

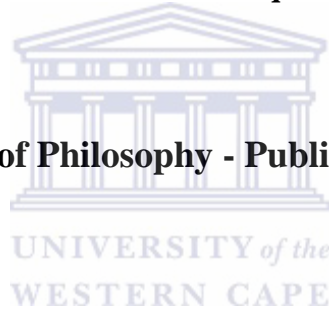


Feasibility of introducing an onsite test for syphilis in the package of antenatal care at the rural primary health care level in Burkina Faso

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Thesis submitted in fulfillment of the requirements for the degree

Doctor of Philosophy - Public Health



At the

School of Public Health - University of the Western Cape

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December 2015

DECLARATION

I declare that “Feasibility of introducing an onsite test for syphilis in the package of antenatal care at the rural primary health care level in Burkina Faso” is my own work, that it has not been submitted before for any degree or examination at any other university, and that all the sources I have used or quoted have been indicated and acknowledged as complete references.

This thesis is written in monograph format with Results written in the form of four manuscripts which have either been published or submitted for publication. This serves to confirm that I am listed in all the manuscripts as the first author and my supervisors were co-authors. Below is the list of the papers:

Paper I: Fadima Yaya Bocoum, Seni Kouanda, Christina Zarowsky, Barriers to antenatal syphilis screening in Burkina Faso, *Pan Afr Med J.* 2014; 17(Suppl 1): 12, 18 January 2014

Paper II: Yaya Bocoum F, Ouédraogo HG, Tarnagda G, Kiba A, Tiendrebeogo, Simon Bationo F, Liestman B, Diagbouga, Serge Zarowsky, Christina Ouédraogo/Traoré R, Kouanda S: Evaluation of the diagnostic performance and operational characteristics of four rapid immunochromatographic syphilis tests in Burkina Faso. *Afr Health Sci* 2015, **15**.

Paper III: Fadima Yaya Bocoum , Tarnagda G, Bationo F, Savadogo J R, Nacro S, Kouanda S, Zarowsky C; Introducing onsite antenatal syphilis screening in Burkina Faso: implementation and evaluation of a feasibility intervention tailored to a local context. Under review in *BMC Health Services Research* (manuscript ID: BHSR-D-15-00765)

Paper IV: Fadima Yaya Bocoum, Christina Zarowsky, Seni Kouanda; Incremental costs of adding rapid syphilis test to existing antenatal services at the primary healthcare level in Burkina Faso. Under review in *BMC Health Services Research* (manuscript ID: BHSR-D-15-00773)

Short versions of the chapters were also presented at meetings, national and international conferences as listed below:

- 1) Guest lecturer at the Chair of Development Economics, Barriers to antenatal syphilis screening in Burkina Faso; may 2014, University of Passau, Passau, Germany
- 2) 1^{ère} Journée scientifique sur « Femmes dans la recherche, un défi pour les pays en développement », « Accès des femmes enceintes au dépistage de la syphilis dans le district sanitaire de Kaya: contraintes et perspectives » , 26 mars 2014, Institut de Recherche pour le Développement, Ouagadougou, Burkina Faso
- 3) 3rd AFHEA conference, Nairobi, Kenya, 11-13 march 2014
Fadima Yaya Bocoum, Aristide Bado, Simon Tiendrebeogo, Christina Zarowsky, Seni Kouanda, Acceptability of point of care test for syphilis among pregnant women in Burkina Faso, poster presentation
- 4) SOPH-UWC, PhD seminar, September 2013, School of public health, University of Western Cape, South Africa



Fadima .Yaya Bocoum

December 2015

ACKNOWLEDGEMENTS

First of all I would like to thank the Almighty GOD for his blessings upon my life and during my doctoral studies.

I DEDICATE THIS WORK TO my late Father, who was the first who put his faith in me and encouraged me to pursue this highest academic level that he always dreamed of.

I want to thank everybody who has contributed in whatever way to the completion of this work. My apologies that I may not be able to mention each and every person individually but I would like to express my deeply thanks to:

My supervisors Prof Christina Zarowsky and Prof Seni Kouanda for your valuable support during this research, your professional guidance and constructive criticism help improving that work. I learnt much from you.

Professor Christina Zarowsky, no special words can express my deep and sincere thanks. You provided me home for my first visit in Cape Town and made me feel at home with Ifrah and Esther. After you moved to the University of Montreal you remained available to travel to my fieldwork and provide insightful comments. I am impressed by your intellectual support and your dynamism. *Grand Merci.*

Professor Seni Kouanda, my co-supervisor, thanks for your encouragements and generosity of time. You allowed me to take time for my research and doctoral studies. Your encouragement has allowed me to achieve this high level in academia. Your competence in research and your support are greatly appreciated. *Merci beaucoup.*

Bado Aristide for your invaluable support, GOD blesses you.

Dr Taghreed Adam for accepting to revise the article on incremental costs thanks for your availability during your maternity leave.

All the staff of Kaya health district, laboratory of the region hospital, health workers,

pregnant women, research assistants, who contributed to this work.

All the staff of school of public health who accompanied me on this journey in South Africa.

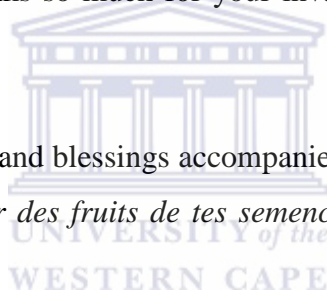
My colleagues at the Institut de recherche en sciences de la santé in Ouagadougou and Kaya for their moral supports. Special thanks to laboratory staff, Gautier, Grissoum and Fabrice.

The little community of Burkinabè in Cape Town, specially to Siaka Lougué and family, Ousmane Sawadogo and family. *Merci*

All my friends in South Africa and Burkina Faso, who encouraged me during this journey.

My family for all your support provided to me morally, financially and spiritually. My sisters and brother and their family thanks so much for your invaluable supports *que Dieu vous le rende au centuple.*

My dearest Mother, your prayers and blessings accompanied me *que Dieu te garde auprès de nous pour que tu puisses profiter des fruits de tes semences.* Thank you for supporting my absences.



This research was made financially possible by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR); and the African Doctoral Dissertation Research Fellowship (ADDRF 2012) award offered by the African Population and Health Research Center (APHRC) in partnership with the International Development Research Centre (IDRC).

ABBREVIATIONS AND ACRONYMS

ANC	Antenatal care
BBP	Benzathine penicillin
CFA	Communauté financière d'Afrique
CMA	Centre Médical avec antenne chirurgicale
CSPS	Centre de Santé et de Promotion Sociale
HDSS	Health and demographic system surveillance
ICS	Immunochromatographic strip
IRSS	Institut de recherche en science de la santé
LMIC	Low and middle income countries
MOH	Ministry of health
NGO	Non government organisation
PBF	Performance Based Financing
PMTCT	Prevention Mother to Child transmission
POC	Point of Care
RDT	Rapid Diagnostic Test
RPR	Rapid plasma reagin
RST	Rapid syphilis test
SM	Syndromic management
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
TPHA	Treponame pallidum hoemagglutination assay
USD	United States dollar
UWC	University of Western Cape
VDRL	Venereal diseases research laboratory
WHO	World Health organization

ABSTRACT

Background: Syphilis transmission remains a global problem with an estimated 12 million people infected each year. Ninety percent of syphilis cases occur in low income countries. Syphilis is a serious source of adverse pregnancy outcomes for both mother and infant. Ideally, syphilis screening should be provided as part of a package of maternal and newborn health-care services. This thesis reports on a pilot intervention study to develop, implement and evaluate a point of care test for syphilis in antenatal care services in rural Burkina Faso.

Methods: This study used a pre post intervention mixed methods quasi-experimental design with a group of health facilities offering ANC services (primary health centers in rural area) as the sampling units. This study was conducted in three phases, which consisted of a situational analysis using qualitative methods (Phase 1), selecting an appropriate test through evaluating 4 candidate tests and the participatory design and implementation of an intervention that included onsite training, provision of supplies and medicines, quality control and supervision (Phase 2), and an evaluation combining review of record tools, interviews, time motion study and estimating incremental costs (Phase 3). The conceptual framework draws on multilevel assessment (MLA), policy triangle framework, MRC framework for designing complex interventions and the Normalization Process Model (NPM). Methods included document review, seventy five interviews were conducted with health providers, district managers, facility managers, traditional healers, pregnant women, community health workers, and Non-Governmental Organizations (NGO) managers in phase I and fourteen in phase III, non-participant observation, time-motion study, incremental cost analysis, and sensitivity, specificity and ease of use analysis of four candidate point-of care tests. Data were collected between 2012 and 2014. Qualitative data were analyzed through thematic analysis supported by Nvivo software. Quantitative data were analyzed through descriptive statistics such as frequency, mean and median supported by SPSS.

Findings: Phase I identified barriers to implementation and uptake of syphilis testing at health provider and community levels. The most important barriers at provider level included fragmentation of services, poor communication between health workers and clients, failure to prescribe syphilis test, and low awareness of syphilis burden. Cost of testing, distance to laboratory and lack of knowledge about syphilis were identified as barriers at community level. Phase II: Alere Determine™ Syphilis was the most sensitive of the four point-of-care tests evaluated. The components of the intervention were successfully implemented in the selected health facilities. Overall, phase III showed that it is feasible and acceptable to introduce a point of care test for syphilis in antenatal care services at primary health care level using the available staff. The intervention was reported as acceptable, but of 812 pregnant women who came for their first visit 39% were screened during the study period. Rural facilities had higher coverage (66.8%) than the urban ones (25.6%). Quality control found no discordance between the rapid test and TPHA results. The average cost of ANC per unscreened pregnant woman was 3.11 USD (± 0.14) vs 5.06 USD (± 0.16) per screened woman. The main cost driver was the material costs notably the test itself. The test's cost is

comparable to HIV test costs, but funder support for integrating this additional test is less readily available than for HIV tests.

Conclusions: The findings suggested that an intervention that introduces point of care test for syphilis at antenatal care services is feasible, acceptable, and of comparable costs to HIV screening in pregnancy. Nonetheless, instructions and supervision need to be clearer to achieve optimal levels of screening and quality control, and barriers identified by health workers need to be overcome. The point-of care test for syphilis is likely to be acceptable by health workers as a routine service and incorporated as a normal practice in Burkina Faso context.

Keywords: Syphilis screening, antenatal care, prenatal diagnosis, point of care test, incremental cost, health policy and systems, primary health care, feasibility, Burkina Faso.



