

Project Planning for an OASIS – II Evaluation Approach

IDRC-CRDI Project
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Consultant's Report

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Main Messages¹

Where we are:

- IDRC is committed to assessing the value of their investment in e-health (ICT in health) initiatives, and continuing this investment through research networks as appropriate.
- A successful and recently funded e-health network initiative in Africa, OASIS, has been identified as having potential to expand, and to be given supplementary funding in order to enhance its value.
- Related and other African eHealth initiatives have been identified as potential leveraging or partnering activities to expand OASIS; Open-ROSA, Open-MRS, and MVP.
- This study addressed the issue of how best to evaluate the evolving ehealth activities in the new supplemented OASIS program, referred to here for convenience as OASIS II.

What were the findings?

- OASIS, an IDRC funded initiative, has reportedly been successful, has an internal evaluation process in place (of uncertain detail), and has no independent evaluation planned.
- Open-ROSA, supported by OASIS, is well established. It is seen as a facilitating activity for growth of mobile open source software applications rather than an activity that implements specific ehealth solutions. As a consequence, it has not had a formal evaluation approach included as a component of OASIS.
- OpenMRS, supported by OASIS, is also well established, but is also seen as a facilitating activity for growth of medical records open source software applications, rather than an activity that implements specific ehealth solutions.
- MVP, an independent UNDP supported initiative, is well established, and through Columbia University has done significant and high quality work on identifying 'outcomes' for evaluation. These outcomes would benefit from re-examination, placement in a more structured framework, linking to stronger measures, and identification of specific tools for data collection.
- OASIS II will require structured evaluation, including measurement of discrete and defined outcomes, in order to demonstrate value to IDRC and to current sponsors of the component ehealth activities and to strengthen the evidence-base for application of open-source ehealth solutions in Africa.

Lessons Learnt:

- A clear project proposal is still in development rendering detailed consideration of evaluation premature.
- Evidence of value differs between sponsors (IDRC and sponsors of existing individual projects), requiring compromise and clear description of an evaluation framework and provision of guidelines.
- Greater focus on knowledge translation would benefit local and regional ehealth growth and application to establish sustainable, scalable application of proven e-health solutions in Africa.

Moving forward:

- Evidence of value to all sponsors is desired, and high-level guidance to evaluation options has been provided in this report.
- Development of a detailed, structured approach to evaluation of OASIS II is necessary, and the proposed concept of a research methodology workshop to achieve this, as indicated in the draft proposal, is strongly supported.

¹ The format adopted for this report aligns with that recommended by CHSRF. (CHSRF. Reader-Friendly Writing — 1:3:25. Available at: http://www.chsrf.ca/knowledge_transfer/pdf/cn-1325_e.pdf (last accessed 14 November 2006). This indicates that for maximum utility and impact, reports should be formatted with 1 page of Main Messages, up to 3 pages of Executive Summary, and up to 25 pages of report. Multiple appendices can be attached for reference.

Executive Summary

Background:

OASIS (**O**pen **A**rchitecture, **S**tandards and **I**nformation **S**ystems for healthcare in Africa) is a successful ehealth initiative funded by IDRC. An opportunity has arisen for supplementary funding to be made available to leverage OASIS related activities (OpenROSA and OpenMRS) and to engage with new partners (MVP) in order to grow OASIS. It is necessary to develop a proposal for this new opportunity termed, for convenience, OASIS II, and to include in the project proposal adequate consideration of evaluation and knowledge translation.

Requirements:

This consultation had six requirements, as follows (note that these were interpreted as referring more to the OASIS II opportunity, rather than to just the already funded OASIS program):

1. Review the written documents for the OASIS Projects and supplements and provide a critique of the identified research methodology.
2. Advise on any supplementary research methodology
3. Advise on policy changes that should be accommodated by boundary partners
4. Chair a workshop in Ottawa that will harmonise the research methodologies of the individual components
5. Critique and identify a research methodology for the OASIS project, and,
6. Submit to the Centre a detailed and satisfactory report of the work accomplished by 15th December 2008.

Results:

1. *Review the written documents for the OASIS Projects and supplements and provide a critique of the identified research methodology.*

In preparation for the engagement, the document 'OASIS Funding Proposal Final Version 8' was reviewed to situate the prior OASIS work. In addition, the material made available by Dr. Seebregts on the OASIS Google Group site (<http://groups.google.com/group/oasisproject>) was reviewed also. A draft OASIS II proposal (OASIS Supplement Proposal Nov 2008) was made available on 12th December 2008, and reviewed in order to develop this report.

In addition, the following documents were shared with Dr. Chris Seebregts as requested:

1. Lear SA, Bates J, Lavoie JG, Johnston S, Scott RE. The British Columbia alliance on telehealth research and policy. *Healthc Q* 2008;11:52-6.
2. Scott RE, McCarthy FG, Jennett PA, et al. Telehealth outcomes: a synthesis of the literature and recommendations for outcome indicators. *J Telemed Telecare* 2007;13 Suppl 2:1-38.
3. Scott RE. e-Records in health--preserving our future. *Int J Med Inform* 2007;76:427-31.
4. Khoja S, Scott RE, Casebeer AL, Mohsin M, Ishaq AF, Gilani S. e-Health readiness assessment tools for healthcare institutions in developing countries. *Telemed J E Health* 2007;13:425-31.
5. Khoja S, Scott RE. Developing needs-assessment tools for e-learning initiatives in preventive medicine in Pakistan. *J Telemed Telecare* 2006;12:431-2.
6. Scott RE, Ndumbe P, Wootton R. An e-health needs assessment of medical residents in Cameroon. *J Telemed Telecare* 2005;11 Suppl 2:S78-80.
7. Scott RE, Jennett P, Yeo M. Access and authorisation in a Glocal e-Health Policy context. *Int J Med Inform* 2004;73:259-66.

Critique and reflection of the OASIS research methodology has been included in this report as required.

2. *Advise on any supplementary research methodology*

Section 3 of this report examines options for research methodology, including Action Research, Outcome Mapping, Agile Development, Utilisation-Focused Evaluation, and Pragmatic Evaluation, plus a brief review of the eHealth Outcome Indicator Development Framework. Section 4 provides a critique of the draft proposal, and Section 5 provides a brief discussion and recommendations for the Evaluation Workshop.

3. *Advise on policy changes that should be accommodated by boundary partners*

and:

4. *Chair a workshop in Ottawa that will harmonise the research methodologies of the individual components*

In preparation for the Workshop, proposed Agenda Items were shared with Dr. Chris Seebregts prior to the meeting. The meeting was attended and 'co-chaired' by the consultant. Non-IDRC participants were Chris Seebregts, Andrew Kanter, Neal Lesh, and Richard Scott. Additional and primary IDRC participants included Heloise Emdon, Genevieve Lefebvre, and Chaitali Sinha, with additional IDRC staff attending during specific periods.

The workshop proved critical in identifying, discussing, and resolving a variety of project-related issues. However, the goals of a) identifying and advising on policy changes to be accommodated by boundary partners, and b) harmonising the research methodologies, were both premature, as no formal and sufficiently detailed proposal was available prior to the workshop, nor developed during the workshop. As noted above, a preliminary draft proposal was made available on 12th December 2008.

5. *Critique and identify a research methodology for the OASIS [II] project*

The draft OASIS II proposal was critiqued, and this report contains several recommendations regarding an appropriate evaluation approach, including research methodology and outcome indicator development approaches.

