interview process with members needing to demonstrate an ex ante commitment to the RC and its aims if the TAP seeks to "promote the adoption and application of the RC".

Accountability:

As well as linking into the BMGF's mission, the TAP will specifically help to further BMGF's Evaluation Policy. This quote is taken from the policy and illustrates the extent to which evaluation underpins the work of the BMGF: "*evaluation being recognised as a powerful tool to inform foundation and partner decision making about how to optimize scarce resources for maximum impact. Evaluation can help to resolve uncertainty and determine the relative cost-effectiveness of different interventions, models, or approaches. Our evaluation policy is a starting point for strengthening how we use evaluation within the foundation and with our partners. We complement it with resources and designated roles within the foundation that enable clear decision making about when and how to use evaluation and facilitate consistent management of evaluations and use of findings".*

The TAP would most likely operate under the Global Health Division which *aims to harness advances in science and technology to save lives in developing countries*; and also the Global Policy & Advocacy Division which *seeks to build strategic relationships and promote policies that will help advance our work*.

It could be accountable to the BMGF's Global Health Program advisory committee. This is a group *comprised of esteemed experts from outside of the foundation who offer a wide range of experiences and perspectives. This group plays an important role in strengthening our work by offering independent assessments of our strategies and helping us evaluate results.*

It could also be accountable to the Foundation's central Strategy, Measurement and Evaluation team which is *responsible for setting and promoting evaluation standards, creating tools and resources for foundation and partner use, and advancing cross-program evaluation and learning. Their responsibilities include assuring evaluation is integrated into foundation business process, maintaining a roster of independent evaluators, funding evaluations that fill critical evidence gaps or answer questions that are relevant to more than one program, providing foundation staff and partners with training and skill-building support, and assisting program teams and partners who need support or advice on evaluation design or management.*

Working methods / ways of working:

The mode of operation and administration of the group, and how will it be lead or chaired needs to be considered.

It could be a virtual group given the likely nature of its memberships' geographic spread and thereby allowing BMGF to disseminate feedback swiftly to researchers.

A face-to-face meeting should be held after each annual (?) funding cycle and reporting cycle, possibly in Seattle.

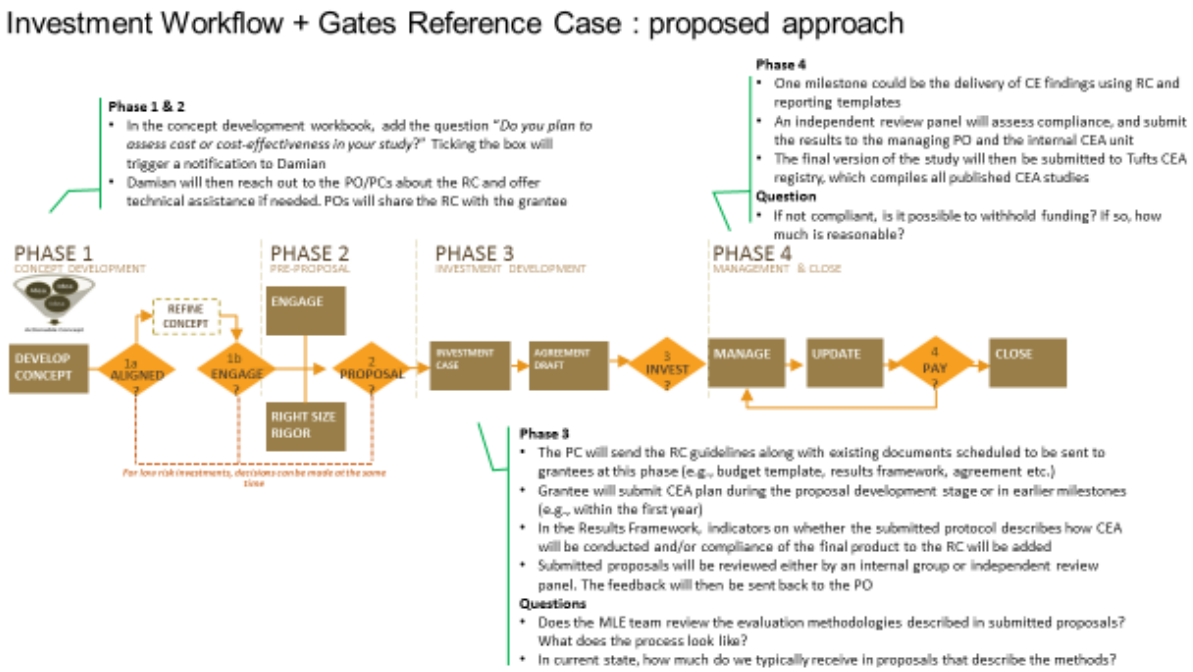
Sub groups could be convened though members expressed thematic, geographic or methodological areas of expertise. These sub groups could be consulted periodically as required.

A secretariat or administrative support would be required to organise the meetings and service the TAP. Topics for agendas would necessarily arise out of the application and reporting proposals which should be circulated 6 weeks in advance. Given this work is confidential, consideration will need to be given as to how members share information.

Finally, how it could interface with IDSI Secretariat needs to be discussed with the BMGF.

Resources required: Budgetary, administrative support, Secretariat support.

Figure 1: Workflow



Note: name has changed from Gates to iDSI Reference Case.

Objective 3: *Propose a process of review building on existing BMGF peer review process*

It will be necessary to have an ongoing process of review of the RC's methodological specifications and to update the RC reporting standards and RC templates – 1) in order to address conceptual, methodological and practical advances in the field and 2) to support those areas identified as requiring additional methodological guidance or input. The focus would most likely be on the ongoing refinement of the methodological specifications and templates – rather than the Principles. Methodological specifications may, in turn, need to be reflected in RC reporting and/or application template amendments.