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CHAPTER 1: Introduction

1.1. Background

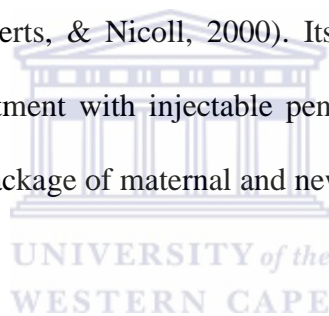
Syphilis transmission remains a global problem with an estimated 12 million people infected each year (WHO, 2007b) . The prevalence ranges from less than 1% to 10% and ninety percent of syphilis cases occur in low income countries (Peeling & Mabey, 2004).

Syphilis is a serious source of adverse pregnancy outcomes for both mother and infant (Di Mario, Say, & Lincetto, 2007) and can also facilitate HIV acquisition and transmission (Mwapasa et al., 2006; Reynolds et al., 2006) . If left untreated, maternal syphilis infection has significant medical, economic, and societal consequences (Levin et al., 2007). Among infected pregnancies, a quarter will end in stillbirth or spontaneous abortion (S. Hawkes, 2009). Neonatal deaths and prematurity or low birth weight are respectively 9.3% and 5.8% more frequent in untreated pregnant women with syphilis (Gomez et al., 2013).

Congenital syphilis is also a consequence of undiagnosed, untreated, or inadequately treated maternal syphilis (D. G. Walker & Walker, 2002). Mother to child transmission of syphilis decreases from 100% at the early stage of the infection to up to 70% four years after the acquisition of the disease, to almost 0% at the late latent stage (Berman, 2004). Thus early detection and prompt treatment of maternal syphilis will reduce adverse pregnancy outcomes, avert costs of subsequent treatment of live born infants infected with syphilis, and benefit the mothers' health (S. J. Hawkes, Gomez, & Broutet, 2013).

However, maternal syphilis is an under-recognized health problem (D. G. Walker & Walker, 2002). Health care systems increasingly concentrate on preventing infants from becoming infected by HIV. The scale-up of programs for the prevention of mother-to-child transmission of HIV (PMTCT) has attracted the attention of new global funding initiatives in resource-poor countries (Thorne and Newell, 2003). In contrast, syphilis screening and prevention have been ignored by both national programmes and international funders, even though the prevention of maternal syphilis is inexpensive and cost effective and thus compares very favourably with PMTCT (F Terris-Prestholt et al., 2003).

Screening and treatment of pregnant women for syphilis remain cost-effective even when the prevalence is low (Connor, Roberts, & Nicoll, 2000). Its management relies on serologic screening in pregnancy and treatment with injectable penicillin. Ideally, syphilis screening should be provided as part of a package of maternal and newborn health-care services (WHO, 2007b).



1.1.1. Accelerating global action for controlling congenital syphilis

In the last ten years, publications on syphilis have increased, especially about maternal and congenital forms. This indicates a reawakening of concern and has led to the launch of a global initiative. In 2007, World Health Organization (WHO) launched a global initiative for the elimination of congenital syphilis. A five year plan (2010-2015) was developed, aimed at eliminating congenital syphilis in up ten countries which account for over 40% of the 1.2 million adverse pregnancy outcomes related to syphilis in pregnant women (WHO, 2007b). The strategy of WHO rested on four pillars. Among these pillars screening and treatment of pregnant women and their partners is a key component. The process should be country-driven

taking into account contextual factors such as antenatal conditions. Each country has to define the best way for screening and treatment of pregnant women and their partner in an integrated approach for delivery a total package for maternal and newborn health care.

1.1.2. Need for effective comprehensive antenatal care package

The philosophy of antenatal care is to detect and treat conditions in the mother and her fetus (es) which may threaten her pregnancy (Lumbiganon, 1998). In the early 2000s, WHO launched the focused ANC strategy that emphasized a limited number of evidence-based essential practices and screenings. Most low and middle-income (LMIC) countries are implementing the focused antenatal care approach, in which early detection of existing diseases such as malaria, HIV, syphilis and other STIs is one of the goals. Many national policy and management of maternal care guidelines emphasize the importance of diagnosing and treating pregnant women for reproductive tract infections (RTIs) using the syndromic approach, and screening all women for syphilis with available tests.

In 2001, a study among 22 ministries of health in sub-Saharan Africa found that 77% reported universal syphilis screening to be a national norm for pregnancy care (S Gloyd, Chai, & Mercer, 2001). However, the levels of actual implementation of the syphilis component of the ANC package are low with on average 38% (with a range of 1-92%) of women with syphilis screened and treated (S Gloyd et al., 2001; Hoque, Hoque, & Kader, 2008; Manabe et al., 2015).

In most African countries, including Burkina Faso, blood pressure checks, urine tests for sugar and protein, testing for HIV and provision of medicines such as iron tablets and

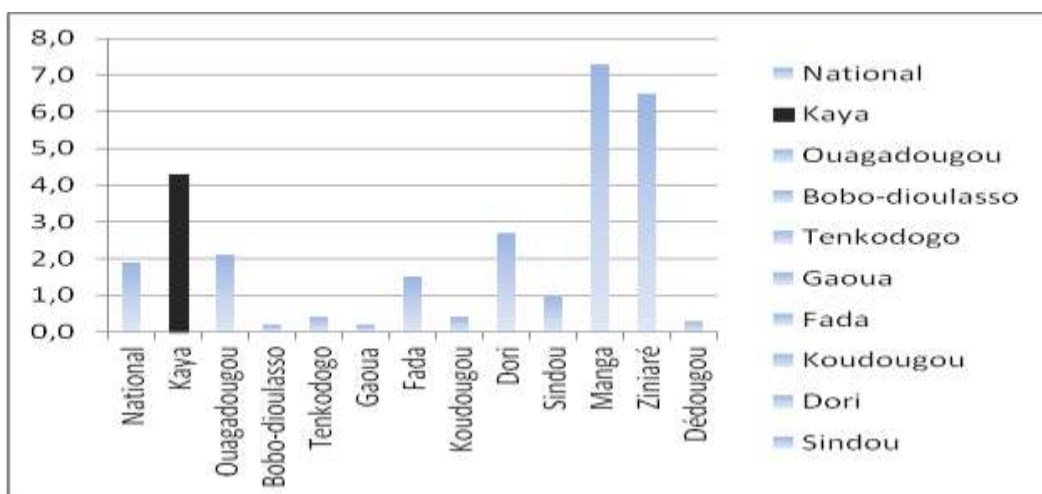
sulfadoxine–pyrimethamine for intermittent preventive treatment of malaria are an integral part of ANC in many public primary health facilities. In contrast, screening for syphilis is largely restricted to facilities with laboratory services. Thus there are clearly unmet needs that need to be covered with a comprehensive ANC package for all pregnant women wherever they are. It is also important to identify the barriers and challenges to the implementation of the antenatal syphilis screening policy in the field.

1.2. Rationale

In Burkina Faso, syphilis remains an important public health problem, with significant regional variations. The National HIV/STI Sentinel Surveillance program has reported a national prevalence of 1.9% in 2011 with important sites variations from 0.2 to 7.3 % (figure 2).



Figure 1: Prevalence of sites surveillance in 2011 in Burkina Faso



Source data: PSSLS-IST, report 2011 (PSSLS-IST, 2013)

Prenatal syphilis testing is not systematic even though the detection of STIs is listed in the national prenatal consultation guidelines. When it does occur, detection of syphilis and STIs in general, is based on syndromic management. At the early stage with genital ulcers, syndromic management works well. In general syndromic management is effective if symptoms are reasonably sensitive and specific indicators of STI (Colvin et al., 2006). In the case of syphilis, however, the primary lesions are often painless and unseen, and secondary syphilis is also often characterized by non-specific signs and symptoms (Nessa et al., 2008).

Most pregnant women are treated presumptively, based on symptoms. This is particularly true at primary health care settings. In 2001, the assessment of this syndromic management approach which had theoretically been implemented since 1996, showed low rates of screening: 4 to 13% (Kouanda, Sama, Catraye, Nougara, & Ki-Zerbo, 2003). These data suggest that policy makers, program managers and health professionals might benefit from knowing if there are other feasible and affordable strategies for detection of early maternal syphilis in order to prevent congenital syphilis.

A wide range of tests for diagnosis of syphilis are now available but there is no single optimal test (Ratnam, 2005). A number of laboratory test methods are used for syphilis diagnosis. The two tests most commonly used are the VDRL (Venereal Disease Research Laboratory) and the RPR (Rapid Plasma Reagin) tests (S Gloyd et al., 2001). In Burkina Faso, syphilis testing is laboratory-based- using VDRL and *Treponame pallidum hoemagglutination assay* (TPHA) tests that require appropriate laboratory instrumentation with trained personnel and a source of electricity. Access to laboratory based tests is restricted to facilities with laboratory services, mainly urban facilities. Generally laboratories are not available in primary health care settings. In addition this mode of testing does not

allow providers and patients to get results and provision of treatment in the same day, resulting in additional direct and opportunity costs for returns to health facilities, as well as loss to follow up.

Recently, a number of simple and rapid tests have become commercially available. These tests are simple, robust, and affordable and can be stored and transported without need for refrigeration (Herring et al., 2006a). In addition they provide results in about 15 minutes, enabling immediate treatment (D Mabey et al., 2006). Both VDRL and rapid treponemal tests are cost-effective but the rapid test offers the potential to reach greater numbers of women, especially in areas where screening with VDRL is difficult to implement (Rydzak & Goldie, 2008; Watson-Jones et al., 2005).



These rapid syphilis tests have been introduced in some countries in Africa ((Bonawitz et al., 2015; Dassah, Adu-Sarkodie, & Mayaud, 2015; Stephen Gloyd et al., 2007) . They are also available in Burkina Faso but they are not used for antenatal screening in the health system. To our knowledge no study has provided evidence regarding which rapid syphilis tests could be used in the Burkina Faso context, nor on how they could be introduced as part of the ANC package.

It is against this background that our study assessed the feasibility of integrating syphilis point-of-care diagnostic testing in the package of antenatal care, with the aim of guiding decision makers on a feasible, acceptable and affordable approach to adopt for maternal syphilis screening and treatment in order to enhance the prevention of congenital syphilis.

The following research questions were formulated:

Is it feasible to introduce a rapid syphilis test in the package of antenatal care in limited resources countries at primary health care level (case of Kaya health district, Burkina Faso)?

Subsidiary questions included:

1. How do antenatal syphilis screening and treatment currently perform operationally in primary health care facilities in Kaya health district?
2. What are the facilitators and barriers to introduce rapid syphilis tests in the package of antenatal care services at the rural primary health care facilities?
3. What are the additional costs of introducing the rapid syphilis tests in the package of antenatal care services at the rural primary health care facilities?

