

PROMS in HIV: current science and practice

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Background: why PROMS?

- PROMS form a core of UK policy
- Emerged from surgical contexts
- Aim to promote quality and equity (Dawson, BMJ)
- *“From the life of the virus to the life of the host”*
(Alexander, IHV)
- Utility
 - Structure clinical encounters/ direct care
 - Audit services. Benchmark, support standards
 - Allocate resources/programme planning/ commissioning
 - Research
 - Allows us to determine/ attend what matters most to the person

PROMs: formats

- Can be “quality of life measures”
 - E.g. MOS-HIV
- Can be problem-specific
 - E.g. HIV signs & symptoms checklist
- Can be generic unidimensional
 - E.g. GHQ
- Generic multidimensional
 - E.g. EQ-5D, WHOQOL

HIV & PROMS

- Quality of life has long been of interest in HIV
 - ? Clinical utility compared to problem-measures
- Process of development is unclear- how “person-centred”?
- How “different” is HIV?
 - Specific populations/ stigma/ psychosocial dimensions/treatment/ chronic & progressive
- What matters in 2014?
 - Multidimensional problems from diagnosis (Simms Lancet Infect Dis 2012, J Pain Symptom Manage 2011) & alongside ART (Lowther Int Nurs Res 2014)

Crucial methodological considerations

Validity

- *Face/content validity*
- *Construct validity*
- *Acceptability (cognitive interviewing/format/length)*
- *Internal consistency*

Reliability

- *Ability to discriminate between known groups*
- *Test-retest reliability*
- *Sensitivity to change*
- *Minimal Clinically Important Difference*

Implementation

- Beyond face/content validity
 - What makes promotes engagement with “users”
 - Community & clinicians
 - Commissioners (take it beyond “virological control”)
 - Support BHIVA standards
- Enormous “change management” potential in PROM implementation
 - Antunes 2014: how to routinely implement
 - Etkind 2014: feedback loop & changing outcomes

An example of a successful PROM in HIV the "POS"

Harding et al. *Health and Quality of Life Outcomes* 2010, **8**:10
<http://www.hqlo.com/content/8/1/10>



RESEARCH

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Validation of a core outcome measure for palliative care in Africa: the APCA African Palliative Outcome Scale

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Abstract

Background: Despite the burden of progressive incurable disease in Africa, there is almost no evidence on patient care or outcomes. A primary reason has been the lack of appropriate locally-validated outcome tools. This study aimed to validate a multidimensional scale (the APCA African Palliative Outcome Scale) in a multi-centred international study.

Methods: Validation was conducted across 5 African services and in 3 phases: Phase 1. Face validity; content analysis of qualitative interviews and cognitive interviewing of POS; Phase 2. Construct validity; correlation of POS with Misoula-Vitas Quality of Life Index (Spearman's rank tests); Phase 3. Internal consistency (Cronbach's alpha calculated twice using 2 datasets); test-retest reliability (intraclass correlation coefficients calculated for 2 time points) and time to complete (calculated twice using 2 datasets).

Results: The validation involved 682 patients and 437 family carers, interviewed in 8 different languages; Phase 1. Qualitative interviews (N = 40 patients; N = 38 carers) showed POS items mapped well onto identified needs; cognitive interviews (N = 73 patients; N = 59 carers) demonstrated good interpretability; Phase 2. POS-MVQoL Spearman's rank correlations were low-moderate as expected (N = 282); Phase 3. (N = 307, 2nd assessment mean 21.2 hours after first, SD 7.2) Cronbach's Alpha was 0.6 on both datasets, indicating expected moderate internal consistency; test-retest found high intra-class correlation coefficients for all items (0.78-0.89); median time to complete 7 mins, reducing to 5 mins at second visit.

Conclusions: The APCA African POS has sound psychometric properties, is well comprehended and brief to use. Application of this tool offers the opportunity to at last address the omissions of palliative care research in Africa.