We propose a Delphi survey methodology and design to facilitate this process of on-going refinement of the RC. A two-round, modified Delphi survey with representatives from academia, health technology assessment agencies and researchers would be used to identify a key list for review. It is envisioned that the TAP would be best placed to be the working group to implement this process and distil this list. Members of the TAP would be required to identify possible candidates for a Delphi panel from a pool of active researchers and stakeholders who should have considerable expertise in either conducting or using economic evaluations in their work. Panellists would be asked to complete a 2-stage survey to rate / rank importance of issues. This initial list could be complied by TAP based on compliance issues identified during their peer review assessments of applications and reports.

Additional ways to identify issues for refinement and identification of potential panellists include:

- Add an area to website (iDSI/BMGF) to request feedback on usefulness of templates/ process/ RC and give suggestions for improvement.
- Allow grantees to express interest in potentially become a reviewer / panellist.

A modified version of the Research ANd Development (RAND)/University of California Los Angeles (UCLA) appropriateness method has been used previously to analyse such survey responses[1]. Based on these methods, a consensus list of methodological specifications / reporting standards to facilitate ongoing refinement of the RC can be developed. The TAP should assess the need for an update of the RC every 3-4 years. Cross-fertilisation with objectives 2 and 3 is envisaged; i) the TAP has responsibility for implementing the Delphi process; ii) importantly, utilising the review process itself would/should help to identify expertise and panellists beyond the 'usual suspects', and iii) both the TAP and the review process will help to support capacity building in economic evaluation methods - a key recommendation made in the RC pilot studies report.

[1] *Fitch K, Bernstein S, Aguilar M, Burnand B, LaCalle J, Lazaro P, van het Loo M, McDonnell J, Vader J, Kahan J. The RAND/UCLA Appropriateness Method User's Manual. Santa Monica;2001.*

Objective 4: Application of the iDSI Reference Case to pilot assessments

International Decision Support Initiative

Application of the iDSI Reference Case to pilot assessments:

Lessons for institutional adoption and future methodological research

Executive summary

Under the international Decision Support Initiative (iDSI), a Reference Case (RC) has been developed which outlines fundamental principles for researchers to use in the planning, conduct and reporting of economic evaluations, with a primary focus on meeting the informational needs of decision makers in low- and middle-income countries (LMICs).

A set of studies have piloted the application of the RC to healthcare interventions in LMICs. Each of the pilots have written up a case study of their respective economic evaluations using the reporting RC template structure.

Feedback obtained on the methodological specifications of the RC includes more guidance required around DALY calculations, constraints and economies of scale.

Feedback obtained on the reporting template includes better accommodating the different types of study design and making the process as straightforward as possible for researchers to complete.

Key considerations to support the compliance and application of the RC going forward are establishing a Secretariat and building the necessary research capacity in LMICs.

Introduction

Under the international Decision Support Initiative (iDSI), a Reference Case (RC) has been developed which outlines fundamental principles for researchers to use in the planning, conduct and reporting of economic evaluations, with a primary focus on meeting the informational needs of decision makers in low- and middle-income countries (LMICs). The RC also provides a framework highlighting where further methods development is likely to be of greatest value.

A set of studies have piloted the application of the RC to healthcare interventions in LMICs. The remit of the pilots were to apply the RC to economic evaluations that have already been conducted or are in production.

An accompanying reporting template has been developed. The main objective of the template is to confirm compliance with the RC and provide opportunity for authors to justify why they have deviated from the RC. The template is not primarily about reporting of results as this will be done in final manuscripts or reports although necessarily some results will need to be reported on the template. Each of the pilots have written up a case study of their respective economic evaluations using the reporting RC template structure.

The initial intention of the RC was for use by the BMGF to improve the quality and transparency of economic evaluation and to guide researchers in undertaking and reporting well-conducted and robust analyses. This workstream has enabled the RC to be tested, yielding useful information on issues regarding practical implications of applying the RC principles and its methodological and reporting standards, how authors interpret the different methods specification, and the usefulness of RC "compliant" economic evaluations. We hope this information helps supports the Gates Foundation to launch the RC as a component of future research applications and to check compliance over the short-medium term.

Objectives of the pilot workstreams:

- To gain insight into the use of the RC in actual practice of economic evaluation in LMIC settings;
- To inform RC improvements;
- To contribute to template development and improvement.

We provide a brief overview of the pilots, followed by separate feedback on the methodological standards and the reporting template.

Quality assurance of the pilots will be undertaken through the usual peer review process prior to publication.

Overview of pilot assessments

A brief overview is provided below of the pilot studies which applied the RC to their interventions in LMICs, including the decision problem, how the RC was applied, methods used and results. Their remit was not to explicitly adhere to the methodological specifications but rather an exploration of the use and challenges in making use of the RC principles. The pilots consisted of three individual HTAs/economic evaluations, each employing a different study design, as well as two programme evaluations. We consider how the RC principles might improve generation of evidence for individual technologies as well as programme evaluations.