6. *Submit to the Centre a detailed and satisfactory report of the work accomplished by 15th December 2008.*

This report constitutes the final documentation in compliance with the requirements of the contract, and it is hoped will be seen as sufficiently detailed and satisfactory given the realities of the engagement. The preliminary draft proposal was made available on 12th December 2008; thereafter e-mail discussion between Heloise Emdon and the consultant took place, with an extension indicated for receipt of the report to the beginning of 2009, when consideration of the OASIS II project would begin once more.

Conclusion:

A practical and achievable evaluation framework, complemented with insight regarding fundamental evaluation (or research) design, is required for OASIS II. Beyond establishing value of the overall project and its component activities, there is a real opportunity to utilise and enhance the outcome evaluation scheme provided by the MVP, and thereby demonstrate clinical impact of selected ehealth interventions. Given the early stage of proposal development for OASIS II, only modest insight for specific evaluation options has been described, but clear recommendations have been provided. The final evaluation development should take place during a focused, multi-stakeholder workshop, as currently proposed.

1. Introduction

1.1 Context

OASIS (Open Architectures, Standards and Information Systems for healthcare in Africa), a successful IDRC-funded initiative, has established health informatics units (OASIS nodes) at universities in South Africa, Mozambique, and Zimbabwe, and built partnerships with local Ministries of Health to develop and strengthen public health information system. OASIS has also supported other activities, such as the OpenMRS Implementers meeting held in Durban in 2008.

OASIS recently applied to IDRC to supplement the original grant, which would allow other initiatives to be aligned with OASIS or added as components. These initiatives include OpenROSA (a mobile data collection application supported through OASIS), and establishment of an additional nine 'nodes' in other African countries through the Millennium Villages Project (MVP) of Columbia University. There is a desire to also harmonise these activities with OpenMRS and architecture initiatives.

For this current IDRC initiative, termed OASIS II, funding will be made available from IDRC and / or CIDA sources. In order to align with IDRC principles of supporting applied research in developing countries, OASIS II must include a rigorous and appropriate evaluation component. This report addresses assessment of OASIS II for 'value'; i.e. evaluation of OASIS II, and presents a series of options before making recommendations for an evaluation approach. The findings will support the subsequent detailed design and development phase, which will be undertaken during an OASIS II workshop targeted for early 2009.

Of additional relevance to the context for this proposal is the Millennium Village Project, and the Millennium Development Goals (MDGs). In 2000, the nations of the world committed to the MDGs and set time-bound and measurable targets for halving extreme poverty by 2015. Subsequently in 2005 leaders from all 191 UN member states recommitted to achieving the MDGs at the World Summit, and leaders at the G8 Summit in Gleneagles agreed to double aid to Africa to \$50 billion per year by 2010 (roughly \$70 per African per year) and to cancel debts for the poorest countries. Despite these initiatives, it is widely accepted that Sub-Saharan Africa will not achieve the MDGs by 2015, and is struggling to progress on almost every dimension of poverty, including hunger, lack of education, and health.

Millennium Villages, a component of the UN Millennium Project, seek to end extreme poverty by working with the poorest of the poor, village by village throughout Africa, in partnership with governments and other committed stakeholders, providing affordable and science-based solutions to help people lift themselves out of extreme poverty. Villages are empowered with proven, powerful, practical technologies, with the anticipation that they will then be able to transform themselves and meet the MDGs. Millennium Villages have been initiated or are being developed in 10 countries throughout Africa, and as noted in the proposal they represent a microcosm of the wider world and are therefore ideal for implementing and evaluating the development of effective and universally applicable ehealth solutions.

1.2 Rationale for OASIS II

Four health information system development initiatives stand at a point where a timely opportunity exists for focused collaboration to embed locally developed and locally owned technology-based solutions. Supplemental funding will permit growth of OASIS as a lead activity in ehealth within Africa. Combined as a single cohesive entity, this would offer a forum to bring together and leverage expertise and solutions around three specific

established initiatives that are implementable and sustainable at the local level. These initiatives (MVP, OpenRosa, OpenMRS) would fall under the umbrella of OASIS II as specific programs.

As described in the draft proposal, OASIS II would:

- (i) expand the support for the development of OpenROSA,
- (ii) expand the number of OASIS country nodes at additional African institutions through a close partnership with the Global eHealth Program and the Millennium Villages Project at the Earth Institute, Columbia University;
- (iii) expand the OpenMRS Implementers Network and support the development of additional collaborative networks for OpenMRS partners, and;
- (iv) develop an open enterprise health information system architectural framework in collaboration with a global consortium of public and private partners.

Each OASIS II program would have a broad scope and impact many stakeholders at all levels. The magnitude of anticipated benefits, the breadth and complexity of applicable technologies, and the scalability of solutions to different settings (sizes and types of environment) are significant. To demonstrate value, a systematic approach for assessment must be developed that establishes a common framework using accepted methodologies to build replicable evidence for large scale and broadly impacting initiatives.

2. OASIS II - Interrelated African e-Health Projects

Descriptions provided below are for perspective only in the context of this evaluation report; fuller descriptions are provided in the OASIS II proposal.

2.1 OASIS

This project was designed to promote development in low- and middle-income African countries by investigating, establishing, and evaluating the various methods, tools, and techniques required to develop and implement sustainable open architectures, standards, and information systems to support healthcare in three Southern African countries (South Africa, Mozambique, and Zimbabwe). It evolved from prior successful IDRC-funded projects.

Anticipated outcomes included creation of (i) an African open health information system research, education, implementer, and developer network focused around the OpenMRS collaborative and related networks; (ii) new functionality developed for OpenMRS and related health software by the African developer network; (iii) working implementations of OpenMRS and related integrated and interoperable open source healthcare applications for one or more defined health systems in at least three Southern African countries and in a dedicated test bed; (iv) a comprehensive set of documentation, including inventory and manuals, best practices, research reports, policy briefs, publications, evaluations, data and interchange standards for open source health software and integrated information systems; and (v) an evaluation and realization of plans for sustainability of the network and activities. OpenROSA and OpenMRS (see below) were supported through OASIS.

2.2 Open-ROSA (<http://www.openrosa.org/>)

OpenROSA is a consortium formed to reduce duplication of effort among the many groups working on mobile data collection systems. The goal is to create open source, standards-based tools for mobile data collection, aggregation, analysis, and reporting. By developing open source solutions and conforming to standards based on the XForms specification, it is anticipated that different projects will be able to easily share code, data, ideas, and infrastructure.

Many of the consortium members are working on JavaROSA, an open source J2ME codebase that conforms to the OpenROSA standards. JavaROSA is being developed for a wide range of uses, including disease surveillance, household surveys, collection of longitudinal data for electronic medical records, guiding health workers through medical protocols at the point of care, and supporting community health workers.

2.3 Open MRS (<http://openmrs.org/wiki/OpenMRS>)

OpenMRS[®] is a community-developed, open-source, enterprise EMR system framework. With its origin in OASIS, a sub-group of individuals focus their interests to specifically respond to the needs of those actively building and managing health systems in the developing world. Their mission is to foster self-sustaining health information technology implementations in these environments through peer mentorship, proactive collaboration, and a code base that equals or surpasses proprietary equivalents.

2.4 Millennium Village Project (MVP)

Various entities support the MVP, including the Earth Institute at Columbia University (<http://www.earth.columbia.edu/articles/view/1799>), a planned partner in OASIS II. The MVP is not itself an 'ehealth' project. However, ehealth is a component of some MVP initiatives undertaken through Columbia

University through their Columbia eHealth Program which has a particular focus on aspects of mobile health (mHealth).

MGV-Net is the name given to an integrated eHealth/mHealth infrastructure being developed in all the MVP countries first to help achieve the goals of the MVP, which concern food security, education, environment, energy, and healthcare. MGV-Net is being developed initially in and for healthcare, but it is intended eventually to serve other areas of development as well. OASIS and MGV-Net share many important goals and a partnership would be extremely productive.

