Study Protocol

A community-based oral health promotion model for HIV patients in Nairobi, East District in Kenya: a study protocol

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Significance for public health

HIV-related oral lesions are of public health significance, especially in communities with a high prevalence of HIV, as nearly 90% of HIV-patients will experience them during the course of their illness. Although these lesions are early indicators of onset and progress of HIV infection and failure of highly active anti-retroviral treatment, many patients do not seek early care in the health facilities. This is due to barriers such as social stigma and lack of knowledge or awareness of available care. This health promotion model emphasises collaboration between different sectors of the community, strengthening community action, empowering local people, and developing personal skills through training community health workers to overcome these barriers. Raising the awareness of the community to HIV-related orofacial lesions will increase the frequency of patients seeking oral health care at the health facilities, leading to early detection and management of the lesions while the treatment outcome is still favourable. It will also strengthen the interface between facility- and community-based oral health services.

Abstract

Background: General HIV-related orofacial lesions, most commonly oropharyngeal candidiasis, have a typical clinical appearance and can be recognised by members of the community. Although affected patients often experience pain leading to compromised eating and swallowing, barriers such as social stigma and lack of knowledge regarding available services may prevent them from seeking early care. Educating the community about these lesions through community health workers (CHWs) who are democratically elected community members may encourage individuals affected to seek early oral healthcare in the health facilities. A health facility (HF) is a health centre mainly run by clinical officers (CO), *i.e.* personnel with a 3-year medical training, and nurses. This study aims to evaluate the effect of a CHW training programme on: i) their knowledge and recognition of HIV-related oral-facial lesions at a community level; and ii) referral of affected patients from the community to the HFs.

Design and Methods: All 800 CHWs in 2 administrative divisions of Nairobi East District (test group n=400; control group n=400) will be selected. The test group will receive training. CHWs in both groups will be assessed at 4 time points: –3, 0, +3 and +6 months with reference to the training on: i) their knowledge of HIV-related orofacial lesions (using a written questionnaire); and ii) their performance in referring affected patients to the HFs (using clinical data).

Expected Impact: Early recognition of HIV-related orofacial lesions at a community level will prompt community members to seek early oral care, leading to early HIV testing and counselling regarding failure of antiretroviral therapy, while treatment outcomes are still favourable.

Introduction

Human immune deficiency virus (HIV)-related orofacial lesions are typical in their clinical appearance and could ideally be detected by community members.[1,2] Among the general lesions, oropharyngeal candidiasis (OPC), enlarged parotid gland, oral Kaposi's sarcoma (KS), oral hairy leukoplakia (OHL), oral warts, and orofacial ulcerations are among the typical HIV-related orofacial lesions, OPC being the most common.[3-5] As some orofacial lesions appear in the early stages of HIV infection, their detection may enhance the quality of care for the infected patients in: i) early suspicion of HIV infection when the immunity is not compromised;[1,2,6] and ii) early detection of antiretroviral therapy (HAART) failure, thus providing the option of early management.[7-10] In Kenya, with an estimated population of 34 million people,[10] the prevalence of HIV is high (7.4%). Because of this, and the fact that nearly 90% of HIV-infected people will develop HIV-related orofacial lesions in the course of HIV infection,[6] addressing the oral health needs of HIV-infected people poses an enormous challenge. Although these lesions cause pain and compromise nutritional intake, many patients may not seek oral healthcare at the health facilities (HF) because of associated social stigma, low self-esteem, negative cultural beliefs, and lack of information on available care.[11-14]

In 2007, Kenya implemented a community health strategy (CHS) in an initiative to strengthen HF community linkages in healthcare.[15] In this initiative, the catchment population of a government HF was organised into community units (CU) which are served by democratically elected and much respected members, called community health workers (CHW). These CHWs provide a continuum of patient care through providing a link between HFs to the community and house-

holds, and carrying out health promotional activities, such as community education, care advocacy and social mobilisation. In these ways, CHWs provide a continuum of patient care. CHW health promotion activities are recorded on national standard data tools and consolidated through the link with the HF on a monthly basis by supervisors called community health extension workers (CHEW). Each district uploads the data to national registries.

Community involvement and action, as seen in several chronic conditions,[16-19] could enhance the promotion of oral health for HIV patients. This paper describes the CHW design and methodology of an oral health promotion program for HIV patients in two (test and control) divisions in Nairobi East District, Kenya.