1.3. Overall aim and objectives of the research



1.3.1. Aim

This study aimed to evaluate the feasibility of introducing an on-site test for maternal syphilis into the package of antenatal care services in order to improve practical responses to maternal and newborn health in Burkina Faso.

1.3.2. Objectives

The main objective was to assess the constraints, acceptability and cost of introducing an on-site test for maternal syphilis screening in the package of antenatal care services in rural primary health care in the district of Kaya in Burkina Faso.

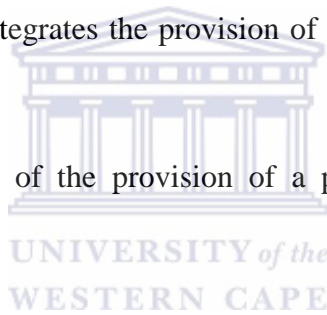
The research was conducted in three phases with the following specific objectives of the study:

PHASE I: *Situation Analysis of the current strategy*

1. To examine health workers' perspectives on strategies for managing antenatal syphilis screening.
2. To analyze the operational performance of the current antenatal syphilis screening and treatment strategy at primary health care facility level.
3. To explore women's perceptions and costs related to syphilis screening.

PHASE II: *Pilot test of the provision of onsite test of syphilis*

4. To design a model that integrates the provision of a point of care test of syphilis for antenatal care services.
5. To implement the model of the provision of a point of care test of syphilis for antenatal care services.



PHASE III: *Evaluation of the provision of the onsite test of syphilis for antenatal care services and Costing*

6. To evaluate the effects of the provision of the on-site test of syphilis on antenatal care services and practices of health workers.
7. To identify barriers and facilitators to introducing a point of care test of syphilis at primary health care facility level.
8. To estimate the additional cost to introducing of the point of care test for antenatal services.

1.4. Structure of the thesis

The thesis is presented in eight chapters with four chapters of results in the form of manuscripts published or submitted to peer-reviewed journals. Chapter 1 is an introduction which includes the aim and objectives of the research. Chapter 2 presents the literature review and the theoretical framework developed for the study. Chapter 3 presents the methods used for the three phases of overall intervention study. In chapter 4, the situational analysis of antenatal syphilis screening is presented. Chapters 5 and 6 cover the design, implementation and evaluation of the intervention. This includes the barriers and facilitators to implementation of the intervention. Chapter 7 discusses the costing analysis of the intervention. Finally chapter 8 discusses the findings, contribution of the thesis, and recommendations.



CHAPTER 2: Literature review

2.1. Overview of Maternal syphilis burden

In a recent review of studies published between 1990-2011, syphilis prevalence estimates were 4.5% (3.9%-5.1%) in East and southern Africa and 3.5%(1.8%-5.2%) in West and Central Africa (Chico, Mayaud, Mabey, & Ronsmans, 2012).

With respect to maternal syphilis, the World Health Organization (WHO) estimates that 2 million pregnant women are infected with syphilis worldwide each year. Approximately 1.2 million pregnant women with syphilis transmit the infection to their newborn (Kamb et al., 2010). The figure below illustrates the global distribution of new cases of syphilis per year. Sub-Saharan Africa and South and Southeast Asia bear the highest burden of the disease.

The prevalence in developing countries ranges from less than 1% to 10%.



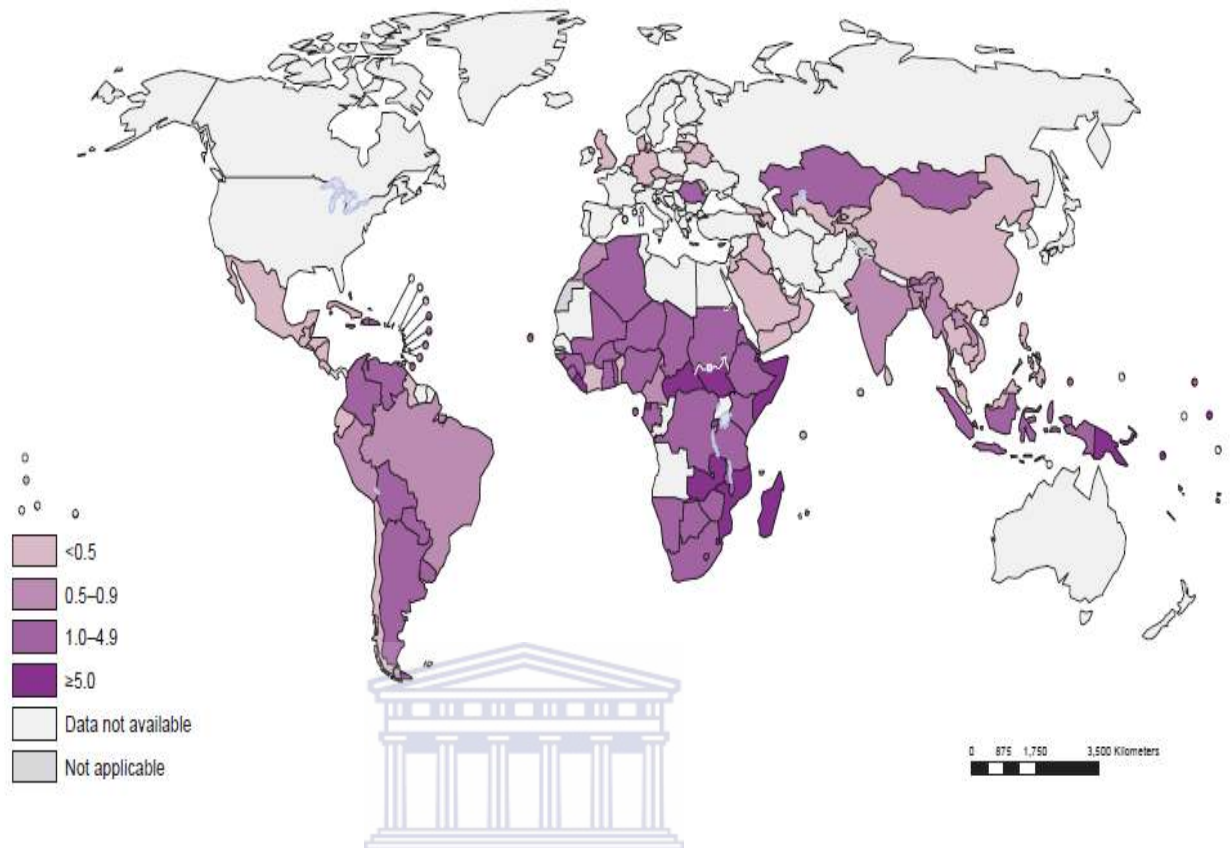
African studies showed prevalence during pregnancy of 2% in Mali (WHO, 2007b), 5.3% in Kampala Hospital and rural ANC centers in Uganda (D. C. Mabey et al., 2012), 9.2% in Lusaka Hospital and rural ANC centers in Mongu District, Zambia (D. C. Mabey et al., 2012), 9% in Sudan (Nagi, Allah, & Khalil, 2008), and 10.9% in 51 facilities in Tanzania (D. C. Mabey et al., 2012). In most of these countries, the prevalence of human immunodeficiency virus (HIV) is also high and syphilis facilitates its transmission. Dramatically increased HIV screening has not been accompanied by improved syphilis screening, so people are ‘avoiding HIV and dying of syphilis’ (Peeling & Mabey, 2004).

In countries where prevalence is low, the question of whether routine antenatal screening for syphilis is still justified has been raised (Kiss, Widhalm, Geusau, & Husslein, 2004; Obi-

nwosu, 2015) . However these figures have to be carefully interpreted because of differences in sources, samples size, type of testing, and health facilities levels. Moreover, most low and middle income countries without a functional syphilis screening program are unlikely to have a functional reporting system (Newman et al., 2013).



Figure 2: Percentage of antenatal care attendees positive for syphilis



Source: WHO Global Health Observatory Data Repository (<http://gamapservr.who.int/mapLibrary/app/searchResults.aspx>).

Source: WHO, 2014. (WHO, 2014)

2.2. Overview of maternal syphilis in Burkina Faso

Kirakoya et al (2010) conducted a serosurvey of 2,136 pregnant women from 98 healthcare facilities in 2003. The study showed a higher prevalence among pregnant women from semi-urban areas (2.2%, 95% CI 1.0 to 4.5) compared with rural areas (1.7%, 95% CI 1.2 to 2.4, $p=0.06$). Age, marital status, location and education were not associated with syphilis infection (Kirakoya-Samadoulougou et al., 2011) .

A study carried out from 1995 to 1998 in three antenatal clinics in Bobo Dioulasso, the second largest city in Burkina Faso, also showed a low prevalence of syphilis infection among 10,980 pregnant women. Syphilis seroprevalence was 0.24% (95% confidence interval (CI): 0.15–0.35) without changes over time. HIV infection, illiteracy, and having casual sex partners were the independent risk factors for syphilis infection (Sombie et al., 2000). But Meda et al (1997) found a high prevalence of STDs in pregnant women in the two largest urban centers in Burkina Faso in 1994. A total of 645 consecutive pregnant women were enrolled and 32.4% presented at least one STD. Among them, 3.6% had recent syphilis (Meda et al., 1997).

Nagot et al (2004) in a review of STI and HIV epidemiological data from 1990 to 2001 suggests a decline and that it could be explained by the adoption of safer sex behavior, the introduction of the syndromic management (SM) approach, or the higher use of antibiotics (Nagot, Meda, & Ouangre, 2004). However, the more recent seroprevalence results (PSSLS-IST, 2013) and the Kouanda et al (2003) evaluation of the syndromic management program suggest in contrast that syphilis remains a significant problem in Burkina Faso, and that existing policies and strategies face serious implementation gaps (Kouanda et al., 2003).

2.3. Impact of syphilis on pregnant women and their babies

Syphilis infection in pregnancy is associated with fetal and early infant death and adversely affects the issue of the pregnancy. The risk of vertical transmission could be up to 80% in early latent syphilis (WHO, 2007b). Many studies in Africa demonstrated an association between syphilis and adverse pregnancy outcomes. Schulz et al. (1987) estimated that 5- 8% of all pregnancies surviving past 12 weeks will have an adverse outcome caused by syphilis,

such as spontaneous abortion, perinatal or infant death or a living infant with syphilis in Africa (Schulz, Cates, & O'Mara, 1987).