Background

The lack of clinical and research activity to enhance care of the dying among those HIV-infected is a global challenge. Despite two million deaths during 2007, with emerging international data reporting high mortality even as access to therapy increases, very little scientific attention is paid to improving the experience of death and dying [1].

The burden of progressive, life-limiting disease in Sub-Saharan Africa is reflected in the epidemiology of HIV

[2,3] and cancer [4]. In sub-Saharan Africa during 2007 there were 22.5 million people living with HIV infection; 1.7 million adults and children became infected with HIV; and 1.6 million died of AIDS [1]. Based on GLOBOCAN 2002 cancer rates and UN population predictions, there are an estimated 7.6 million new cancer cases and 6 million deaths from cancer in Africa in 2007 [5], and malignancies are a common presentation of HIV progression. The burden of other progressive non-malignant diseases is unknown.

Significant advances have been achieved in African palliative care provision to manage the highly prevalent and burdensome problems experienced by those with incurable terminal disease. However, there is very little

deaths in Africa³ and that by 2020, 1 new cancer cases will be in the developed world⁴. For the overwhelming majority of us who currently endure these and other severe, life-limiting illnesses, access to culturally appropriate holistic palliative care (that is effective pain management) is at best limited, and at worst nonexistent⁵. Addition to extending the coverage of palliative care services across the continent, the APCA African Palliative Care Association (APCA) was established to ensure those at least of their resource-constrained optimal environment. Progress achieved in Africa of care provided as part of a continuous improvement strategy, however, must be led in, and inform, routine service-level practice to be sustainable. Despite the need among care providers⁶, measuring the quality of palliative care provision in Africa is problematic in the absence of validated outcome instruments⁷, resulting dearth of empirical evidence is scarring to palliative care but indeed is symptomatic of a wider problem: the "mismatch" of African health research⁸, consequently, this study sought to develop a simple and brief multidimensional outcome measure for palliative care (the APCA African Palliative Outcome Scale (POS)) using patient-level indicators could be used in routine clinical practice.

Methods

alpha and beta testing protocol followed sequential stages in outcome tool and validation, prior to the final phases validation. An expert panel review was conducted. WHO's definition of palliative care⁹, an expert panel represented six countries (4 which were African) and was multidisciplinary in nature, comprised of clinical, academic and advocating professionals. Five key areas of palliative care were identified for content: pain and symptom relief, access

to and current use. Participants addressed views of appraising current practice and priorities for the development and application of the development and application of feasible, acceptable and appropriate outcomes within the African context.

None of the 32 multiprofessional palliative care participants were currently using a multidimensional palliative care scale. Current practice of outcomes relied on the use of ad hoc scales, longhand note taking, and use of 'recall' of previous health status. Recommendations for future measures included items that take account of the family of disease, the differences between HIV patient trajectories, and the palliative of advanced disease in South Africa. Resources should be allocated to staff to familiarise them with measure use, restructure to be able to utilise outcome of ensuring acceptability and appropriate patients and families in terms of formulation and identifying mechanisms to facilitate data collection.

Recommendations have been generated from the data, addressing: (i) service enabled and translational research; (ii) development of equally applicable to HIV and cancer but tools for children; (iii) inclusion of families; and (iv) support for staff to their activities. The design of multidimensional outcomes using this guidance is timely to inform current practice, and to guide funding and service development.