Study aims

This study aims to evaluate the effect of a CHW training program on their knowledge of HIV-related orofacial lesions, early recognition of suspected HIV orofacial lesions at a community level, and referrals of patients from the community to the referral HF. In both study groups, CHW knowledge of and opinions concerning oral health-related topics will be assessed using written questionnaires. Before and after the training, the numbers of CHW referrals from the community to the HFs for HIV-related orofacial lesions will also be assessed.

Scientific hypotheses

Two scientific hypotheses will be tested: i) a CHW training program in HIV-related orofacial lesions will increase their understanding and knowledge on HIV-related orofacial lesions. Trained CHWs will be more informed about suspected HIV orofacial lesions than those who are not trained; ii) currently, community members may not seek oral health care at the HFs because of social stigma and lack of information on available care. Raising awareness of the community towards HIV-related orofacial lesions will increase the frequency with which patient seek care at the HFs. This will also increase the number of diagnosed HIV-related orofacial lesions at the HF.

Materials and Methods

Study design

A prospective cohort study using a pre-post control group design (Figure 1) in 2 administrative divisions will be applied.[20] These 2 divisions (Njiru and Makadara) participated in an earlier primary health care (PHC) providers study in the Nairobi East District,[21] and this study will ensure continuity. The test group will comprise all 400 CHWs from 8 CUs that are linked to 4 HFs in the Njiru Division (Dandora 1, Dandora 2, Ruai and Njiru). For comparison studies, 400 CHWs from 8 CUs that are attached to 4 HFs in the Makadara division (Kaloleni, Lungalunga, Remand and Police Band) will be assigned to the control group. The test and the control divisions are geographically far apart to prevent confounding results.

Development of information education and communication materials

Since information education and communication (IEC) materials in oral health promotion for HIV patients are not available in Nairobi, these will be developed using existing guidelines and current experience in consultation with the Kenya National Acquired Immunodeficiency Syndrome and Sexually transmitted infections Control Program (NASCOP) and the health promotion department of the Ministry of Public Health and Sanitation in Kenya.[22-25]

As *per* current guidelines, segments of the community, such as *expert* HIV patients (adult HIV patients who have publicity declared their HIV status and are trained to use their personal experience to educate the community), health workers, advocates, general community members, peer educators and CHWs, who promote HIV education in the district, will be involved throughout the development of acceptable IEC materials.[15] They will participate in focus group discussions, individual interviews, and pre-testing of the materials. In addition, local organisations in the district with an experience of IEC material production and advocacy in the field of HIV/AIDS will participate, to ensure the appropriateness of the IEC materials. The team will produce brochures and flip charts with coloured pictures covering HIV-related oral lesions and general oral health care for use in the community and at the health facility.

Data tools

CHWs currently use an official Government of Kenya community-based health management information system data tool called Ministry of Health (MOH) 514, also referred to as a *community health worker service delivery log book* (CHWSDLB) to document their health-related activities in the community. The current CHWSDLB has 31 indicators covering CHW general healthcare activities such as household visits, provision of health education, tracing of tuberculosis (TB) and immunisation defaulters (case findings, tracking and referrals), and is under the governance of the CUs kept by the CHWs. It also has a provision for re-coding date, the name of the CU, and details of the reporting CHWs, but it has no indicators covering CHW oral health activities. The log book will be modified three months before the CHW training programme starts to enable base-line data collection. Two columns will be added, thus enabling the CHWs to record the numbers of community members (children and adults) identified with HIV-suspected lesions and referred to the HF by a CHW. During the same period, interviews will be conducted with randomly selected patients from the outpatient department of each group. The patients will be asked their reasons for visiting the HF and whether they had been referred by the CHWs.