Results from a study in Malawi have shown that nearly 1 out of 4 stillbirths, 1 out of 9 neonatal deaths, and 1 out of 25 post neonatal deaths were attributed to maternal syphilis (McDermott, Steketee, Larsen, & Wirima, 1993) . Gomez et al. (2013) conducted a systematic review and meta-analysis of reported estimates of adverse pregnancy outcomes among untreated women with syphilis. They found that among untreated pregnant women with syphilis, fetal loss and stillbirth were 21% more frequent, neonatal deaths were 9.3% more frequent and prematurity or low birth weight were 5.8% more frequent than among women without syphilis (Gomez et al., 2013).

Untreated maternal syphilis results in congenital infection of newborns. Half of infants born with congenital syphilis die within their first year of life (WHO, 2007b) and 492 000 infants in Sub-Saharan Africa die annually from congenital syphilis (Schmid, 2004). Diagnosis of congenital syphilis is based both on a clinical evaluation and laboratory investigations (Saloojee et al., 2004a). Clinical suspicion of syphilis may lead to laboratory tests. However, clinical diagnosis is complicated because more than half of infants are asymptomatic at birth and signs such as prematurity, low birth weight, respiratory distress or fever, are nonspecific to syphilis (Genc & Ledger, 2000) .

Confirmation of a clinical suspicion requires combination of different tests such as IgM immunoblotting, PCR, lumbar puncture or bone radiograph. In poorly-resourced settings access to these tests are generally restricted or inexistent. The available tests such as VDRL and RPR are difficult to interpret because they should be compared with maternal serological

titres using the same test (Saloojee et al., 2004a). The main factor responsible for the continued incidence of congenital syphilis is the lack of adequate prenatal screening and treatment.

In conclusion, many studies in sub-Saharan Africa have explored the effects of Syphilis on pregnancy outcomes. Few have examined the potential confounding effects on pregnancy outcome of factors such as human immunodeficiency virus (HIV) infection, and maternal malaria or anemia.

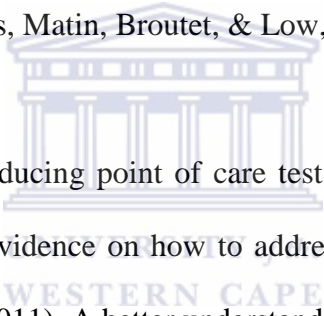
2.4. Screening and treatment of syphilis in pregnancy

The cornerstone for the control of maternal syphilis is the screening and treatment of women during pregnancy. Different interventions, such as mass treatment, and antenatal screening and treatment have been explored and evaluated.

Mass treatment means that treatment is given to people without screening. A home-based antibiotic mass treatment in 15-59 year olds in an area in Uganda resulted in a significantly reduction of syphilis prevalence (Wawer et al., 1999). Targeted mass treatment also has an effect. Terris-Prestholt et al. showed that in high prevalence settings, mass treatment of all pregnant women presenting at ANC was relatively cheap and effective in the absence of screening supplies (Fern Terris-Prestholt et al., 2015).

With screening supplies, antenatal syphilis screening could be implemented. Blencowe and colleagues argue that detection and appropriate, timely penicillin treatment are a highly effective intervention to reduce adverse syphilis related pregnancy outcomes (Blencowe,

Cousens, Kamb, Berman, & Lawn, 2011). Examples of effective antenatal syphilis screening programs were documented for different settings including Bolivia (Garcia et al., 2007) , China (Cheng et al., 2007), Haiti (Schackman et al., 2007), Kenya (Fleming et al., 2013; Jenniskens et al., 1995), Mongolia (Munkhuu, Liabsuetrakul, McNeil, & Janchiv, 2009), Mozambique (Stephen Gloyd et al., 2007; Osman, 2000), South Africa (Bronzan et al., 2007a; Myer, 2003) and Zambia (Bonawitz et al., 2015; Hira et al., 1990). With development of diagnostic tests, most of these programs involve decentralized interventions using point-of-care testing and same-day treatment. A systematic review on interventions to improve screening for syphilis in pregnancy found that the effects on the uptake of testing for and treatment of antenatal syphilis were varied and the incidence of perinatal death and stillbirth was decreased by 50% (S. Hawkes, Matin, Broutet, & Low, 2011). .

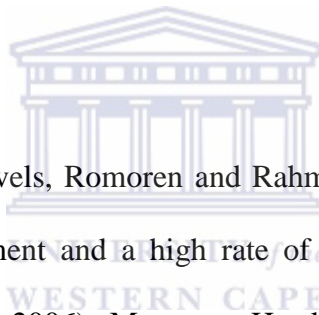


Although the advantages of introducing point of care test for syphilis in antenatal care are well documented, there is little evidence on how to address the structural issues within the health system (S. Hawkes et al., 2011). A better understanding on how the interventions work in a range of settings and contexts is needed in order to overcome bottlenecks at health system level.

Most interventions for syphilis screening are implemented within antenatal services. Thus factors affecting attendance to ANC also affect syphilis screening for pregnant women. The barriers to the effectiveness of maternal syphilis screening and treatment are at policy, health provider, patient, and community levels. Many ANC programs in sub-Saharan countries do not provide syphilis testing, even if there is a national policy of testing. Gloyd et al. carried out a survey among 22 Ministries of Health in sub-Saharan Africa, complemented by data from published sources and key informants. This study found that over three-quarters of them

had national policies for syphilis screening in pregnancy. But of women in antenatal care, only 38% were estimated to be screened for syphilis. Cost of testing or treatment and the organization of services are the principal obstacles (S Gloyd et al., 2001).

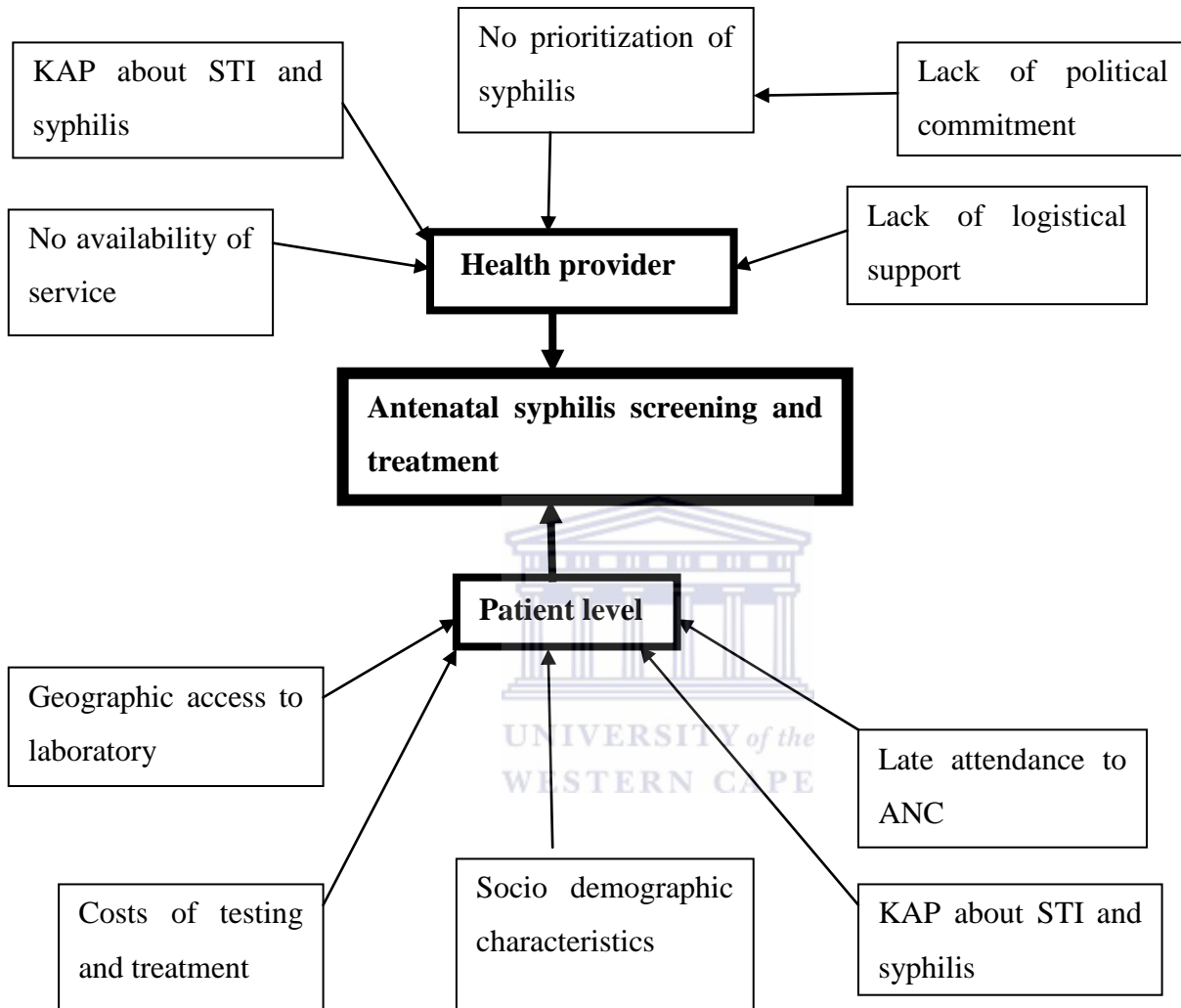
At facility and health provider levels, supplies, drugs, notification cards, and other consumables are often unavailable (Deperthes, Meheus, O'Reilly, & Broutet, 2004). Non prioritization of syphilis screening for the first antenatal visit, unawareness of the burden of congenital syphilis, difficulty to access to laboratory, especially at lower level facilities, are identified barriers (Schmid, 2004). Other factors such as the skills and motivation of healthcare workers are also contributing to the failure to screen women (Stephen Gloyd et al., 2007; Watson-Jones et al., 2005).



At the patient and community levels, Romoren and Rahman in Botswana show that uptake late in pregnancy delayed treatment and a high rate of seroconversion after testing were obstacles (Romoren & Rahman, 2006). Moreover Hawkes et al. argue that women who received the appropriate antenatal services in their two first trimesters were more likely to have a healthy infant, compared to women who were first seen in the third trimester (S. J. Hawkes et al., 2013). Communities may not perceive syphilis to be a problem because of its lack of visibility (Saloojee et al., 2004a). This influences the perception of the patient and his/her health-seeking behavior.

The potential factors affecting syphilis screening at health provider and patient levels are summarized in the figure below.