Point of Care CD4 diagnostic testing strategy in South Africa

This project demonstrates the application of the RC by applying it to assess the cost-effectiveness of introducing point-of-care CD4 (POC CD4) testing in the HIV treatment cascade in South Africa compared with laboratory based CD4 testing, the current standard of care (if available) throughout sub-Saharan Africa. The optimal treatment cascade includes early diagnosis, efficient linkage to care, immunological staging, timely antiretroviral therapy (ART) initiation and regular follow up to ensure adherence and successful viral suppression. However, a high percentage of HIV positive individuals are lost from care between initial diagnosis and ART eligibility assessment. Alongside clinical assessment, ART eligibility is assessed by measuring CD4 cell counts. CD4 cell counts have been used to define thresholds for ART initiation (this guideline has been removed by the World Health Organisation in December 2015), monitoring response to treatment as well as defining AIDS. In 2013, the WHO highlighted the benefits of expediting CD4 test results through POC CD4 testing as well as its potential role in improving linkage to care. POC CD4 tests allow results to be delivered at the same point within the treatment cascade where blood sampling was performed. This greatly reduces the number of visits a patient is required to make within the treatment cascade as well as increasing the rate at which treatment is initiated.

A dynamic model of HIV transmission was built to study how point-of-care CD4 testing would translate into a reduction in HIV incidence in South Africa. Two policy options were assessed: HIV testing with POC CD4 testing compared with HIV testing with lab based CD4 testing (standard programme); and an enhanced counselling and testing intervention with ART initiation regardless of CD4 count and POC offered to all at central clinics compared with an enhanced counselling and testing intervention with ART initiation regardless of CD4 count and lab based CD4 testing (enhanced programme). The introduction of POC CD4 testing was found to be cost-effective in both the standard and enhanced programmes when using the GDP per capita of South Africa as the threshold.

Pneumococcal Conjugate and Human Papillomavirus Vaccine programs, Philippines

Previous QALY-based economic evaluations on HPV and PCV vaccines were conducted in Thailand and the Philippines. Here, the work in the Philippines is used to test the RC by re-conducting the analysis as DALY-based economic evaluations, the outcome measure recommended in the RC. The aim was to show any systematic differences in results and to explore the impact of parameters in the DALY methodology such as age-weighting, discounting and the use of standard life expectancy tables. Implications for policy recommendations would be considered as a result of using a different outcome measure.

The cost-effectiveness of different screening and vaccination strategies were assessed using Markov models based on country-specific epidemiologic, cost and clinical parameters from a health system perspective. The original QALY based analysis recommended the inclusion of PCV in the national immunization program. However, the affordability and sustainability of PCV implementation over the long-term should be considered by decision makers. For HPV, it was found that high visual inspection with acetic acid (VIA) coverage targeting women aged 35-45 years old at five-year intervals is the most efficient and cost-saving strategy in reducing cervical cancer burden in the Philippines. Adding a vaccination program at high coverage among 11-year old girls is potentially cost-effective in the Philippines assuming a life-long duration of vaccine efficacy.

The cost-effectiveness of the HPV vaccination with VIA screening improved when using DALYs. However, disability weighting resulted in a less cost-effective result for PCV vaccination. Age-weighting and using standard life expectancies reduce the DALYs averted for HPV preventative strategies with the benefits accrued among older women facing declining age weights and where additional life years lead to a bigger burden of disease. In contrast, the PCV vaccination became more cost-effective strengthening the view that the DALY approach favours the young and those of an 'economically productive' age in the population. Discounting future costs and benefits at 3.5 % consistently yielded higher ICERs for both interventions but proportionately more for cervical cancer prevention which has a longer latency period.

Xpert MTB/RIF diagnostic testing strategy in South Africa

A central challenge to the reduction in deaths from TB is to correctly identify TB cases in a timely manner. Historically, diagnosis has been conducted using smear microscopy but this has a limited sensitivity, especially in People Living with HIV/ AIDS (PLWHA). In 2010 a new diagnostic test, Xpert MTB/RIF, received a global programmatic recommendation from the World Health Organisation (WHO). The Xpert MTB/RIF assay is test that can detect TB as well as rifampicin resistance. Several modelled based economic evaluations predicted that Xpert MTB/RIF would be cost-effective if rolled-out across sub-Saharan Africa. In the absence of data,

these early ex-ante economic evaluations had to make assumptions on how the test would perform in 'real world' settings.

The costs and potential cost-effectiveness of Xpert MTB/RIF in South Africa was explored ex-post in a pragmatic trial conducted during the early stages of roll-out. Xpert MTB/RIF was compared to smear microscopy diagnostic algorithm for the trial population cohort from a societal perspective. It was found that Xpert had little impact on the total costs of diagnosing and treating presumptive TB cases. In combination with the trial results on mortality impact, no strong evidence of cost-effectiveness over a six month period was found.

Value for Money framework of the Department for International Development

This explored the extent to which each of the principles recommended in the RC could contribute to the Value for Money (Vfm) analysis done by the UK's Department for International Development (DFID). This framework is used by DFID to maximise the impact of its expenditure and assess programme costs retrospectively, covering the wide variety of sectors in which DFID operates. Whilst outcomes and impact of individual DFID funded programmes are evaluated, and against which their costs can be weighed, there is a difficulty in establishing a common unit of benefit – a general outcome measure of Vfm – across the different sectors. Nor is there a decision rule applied to represent Vfm and assess opportunity costs. Thus, DFID's ability to make decisions with respect to maximising its overall expenditure (allocative efficiency) remains limited. Instead, the focus of the Vfm framework is on achieving the generalisable conditions of 'economy, efficiency and effectiveness' across programmes (which is approximated to technical efficiency in their report but is not explicitly stated as such in the Vfm framework). A lack of selection of appropriate comparators nor an incremental analysis also means net or relative impact cannot be addressed. The report concludes that the principles and methodological techniques of the RC could contribute to DFID's approach, and that at least partial adherence to eight of the 11 principles could feasibly be achieved through technical improvements to *DFID's approach to VfM* guidelines. These include:

- Defining the scope of relevant evidence on both costs and benefits.
- Being explicit that infeasibility of data collection does not mean irrelevance of data, and that missing data should be labelled as missing.
- Offering guidance on the incorporation of future costs and benefits, and how to inflate and deflate costs and benefits to reflect their present value.
- Requiring that the implications of total programme costs on all relevant budgets be expressed.
- Requiring that the implications of programmes on non-financial constraints (such as the stock of skilled labour) be presented.
- Requiring that benefits from multiple sectors be presented disaggregated by sector.