Given this focus on mhealth, the potential linkage with OASIS II and related activities (Open-MRS and OpenROSA) is evident.

3. Evaluation Approaches and Proving Value

Evaluation has been defined by Øvretveit² as “attributing *value* to an intervention by *gathering reliable and valid information* about it in a *systematic way*, and by making *comparisons*, for the purposes of making *more informed decisions* or *understanding causal mechanisms* or *general principles*.” This implies the need to be rigorous in the design and execution of the evaluation process. A variety of approaches and methods are available.

3.1 Evaluation Approaches

Original thoughts included use of an Action Research, Outcome Mapping, or Agile Development approach to evaluating OASIS II. During discussions in Ottawa, consideration was also given to adopting other established IDRC evaluation approaches, including Utilisation-Focused Evaluation. In addition, the consultant’s approach, termed ‘Pragmatic Evaluation’ was considered. Each is briefly described below, followed by concluding comments.

3.1.1 Action Research (AR) / Participatory Action Research (PAR)

Sometimes used interchangeably, these approaches have become a significant methodology for intervention, development, and change within communities and groups. PAR evolved from action research, and is now promoted and implemented by many international development agencies. Perhaps the biggest difference is that research in PAR is effectively conducted *by* the local people and *for* the local people, thus the research is designed to address specific issues identified by the local community, and the results are then directly applied to the identified problems.

The novelty of Action Research, originated by Kurt Lewin and initially used in social psychology research, is that it involves conducting experiments by making changes while simultaneously observing the results (almost a continuous formative evaluation process). It involves utilizing a systematic cyclical method of planning, taking action, observing, evaluating (including self-evaluation), and critical reflecting prior to planning the next cycle. PAR also proceeds through similar repeated cycles, but in PARs case both the researchers and the community identify the major issues, concerns, or problems, initiate the research, take action, learn from that action, and then proceed to a new research and action cycle.

When using PAR, outcomes are very difficult to predict from the outset, challenges are sizeable and achievements depend to a very large extent on the researcher’s commitment, creativity, and imagination.

3.1.2 Outcome Mapping (OM)³

According to IDRC, it’s Outcome Mapping approach is an integrated participatory monitoring and evaluation tool that looks at both development results and internal performance within a program or project. It aims to strike a balance between accountability and learning. OM focuses on changes in the behaviour of direct partners (as outcomes); assesses contributions to the achievement of outcomes; and designs in relation to the broader development context. Focussing on changes in partners’ behaviour, relationships or actions allows a program to measure results within its sphere of influence, obtain feedback about its efforts to improve its performance, take credit for its contributions to the achievement of outcomes, and show progress towards outcomes. Overall OM looks at outcomes in the context of achieving developmental goals

² Øvretveit, J. (2003). Evaluating health interventions, London, Open University Press. p9.

³ There is some potential for confusion here, as there is a process termed “Outcome Mapping” which, while named the same, is different from the outcome mapping methodology developed by IDRC. The former is a modelling technique that creates a visual representation of strategy on a single page (almost like mind mapping); the latter focuses on outcomes in the form of behaviour change.

rather than focussing on pure impacts. In practice Outcome mapping proceeds through three distinct stages: 1. Intentional Design, 2. Outcomes and Performance Monitoring, and 3. Evaluation Planning.

3.1.3 Agile Development (AD)

It has been assumed that consideration of Agile Development stems from the considerable focus on open source software development, central to OASIS.

The concept of agile software development evolved in the mid-1990s as an alternate approach to traditional methods perceived to be heavily regulated, regimented, and micro-managed, and that focussed on use of the waterfall model of software development. In contrast, agile development “promotes a project management process that encourages frequent inspection and adaptation, a leadership philosophy that encourages team work, self-organization and accountability, a set of engineering best practices that allow for rapid delivery of high-quality software, and a business approach that aligns development with customer needs and company goals”⁴. Essentially, the goal is to allow projects to be flexible, adapting to changes more quickly. This is achieved by accomplishing things in small increments with minimal planning, and using cross-functional, self-organized, non-hierarchical, and self-determining teams.

Many specific agile development methods are available, with most promoting multiple development iterations (short 'timeboxes' of 1 - 4 weeks), teamwork, collaboration, and process adaptability throughout the life-cycle of the project (planning, requirements analysis, design, coding, unit testing, and acceptance testing by product demonstration to stakeholders).

3.1.4 Most Significant Change (MSC)

Although not identified, MSC offers an additional option, and is recognised by IDRC. Stemming from PhD thesis work done in Bangladesh by Rick Davies, the process involves the collection of significant change (SC) stories emanating from the field level. These then undergo a systematic selection by panels of designated stakeholders or staff to identify the ‘most significant’ stories showing project impact. Thereafter, stakeholder groups gather read the stories aloud and have regular and often in-depth discussions about the value of these reported changes. When the technique is implemented successfully, whole teams of people begin to focus their attention on program impact.

3.1.5 Utilisation-Focused Evaluation (UFE)

As the name implies, Utilization-Focused Evaluation (UFE) begins with the premise that evaluations should be judged by their utility and actual use, i.e. their utilization. Evaluators should facilitate the evaluation process by designing an evaluation with careful consideration of how everything that is done, *from beginning to end*, will affect ‘intended use by intended users’. Particular attention is given to the question of whose values will frame the evaluation by working with clearly identified, primary intended users who have responsibility to apply evaluation findings and implement recommendations.

Utilization-focused evaluation is highly personal and situational. The evaluation facilitator develops a working relationship with intended users to help them determine what kind of evaluation they need. This requires negotiation in which the evaluator offers a menu of possibilities within the framework of established evaluation standards and principles.

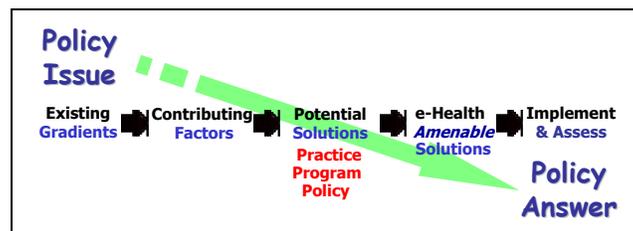
Utilization-focused evaluation does not advocate any particular evaluation content, model, method, theory,

⁴ http://en.wikipedia.org/wiki/Agile_software_development

or even use. Rather, it is a process for helping primary intended users select the most appropriate approach to, and use of, an evaluation in their particular situation. Utilization-focused evaluation is a process for making decisions about these issues in collaboration with an identified group of primary users focusing on their intended uses of evaluation.

3.1.6 Pragmatic Evaluation (PE)

The 'Pragmatic Evaluation' approach was developed by the author of this report for evaluation of telehealth initiatives by 'non-researchers' / 'non evaluators' who often find themselves obligated to perform such an evaluation. Although first developed for the telehealth environment, it has been found to be equally applicable to approaching evaluation of e-health initiatives in general. Developed over a period of several years (2003-2005) the concept was first presented at two international conferences in early 2006⁵, and continues to be refined (diagram below.)



Pragmatic Evaluation applies lessons from the policy, knowledge translation, and health services outcomes literature, as well as solid evaluation approaches, to provide an evidence-based, structured, and systematic approach to evaluation of e-health initiatives. Pragmatic evaluation accepts the view expressed by Glover that "the aim should be to support practical, applicable research, be it theoretical or empirical, rather than applied research *per se*". It also supports IDRC's recognition that policy relevance cannot come at the price of scientific excellence, and that capacity building cannot be seen as an excuse to support work that is not credible.