Figure 3: Potential factors affecting syphilis screening and treatment at health provider and patient level



2.5. Economic studies on maternal syphilis

The use of point of care tests such as immunochromatographic strip (ICS) tests for antenatal syphilis screening is highly cost-effective in sub-Saharan Africa (Kuznik, Lamorde, Nyabigambo, & Manabe, 2013). Screening and treatment of pregnant women for syphilis remain cost-effective even when the prevalence is low (Kahn et al., 2014; Schmid, 2004; Ferris-Prestholt et al., 2003). Studies used cost analysis or cost effectiveness approaches and cover one or more countries.

Among studies in one country, Hira et al (1990) estimated the incremental cost effectiveness of a syphilis screening program that included health education and attempted to screen women twice during pregnancy in Zambia. The cost of each prenatal screening is US\$0.60 and of averting each adverse outcome US\$12. It appears that they modeled the costs, rather than costing the actual project as implemented, and did not include any training or labour costs (Hira et al., 1990). A more recent and comprehensive study found that among new ANC patients cost effectiveness improves dramatically if those found positive are treated because additional treatment costs little but DALYs avoided are substantial (Larson et al., 2014).

Fonck et al (2001) assessed the performance, effectiveness, and costs of a decentralized antenatal syphilis screening program in Nairobi, Kenya after 6 years. A cost analysis was conducted from the viewpoint of the payer. The total cost of the syphilis screening program for 1 year was US \$30996. The total cost of testing and treatment was \$18 429. The cost per case averted varies between US \$95 and US \$112. More detailed costs were presented, but neither the costs of initial staff training nor clinic staff salaries were included (Fonck et al., 2001).

Terris-Prestholt et al. estimated the cost effectiveness of on-site antenatal syphilis screening and treatment in Mwanza, Tanzania and compared this intervention with other antenatal and child health interventions, specifically the prevention of mother to child transmission of HIV (PMTCT). They found that syphilis screening is at least as cost effective as PMTCT and more cost effective than many widely implemented interventions (F Terris-Prestholt et al., 2003). In the same site, Vickerman et al. estimates the relative cost-effectiveness of using these points of care tests in the Mwanza (Tanzania) syphilis screening intervention. Empirical cost and epidemiological data were used to model the potential benefit of using Point of care (POC) tests instead of RPR. The cost-effectiveness of using POC tests is mainly dependent on their cost and sensitivity for high titre active syphilis (HTAS) (Vickerman et al., 2006).

Multi-countries studies show similar results. Rydzak et al compared 3 approaches; screening with ICS, conventional screening and no screening from the societal perspective in sub-Saharan Africa. Universal antenatal syphilis screening using rapid point of care tests is cost effective. But RPR was preferred when the ICS cost more than doubled or ICS test sensitivity fell below 88% (Rydzak & Goldie, 2008). Kuznik et al. found that syphilis screening using ICS in 43 sub saharan countries was highly cost-effective, with each DALY prevented on average costing only US\$11(Kuznik et al., 2013). A study of 10 antenatal syphilis screening and treatment approaches found that single rapid syphilis tests (RST) were the most cost effective follow by dual RST. But in case that the costs of dual RST were halved, the dual became more cost effective (Fern Terris-Prestholt et al., 2015).

Cost effectiveness studies in Africa are concentrated in high prevalence countries such as Zambia, Kenya, or Tanzania. Studies on low prevalence countries such as West African

countries, used literature data and deplored the lack of field data (Kuznik et al., 2013). Thus data from these settings are needed for adding knowledge to the existing literature.

2.6. Conceptual framework

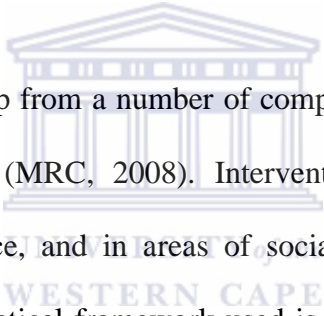
This section discusses the theories or models that have influenced the design of the research or data analysis and how they were adapted to the various phases of this research.

Research including intervention studies for antenatal syphilis screening have tended to focus on understanding one or two domains within a program , such as the perspectives of the community or the providers (S. Hawkes, Miller, Reichenbach, Nayyar, & Buses, 2004). The Multilevel assessment (MLA) approach was developed by Hawkes et al.(S. Hawkes et al., 2004) in order to understand the viewpoints and expectations of all major stakeholders as identified in section 2.4. MLA is based on a number of existing methods for assessing needs in health programs. Undertaking MLA consists in identifying stakeholders, identifying interlinked perspectives, and analyzing these perspectives within the socioeconomic, cultural and political environment within which an intervention is designed to be delivered. MLA approach was adapted for the situational analysis that was conducted in phase 1.

A complementary approach was also adopted for policy analysis of antenatal syphilis screening. This approach was based on the policy triangle framework developed by Walt and Gilson (Walt & Gilson, 1994). This framework has been used to analyze a large number of health issues, including antenatal syphilis control. The framework takes into account the program content, the actors involved, the processes contingent on developing and implementing change, as well as the context within which changes are introduced. In our

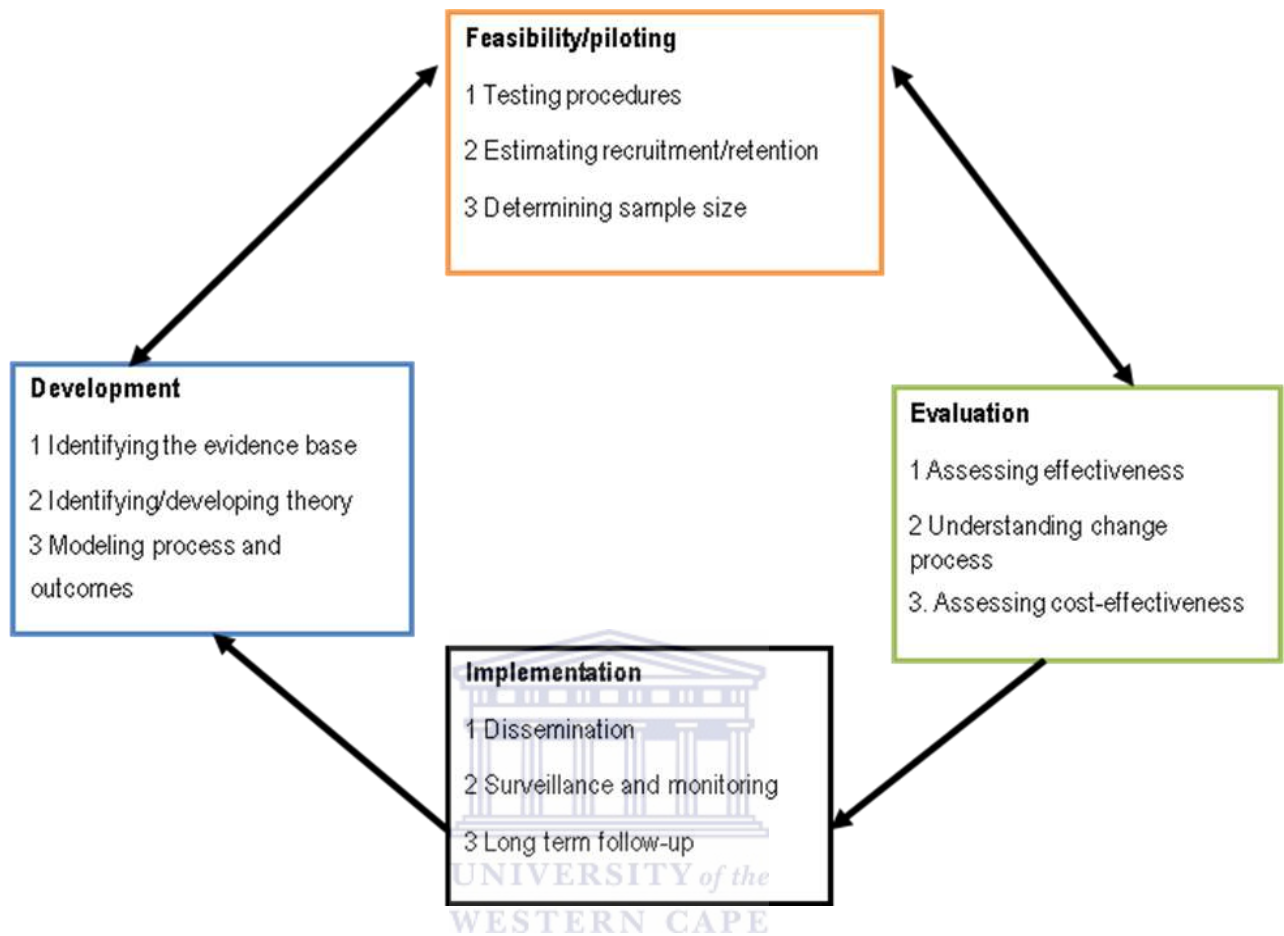
case, it was useful for examining factors that have affected implementation of the policy in practice, and circumstances that have influenced its outcomes.

Many simultaneous activities are necessary to reduce syphilis because of the interactive behavioral and biologic dynamics of sexual spread. The approaches taken for syphilis, and the measures used, have been a model for other control programs such as tuberculosis, immunization, maternal and child health, and human immunodeficiency virus (HIV) (Cates et al., 1996). A syphilis control intervention is a complex intervention that requires exploring theory on complex interventions.



A complex intervention is built up from a number of components, which may act both independently and interdependently (MRC, 2008). Interventions widely used in the health services, in public health practice, and in areas of social policy could be considered as complex interventions. The theoretical framework used is grounded in the United Kingdom Medical Research Council (MRC) framework. In 2000, the UK MRC published a Framework in order to help researchers and research funders to recognize and adopt appropriate methods. This approach has been influential internationally. In 2008, the Council has revised and updated the guidance. The MRC framework emphasizes a staged approach to establishing the feasibility of interventions before embarking on large-scale evaluations (May et al., 2007). The revised approach comprises four major phases: development, feasibility, evaluation and implementation (see figure below). The process from development through to implementation of an intervention does not follow a linear sequence (Campbell et al., 2007).

Figure 4: Key elements from the development to the implementation of MRC framework



Source: adapted from Craig et al., 2008

Our process consisted in identifying the existing evidence in order to learn about and from similar interventions; then to develop a theoretical understanding of the intervention and incorporate insights from the theory into an explicit model of how the intervention might influence outcomes.

2.6.1. Identification of components of intervention

From the phase of identifying evidence from antenatal syphilis screening interventions, we identified key components that are screening, and treatment as highlighted in section 2.4.