- Requiring that the heterogeneity of target populations be described.
- Requiring that the uncertainty of the conclusions due to the low quality and quantity of data used to inform them be characterised.

Assessment of vaccine cost-effectiveness in the ProVac Initiative

ProVac aims to strengthen countries' technical capacity for evidence-based decision-making on new vaccine introduction. To aid countries in doing this, the ProVac initiative built technical models - CERVIVAC and TRIVAC - and imparted technical expertise to country-level decision makers. The RC principles were used as an evaluation framework to assess the quality of the economic evaluation studies supported by the ProVac Initiative (n = 17) and compared against non ProVac studies (n = 25). Whilst the models have worked well for the initiative, limitations – and the consequent limitations of those cost-effectiveness studies that emerged from them – included: initial models did not allow for direct comparison of all possible interventions; the models were programmed to report cost-effectiveness in relation to WHO-recommended GDP per capita-based thresholds – thresholds that lack theoretical or empirical basis and may not make sense in specific country contexts as a proxy for the affordability of the adopted vaccine; the calculation of average cost-effectiveness ratios (ACERs) as the built-in function of the program instead of incremental cost-effectiveness ratios (ICERs) may have led to errors in the interpretation of results.

In general, better reporting practices were observed in non-ProVac evaluations, likely a result of their review and publication in peer-reviewed journals. However, in four categories, ProVac evaluations were closer to best practices, including equity, time horizon, method used to adjust costs and inclusion of most relevant payers. Many RC compliant aspects would appear to have been undertaken, for example, sensitivity analyses in conjunction with time horizon and discount rates, but were not always included in the write-ups. To the RC set of standards, the authors added: analysis of all authors to understand the networks of research and cooperation generated by the program; analysis of comparators in greater detail; assessment of unit prices used in studies to understand if likely market price is used; analysis of costs included; assessment of and rationale for the cost-effectiveness threshold used.

Methodological lessons from the RC pilots

General

The feedback generally from the pilots was that the RC was easily applied and useful. Key advantages of RC are the focus on a return to first principles and on the needs of decision makers when conducting analysis.

Individual technologies

Given the different study designs of the pilots, lessons were noted on its applicability to epidemiological models (especially uncertainty characterisation) versus single within-trial cost effectiveness analysis (especially using pragmatic trials). Certain types of study design seemed to fulfil different aspects of the RC better. For mathematical disease and decision analytic models, evidence synthesis is a core activity in constructing and parameterising models. Yet, the authors of that report felt that the structure of the RC is very focussed in some aspects on evaluation of 'technologies' in trial settings.

For example, the feasibility of disaggregating resource use and costs was questioned when using large secondary data studies and nationally representative sample sizes in modelling studies versus trial based designs. In general, it would appear the standards around evidence synthesis, uncertainty, scenario analysis and budgetary impact are more easily handled in a modelling study. It is noted that standards on resource use and costs were more easily completed by the pilot which had invested a lot of resources in collecting this – but that meeting these standards had required extensive work and extra primary data collection.

How to adhere to the heterogeneity principle effectively (where does sub-group analysis end?) especially, when time/resources are limited. On the other hand, sub-group analysis was not able to always be undertaken, mostly due to limited data on parameters on gender, age, socio-economic status and other strata.

To incorporate sub-group analysis and heterogeneity the compartmental model must be parameterised by sub-group (gender, income group). Such information is currently unavailable in the HIV literature – the only parameter where there is some information is rates of HIV testing by men and women. There are no estimates for the other parameters such as loss-to-follow-up, retention in care, rates or return to care or adherence. This prevents us from modelling different sub-groups.

The issue of being able to practically (or ethically) apply policy differentially by subgroups, for example, to people who are HIV positive when so many have unknown HIV status was highlighted.

The explicit distinction in the RC between "base case" and supplementary analysis were not found easy to adhere to in disease dynamic models. An important aspect of applying the RC in dynamic disease models is that uncertainty cannot be independent of the core results meaning that in order to generate a base case analysis, a large amount of parameter uncertainty has to be first captured by the epidemiological model. The usefulness of a base case (representing a most plausible ICER) is still recognised as important but consideration of the full range of results is also useful in such dynamic disease models.

The importance for policy makers and economic analysts of considering the 'full intervention' beyond the technology in the 'real world' and the value of 'post-hoc' evaluations before conclusively declaring an intervention 'cost-effective' was made by the study which undertook the pragmatic trial.

Our findings have highlight the importance for policy makers and economic analysts of considering the 'full intervention' beyond the technology – in the 'real world' and the value of post-hoc evaluations are done before conclusively declaring an intervention is 'cost-effective'.

Finally, the Thailand/Philippines pilot identified specific aspects warranting exploration in further detail in its application of the RC: specification for DALY estimations, economies of scale in cost-estimations, human resource impact analysis, equity and structural uncertainty. These are considered below.