3.1.6.1 Five Tenets of Pragmatic Evaluation

1. Ask – and answer - policy relevant questions (this is 'applied' research, intended to instigate change)
2. Adopt a scientifically valid research approach (the study design and methods; see diagram below)
3. Establish a clear outcomes framework (which indicators, measures, and tools)
4. Align with existing strategies (maximize value by interweaving with other programs / projects)
5. Get the knowledge to where it is needed (ensure effective knowledge translation)

3.1.6.2 Staged Evolution of eHealth Interventions

Similar to UFE, PE is designed as a process for selecting the most appropriate approach to evaluation of an ehealth intervention. Thus, a major aspect of Pragmatic Evaluation is the 'staged' perspective of ehealth implementation, and application of different study designs at various stages. In the diagram below, it is suggested that growth of ehealth initiatives proceeds in a generally sequential manner through several 'stages' – the pre-ehealth stage, the ehealth development stage (e.g. introduction of telehealth 'activities'⁶), the ehealth implementation stage (e.g. introduction of telehealth 'applications'⁷), the ehealth integration

⁵ i) Developing an e-Health Evidence Base – Pragmatic Research. Transforming Health and Healthcare through e-Health Technologies; An e-Health Conference in collaboration with the Sahyadri Specialty Hospital, Pune, India. 11-12 March 2006; ii) 21st Century Health Care – Managing Information for Evidence-Based Decision-Making, Hosted by CIIT, Islamabad, Pakistan; 7-8th April 2006.

⁶ **Telehealth Activity:** A telehealth mediated pursuit, at the pilot or experimental stage.

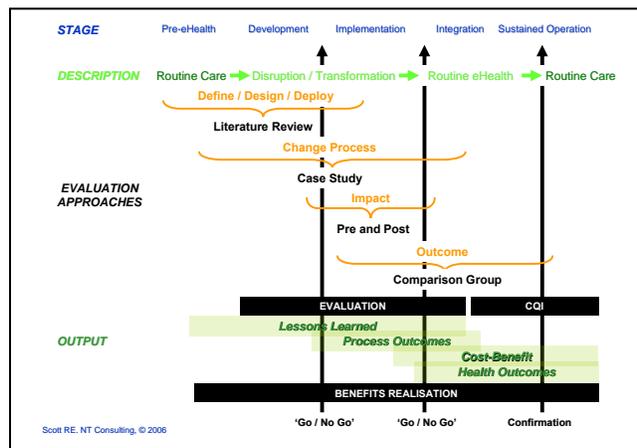
⁷ **Telehealth Application:** A traditional or novel healthcare related pursuit (clinical, administrative, educational, or research) demonstrated to be effectively facilitated through the use of telehealth.

stage (e.g. establishing telehealth ‘services’⁸), and ultimately the sustained operation stage (e.g. introduction of telehealth ‘programs’⁹) where ehealth is regarded as just another healthcare process. The stages of development, implementation, and integration are disruptive and transforming processes that take current routine clinical care to an environment where ehealth is no longer disruptive, but simply routine.

3.1.6.3 Which Study Design?

Based on this perspective, the appropriate study design can be related to the stage of the ehealth initiative and the goal of the evaluation. For example:

➤ If the ehealth initiative is in the design or pre-deployment phase, and the goal is to understand the best design or deployment options, then performance of a comprehensive, focussed (not systematic) literature review is recommended.



➤ If the ehealth initiative is being actively developed, implemented, or integrated, and the desire is to understand the many change processes that occur at these stages, then it may be appropriate to look at a case study approach for the evaluation.

➤ If the ehealth initiative is late stage development, and being implemented (e.g. a telehealth ‘activity’ transitioning to a telehealth ‘application’, or a telehealth ‘application’ transitioning to a telehealth ‘service’), and the goal is to understand the impact (on process or health), then a pre-post or comparison group evaluation design would be appropriate.

➤ If the ehealth initiative is undergoing implementation, integration, or even sustained operation, and the goal is to understand the outcomes (health or economic), then a rigorous comparison group evaluation design would be recommended. (Naturally an RCT is also appropriate, but may be difficult to undertake).

3.2 Proving ‘Value’ – A Focus on Outcomes

How do we know that an ehealth intervention has had any impact? Unless we determine that a change has taken place between two states, and that the intervention was responsible for that change (attribution), we simply do not know (this argues strongly for comparative / controlled study designs). In order to estimate if a change has taken place we turn to certain markers, or outcomes, that can be measured (quantitatively or qualitatively). Even then comfortably assigning attribution in ‘real-world’ (uncontrolled; confounding interventions) research is difficult. To achieve greater confidence in attribution requires a simple research question, a sufficiently rigorous study design, selection of appropriate methodologies, and collection of sufficient high quality data for specified outcomes.

From the health services research literature an ‘outcome’, in its plainest sense, is a ‘result or visible effect’¹⁰, and is a relative value (being a measure of change attributable to an intervention or series of interventions). An

⁸ **Telehealth Service:** A specific *Telehealth Application* offered routinely between *Telehealth Sites* typically within a *Telehealth Program*.

⁹ **Telehealth Program:** A distinct, appropriately conceived, designed, staffed, managed, and funded set of *Telehealth Services* orchestrated under a common administrative structure .

¹⁰ Wilkin *et al.*, 1992; UK Clearing House on Health Outcomes website; Outcome Analysis Workgroup, 1999

unclear and complex relationship exists between health, health services, e-health, and a myriad of other factors in the social system, therefore an improvement in health need not be solely a result of improved health services.

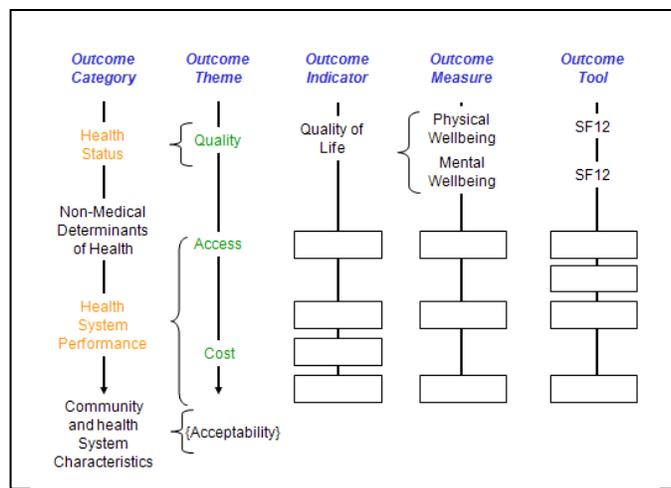
Extending the accepted health services research view of an outcome, research from Canada developed clear definitions for ehealth related outcome terms¹¹ in an attempt to guide future research (see Appendix II). Thus a 'health outcome' can be considered the result or visible effect on *health* (healthcare, healthcare related services, public health) of any type of intervention or series of interventions. This would include not just assessment of healthcare services provided to patients, but it would also include assessment of other socio-economic determinants of health (e.g. housing, social services, employment). In relation to ehealth the 'type of intervention' would be any that employ information and communications technologies.

In order to determine if an 'outcome' has occurred, outcome 'indicators' are used as yardsticks. Often the specific outcome indicator it is desired to assess cannot be accessed or measured, so 'surrogate indicators' are used instead. The question then arises – can the outcome be attributed to the intervention? Here the terms 'proximal' and 'distal' are often applied. In general, proximal outcomes are those results or visible effects that are seen relatively close to the point of intervention along the continuum of the process or procedure being assessed. Changes in proximal outcomes are more likely to be directly related to the e-health intervention, and able to infer attribution. Distal outcomes are those results or visible effects that are seen relatively far from the point of intervention along the same continuum.