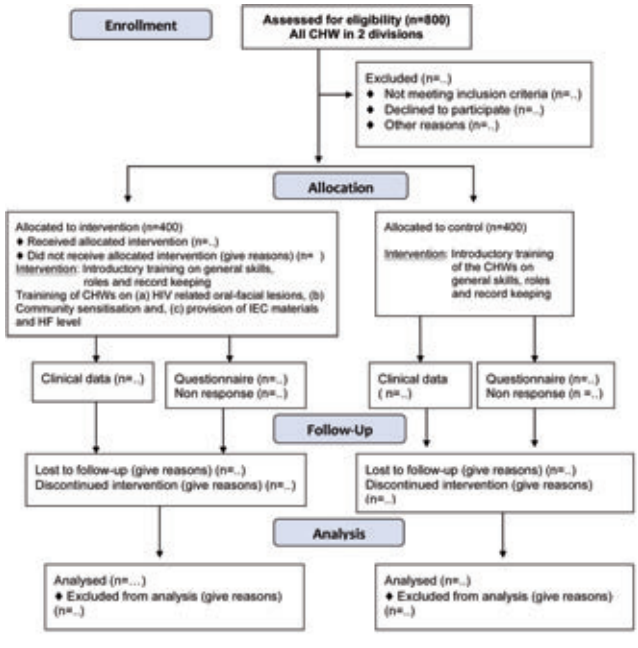

Figure 1. Flow diagram of study design, timeframe and flow of the participants (community health workers) through all stages of the study.

Pre- and post-test questionnaire

A pre-test written questionnaire will be used to assess CHWs' opinions and knowledge of HIV-suspected orofacial lesions and current care related to their management and common oral problems in their communities. The questionnaire will be developed using guidelines and field experiences,[26-30] and will be administered to all CHWs in both divisions. To minimise any cross-over effect, the questionnaire will be pretested among CHWs from a non-participating division (Embakasi) in Nairobi East District. The questionnaire will be translated into a local language, Kiswahili, with the participation of the CHWs, who will also verify whether the questions are clear. Common terminologies used in the community to describe the signs and symptoms of HIV-suspected orofacial lesions will be used to ensure that the assessment is inserted into the local social and cultural context. For compatibility of the CHWs in the test and control divisions, the questionnaire will also assess demographic factors such as sex, age, HIV status, past training in oral health, and level of education.

Community health worker selection

Elected community health committee (CHC) governance structures in Nairobi province are made up of CHWs who are assigned to provide health promotion and education to 100-200 mapped households in the catchment area of a linking government HF. A CU is made up of 50 CHWs. Each CU is governed by a democratically elected CHC (comprising 9 village elders) who, together with the CHEW, supervise the selection process and health activities of the CHWs. At the referral health facility, the facility health committee (FHC), which includes representation of the CHCs, supervises all the CUs and the CHCs that are assigned to the HF. Other members of the FHC comprise the area chief, the community health extension workers (CHEW) and the HF in charge. The district community strategy co-ordinator, who is also a member of the district health management team (DHMT), takes charge of all CUs in the district through the FHCs and the CHCs, including channelling of all health data to the provincial and national registries from the district. Selection of CUs, CHCs and FHCs takes place democratically in the chiefs' formal meetings with the community, commonly referred to as *Barazas*, with full participation of the DHMTs.

Formation of community strategy governance structures in Nairobi province began in 2009.[31] The government has charged the DHMTs with the responsibility of co-ordinating health sector stakeholders (members of the community, community and provincial chiefs, village elders, opinion makers, religious leaders and healthcare organisations, *i.e*. mainly non-governmental organisations) in the process.

The principal investigator (PI), an experienced dentist with five years of experience as a district medical officer who administrates public health programmes in the target community, will lead the selection of FHCs, CHCs and CHWs. The health sector stakeholders will participate in a series of meetings held to prepare them for the programme, solicit acceptance and support, and avoid duplication of activities. A total of 800 CHWs will be democratically elected in the chiefs' *Barazas,* in accordance with government guidelines and other field experiences,[15,32-37] to form 16 CUs, 8 in each division. CHWs will be selected regardless of gender and will be at least 21 years of age, preferably married, with at least eight years of primary education and preferably secondary education, no criminal record, the will to serve as a volunteer for five years, and the ability to speak English or Kiswahili or both languages.