HIV, cancer, outcomes, outcome measure, Sub-Saharan Africa, South Africa. The design of multidimensional outcomes using this guidance is timely to inform current practice, and to guide funding and service development.

adults and children living with HIV/AIDS in Sub-Saharan Africa, with 2.4 million AIDS-related deaths and 3.5 mil-



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aharan Africa: a survey

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2007

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initiatives to HIV/AIDS care in challenges to delivering end-of-

addressing the domains of service and strategies, funding, responses were sought.

in 14 countries with a mean 37 years across diverse settings. Care in advanced stages (65% offering care for a mean of 30) patients. Availability, lack of trained staff, effects of poverty on disease and Government endorsement, not.

balancing quality and coverage, collaborating between donor and directors of end-of-life care

tions. Even considering the current global treatment, it must be recognized that the nature of the disease, weak public health infrastructure and other factors [1] make quality palliative and end-of-

Page 1 of 6
(page number not for citation purposes)

of palliative care and evaluation findings. During 2003, funders, non-governmental organisations, associations, and practitioners involved in

Review

the HIV and cancer care in sub-Saharan Africa, and how to develop such services that carry resource implications. Home capacity and the resources and clinical trials must be primary concerns. Simple remains a major constraint. Areas of good return to community needs and capacity throughout the disease course (including and dissemination of diverse referral and a audit and quality assessment.

Definition of palliative care⁹

that improves the quality of life of patients facing the problems associated with illness, through the prevention and relief of pain of early identification and impeccable of treatment of pain and other problems, social and spiritual¹⁰.

In African countries were asked to prepare reports on their activities, listing lists and websites that promote and sub-care services in Africa (eg, the Association for Hospice and Palliative Care (Hospice and Palliative Care Online) (hospiceonline.org) requests for information. From the unpublished work, service and research traced and reviewed with respect to impact, lessons, and findings (panel).

26 palliative care service organisations, described in 38 reports. Research, monitoring findings from 15 studies were published organisations. A further 169 relevant reports were included. The full review tables with reference lists are available on of charge¹¹.

Search strategy and selection criteria

binarisation of a systematic review and documentary analysis. We searched databases with supplementary hand searches in July 2003. We searched (1981-2003), CINAHL (1981-2003), AMED (1985-2003), Cochrane Database of Systematic Reviews (1987-2003), EMBASE (1980-2003), Science Citation Index and Social Sciences Citation Index (1981-2003). Search terms were the "end of life", "advanced disease", "palliative care", "terminal care", "terminally ill", "palliat", "hospice", "dying", "end of life", "advanced disease", "sustainability", and "coverage" together with the union of all named sub-Saharan African countries and Africa.

Evolution of HIV PROM use in Africa

1. Embedded into routine practice, audit, training, management, resource allocation & research across Africa (e.g. CASIPO)

Commentary

Feedback from African palliative care practitioners on the use of the APCA POS

Kath Downing, Julia Downing

An appraisal of the status of palliative care in Africa conducted on behalf of the 2004 Founding of the World Health Organization, for the overwhelming majority of Africans including cancer, HIV/AIDS, and other life-threatening diseases, access to culturally appropriate palliative care that includes effective pain management was 'not best known' and 'at worst nonexistent' (Harding and Higginson, 2006). The surprising need for increasing the accessibility and coverage of palliative care without compromising on quality was identified as a primary concern among palliative care practitioners in the region (Harding et al., 2010). However, ensuring the quality of care provided was problematic, without rigorously validated outcome measures that reflected the disease profile on the continent and were suitable for use within the resource-constrained and culturally different African context. The Palliative Outcome Scale (POS) measures patient physical symptoms, their psychosocial, emotional, and spiritual needs, and the provision of information and support at the end of life (Hosmer and Higginson, 1999; <http://pos.pallcare.org>), but although it has been widely used for cancer patients in the developed world it had not been validated for the African setting.