With advances in diagnostic tools, screening is very helpful in identifying individual with or without syphilis. The type of screening depends on the epidemiology of conditions, but targeted screening is generally more cost effectiveness than mass screening (D. G. Walker & Walker, 2002). In our case, targeted screening was selected for pregnant women according to the evidence on its effectiveness (Shahrook, Mori, Ochirbat, & Gomi, 2013).

The literature also identifies different types of treatment. Selective or mass treatment are the two major interventions. Depending on the prevalence, one or the other intervention is adequate and effective. A mass treatment is useful to interrupt an ongoing syphilis epidemic. Community mass treatment could be also interesting, in the case of maternal syphilis, when partner notification is not effective. For this intervention, selective treatment for pregnant women was chosen as the target of the study was pregnant women in ANC services.

In addition to these components, partner notification is also an important element for preventing re-infection of the patient and transmission of the STI to others. The partner notification process involves a series of interrelated activities. Strategies such as patient referral (in which the index patient informs the partner and refers him/her for care, provider referral (in which healthcare staff notifies the partner) and contact referral (in which the index patient notifies the partner with the understanding that health care staff will contact the partner when s/he has not visited the clinic by a certain date) have been developed with the aim to reach and treat partners. Through a comprehensive literature review, Alam et al. found that counseling of index STI patients and patient delivered partner medication were

somewhat effective in Africa (Alam, Chamot, Vermund, Streatfield, & Kristensen, 2010). For this intervention, the national partner notification strategy was followed, consisting of patient referral.

Theoretically antenatal syphilis screening using point of care test should improve the coverage rate of screened women and enable to promptly treat pregnant women with positive result.

Quality control is also one of essential elements of an intervention using rapid test for syphilis (Ratnam, 2005; Schmid, 2004). A guideline for syphilis rapid testing was elaborated and adapted by some implementers. Quality control measures are important for ensuring that results delivered to clients are both accurate and reliable (Elizabeth Glaser Foundation, 2011). A quality control assesses whether a product provides sufficient internal quality control mechanisms and is compatible with external quality schemes (Lehe et al., 2012). Two components are frequently implemented, internal and external quality control. For our research, we adopted definition from study implemented in Zambia and Uganda (Elizabeth Glaser Foundation, 2011). This study defined internal control as assessment of the ability of the test to distinguish between samples that are known to be positive or negative, and the external one as assessment of the ability of health workers to use the test as described by manufacturers in their guidelines.

The involvement of stakeholders in the design of an intervention is important for its smooth implementation. The design of the intervention with its components was discussed during a workshop with district managers and health workers before its implementation.

2.6.2. *Implementation and evaluation of intervention*

The feasibility or pilot stage is an essential step in the development and testing of an intervention, prior to a large-scale evaluation. In summary, it is an opportunity to check whether the intervention that one is proposing to deliver, can be delivered. After the development stage in this study, the feasibility of the model was tested.

For the evaluation stage, the MRC approach was complemented by the Normalization Process Model which is a conceptual tool intended to assist in understanding the factors that affect implementation processes in clinical trials and other evaluations of complex interventions like this intervention (May et al., 2007). This approach focuses on the workability and integration of the components of the intervention in practice. Our study was focused on the factors which facilitated or hindered the full implementation of the intervention. Moreover we explored the likelihood that point of care test for syphilis will become routinely incorporated in practice through four factors identified by the Normalization Process Model. These factors are interactional workability, relational integration, skill-set workability, and contextual integration (May et al., 2007) . Each of factors has two dimensions (See table below).

Table 1: Factors and dimensions of the normalization process model (NPM)

Factors	Dimensions
<p>Interactional workability</p> <p>The interactional workability construct seeks to examine whether the complex intervention promotes ease and efficiency of interaction between people and practice. The model proposes that the new intervention is more likely to be normalized if the intervention maintains or enhances existing norms and social relations.</p>	<p>Congruence</p> <p>Congruence requires shared expectations of normal conduct and purpose of the clinical encounter.</p> <p>Disposal of work</p> <p>This requires an investigation into the level of agreement about the meaning and consequences of the work and of expectations about its goals.</p>
<p>Relational workability</p> <p>The relational workability construct investigates the extent to which the complex intervention can be integrated with existing knowledge, practices and relationships. The model proposes that normalization is more likely if the intervention maintains or improves accountability and confidence within existing professional networks.</p>	<p>Accountability</p> <p>Accountability requires agreement about the validity and expertise of knowledge and role divisions underpinning the work.</p> <p>Confidence</p> <p>Confidence requires agreement on the credibility and utility of the knowledge and expertise, and the criteria by which it is evaluated.</p>
<p>Skills-set workability</p> <p>Skills-set workability is concerned with how the current division of labour is affected by the intervention, the capacity of participants to deploy the required tasks and how the quality of the work is monitored. The model proposes that normalization is more likely if the intervention has a good fit with an actual or realizable division of labour.</p>	<p>Allocation</p> <p>Allocation requires agreement on the formal and informal rules about the assignment of tasks, beliefs about ownership and appraisal of skills, rewards linked to roles and how work is monitored.</p> <p>Performance</p> <p>Performance involves the ability of the organization and people to deploy the intervention as planned and includes agreement about the tasks, boundaries, responsibility and autonomy of participants.</p>
<p>Contextual integration</p> <p>Contextual integration focuses on how the organization uses its capacity and resources in the normalization of the complex intervention.</p>	<p>Execution</p> <p>Execution refers to the organizational factors influencing practical implementation and monitoring of the</p>

<p>The model proposes that the complex intervention is more likely to be normalized if the organization is able to be responsive and flexible in executing the work.</p>	<p>intervention. This includes decisions about distributing responsibility, power and resources and linkages to organizational structures.</p> <p>Realization Realization is made possible by agreement about the value of the intervention, policies about procurement, delivery of personnel and equipment and mechanisms for modifying organizational objectives</p>
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Source: (Leon, Lewin, & Mathews, 2013)

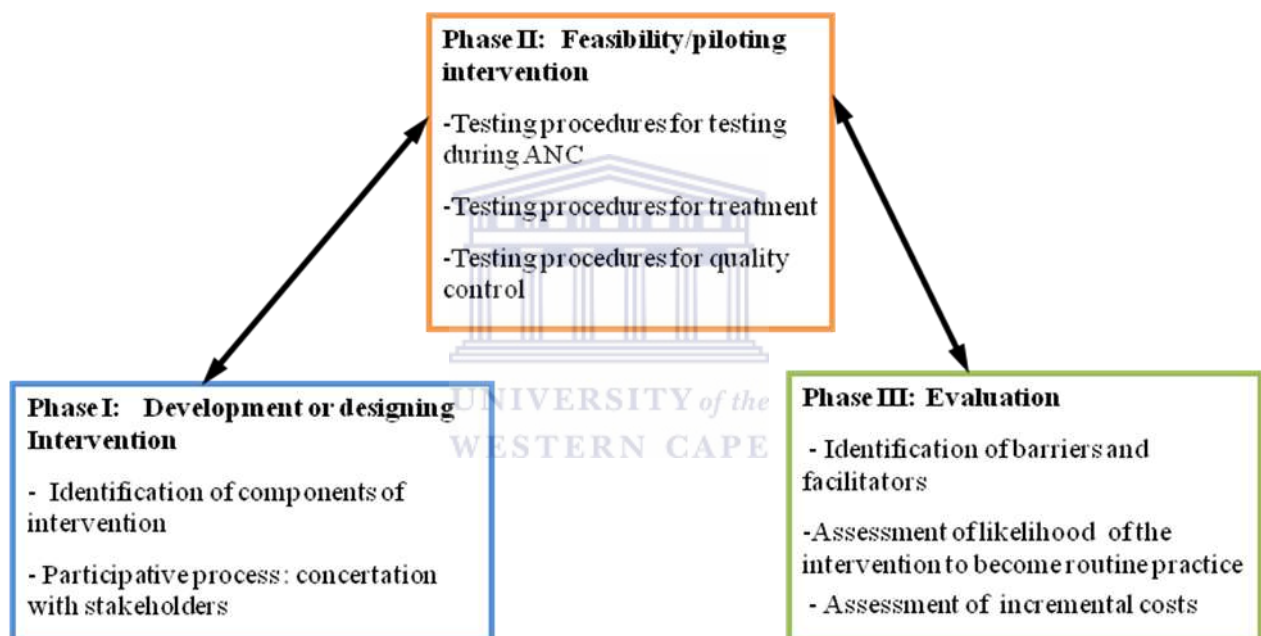
Costs are also important elements in feasibility of intervention.

Undertaking an analysis of costs depend largely on the purpose of the study. In the review in section 2.5, several studies found that introducing the point of care test for syphilis is cost effective even in low prevalence settings (Kuznik et al., 2013; Fern Terris-Prestholt et al., 2015; WHO/TDR, 2006), so we did not consider it necessary to do a formal cost-effectiveness analysis in this setting. What could be of more interest for decision makers such as senior ministry of health or ministry of finance officials, managers or head of districts is to know the cost for replication, scaling up, or sustainability. For this a cost analysis (rather than a cost effectiveness analysis) could be conducted. Cost analysis is not an economic evaluation because it does not compare the ratio of costs and effects of at least two alternatives. However it is a key component of economic evaluation (D. Walker, 2001). In a costing exercise, it is important to clearly state the purpose of the work because it is helpful for establishing the boundaries of costs to be included or excluded (Fern Terris-Prestholt, Santos, Sweeney, & Kumaranayake, 2011). For instance costs for replication will include both on-going and start-up costs whereas start-up cost could be excluded in case of examining efficiency of an intervention. In our case, sustainability of the intervention in the

selected facilities was examined instead of costs for scaling up or replication of the intervention which required more funds from the health district.

The overall conceptual framework of our research is summarized in the figure below. This figure was adapted from Craig et al. (Craig et al., 2008) who presented the revised MRC guidance.

Figure 5: The conceptual framework of the research



Source: adapted from Craig et al. 2008

In conclusion, this chapter provides a clear understanding of the issues related to maternal syphilis and the factors that affect uptake of screening. Finally, based on literature a conceptual framework was developed for conducting the research.

CHAPTER 3: Methods

3.1. Research setting

3.1.1. Burkina Faso context

Burkina Faso is a landlocked country located in the heart of West Africa. It has around 17 million inhabitants. Its population is very young, 65% of population being less than 25 years old (Institut National de la Statistique et de la Démographie (INSD), 2008). The urban population represents about 26.5%. Burkina Faso has achieved regular economic growth over the last decade - 6% per year between 2000 and 2013. The majority of the population (90%) is engaged in subsistence agriculture. There are few natural resources and a weak industrial base. Cotton and gold are key exports (CIA, 2014). In 2013, 43.9% of populations were living under the poverty line. Households contributed to 31.7% of total health expenditures, mainly through out of pocket payment (DGISS, 2015).