Nairobi East District is home to a suburban low-income community with nearly 10 ethnic groups and various religious faiths. These demographic variables will be balanced during the selection process. Elected CHCs, FHCs and the CHEWs will confirm the elected CHWs as well as their commitment to serve as volunteers. People living with HIV/AIDS (PLWHAs) and CHWs involved in the programmes of other stakeholders will be encouraged to participate, since they have personal experience and have more credibility in the community. The CUs will be linked to the 4 health facilities in the control division and 4 in the test division to ensure continuity with the earlier study. Mapping and household registration will be carried out using a community-based health management information system data tool called *Ministry of Health (MOH) 513*, also referred to as the Household register, to ensure adequate coverage during home visits and community mobilisation, and also to minimise duplication of reported referrals. According to the current catchment population of nearly 300,000 in both divisions,[35] it is estimated that each CHW will be allocated nearly 160 households, *i.e*. 800 community members.

All 800 CHWs will be registered and given a confidential code. Their telephone contacts will be recorded for easy follow up and for programmed monthly communication. Since CHWs and CHCs need core skills to allow them to serve their communities,[33,36] they will, in groups of 50, receive a regular 5-day introductory training session in collaboration with the district health stakeholders.[37] This is in line with regular stakeholder-supported training programmes that are administered to each community unit.[38] The main topics will include their roles and responsibilities (such as household visits, health education, advocacy and socio-mobilisation, role modelling, contact tracing and referral of patients to the health facility), qualities of a CHW, governance and co-ordination mechanisms in the community, communication, leadership, correct usage of the CHWSDL (MoH 514) described earlier, and record keeping. CHWs in both divisions will be provided with adequate data-reporting tools (*i.e.* CHWSDLB) for their activities and their monthly reports to the reference health facility. Indicators in the CHWSDLB that summarise their roles and responsibilities will provide a constant reminder of what is expected of them. CHCs will be charged with the responsibility of continuous supervision of CHWs in their respective CUs, as well as of organising monthly meetings. The CHEWS who have already been trained will supervise both the CHCs and the CHWs.[39]

Although the CHWs work on a voluntary basis, the DHMT will be co-ordinated with various other stakeholder programmes, mainly HIV, bTB, family planning (FP) and immunisation programmes. The CHWs may receive gifts of money, further health education training, certificates enabling them to look for paid jobs, foodstuffs and support for income-generating activities.

Community health worker training

Current CHW and CHEW training programmes in HIV care in Kenya do not include an oral health module.[37,39] The Radboud University Nijmegen Medical Centre, Department of Global Oral Health will, therefore, collaborate with the University of Nairobi Dental School in developing a one-day CHW program to cover this topic. To ensure consistency, the training will build on the existing modules and be in line with the Kenyan training curriculum on HIV care.[40-42] It will also incorporate the findings into the IEC material development process to contextualise it. All 400 CHWs in the intervention division will be divided into groups of 50 CHWs, to be trained in general oral health, in HIV-related orofacial lesions, and the oral conditions common in dental caries and periodontal disease, to enable them to perform oral health promotion effectively for HIV patients in their community. CHEWs and CHCs will also attend the training sessions. The University of Nairobi Dental School (the PI), Radboud University Nijmegen Medical Centre staff, and selected PHC providers who were trained in the earlier PHC study will be responsible for training the CHWs, CHEWs and the CHCs at a regular training venue in Nairobi East District.[21] The PHC providers are involved in regular CHW courses and staff supervision, and will be involved in the planned supervision of CHWs and CHCs, and subsequent evaluations. During training sessions, PowerPoint presentations will be used including photographs of various HIV-related oral lesions.

Flip charts will also be used to explain issues that may not be clear, while topics such as communication techniques will be emphasised through role-play activities. CHWs will participate in group discussions and interactive activities to address various aspects of oral health of HIV patients, as well as issues that come up during the development of the IEC materials. IEC materials will be used throughout the sessions to familiarise the CHWs with the contents. The groups will present their discussion in a plenary session using an interactive approach. Expert HIV patients will also be invited to share their personal experiences with HIV-related orofacial lesions to reinforce the training sessions, especially in helping to build a positive attitude towards identifying HIV-related orofacial lesions. Aspects such as confidentiality will be re-emphasised during the training.