Programme evaluations

The RC principles are a useful tool for a programme evaluation framework if the objective is to generate information for decisions concerning allocative efficiency in health. DFID's Vfm assessment is carried out retrospectively rather than prospectively - the latter being the aim of the RC in order to inform decisions. A key limitation of applying the RC to a programme evaluation is that many programmes have multiple health and non-health objectives, and the nature of resource allocation indicates that at point analysis is being used, with concerns of technical efficiency having primacy over allocative efficiency.

Issues were raised about economic evaluation being seen to be a one off exercise versus a useful tool for policy deliberation before a decision is made and that it is not just whether benefits outweigh the costs on average but whether that intervention is the best possible use of scarce health resources given a set budget constraint and competing priorities. Compliance to the RC would better promote these values.

Three key areas identified by DFID as warranting further research are: measuring benefits in a comparable manner; characterising uncertainty, especially in contexts where evidence and data are limited; and better estimating equity implications.

Reporting lessons from the RC pilots

The building blocks of RC include reporting standards in addition to the methodological specifications and principles. An application template and a reporting template have been developed - see annexed latest versions of the application template (Annex B) and the reporting template (Annex C) and also a version of the reporting template shared with WHO CHOICE (Annex D).

The shorter application template would be used at the application stage and is geared to the commissioner of the research only (BMGF in the first instance). It is

envisioned that in due course, the latter template would be used for reporting back to BMGF following completion of an economic evaluation. The focus of these pilots has been on the reporting template. The current version of the reporting template used by the pilots is structured by Principles 1- 11. Methodological specifications are listed and the reporting standards provide the guidance to authors to complete the form. It is proposed that the case study (in template write-up format) is put on the iDSI website (subject to manuscript).

The main objective of the reporting template is to confirm compliance with the RC and provide opportunity for authors to justify why they may have deviated from the RC. It is not primarily about reporting of results as this will necessarily be done in final manuscripts or reports (although some results will need to be reported on the template). This would make the "user" of the reporting template the commissioner of the research plus those wanting to use the research to inform policy.

Summary of major feedback themes:

- Positive feedback having reference to policy upfront. Suggestion that there might also be a specific section on inference and policy application. The key reason that transparency is the first principle in the presentation of the analysis is to facilitate translation into policy. This goes beyond the imperative to report clearly and fully but to remain consistent with the decision problem and maintain a focus on the decision maker.

- Authors found it a useful mechanism to maintain high quality (and also to acknowledge limitations of their analysis).

- Felt it would be helpful to consider modifying the template to make it easier to report within-trial analyses without losing essence of the principle-based approach. Note that this was from the perspective a negative trial which found the methods section particularly challenging to complete, and modelling negative or non-significant effect results into a longer term outcomes. While post-hoc economic evaluations are rare, negative trials results are not – and it is difficult to balance a focus on the areas that may still best inform policy. We consider below the limitation of a single trial analysis (in terms of being sufficient to inform a policy decision) as it is recognised that a lot of funded research is about undertaking a single within-trial evaluation.

- Potentially onerous – it was queried whether researchers would use the template without an incentive, or whether it would need an innovative mechanism to collect this information. Options such as withholding a percentage of funding until RC compliance is shown have been raised. Regardless, the process needs to be made as straightforward as possible whilst giving BMGF reassurance that "RC compliance" (or justification for non-compliance) has been met. One option to make this less onerous could be to

make it less of a reporting template and more of a compliance checklist ie where researchers simply tick a series of boxes to agree that they have complied with particular methodological specifications and reference where in the manuscript/report this information can be found. An electronic, on-line version might also make things smoother and quicker.

- Avoiding duplication of results needs to be addressed in terms of what goes in report and what goes in the template. The duplicative nature of the RC reporting is recognised. It is made clear within the documents that we allow those filling in the template to cross-reference other material (literature, data) and use appendices where they can rather than duplicating information.

- Need for clarity on what the template would be used for – fundamental difference between "self assessment of compliance" (and whether we even use the term "compliance") and recording information that, for example, might not have been included in a manuscript. Envisage a repository of BMGF economic evaluations (using either the template or final manuscript) to provide a suite of examples of application of the RC (*see objective 5 under this workstream*).

Discussion

The RC has helped surface some issues including gaps in evidence and data availability, valuation of non health benefits and the limitation of drawing policy conclusions from single trial evaluations. We consider these concerns below, and attempt to distinguish between those issues which we think must be addressed through the RC, and those concerns which reflect wider contextual issues and how they might be addressed (as opposed to not applying the RC).

One of the pilots identified the following as what they perceived to be the value-added of the RC compared to using existing economic evaluation guidelines around the world:

- *Although most LMICs do not have their own national economic evaluation guidelines, they may be reluctant to adopt other countries' guidelines. The RC has unique characteristics compared to other available international guidelines proposed by WHO or ISPOR. The RC contains principle-based guidance while others propose more methods-based recommendations. This makes the RC accessible (readable) by non-health economists including health care stakeholders in LMICs. We strongly believe that to conduct policy-relevant economic evaluations, stakeholder consultations should be performed and if scholars adopt this RC, it is easier for stakeholders to discuss the appropriate use of the methods in the evaluation. Thus, it will help support the acceptability and usefulness of economic evaluations by stakeholders.*

- *The RC considers budget impact, human resource constraints and equity concerns while most other guidelines focus only economic evaluation methodological issues.*
- *The principle-based guidelines give flexibility and room for scholars in LMICs to modify different techniques applied in economic evaluations. This allows further development and fine-tuning of techniques used in these settings. For example, our pilot test in the Philippines showed innovations in estimating intervention costs when taking into account economies of scales in the implementation of vaccination programmes.*