The public healthcare system is organized into three levels that provide primary, secondary and tertiary care. The first level is the health district level with two layers:

- Health and Social Promotion Centers (CSPS). These are the lowest level of the health system and provide primary health care. There were 1,643 CSPS in 2014.
- Medical Centers with Surgical Units (CMA) or district hospital. These are reference facilities for the districts. There were 47 CMAs in 2014.

The second level in the health structure is the regional hospital (CHR). The CMAs refer up to the CHRs. There were 9 CHRs since 2012.

The third level includes the teaching hospitals. This is the highest referral level and provides

specialized care. In 2013, there were 3 teaching hospitals.

In addition to these public facilities, Burkina Faso had 407 private facilities in 2014. Traditional medicine is widely available and is recognized by the law no. 23/94/ADP of 19/05/94 covering the public health code (DGISS, 2013).

Focused ANC is the national norm in Burkina Faso (see figure 5 below). A minimal number of 4 visits are required for each pregnant woman. The rate of first antenatal care attendance (ANC 1) has increased modestly in the last decade from 81.9% in 2004 to 84.8% in 2014. However less than 30% of women attended in the first trimester. The proportion of pregnant women who attend four ANC visits is also weak (35% in 2014) (DGISS, 2015). Syphilis screening is strongly recommended for premarital tests and during pregnancy (see figure 5 below).

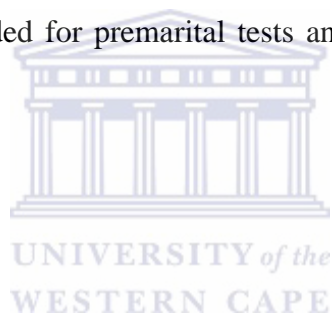
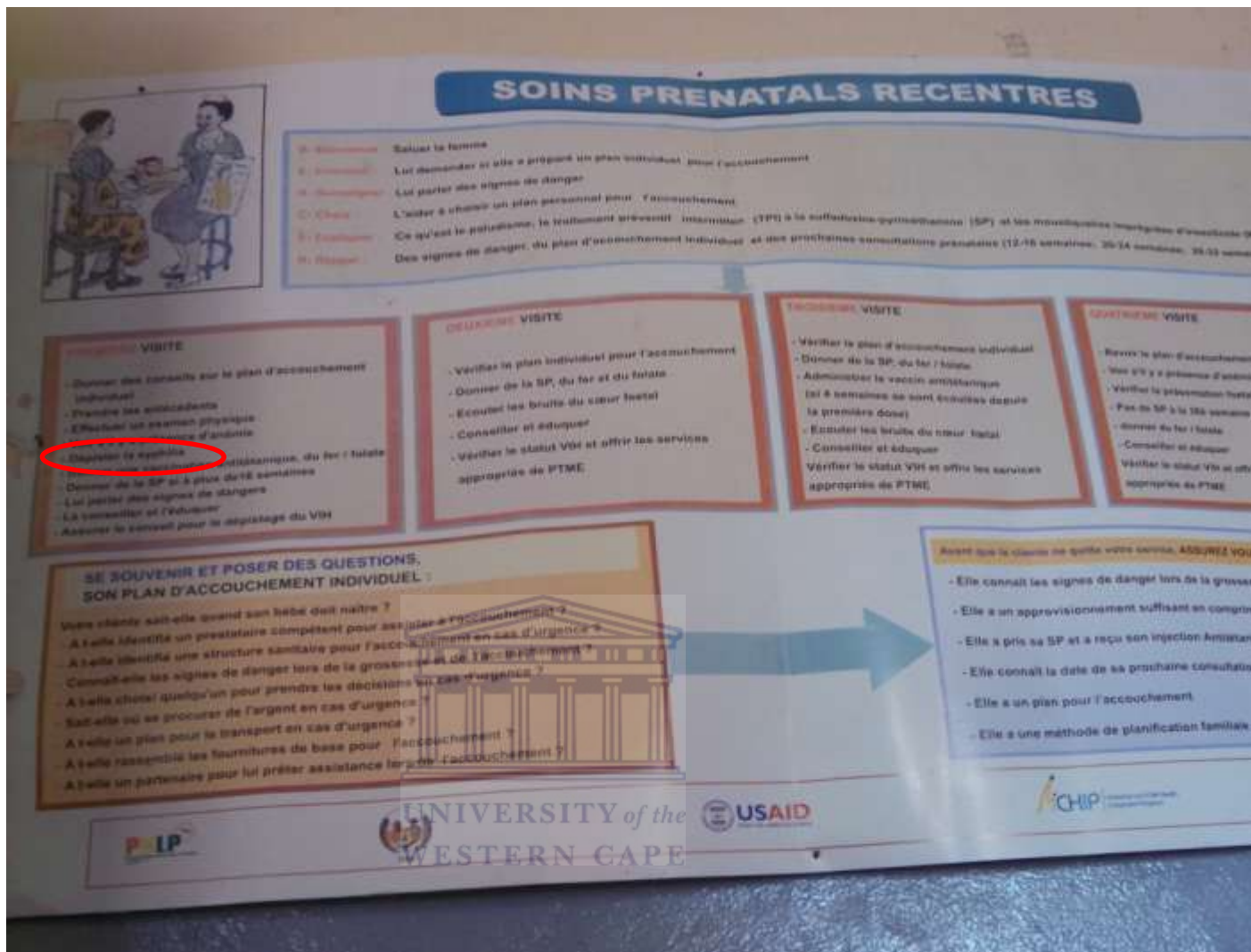


Figure 6: Guideline for conducting focused antenatal care in a primary health facility



As for other STIs, a syndromic management is mainly used by health workers for syphilis screening. Syndromic management of sexually transmitted infections is a recommendation of WHO that “is based on the identification of a group of symptoms and easily recognized signs associated with infection with well-defined pathogens” (WHO, 2007a). The recommended treatment at national level is benzathine penicillin G, 2.4 million (BBP) units intramuscularly as a single dose in addition to polyvidone- iodine for ulceration treatment. For those who are sensitive to BBP, the protocol is erythromycin 500mg 1 tablet, 4 times per day during 14 days

in addition to polyvidone-iodine for ulceration treatment (Ministère de la santé du Burkina Faso, 2010) .

3.1.2 *The study site: Kaya HDSS*

The intervention was nested in the Kaya Health and Demographic Surveillance System (Kaya HDSS), which was launched in 2007 by the Health Sciences Research Institute (IRSS). Kaya HDSS is located in the Kaya health district that is situated in the North Central region of Burkina Faso, 100 Km from Ouagadougou the capital city. Syphilis prevalence in the district of Kaya is among the highest (3rd in 2011) in the country. Kaya HDSS covers 7 urban areas and 18 villages of the health district (figure 7).

Subsistence farming and livestock breeding are the two main occupations. Handicrafts also contribute to the local economy. Traditional artisanal gold mining has developed rapidly since 2013 and there are some sites in Kaya HDSS area.

The landscape is semi-arid. The climate is tropical, with two seasons, a long dry season and a short rainy one. Within Kaya HDSS, dirt roads and bush paths provide means of access to the villages. These roads present a challenge for users especially during the rainy season when there are floods.

By the end of 2011, 64 480 inhabitants living in 10 587 households were being followed. The population is very young 55.5% are under 20 years of age. The Mossi are the predominant ethnic group and Islam is the main religion (78.9%). The majority of the population of the HDSS (53.3%) has not attended school. The main causes of death are malaria (20%), diarrhea

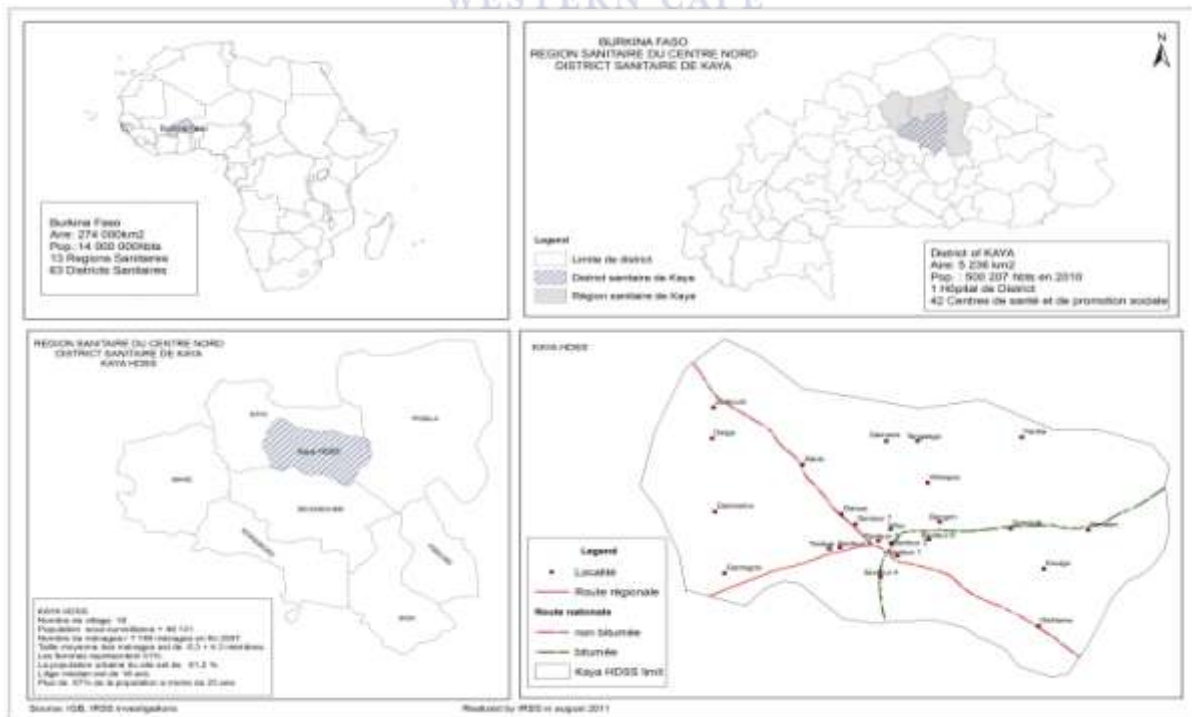
(12.4%), and renal failure (7.5%) (Kouanda et al., 2013).