The African Palliative Care Association (APCA) POS is a brief multidimensional outcome measure that uses patient and family level indicators specifically developed and validated for use in the African context (Powell et al., 2007; Harding et al., 2010). This tool was developed under the auspices of the APCA by a multi-professional expert group that included approximately 50 African and international palliative care practitioners. It was adapted to be significantly adapted from the original POS (see 2012). The group deemed it important that a palliative care measurement tool for use in Africa be locally validated, appropriate for use by both people with cancer and

people with HIV, and relevant across the disease trajectory (Hosmer and Harding, 2010). Although the scientific principle underpinning palliative care outcome measurement are transferable, it is essential that outcome measures reflect the prevailing diseases and culture (Harding et al., 2007). Owing to the varying levels of patient and family literacy in Africa, the APCA POS can be completed either by the patient themselves or by a number of staff asking the questions. All answers are scored using Likert scales from 0 to 5, with numerical and descriptive labels. The items address physical and psychological symptoms, spiritual and emotional concerns, and psychosocial needs. The APCA POS measures the key domains of palliative care, which include pain and symptom relief, emotional and spiritual support and grief counselling, support for family caregivers, and advanced care planning. Unlike with the original POS, there is only one version for both the patient and the family carer, with the few seven questions asked at the patient and the remaining three at the carer (Powell et al., 2007; Harding et al., 2010). It was necessary for the tool to be simple and easy to use so that progress achieved in the quality of care provided could form part of a continuous improvement strategy that could be used to inform daily practice (Harding et al., 2008).

Workshop on using the APCA POS to improve patient outcomes
A workshop convened by the authors of this article took place during the recent APCA and Hospice Palliative Care Association of South Africa conference held in Johannesburg on 17–20 September 2012. The 72 conference delegates who participated in the workshop came from a number of African countries, including Zimbabwe, Uganda, Kenya, South Africa, Rwanda, Botswana, Swaziland, Nigeria, Tanzania, Malawi, Namibia, Ghana, Cameroon, Guinea, and the Ivory Coast. They included clinicians currently providing

2. Devtpt & validation of first PROM for children

National viewpoint

A palliative care outcome measure for children in sub-Saharan Africa: early development findings

Julia Downing, Macklin Ojing, Richard A Powell, Zipporah Ali, Joan Marston, Michelle Harding, Jennifer Ssemogoba, Stephen Williams, Faith Mwangi-Powell and Richard Harding discuss the initial phases of creating a palliative care outcome scale for children in sub-Saharan Africa

The need for palliative care for children in sub-Saharan Africa is significant, with a mortality rate of 34.5% for children under five years of age.¹ In addition, 2.1 million children in sub-Saharan Africa are

living with HIV² and 84% of the 166,000 children diagnosed annually with cancer live in the developing world, many of them in sub-Saharan Africa.³

Children's palliative care is a relatively new discipline to the continent, and continuing effort is required to expand access to quality palliative care for children. The measurement of the care domains of palliative care is essential to ensuring that the quality and efficacy of palliative care are demonstrated at both the patient level and the family outcome level.

While the development of the African Palliative Outcome Scale (APCA POS) of the African Palliative Care Association (APCA) was an important advance in measuring patient and family outcomes, a comparably validated paediatric tool was lacking. The authors of this article thus sought to develop such a tool – the APCA African Children's POS (ACPOS).

Key palliative care domains were identified against which potential measurement indicators were developed, including pain, symptoms, distress, quality of life, communication and family support. Two versions of the APCA African ACPOS were developed (for non-verbal and verbal children) and piloted across four sites.

High baseline needs were evident in terms of pain, symptoms and worry about the child's illness, with significant improvements seen in these domains. Healthcare professionals felt the tool enhanced communication and increased insight into children's conditions.

The results of the pilot study suggest that the APCA African ACPOS is a useful tool to measure outcomes and its responses to change. Amendments were made to the tool following an expert review of the findings, and further validation is under way.

Key points

● In sub-Saharan Africa, the high prevalence of life-threatening illness among children necessitates a public health approach to palliative care provision. To ensure quality and efficacy are demonstrated, measurement of the care domains of palliative care is essential.