However, they are also identified some weaknesses of the RC. *Firstly, it provides minimal recommendations regarding technical specifications. Thus, it may be difficult to use for those without or with little experience in conducting economic evaluations. Secondly, its flexibility may allow economic evaluations conducted within the same settings employing different technical specifications and resulting in incomparability of results. This problem can be resolved by the development of the RC for a base case analysis but this would undermine the flexibility of the RC itself. This trade-off needs to be explicitly addressed.*

It is difficult to assess key changes made to the pilots' analyses as a result of applying the RC nor to say how (if) the changes improved the usefulness/applicability/relevance to health policy decisions but it has yielded useful information, especially in applying the RC to different study designs. For example, the difficulties faced by the math modellers resonated with others (in their other projects) in that the demands for cost data are high - and the issues with the base case in terms of characterising the uncertainties around disease progression, transmission and impact on intervention relative effects. But both are recognised as important in terms of getting useful results.

Data/gaps in evidence

Data limitations/data scarcity appear to be one of the key concerns in being able to adhere to the RC. Rather than this being down to the structure of the RC, it is more a consequence, for example, of the lack of routine reporting systems, especially on unit costs and on subgroups.

Improving the quality of cost data (given often its scarcity) is recognised as important to overall results in terms of both cost-effectiveness and affordability. The Gates costing consortium led by LSHTM is a welcome development in this area. Also, the Working Group on Evidence (and issues around transferability/generalisability of research from other settings) and the planned iDSI research (led by LSHTM) on applying the RC in transmission models should help support in being able to better address such issues.

Subgroup analysis

We consider here what one should do regarding sub-group analysis when no data or no access to data by groups of interest, or when research is reliant on secondary literature with no information on subgoups. Given the above raised on data limitations, it is legitimate to have challenges in applying subgroup analysis.

However, if high risk groups are known, should the researchers try to parameterise even by assumptions or undertaking sensitivity analysis? Might it be possible, for example, to parameterise an assumption? One would need to know, of course, in the first instance who are of interest as a subgroup. We propose that where high risk subgroups are known, sensible predictions should be made – and could be linked to value of information analysis.

Single trial evaluations

It is often the case that researchers are funded to do a single study evaluation but (in the RC) there is a strong argument that single trial evaluations should be viewed as one source of data – and then used to for synthesis/adjustment of models. Given the focus of the RC on policy recommendations, what should the RC say about single trial evaluations and the aim of the RC to help decision-makers in drawing policy conclusions?

To partly answer this, the researcher needs to understand to what extent the trial represents the body or totality of 'unbiased' evidence? One trial within a much wider context of evidence does need synthesising. So whilst it is legitimate to present the results of that one study, the researcher should not be drawn into policy conclusions.

We propose that if funders sign up to the RC, we suggest that they should also sign up to researchers to be funded to look at the totality of the evidence base. For example, the NIHR in the UK would often fund a systematic review and/or meta-analysis before a trial.

Ex-post studies

Distinctions have been made in the pilots between ex-ante and ex-post evaluations. It is clear that the RC needs to perform well when supporting decisions 'ex-ante' – and that by 'ex-post', we simply mean the updating of the original 'ex-ante' HTA with further evidence from appropriately designed research, for example, from a subsequent pilot of the intervention, in order to understand what additional evidence suggests about expected and actual gains in population health. HTA is an iterative process, and decisions will need to be made based on the best available evidence at that time. The RC supports this with its focus on first principles that cover the range of issues that are important to decision makers.

If ex-post is defined here as including an economic evaluation after or alongside implementation of an intervention in the 'real world', we do recognise that this is

likely to ‘impact on impact’ as it may capture aspects of reality on the ground. We would not expect, however, the Principles to change – although parameterisation and the model itself may. We do not see there being a distinction between application of the RC to ex-ante or ex post analysis, or how this affects interpretation of the principles and methods choice.

Methodological issues

It is clear that further methodological specification on calculating DALYs is required, and that clarity and standardisation of the assumptions on the use of DALYs in the RC would help guide uniformity in assumptions with regard to the components of age weighting, standard life tables for estimating life expectancy, discounting for DALYs gained, and standard disability weight. Currently, the RC asks that the methods used be reported but recommendation of a particular method for the RC should be the next step.

Further specification of economies of scale is also required. The vaccination programmes tested this, recognising that the cost of the supply chain (with a fixed cold chain) and vaccine procurement (variable cost) can be significantly affected by the coverage of vaccinations. Although the cost-effectiveness results did not change from the original policy conclusion (at least, for one of the vaccines), the potential reduction in budgetary impact may lead to different conclusions from the initial analysis undertaken.

It is clear that many studies use GDP based thresholds which do not accurately reflect the opportunity costs associated with healthcare resources in terms of the health gains resources could generate if used for other purposes. The outputs of the current Methods Working Group on thresholds should provide support on this going forward.

It was felt that it would be beneficial to have more clarity on impact of constraints. Specifically, human resource requirements were considered. Further support should be available from the results of the Evidence Working Group on constraints.

Valuation of non-health benefits was raised as challenging by at least three of the pilots – both individual technologies and programme evaluations. Two of the pilots only considered a health system perspective.

The do nothing comparator was queried and is possibly not always helpful.