Community mobilisation

CHWs in the test division will be asked to perform continuous social mobilisation and advocacy approaches by using a public address system, during house visits, and in places of social interaction (such as churches, mosques and schools) throughout the observation period. They will educate and involve community members in their mapped areas in the issue of HIV-related orofacial lesions and urge them to seek oral healthcare at the local HFs. They will be provided with sufficient quantities of IEC materials to ensure adequate community coverage. The IEC materials will be replenished every three months or more frequently as required. The IEC materials will include brochures and posters that will be displayed in strategic places both in the community and in the HFs. CHWs in the control area will not receive any training. However, CHWs in both divisions will receive a short message on their telephones each month to thank them for their help, to remind them of their roles, and to invite them to submit their monthly data to the referral HF. They will receive adequate reporting tools throughout the observation period through the CHEWs. CHCs and CHEWs usually organise monthly review meetings with their respective CUs. Every CHW is expected to attend together with the community strategy coordinator who represents the DHMT. The PI and/or the trained DHMT supervisors will attend the meetings to monitor the progress of the programme and to address any issues that have been raised, such as availability of tools, adequacy of data, and to up-date addresses and telephone numbers. During these meetings, the CHWs' data will be collected and checked for completeness and accuracy.

Sample size

The primary outcome measures in this study will be collected from individual CHWs clustered within existing divisions.[21] The convenience sample consists of all CHWs in both divisions to prevent any confounding effects or bias. As no further information about exact minimum sample size in this study in Nairobi East District was available, we think that the expected high number of participants (n=400 in both trial arms) will be sufficient to detect any statistically significant differences caused by the intervention.

Evaluation

To evaluate the effect of the training programme on CHW's knowledge, a written pre-test (base-line assessment) will be administered in both divisions before the training programme starts to measure the CHWs opinions, knowledge and current care of HIV-related orofacial and common oral lesions, and to test the comparability of both groups. All participating CHWs will be scheduled for subsequent written assessments. The 1st and 2nd post-test written assessments will be given to the intervention group immediately and three months after the training course, respectively, using the same questionnaire that was presented at the pre-test assessment. Participants who have not done the 2nd written assessment will be allowed to do the 3rd assessment in order to motivate them to continue with social mobilisation. The 3rd post-test written assessment in the intervention group and the 1st post-test assessment in the control group will take place six months after training is completed (Table 1). The data analyst will be blinded and individual performance will not be examined, therefore it will be impossible to provide feedback on an individual basis. However, after the last post-test assessment, CHWs will receive additional training on aspects that were not adequately covered or that the answers of a substantial part of the intervention group CHWs showed not to be sufficiently understood.

To determine whether the training programme increases the number of referrals of patients from the community with HIV-related orofa-

Table 1. Schedule for evaluation of the training programme for community health workers in Nairobi East District in the test and control groups.

Assessment	Time frame	Data to be collected for analysis	
		Intervention group (PHC trained)	Control group (PHC not trained)
Pre-test assessment	Base-line data pre-training (-3 months)	Base-line data Clinical records data Patient interviews	Base-line data Clinical records data Patient interviews
	Pre-training (0 months)	Pre-training written assessment	Pre-training written assessment
Post-test: 1st assessment	Training 1st assessment post training (0 months)	CHWs trained 1st CHWs post-training written assessment immediately after training	No action No written assessment
Post-test: 2nd assessment	2nd assessment post training (+3 months)	Community mobilisation 2nd CHWs post-training written assessment Clinical records data Patient interviews	No action No written assessment Clinical records data Patient interviews
Post-test: 3rd assessment	Post training (+6 months)	PHC trained, CHWs trained, community mobilisation performed 3rd CHWs post-test written assessment Clinical records data Patient interviews	PHC not trained CHWs not trained, community mobilisation not performed 1st CHWs post-test written assessment Clinical records data Patient interviews

PHC, primary health care; CHW, community health worker.

cial lesions, retrospective base-line data at outpatient departments will be collected three months before the training programme starts and throughout the evaluation period (Table 1). The number of people with HIV-related oral lesions who have been referred from the community to the HFs will be assessed from the CHWSDLB. In addition, to clarify whether patients with oral lesions who visited the HF were referred from the community by the CHWs, data from patient interviews will also be assessed. The number of HIV patients who have been identified as having HIV-related lesions, dental caries and gum diseases will be determined from the clinical records in the referral health facilities.

Statistical analysis

To determine the effect of the training programme on referral rates for HIV testing, clinical records and patients' interviews conducted three months before the intervention will be assessed, providing the base-line record data for both the intervention and the control division. The pre-test (1st written assessment) data for both groups will also be compared. For the intervention group, the base-line data will be compared with the data that will be generated during the1st, the 2nd and the 3rd post-test written assessments, planned immediately after the training, at the 3rd and at the 6th month after the start of the intervention, respectively. These data will also be compared with the corresponding record data from the control group (Table 1). The flow of participants is shown in Figure 1.