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3. Sensitivity & specificity of scoring systems for low literacy

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Self-report measurement of pain & symptoms in palliative care patients: a comparison of verbal, visual and hand scoring methods in Sub-Saharan Africa

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Abstract
Background: Despite a high incidence of the limiting disease, there is a deficit of palliative care outcome evaluation in sub-Saharan Africa. Provision of end-of-life care calls for appropriate measurement tools. The objective is to compare four approaches to self-report pain and symptom measurement among African palliative care patients completing the African Palliative Care Association African Palliative Outcome Scale (APCA POS).
Methods: Patients were recruited from Kenyan services (in South Africa and in Uganda). Research nurses cross-sectionally administered POS pain and symptom items in local languages. Both questions were scored from 0 to 5 using 4 methods: verbal rating, demonstrating the score using the hand (0), holding a fish on a visual scale (2), and indicating a point on the journey visual scale (3, 4, 5). Scores were correlated with verbal scores as reference using Spearman's rank and weighted kappa. A Receiver Operating Characteristic (ROC) analysis was performed.
Results: 315 patients participated (mean age 43.5 years, 60.8% female). 21.1% were HIV positive and 33.8% had cancer. 49.7% lived in rural areas. Spearman's rank correlations for pain scores were 0.80% (F 0.02), 0.73% (p < 0.001) for symptoms (H 0.81, F 0.02), 0.72% (p < 0.001) diagnosed. Correlations for pain were 0.70% (F 0.02), 0.73% (p < 0.001) for symptoms (H 0.81, F 0.02), 0.72% (p < 0.001). There was lower agreement between verbal and both hand and face scoring methods in the Ugandan sample. Correlation for the verbal scale was the accuracy of predicting high pain/symptoms was 94.7% (F 0.04–0.06) in ROC analysis.
Conclusions: Verbal and face scoring methods correlate highly with verbal scoring. The journey method had only moderate agreement with APCA POS scores and was easily misread and easy to use for face score.
Keywords: Outcomes, Africa, Assessment, Pain, Squamous

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BHIVA PROM/PREM Project

- Project inspired by Prof. Jane Anderson
- Funded by MAC AIDS Fund
- Managed by BHIVA
- 'Connected' to BHIVA treatment guidelines
- Comprised: community, clinicians, researchers
- Connected to PHE work on experience of care

What are we trying to achieve?

- Create structures to enable measurement
- Map BHIVA standards of care to experience
- Ensure clinical priorities mapped
 - Reference existing PROMs tools, e.g. EQ5D
- Develop patient experience priorities
 - PREMs
- Enable regular monitoring, improvement

What have we done?

- Created on-line survey for groups & individuals
- Facilitated community engagement events
 - Explained conceptual background
 - Allowed for free discussion
 - 3 Mixed groups – London & South East
 - 8 African groups – London & England
 - Positively UK conference 2013
- Presentation at BHIVA Autumn Conf 2013

What have we learnt?

- All groups support the concepts
- Appetite for engaging with the work
- Key concerns:
 - Clinic care and arrangements
 - Emotional and psychosocial issues
 - Care from non-HIV services, e.g. GPs, social care
- Specific community issues
 - Stigma, legal and immigration matters
 - Discrimination in treatment

What did we hear?

- “Nurses treat you differently; they say they can't deal with it”
- “There is no confidentiality in hospitals as they share your medical details with other staff...”
- “I went to hospital for surgery and as soon as they learnt about my HIV they postponed it...”
- “Some of the nurses have showed a degree of ignorance “I'm surprised you look so well” being an example

What next?

- More detailed engagement
 - Clinicians, including nurses
 - Commissioners
 - Provider organisations, including 3rd sector
- Production of report with proposal for continuation
- Development of second research proposal
 - Submission to MRC
 - Community researchers
- NIHR research proposal 'post implementation'

Key messages

- 1) PROMs/PREMs offer great potential to influence care and evaluate outcomes, but science is very challenging
- 2) UK consultation has shown engagement and support, and highlighted the need for careful protocol development
- 3) An opportunity exists to develop innovative methodology for an HIV PROM/PREM that has strong involvement and user empowerment potential