It is a given that each of the Principles are accepted. However, ongoing support regarding methodological specifications would be required to facilitate application and compliance to the RC. It is envisaged that the outputs of the Methods Working Groups (currently working on constraints, thresholds and evidence) would provide the basis for supporting materials to the RC and to which authors would be sign-

posted. This body of research will continue into iDSI2 to support the use and application of the RC. Identifying which methodological specifications (in addition to those highlighted in this report) as well as ongoing refinements could be facilitated through a modified Delphi process (*see objective 3 of this workstream*). (see Table 1).

Table 1: Methods research

	Current Methods Working Group	Further RC-related methods research based on findings from pilots
Constraints	X	Human resources highlighted
Thresholds	X	
Evidence	X	
DALY calculations		X
Economies of scale		X
Valuation of non health benefits		X

WHO-CHOICE team is developing materials to support their in-country teams in interpreting economic evaluation evidence. They have advised that assistance requests have increased substantially following the WHA resolution on HITA. Continued support for a RC workstream/Secretariat would provide a useful input to offer support next year as we would be keen to develop this engagement with WHO colleagues.

Reporting templates

The templates annexed are the versions completed by the pilot authors. There has been an iterative process of feedback and amendment. Feedback from the different studies indicated that some requirements of the RC reporting template (because of the structure of the RC itself) were better suited to some aspects of a particular study design than others, and vice versa. We have briefly compared how the RC reporting standards differ in terms of reporting for a donor as per the RC template compared with reporting for publications as per, for example, the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) – as an alternative way of testing the template. Whilst CHEERS is subdivided into six main categories: (1) title

and abstract; (2) introduction; (3) methods; (4) results; (5) discussion; and (6) other, it covers similar reporting requirements by studies. A notable addition in CHEERS is that the reporting guidance is split into a single study-based economic evaluation and model-based evaluation for estimating costs and resources, and for characterising uncertainty. Measurement of effectiveness is also split into single-study based estimates and synthesis-based estimates.

Within the existing budget, we have incorporate the initial feedback from the pilots into the templates using an iterative process. We would continue to revisit the templates (for example, to make distinctions such as the above) but obviously keeping in line with the RC structure and principles. We envisage further template developments (version 2.0+) which can then be further consulted upon. Whether reporting materials should be translated into other languages needs to be considered.

Finally, this process has revealed that even experienced health economists found the RC challenging to fulfil every methodological and reporting standard. The application of the RC requirement ought to be accompanied by extensive efforts to build research capacity in modelling (mathematical, decision analytic) and cost-effectiveness analysis in LMICs. This would enable wider use of these approaches and closer adherence to the requirements of the RC.

Objective 5: Develop a repository of economic evaluations to catalog findings of BMGF-funded CEAs

We have considered below a process to establish a repository of BMGF-funded economic evaluations. This makes particular reference to Tufts DALYs database as well as links to a proposed Southern Africa economic evaluation database (part of iDSI 2016-18) as the BMGF repository would significantly crossover with both these databases. We have briefly discussed this repository with Tufts who have shared their latest extraction process. Here, we review Tufts process of extraction, provide some other models for consideration, and finally make recommendations as to how to proceed.

Tufts Medical Center DALY database

https://research.tufts-nemc.org/cear4/default.aspx

The Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies, Tufts Medical Center, Boston, MA developed the Cost-Effectiveness Analysis (CEA) Registry, focused on cost-utility analyses (CUAs) that quantify health benefits in terms of Quality Adjusted Life Years (QALYs).

They are now funded by BMGF to include information on cost-per Disability Adjusted Life Year (DALY) studies. The Registry has four main sheets: the article sheet, ratio sheet, the utility weight sheet, and the variables sheet.

A formalised review protocol is undertaken. The Registry team searches MEDLINE for English-language articles using keywords "DALYs", and "disability-adjusted". Abstracts from these articles are screened to determine if the paper contains an original cost-utility estimate. Each article meeting these criteria is assigned a disease classification by a clinician. Two readers with training in decision analysis and cost-effectiveness analysis independently review each article and record information using a standardized set of forms and instructions. A third reader may be called upon to help settle disputed items. Data on over 40 variables are collected for each article.

Article information reported includes:

The type of intervention evaluated; the country of the analysis; the funding source; whether the article correctly calculated incremental cost-effectiveness ratios; the analytic time horizon and analytic perspective (e.g., societal or health sector); what discount rate, if any, was used; the currency used; types of costs included; the type of sensitivity or uncertainty analysis used; whether the article specified a threshold for identifying acceptably favorable cost-effectiveness ratios; and a subjective assessment regarding the article's overall quality

Ratio information reported includes:

The health intervention and comparator intervention, and the population that is eligible for the intervention; the costs and health benefits (DALYs averted) associated with both the target and comparator interventions (if available); the value of the ratio reported in the original article, as well as the value calculated directly from the cost and DALY information in the article; and the ratio quadrant.

Disability Weight Information reported includes:

The health condition and demographics of the considered population (e.g. sex, age, and comorbidities), disability weight or disutility value, and range of plausible values; secondary literature sources relied upon to provide weight values.

Tufts extraction process can identify BMGF-funded evaluations. However, there will be a subset of evaluations not captured by Tufts DALYs database but how large this is unknown – and is likely to become less going forward with the implementation of the RC which stipulates DALYs as preferred outcome measure.

The Registry started cataloguing in 2013. Tufts are very happy to co-ordinate on an extended database initiative, especially as they are potentially capturing the majority of BMGF-funded economic evaluations.