The SAS version 9.2 statistical programme (SAS Institute, Cary, NC, USA) will be used for all analyses. Chi-square tests will also be used. Logistical regression will be used to simultaneously test the effect of background variables.

Main outcome benefits

The intention of the training and refresher sessions of the intervention programme is to increase CHW competencies and skills in the early recognition of HIV-related orofacial lesions among their community members and early referrals to the HFs. The expected result is that the number of patients with HIV-related, early detected orofacial lesions referred by CHWs from the community to the referral HFs will increase. An increase in referral rates to the HFs of community members with suspected HIV infection will consequently increase the HIV testing rates, as will the number of HIV-positive test results.

Discussion

Barriers such as social stigma and lack of community awareness of available services may prevent members of the community from accessing oral health care.[12-14] Community and health stakeholders will participate in various phases of the programme and within government structures to promote sustainability, future integration and long-term commitment to oral health care of HIV patients, as well as making the programme more acceptable to the community.

The introductory training of CHWs will provide them with the competences and skills needed for their effective participation in the programme. The programme design ensures a 3-fold approach to reach community members with HIV-related oral lesions. Firstly, trained CHWs will acquire appropriate skills to identify and refer community members with HIV-related orofacial lesions in their mapped areas. Mapping will also minimise double reporting. Secondly, CHWs will educate and mobilise the community on the issue of HIV-related oral lesions. A pro-active community will participate in preventive oral care, will identify lesions, and will seek social support and referral of affected community members. Thirdly, the content of the training to address barriers to use of oral health care and of self-explanatory IEC materials will further promote self-referral of the affected patients to the HFs.

Although the high number (800) of participating CHWs will enable differences in the intervention group to be detected, we envisage resistance from some CHWs. This programme incorporates government guidelines and experiences in the field in the democratic selection criteria with the participation of various stakeholders and the local community to ensure appropriate CHWs are recruited.[15,21,32,33] Community acceptability and recognition will also motivate the CHWs to perform their duties. Preference to HIV patients and CHWs who are supported in other community programmes will further enhance CHW retention. A barrier may be the role of *witchcraft*, which may still play an important role in the community. Several items in the questionnaire will ask for the reason for a specific disease, and witchcraft is an option provided. In case many participants believe that some illnesses are a result of this, the programme needs to be adapted, and more discussion on this item will be provided in future training modules.

The prospective nature of this study allows repeated observations of CHW performance in the intervention group and comparison with the control divisions at designated time points of the study. This will make it possible to measure early and late effects of the educational and refresher programmes, and to improve the training modules for new CHWs.

Confidentiality and patient safety

Data will be collected at a community level by the CHWs. A module on communication will be included in the CHW training to ensure that patient and household confidentiality is maintained during the study. All patient data and other confidential information will be subject to dental confidentially rules and will be stored on a protected server of the Nairobi University Dental School. All data will be kept under lock and key. Data in electronic devices will be controlled and password-protected. Only members of the study team will have access to the files.

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Key words: HIV, community, oral health.
Contributions: LNK, WJMVDS, AVDV, JM, MAWM and JEF contributed to study concept and design. The manuscript was drafted by LNK, WJMVDS, AVDV, NHJC and JEF.
Acknowledgements: the authors thank Elizabeth Dimba of the University of Nairobi Dental Teaching Hospital, Department of Oral and Maxillofacial Surgery, for reviewing draft versions of the manuscript.
Funding: we are grateful to The Netherlands Organization for International Cooperation in Higher Education (NUFFIC) for supporting this work through the research grant n. CF6832/2010.
Trial registration: Netherlands Trial Register NTR2697 (date registered 13nd January 2011).
Ethics approval: Kenyatta National Hospital/University of Nairobi Ethics and Research Committee (approval number P34/3/2010).
Conflict of interests: the authors declare no conflict of interests to declare.
Received for publication: 23 November 2012.
Accepted for publication: 2 April 2013.

Journal of Public Health Research 2013; 2:e5
doi:10.4081/jphr.2013.e5

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