Distal outcomes (e.g. the impact upon a patient's health status or quality of life) often represent the 'true' and desirable outcome and are the best indicators. However, they are difficult to measure, and the further an effect is from the point of intervention the more other confounding factors may influence the outcome, and the less 'attributable' is the effect. As a result we often strive to identify more proximal and measurable indicators of impact, and use these as surrogate measures of attributable impact.

3.2.1 Designing an Outcomes Strategy

The ehealth literature is generally unclear on what is an outcome, versus an outcome indicator, versus an outcome measure, and very few outcome tools are described or identified as such. The eHealth Outcome



Development Framework was created to assist in conceptualising the flow between these entities, and to also provide linkages with strategies or structures that may relate to them (see opposite). In brief, this Framework recommends:

- a) Outcome Category. Grounding the strategy in some recognised categorisation scheme (e.g. the ISO framework adopted by Canada and other developed countries [seen in the diagram], or perhaps the MDG framework for developing countries).
- b) Outcome Theme. Adopting specific

¹¹ Scott RE, McCarthy GF, Jennett PA, Perverseff T, Lorenzetti D, Saeed A, Rush B, Yeo M. Telehealth outcomes: a synthesis of the literature and recommendations for outcome indicators. J Telemed Telecare. 2007;13(Suppl 2):1-28.

themes to further focus the strategy (themes are based upon 2 observations; 1. identification that health systems of all countries struggle with balancing the same ‘impossible triad’ – quality, access, and cost, and 2. acceptability (also termed satisfaction) of ehealth solutions by users¹² is essential).

- c) Outcome Indicators, Measures, and Tools. Thereafter a limited number of specific outcome indicators (directly relevant to the evaluation in hand and designed to answer the research question) must be identified, together with their associated measures and tools that will be used.

3.3 Planned ‘Outcomes’ of OASIS II

Further comment is made in the next section, but in general terms clear ‘outcomes’ (in the sense described above) have not been identified for OASIS II. Furthermore, as stated in the proposal, the primary ‘outcomes’ of OASIS II will be unchanged from the initial OASIS proposal, which is considered inappropriate.

At this time, the planned primary ‘outcome’ of OASIS II is to establish, develop, and / or support:

- (i) An African open health information system research, education, implementer and developer network focused around the OpenMRS collaborative and related networks;
- (ii) New functionality for OpenMRS and related health software by the African developer network;
- (iii) Working implementations of OpenMRS and related integrated and interoperable open source healthcare applications for one or more defined health systems in at least three Southern African countries and in a dedicated test bed;
- (iv) A comprehensive set of documentation, including inventory and manuals, best practices, research reports, policy briefs, publications, evaluations, data and interchange standards for open source health software and integrated information systems;
- (v) An evaluation and realization of plans for sustainability of the network and activities.

There are however, no accompanying outcome indicators, measures, or tools.

3.4 Concluding Comments

There is no perfect approach or methodology. Of note is that OASIS II is not being developed ‘de novo’, but is bringing together individual ehealth initiatives each with pre-existing structures and at least one with a pre-determined conceptual framework for outcomes evaluation (MVP). Further, OASIS, the ‘parent initiative’ has an established evaluation mindset and process, which will spill over and inevitably impact OASIS II evaluation.

¹² The term ‘users’ is broadly defined – including patients and providers (including family members), as well as well citizens.

4. OASIS II – Critique of the Draft Proposal

The November 2008 draft version of the OASIS II proposal was critiqued to identify opportunities for improving the content and flow.

4.1 General Comment – ‘Endpoints’

The current proposal is replete in having a variety of potential ‘endpoints’. Thus, visions, missions, goals, objectives, and outcomes are presented throughout; but the overall number is large, they often relate to different component activities, and their inter-relationship is unclear. For example:

The proposal has four (or five) ‘somethings’ (goals, objectives) described in the Abstract (pp 2/3), six main objectives (described on pp3/4 and repeated on p10), and then an additional 5 objectives, described on p10. There is another goal, and another 3 objectives (OpenROSA related), listed on pp8/9. There are a further 2 OASIS objectives stated on p9 under the MVP sub-section. Some of these goals and objectives seem to vaguely inter-relate, but mostly it is simply confusing.

It is stated on p5 of the draft proposal that “The primary outcomes of this project will be unchanged from the initial proposal.” This is considered inappropriate. As a proposal for supplementary funding, it is appropriate for the Vision and Mission to remain the same (as proposed, to provide the required linkage), but surely the supplement goes beyond just continuing support for OASIS to provide additional support for *additional activities* – OASIS II and the additional activities should have their own distinct and clearly enunciated endpoints (research question(s), goals, objectives, outputs, outcomes, indicators, measures, and tools.)

4.2 Research Question(s)

A major element missing from the proposal is a clear, succinct research question or questions. As described above, many goals and objectives are identified (the ‘what’), but there is no explanation as to the ‘why’ (research questions). Why exactly is this research being undertaken? What will it answer?

This is considered a fundamental flaw, since a research question (or questions) is the lynch pin for any study, guiding the remainder of the process. From the research question(s) flows understanding of not only goals and objectives, but more importantly:

- Which research design would be most appropriate to answer the question(s),
- What methodologies might be most appropriate to answer the question(s),
- What outcome indicators will it be necessary to determine in order to answer the question(s),
- What data ¹³ will it be necessary to collect (and how feasible will that data collection process be) to answer the question(s),
- What data analysis approaches would be appropriate to demonstrate the question(s) have been answered, and,
- For whom was the question(s) asked in the first place (i.e. to whom should the results – and conclusions - be reported in order to have some impact on policy, process, or practice.)

Every research or evaluation study should be conducted to answer one or more specific questions (although more than one question can be posed, the study complexity rises with each one presented since they must be linked to subsequent goals, objectives, and indicators, and data collected to answer them). The research question(s) are clearly so important, that they must be carefully considered and constructed. If the questions are

¹³ The term ‘data’ is inclusive of both qualitative and quantitative types of data.

not clearly defined then the evaluation is compromised from the very outset and results may produce unsubstantiated - or worse, misleading - conclusions leading to inappropriate decision- and or policy-making.

Using some stated objectives from the draft proposal (see 4.3 below), a potential research question for OASIS II *might* be:

“Will establishment of a common administrative and logistical structure and process for developing, testing, and advocacy of an architectural framework for developing countries lead to better uptake, sustainability, and health outcomes of open source facilitated ehealth interventions in Millennium Village Project locales?”

However, this is more like retrofitting the square peg to fit the round hole. I would recommend that the lead team find the time – before the planned evaluation workshop – to take a step back, reflect on the overall desire of the group, and to ask themselves very simply – “why?”. From this reflection it should be possible to create a solid, simple, and ‘deliverable’ research question(s). Whatever is created, the study’s research question(s) must be sufficiently credible that it (they) can be presented to and fully supported by all OASIS II stakeholders at the outset of the planned evaluation workshop. Without this cohesive starting point – the study’s touchstone - it will be difficult to make progress towards a solid evaluation plan.

4.3 Evaluation Approach

An important tenet of ehealth is that the technology itself is simply a tool. Unless an ehealth solution can be demonstrated to have a positive and lasting impact on the health of individuals, communities, or populations, then the ‘value’ of the ehealth solution being considered must be questioned.

At this time the proposal is weak on describing the evaluation aspect. Although it is clearly stated that an evaluation workshop will be needed to clarify and structure an evaluation, the proposal could be strengthened by inserting aspects around how specific objectives might be evaluated.