Other database models for consideration:

Chief Scientist Office, Scotland http://www.cso.scot.nhs.uk/outputs/focus-on-research-summaries/

A one page logged on website of projects funded by the Chief Scientist Office, Scotland:

> Holders of all CSO awards must produce an executive summary (Focus on Research) as part of their final report. The aims of these summaries are:
>
> > to provide more effective dissemination of research findings and implications to policy makers and health service managers in a form which is more likely to catch attention and provoke thought than a conventional research report
> > to encourage researchers to consider how their findings may contribute to the development of health service policy and practice
>
> CSO has guidelines for the writing of Focus on Research summaries. The summaries are available to download in PDF format and are indexed according to clinical areas. The lists are updated following each research advisory committee meeting.

From 2013 onwards summaries will be indexed using the UKCRC Health Research categories listed below. Each page includes a description of the type of research classified within that category.

NHS-EED

http://www.crd.york.ac.uk/CRDWeb/AboutPage.asp

A model based on York CRD network of health economists who maintained the NHS-EED database of economic evaluations (no longer being funded as of 2015):

NHS EED includes economic evaluations of health and social care interventions. Economic evaluations compare the costs and outcomes of two or more interventions using cost-benefit, cost-utility, or cost-effectiveness analyses.

Weekly searches of MEDLINE, EMBASE, CINAHL, PsycINFO and PubMed were carried out, up until the end of December 2014.

We assessed thousands of citations to identify relevant economic evaluations. Critical abstracts were written for those of importance to the NHS. Each abstract provides details of the key components of the economic evaluation and summarises the effectiveness information on which the evaluation is based. The overall reliability and generalisability of the study are stated along with any implications for the NHS.

A copy of each abstract was sent to the original authors for information. Authors were invited to reply with corrections to factual errors, and other relevant research and where applicable, this information was added to the abstract.

DFID R4D

http://r4d.dfid.gov.uk/

DFID R4D and Open Access Policy for publications and data launched in 2013.

R4D is a free access on-line portal containing the latest information about research funded by DFID, including details of current and past research in over 40,000 project and document records.

You can search the information on the site in many different ways - browsing by region, country or subject, or searching using key words, and an advanced search based on Boolean logic. There is also a search for research contacts. This means that you can quickly find the information you need on the subjects that interest you. For more information on using the different searches, please read the document Searching R4D.

You can also subscribe to receive targeted alerts providing details of new repository content.

Recommendations how to proceed:

- Clarity from BMGF on co-ordination with Tufts who are already funded to establish the DALY database and which is likely to capture a significant proportion of the research.
- Input from BMGF on whether there is more information wanted to be captured which Tufts is not doing, for example, is it envisaged the repository would contain full article, open access to data, metrics only?
- Ongoing co-ordination with Southern Africa economic evaluation database (part of iDSI 2016-18).
- Discuss databases above for those aspects the BMGF would like to mirror or adapt.

ANNEXES

Annex A: Revised workplan

Annex B: RC Application template (see separate PDF)

Annex C: RC Reporting template (see separate PDF)

Annex D: RC Reporting template version shared with WHO CHOICE (see separate PDF)

Annex A: Revised workplan

Workplan of the iDSI RC work stream

Objective 1: Development of compliance templates including a submission/planning template to accompany applications + reporting template (s)

Deliverables:

- Application template
- Reporting template/checklist
- Accompanying document: how to complete templates, their importance, purpose

Objective 2: Propose roster/membership of health economists to form an expert Technical Assessment Panel to be run and convened by BMGF

Clarifications:

- What is the panel's envisaged role?
- How would TAP interface with Gates?
- Could TAP interface with iDSI?

Deliverables:

- Proposed methods by which to bring together suggested mix and representation of expertise and backgrounds
- Draft Terms of Reference (subject to above clarifications)

Objective 3: Propose a process of review building on existing Gates peer review process

Clarifications:

- What is Gates' existing peer review process?
- Would a Delphi survey be useful?

Deliverables:

- Proposal of a survey methodology and design, for example, a modified Delphi process, to enable engagement with stakeholders to facilitate ongoing refinement of the RC (if agreed)

Objective 4: Carry out audit of compliance/test on pilot studies and propose process of improvement

Clarifications:

- As the audit is no longer and with only 4 case studies, proposing an alternative additional means by which to 'test' the reporting templates if considered useful?

Deliverables:

- A report documenting the process of testing and feedback received from the pilots
- A review of testing the reporting template for the RC with CHEERS guidance and Gold (if new version available) standards to compare and rationalise any differences.
- Delphi survey above (see obj 3)

Objective 5: Develop a repository of economic evaluations to catalog findings of BMGF-funded CEAs

Deliverables:

- Review of Tufts extraction process
- Recommendations on how to proceed: 1 page project report catalogued, open access data?

APPENDICES

Smith P, Thomas R, Cori A, Fraser C, Heffernan A, Pickles M. *Point of Care CD4 Testing in South Africa - Pilot of Reference Case*

Suwanthawornkul T, Praditsitthikorn N, Kulpeng W, Haasis M, Guerrero A, Teerawattananon Y. *Incorporating economies of scale in cost estimation in economic evaluation: a game changer?*

Chootipongchaivat S, Chantarastapornchit V, Kulpeng W, Ceria JA, Tolentino NI, Teerawattananon Y. *Estimating human resource impact from introduction of pneumococcal vaccination program in the Philippines: an alongside economic evaluation study*

Vassell, A et al. An economic evaluation of Xpert MTB/RIF: lessons learned from the XTEND cohort

Jones A. *Integration of iDSI's Reference Case principles for economic evaluation and DFID's approach to value for money analysis: Opportunities and challenges*

Glassman A, Canon O, Silverman R. *The Economics of Vaccines: Does Cost-Effectiveness Matter? Lessons from the ProVac Initiative*