The OASIS II ‘Objectives’ appear to be outlined on p10. These are:

1. Establish a coordinating organization that can coordinate the activities of a group responsible for the development of a version one the e-Health architectural framework and the implementations in developing countries;
2. Establish a global partnership of public and private sector individuals and organizations willing to contribute to the development of the framework and galvanize their efforts into a coherent approach;
3. Develop an e-Health architectural framework comprising a methodology and certain artifacts;
4. Apply the architectural framework to the development of e-Health systems in one or more pilot reference implementations and feed the lessons learned back to the main process;
5. Advocate for the adoption and implementation of the framework and run training workshops in the application of the framework and supporting technologies.

If these are to be the Objectives for OASIS II (note my earlier comment about the desirability for distinct goals, objectives, and outcomes for OASIS II), then each should be related to a prior research question (or goal) and to a subsequent outcome indicator (measure and tool). Specifics can be refined during the planned evaluation workshop, but in the interim the proposal should show logical and linked thought within the document. (These Objectives might even be better presented as study Goals, with more specific steps inserted below each as the study objectives.)

4.4 Impact – Process and Health Related Outcomes

As noted, a strong evaluation approach (particularly to demonstrating health impact) is lacking, however, linking with MVP offers an opportunity to correct this. MVP has already undertaken significant thought and established a logic framework, and a proposed outcomes framework. Successful *integration and implementation* of the OASIS II solutions into MVP projects and programs would be the first test of their ‘value’, and could use process indicators. The ultimate test would be demonstrating a health impact on individuals or the population through using ehealth interventions that apply OASIS II solutions (OpenArch, OpenMRS, OpenROSA) , and could use health-related outcome indicators.

As currently written, the proposal frequently uses terms such as ‘enhance’ and ‘improve’. These are very nebulous terms, and do not provide anything upon which to identify some indicator or anchor some measure.

For example, the budget speaks of a large proportion of the funding going to OpenArch partner meetings (nearly \$300,000) and an OpenROSA related meeting and workshop (\$84,000), but there was no clear explanation in the proposal of what might result from these events. Without understanding their purpose or proposed outputs, it is difficult to suggest means by which they might be evaluated, or how their contributions to the overall study might be evaluated. Can greater substance be applied to the description of these activities and intended / desired results? If, for example, the first OpenArch meeting were intended to establish the base open enterprise e-Health architectural framework for specified countries, that would be an important output and a ‘process’ indicator for the study. Similarly if the second OpenArch meeting were intended to establish the data dictionary (identified as needed) or certain standards for the architecture, it becomes more feasible to think about specific indicators – it would be expected the data dictionary and standards be applied to all MVP mhealth related activities, so indicators might be the % of MVP sites complying with the data dictionary, % of MVP sites implementing the base standards within 3 months, 6 months, 12 months (note that these are measures of implementation, not really value, or success).

Could the project be pushed further – what of the OpenROSA activities – will they result in a purpose-built software program that will be implemented in specific MVP locations? If so, this should be clearly stated – what software programs (for monitoring immunization of children under 5 years of age; for determining if community residents practice good hygiene)? If stated, it becomes feasible to consider potential outcome indicators, and related measures, and tools, that would demonstrate the impact and value of OASIS II in relation to health outcomes, not simply process outcomes. (And which would align well with MVP’s current outcomes oriented activities).

A specific undertaking stated in the proposal is introduction of eHealth Specialists to MVP locations. This again is a significant budget line item – can focused outcomes be linked to their activities? Although speculative, a series of likely activities / undertakings by these people were listed (p11). Could key activities / undertakings be selected, and transformed into process and or outcome indicators?

To some degree more specific activities were shown in the timeline (Gantt chart, pp13/14) and the Results and Dissemination section (pp15/16), offering opportunity to identify concrete undertakings, which might well have reasonably anticipated process or health related outcomes. But several specific activities seemed unrelated to the text (e.g. “develop specifications for a drug warehouse and management system” is stated in the timeline, but not mentioned in the text.) It is essential that the Gantt chart activities align with the activities described in the text.

Finally, as indicated, closer alignment with the thought process and potential indicators described in the MVP Monitoring and Evaluation Strategy document (August 2008) might be feasible, and strengthen the OASIS II proposal.

4.5 KT - Knowledge Transfer / Translation

In 'tasks' identified for OASIS II "publication and presentation of the results" is mentioned and similarly the objectives on p10 speak to "Advocate for the adoption and implementation of the framework". Similarly the timeline notes 'Dissemination' and speaks of a website, conference, papers, and a policy brief. Ironically, the Results and Dissemination section (pp15/16) does not really address dissemination (or KT) in a structured and meaningful fashion.

As noted, this is an applied research undertaking intended to have impact and to change policy, process, and / or practice. Missing from the proposal, therefore, is any form of description of a solid communication and dissemination plan to undertake (and to evaluate performance of) a knowledge transfer / translation strategy for OASIS II. Such activities require resources (time, effort, and funding), and must be planned, structured, and budgeted for.

4.6 Conclusion

The draft OASIS II proposal provided for review was complicated and confusing. Primary contributing factors were a lack of a research question(s) to guide the study, a lack of clear OASIS II related 'endpoints', a lack of a strong evaluation approach (particularly in assessing health impact), and an unclear knowledge transfer / translation strategy.

5. Discussion and Recommendations

5.1 Discussion

The ultimate goal is to support expansion of successful IDRC-funded ehealth initiatives in Africa that enhance regional development. In general terms, IDRC activities are characterized by support for *applied research*. ***Therefore a research approach is required that results in documentation of measured outputs and outcomes (process and health related) and validated conclusions.***

The reality is that some of the evaluation options discussed may be difficult to employ, whilst others have common facets that might make selection moot, or permit elements of each to be included in a final OASIS II evaluation model. But, selection of the most appropriate option(s) first requires determination of the research question(s), and description of clear and separate goals, objectives¹⁴, and outcomes for OASIS II. Streamlining these would help the proposal and also help in formulating the planned evaluation, since they guide that process.

Two primary foci can be identified for any e-health evaluation. First, that of the organization providing the financial resources (the funding agency) needs to know – and demonstrate - that their investment has been of ‘value’. Second, that of the organization actually performing the study (the ‘study agency’) which wants to know – and demonstrate – that their e-health solution has been of ‘value’. This simple scenario is often more complex still, since the partnership model means more than one funding agency and more than one study agency (each with different expectations) is involved with any single initiative. The more ‘stakeholders’ involved, the more complex the undertaking becomes in a seemingly exponential manner! It is the job of the Project Team to ensure both foci are adequately addressed in an evaluation plan.

5.2 Recommendations

In complex, multi-partnered research it is well recognised that a participatory approach is more likely to be successful. To this point, only a high-level conceptual basis has been established for OASIS II. It will be essential to bring together broad representation from all major partners, and to guide them through an evaluation design process.

This should begin by gaining clarification and agreement on a minimal number of research questions (this discussion should be initiated by the Project Team’s initial list of research questions). From this will flow a better understanding of the appropriate evaluation approach and methodologies, which it is anticipated will be split between capacity building and intervention components. Understanding the evaluation approach(es) and methodologies will lead to identification of a minimal number of relevant process or health-related outcome indicators (and their associated outcome measures, and outcome tools).

Once this has been achieved, it will be possible for a structured plan (the Evaluation protocol; see Appendix III) to be developed, and for any necessary logistical support and training required for the evaluation to be considered (e.g. field training for data gathering and analysis). Of particular importance will be the need to ensure modest goals are set so that evaluation related workload expectations are realistic, and field workers are not stretched beyond their limits.

¹⁴ Goals are broad, objectives are narrow; goals are general intentions, objectives are precise; goals are intangible, objectives are tangible; goals are abstract, objectives are concrete; goals can’t be validated as is, objectives can be validated. The objectives (being narrow, precise, tangible, concrete, and capable of validation) can then be used to identify desirable outcomes, and subsequently to indicators, measures, and tools.

Although details are limited, it would appear that the MVP already has a well established and hierarchical human resource structure in place in the field that could support the evaluation activity, and this will be enhanced by inclusion of the proposed ‘eHealth Experts’.

Although somewhat unrelated to the workshop goal of developing a sound and universally supported evaluation strategy, this might also be an appropriate time to consider process and needs for Knowledge Translation.

5.2.1 *Evaluation Workshop*

5.2.1.1 *Perspective*

A host of stakeholders are typically involved in any ehealth activity. This raises immediate concerns as to whose perspective is to be addressed in the evaluation. Although contentious, it is suggested that ehealth is intended to serve the needs of individuals, communities, or populations – therefore a patient-centred or societal perspective is the ideal. In reality, those who fund the evaluation are likely to be most demanding that their perspective be reflected. It is anticipated that negotiation and compromise will be needed to bring diverse perspectives closer towards the desirable goal. Once solidified, it is beneficial to reflect this in the research question(s) posed.

5.2.1.2 *Evaluation Approach*

Pragmatic Evaluation, being a base framework rather than a pre- or pro-scribed evaluation approach, offers advantages:

- PE focuses efforts on *policy relevant research*, the intent of which is to implement Knowledge Translation to influence policy, process, or practice change and / or development. (The full history behind OASIS, MVP, Open ROSA, Open MRS, and OpenArch is not fully understood by the consultant, but it has been assumed each has it’s foundation in policy relevant research.)
- PE does not obviate the application of more sophisticated and specific research tools (such as utilization-focused evaluation) if deemed appropriate and feasible.
- PE does not pre-determine or restrict the outcome indicators to be used to determine ‘value’.

Regardless of which specific approach is to be taken, it is recommended that a participatory approach be adopted, thus the suggested workshop identified in the proposal will be an essential component in the evaluation of OASIS II, and should include all significant ‘boundary partners’ / stakeholders.

5.2.1.3 *Study Design*

The proposed OASIS II has essentially two aspects:

- a) A capacity building component (e.g. relating to Objectives 1-3 and 5 seen in section 4.3 above).
- b) An intervention component (e.g. relating to Objective 4 seen in section 4.3 above).

Even if the specific OASIS II objectives change a little, this reality will remain. It is suggested that a more qualitative approach be taken to the capacity building component, and a mixed methods quasi-experimental approach be taken to the intervention component.

- Capacity Building.

This might capitalize on aspects of the Outcome Mapping or Utilisation Focussed Evaluation techniques, or more traditional qualitative methodologies such as interviews, surveys, focus groups, and journaling, to assess impact.

- Intervention.

Based on the Pragmatic Evaluation concept, the recommended study design is related to the stage of the ehealth initiative and the goal of the evaluation. Given the anticipated focus of OASIS II on existing and more mature ehealth solutions or applications within the MVP activities, it is likely that the study design required of evaluators would be either a *pre and post* or *comparison group* study design (perhaps between MVP sites – control sites with no OASIS II solutions, experimental sites with OASIS II solutions).

6. Conclusions

A practical and achievable evaluation framework, complemented with insight regarding fundamental evaluation (or research) design, is required for OASIS II. Beyond establishing value of the overall OASIS II project and its component activities, there is a real opportunity to enhance the outcome evaluation scheme provided by the MVP, and thereby demonstrate clinical impact of OASIS II ehealth interventions. Given the early stage of proposal development for OASIS II, only modest insight for specific evaluation options has been described, but clear recommendations have been provided. The final evaluation development should take place during a focused, multi-stakeholder workshop, as currently proposed.

The purpose of an evaluation is to produce timely, relevant, credible, and objective findings and conclusions (based on valid and reliable data collection and analysis) and to effectively disseminate that knowledge to ehealth researchers, practitioners, decision-, and policy-makers in order to influence current or future decisions. Following the recommendations presented in this report will assist in the efficient design and consistent performance of an OASIS II evaluation, plus effective dissemination of the evaluation findings related to OASIS II in Africa, and thereby aid evidence-based decision making for the field of ehealth and achieve IDRCs goals.

Appendices

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Appendix I

Biography of Author

Dr. Richard E. Scott

Dr. Richard E. Scott is an Associate Professor in the Global e-Health Research and Training Program of the Health Innovation and Information Technology Centre, Faculty of Medicine, Department of Community Health Sciences, University of Calgary. He is also a Canadian Harkness Associate (2004-2005), and a Fulbright New Century Scholar (2001-2002) alumnus; experiences that opened his policy and global e-health perspectives, respectively.

Richard focuses his interests on examining the role of e-health (telehealth + health informatics) in the globalisation of healthcare, including aspects impacting the implementation and integration of e-health globally and locally (*'glocal' e-health*). He promotes the application of **'culturally sensitive and technologically appropriate'** e-health solutions, and is pursuing collaborative research, capacity building, and implementation activities with colleagues in European, Asian, Australasian, African, and Latin American and Caribbean (LAC) countries.

Richard views e-health broadly, as the use of any information and communications technology (ICT) to mediate health, healthcare, health education, or health research. He has over 30 years of healthcare and research experience from Canada, the USA, and the UK; as a medical laboratory technologist, biochemist, clinical chemist, toxicologist (clinical, forensic, environmental, and occupational), Director of Research (for a large hospital corporation), and as a telehealth / e-health researcher. His focus is on finding practical ways to address issues that stand in the way of real-life implementation of appropriate e-health solutions. He also teaches a course: 'Sustainable e-Health – From Business Case to Policy'.

His research program and interests are directed towards **inter-jurisdictional e-health policy** (management and facilitation of the complex interactive trans-border environment of glocal e-health), **strategic implementation** (developing glocal strategies to guide introduction of appropriate e-health solutions to address current and future needs), **outcomes and evaluation** (identifying and defining suitable outcome indicators and developing tools and frameworks for rigorous yet pragmatic demonstration of the value of e-health), and **environmental e-health** (a new area of research spawned by Richard in 2003 to understand the environmental costs [e.g. e-waste] and benefits [e.g. reduced greenhouse gas and particulate emissions] of e-health).

Richard has acted as an expert advisor and reviewer for many international initiatives. Richard has also provided, and continues to provide, expert opinion and active support to national, provincial, and territorial governments, agencies, and healthcare programs in relation to evaluation, outcomes, policy, and strategy. Dr. Scott was a Founding member of the Canadian Society of Telehealth (CST) in 1998, President of CST (2004-2006), and is Co-Chairperson of the CST's International Special Interest Group.

Appendix II

Terminology

When describing indicators and measures it is essential that a common understanding exist of what is meant by any particular term. At this time there is no single, universally accepted source available that describes or defines common terms applied within the ehealth environment. In the absence of such material, the following descriptions have been extracted or adapted from various documents or presentations. Several refer to Telehealth; Health Informatics related terminology is being developed, but is not yet mature enough for presentation. None the less, use of the terms listed below is recommended to ensure consistency as parameters are measured.

1. Outcomes Definitions.

Note that in the definitions below 'e-health' is used exclusively. e-Health is considered an umbrella term; it encompasses both telehealth and health informatics related activities, regardless of the communications modality used to accomplish them.

An **e-health outcome** is defined as:

The result(s) or visible effect(s) on health, healthcare, or healthcare related services of any type of e-health intervention.

As such e-health outcomes would encompass not only impact on patients (perhaps the ultimate outcome), but also other areas including education (provider and patient) and administration (including telematics); i.e. any area in which e-health is employed.

It is important to differentiate between the complementary perspectives of measuring what might be termed true outcomes (patient related) versus measuring process outcomes (health system related). In general we are adept at measuring the latter, but are not as adept at measuring – even identifying – other outcomes.

An **e-health outcome indicator** is defined as:

The parameter it is desired to assess in order to determine if an e-health intervention has had a result or visible effect.

An outcome indicator should provide information in terms of a longitudinal assessment of a change from one point in time to another.

An **e-health outcome measure** is defined as:

The specific component or element of an outcome indicator used to quantify (quantitative measure) or gauge (qualitative measure) the result or visible effect of an e-health intervention.

An **e-health outcome tool** is defined as:

The specific instrument used to collect quantitative or qualitative data for any single outcome measure.

Specific tools would include administrative databases, surveys or questionnaires, logs, case report forms (CRF's), key informant interviews, or focus groups.

2) Functional Infrastructure Definitions

a) **Telehealth Unit:** The related group of elements (hardware and software, including peripheral devices) that comprises a distinct and functioning apparatus that can be used to perform a specific Telehealth Activity, Application, or Service [see definitions below]. A Telehealth Unit may be static, mobile, or handheld, and includes units for off-site use.

b) **Telehealth Facility:** A discrete and identifiable physical location (e.g. dedicated room, or dedicated space within a room) from which Clinical, Research, Education, Administration, or Mixed; (CREAM) telehealth related pursuits are provided or received. A Telehealth Site may have more than one Telehealth Facility.

c) **Telehealth Site:** A discrete and identifiable geographic location (e.g. healthcare facility, clinic, campus) from which one or more Telehealth Activities, Applications, or Services are provided or received. This will include 'client' homes and other locations as home telehealth activities expand.

3) Receiving and Delivering Site Definitions

For clinical telehealth activities, the 'delivering site' is that site at which the specialist or referred clinician is located, and the 'receiving site' is that site at which the referring clinician and / or patient is located.

For administrative meetings facilitated via telehealth, no distinction is made between any sites as delivering or receiving.

For educational telehealth activities, the 'delivering site' is that site at which the primary presenter is located, and the 'receiving sites' are those sites at which the learners are located.

4) Functional Relationship Definitions

a) **Telehealth Activity:** A telehealth mediated pursuit, at the experimental, pilot, or formative evaluation stage.

b) **Telehealth Application:** A traditional or novel healthcare related pursuit (clinical, administrative, research, or educational; CARE) at the summative evaluation stage or demonstrated to be effectively facilitated through the use of telehealth.

c) **Telehealth Service:** A specific and proven Telehealth Application offered routinely between Telehealth Sites typically within a Telehealth Program [e.g. Forensic Telemental Health Assessment; Pre-catheterisation Teleassessment; Home Telemonitoring].

d) **Telehealth Program:** A distinct, appropriately conceived, designed, staffed, managed, funded, and accredited set of Telehealth Services orchestrated under a common theme and common administrative structure [e.g. Telemental Health Program; Telecardiology Program; Home Telehealth Program].

e) **Telehealth Setting:** Type of facility at which a telehealth session is performed (for example: hospital, community health centre, community health facility (LTC facility / residential care facility), general practice, specialist practice, home, or other).

f) **Telehealth Policy:** A set of statements, directives, regulations, laws, and judicial interpretations that direct and manage the life cycle of e-health.

iv) Miscellaneous Definitions

- a) **Client:** A generic term intended to encompass any individual who is the recipient or direct beneficiary of a telehealth session (thereby interacting in some form with the healthcare system). For example; a patient, a patients' family member, a well person, or a clinician. It is NOT intended to imply any monetary transaction or obligation.
- b) **User:** A generic term intended to describe any individual who applies telehealth during the course of their day. A 'user' may or may not be a 'client', and would include participating health personnel.
- c) **Other Sites Connected:** The count of all other sites that were involved in a 'telehealth session' while a site was connected to a session. Recorded by each telehealth site for all other sites, this describes the size of a multipoint connection, It is accepted that there will be some anomalies in the number of sites recorded by each site due to sessions in which some participants drop in and out of the session.
- d) **Emergent:** Refers to a situation where a service cannot be delayed for more than 24 hours from the time of referral.
- e) **Urgent:** Refers to a situation where a service is required within 7 days of referral.
- f) **Routine:** Refers to a situations that are neither emergent or urgent.
- g) **Telehealth Session:** A period of time set aside or used for a telehealth-related activity that involves the use of information and communications technology (ICT)* to link two or more facilities. The activity might include clinical interactions (delivering services, providing inter-professional consults), administrative interactions (management meetings between facilities or jurisdictions), research interactions (assessing 'telehealth activities'), or educational interactions (seminars, rounds, CPD, on-line CBT).
- h) **Telehealth Encounter:** A single 'telehealth session' may be made up of one or several encounters between 'users', which may or may not be recorded individually (e.g. one chronic disease management clinic may provide services to several patients individually or collectively during one session). A single 'telehealth encounter' may be between: a 'client' and a healthcare provider; a client, a healthcare provider, and another person such as an interpreter, another healthcare provider, or a family member or carer; two or more healthcare providers; or individuals involved in administrative, research, or educational interactions, and which may or may not include healthcare providers.
- i) **Telehealth Session Identifier:** This is a unique identifier allocated to each single 'telehealth session'. Use of such an identifier links activity from multiple sites involved in a single telehealth session, and removes ambiguity or inflation of data when quantifying telehealth activity. A 'telehealth session identifier' may vary by jurisdiction, and could be assigned through a centralised scheduling / booking system.
- j) **Telehealth Session Purpose:** The principal purpose for conducting a telehealth session. This may be identified through the acronym CARE: 1. Clinical (including health promotion and / or public health), 2. Administrative (including management meetings), 3. Research (including evaluation activities), and 4. Educational.

Appendix III

Recommended Content of an Evaluation Protocol

Although there are no absolutes, in general terms an Evaluation Protocol would include the contents listed below. The Evaluation Protocol is a distinct and separate document from the Project Proposal.

- Title page (short but accurately descriptive of the proposed study)
- Summary / Abstract (succinct description of the study from rationale through methodology to expected results)
- Introduction
 - Statement of the problem in its local context
 - Literature review
 - Purpose of the study
 - Scope of the study
 - Research question(s) and objective(s)
- Description of the planned eHealth Intervention
- Evaluation Design (what design will be used and why)
- Evaluation Methods
 - Participants – description; inclusion / exclusion criteria; sample size; sampling / recruitment process
 - Data management plan
 - What variables will be measured and why
 - What outcomes indicators will be used and why (and what confounders may exist)
 - What outcome measures will be used and why
 - What outcome tools will be used and why (how will any new instruments be validated)
 - Procedures for data collection (including design of any needed data collection forms)
 - Planned data analysis (what descriptive or inferential statistics will be used)
- Study limitations
- Ethical Review – which Committee will review and approve
- Budget – details of costs for equipment, personnel, consultants, etc.
- Workplan
 - Describe at a reasonably high level the sequential steps needed to execute the evaluation. Include any steps needed for instrument validation, personnel training, access to a secondary database, etc.
 - Timeline (transfer the text above into a graphical presentation for overview; e.g, GANTT chart)
- References (document the literature used to substantiate any background or justify use of any approaches, measures, tools, etc.)
- Appendices (e.g. survey tools; interview guides; data collection tools)

Appendix IV

Acronyms

CIDA	Canadian International Development Agency
IDRC	International Development Research Centre
MVP	Millenium Village Project
OASIS	Open Architectures, Standards and Information Systems (for healthcare in Africa)
Open-MRS	Open Medical Records System
Open-ROSA	