Kaya HDSS covered seven public primary health facilities that offer ANC, one faith-based health center and one regional hospital. The faith-based facility and the hospital do not offer ANC but their laboratories offer the *venereal diseases research laboratory* (VDRL) test and *Treponame pallidum hoemagglutination assay* (TPHA). In 2012, a pharmacy began offering a rapid test for syphilis but due to low demand they stopped selling the test.

The seven public primary health facilities, four urban and three rural, were selected for the intervention. All facilities have a maternity unit, dispensary and drug shop. Health staff in a rural facility are from 2 to 3 whereas urban facilities have on average more than 7. In Kaya, a primary health facility is staffed by cadres as nurse, midwife, auxiliary midwife and itinerant health officer. It is led by a state registered nurse. Nurses and midwives have formal training that includes syndromic STI case management.



Figure 7: Map of Kaya HDSS



Source: IGB, IRSS investigations

3.2. Study design

The study used a mixed-method design. Both quantitative and qualitative methods were collected. According to Leech and Ownuegbuzie (2009) this study could be classified as partially mixed concurrent dominant status design because the quantitative and qualitative portions of the study were collected simultaneously and qualitative portion had the greater emphasis (Leech & Onwuegbuzie, 2009). A major component of this study was a feasibility study. Before introducing a new intervention, one of the recommendations in the MRC framework (MRC, 2008) is to conduct a feasibility or pilot study. The term pilot study is sometimes used synonymously with feasibility study – this was the case in the research reported here. Our feasibility study was carried out in order to guide decision makers on a feasible approach to adopt for maternal syphilis screening and treatment. Decision makers want to understand why they have to make a choice, and then why they should choose a certain option. A feasibility study is an important tool for making the right decisions; it is a preliminary investigation into the potential benefits associated with undertaking a specific activity or project. Thabane et al. argue that pilot studies can be very informative but often, the emphasis is wrongly placed on statistical significance, not on feasibility - which is the main focus of the pilot study (Thabane et al., 2010).

3.3. Sampling

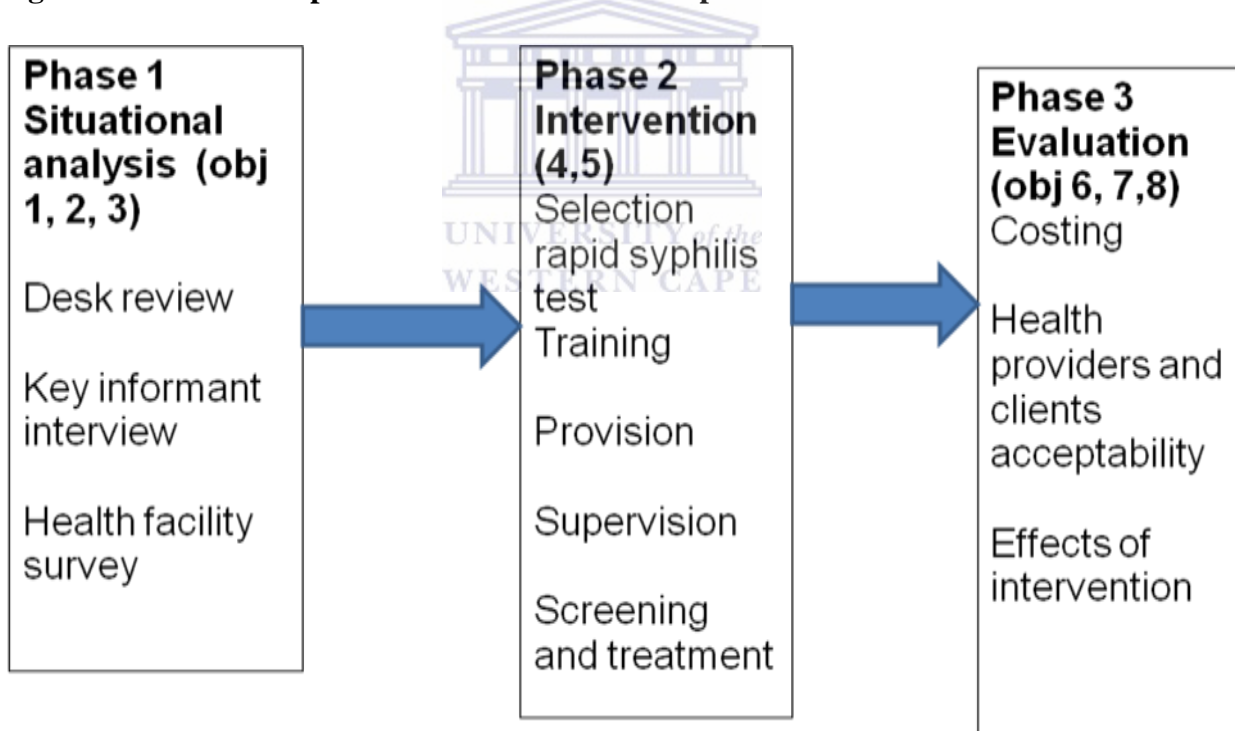
All 7 primary health facilities which offer ANC services in Kaya HDSS were selected for the intervention. Among these facilities, 4 were located in semi urban and 3 in rural areas. Sampling was performed for each phase and study. Details on sampling are provided in each paper (Chapters 4-7). Respondents included the staff of the health centres, key informants from the health district and Ministry of Health, and pregnant women attending first antenatal visit (ANC 1).

3.4. Study description

The study comprises three phases; the first to assess the performance of the current ANC program in detecting maternal syphilis, the second to develop an intervention strategy and introduce the new on-site test for syphilis in the package of antenatal services, and the third phase to assess the acceptability and explore the effects of introducing the on-site test in the package of antenatal services on the organization and staff at the primary health facility and to identify facilitators and barriers to integration of the test into routine ANC.

The phases are summarized in the figure 8 below.

Figure 8: Schematic representation of the research process



3.4.1. Phase 1: Situational analysis

Most studies have tended to focus on understanding one or two domains within a program, such as the perspectives of the community or the providers (S. Hawkes et al., 2004). In order to understand the viewpoints and expectations of all major stakeholders, a comprehensive approach was adopted. Thus phase 1 included a situation analysis that explored health system and client perspectives.

Data were gathered through a desk review and stakeholder appraisal.

Desk review

Desk review was conducted in order to gather evidence on syphilis control programs as well as disease prevalence and any previous studies in local settings that have not been identified through the database searches conducted in preparing this proposal. An exhaustive review of existing documentation, literature, reports and data relating to the key subjects of the study was carried out. This consisted in a review of maternal and newborn national guidelines and national monitoring and evaluation reports at the ministry of health, a review of thesis and other relevant research reports and published literature at local libraries (Institut de recherche pour le développement (IRD), school of nurse (Ecole Nationale de Santé Publique), faculty of medicine (Unité de recherche et de formation en science de la santé de l'université de Ouagadougou)).

Stakeholder appraisal

Participants were purposively selected to capture a range of perspectives across different actors with different roles and responsibilities. These are described below.

- Key informant interview

Interviews were conducted with managers of key national programs relevant to the AIDS, STIs, and maternal and child health programs, laboratory staff, head of the district, district pharmacist, and staff responsible for monitoring. In addition, interviews were conducted with traditional healers in order to explore their perceptions and practices of STI management.

The interview explored the STI management policy, in particular maternal syphilis; identify the barriers and constraints which affect the effective delivery of STI services and particularly maternal syphilis screening, supervision, monitoring, the perceptions of rapid diagnostic test (RDT), and patients. An interview guide was designed and adapted for each profile of respondent (see appendix).

- Individual interviews with pregnant women

Interviews were conducted with pregnant women (N = 35) in order to assess knowledge and perceptions of syphilis. A guide was developed and explored experiences of ANC, satisfaction with ANC, perceptions of syphilis, knowledge about existing tests, and perceptions of additional test. All the interviews were conducted in *Mooré*, a local language.

Health facility survey

The health facility survey documented the current program performance of providing routine syphilis screening to antenatal care (ANC) clients at each health facility.

The facility assessment was conducted through a comprehensive inventory in terms of infrastructure, equipment and supplies. The assessment was conducted in the 7 facilities.

Interviews with providers were conducted to obtain information on their knowledge, attitudes and practices on STI and syphilis, maternal syphilis management including diagnosis and treatment and their perception on content of ANC package. All providers (N = 17) who are

involved in ANC in each facility were interviewed.

A time motion study and structured observation were performed to obtain data on workload, resources used and interaction between patient and health workers during ANC consultation. ANC consultation was observed in each facility during one day. A sheet (see in appendix) for observation was developed. Profile of health provider, materials and consumables, duration for each activity were reported on the sheet for each consultation. Researcher (PhD student) sat in the consultation room and noted all the information.

Data collection and analysis

Each potential participant was contacted by the researcher to invite them to the interview. The researcher was trained two research assistants for interviews with women. After providing information about the study and gaining consent from the participant, the interview was held in a convenient place. Interviews were recorded and transcribed in French. Interviews with traditional healers and pregnant women were recorded in local language (*Mooré*) then transcribed directly in French. Data collection was conducted from August to October 2012 in Kaya and Ouagadougou for decision makers at national level. In total 75 interviews were conducted. Following the principles of thematic analysis (Braun & Clarke, 2006), a thematic framework was developed based on the research question, the guide and familiarization with the first transcripts, and then applied to each transcript using the qualitative software package NVivo (QSR International). Data analysis was conducted by the researcher.

The researcher conducted facility assessment, interviews with health workers and time motion study. Data were collected the day of ANC in the facility. Data were entered with Epidata then analyzed with SPSS. Descriptive and univariate analysis were conducted.

3.4.2. Phase II: Implementation

The process for implementation is presented in Chapter 6. In that manuscript, a summary of each of the main stages is presented. The implementation occurred between November 2011 and August 2014. Before the implementation of the intervention, a workshop was organized where researchers shared the findings of this evaluation, the situation analysis, and the core components of the intervention, with health workers who are involved in ANC in the selected facilities and district managers. This participatory workshop informed the design of the intervention and the implementation process.

The intervention was implemented in five steps:

- Selection of rapid syphilis test

The test was selected among registered tests in Burkina Faso. The selected test respects the following criteria: sensitivity between 85 and 95% and specificity of 95% at least, a detailed notice in French, simple to use, and use of whole blood. Finally, treponemal (TP) test was selected regarding the criteria. The results were published (Yaya Bocoum, Ouédraogo, Tarnagda, Kiba, Tiendrebeogo, Simon Bationo, et al., 2015) and are presented in Chapter 5.

- Training of human resources

The health professionals of the primary health care level were trained on how to perform the test and on the management of maternal syphilis. All health workers at the ANC services received an on-site one-day training (see figure 8). Manuals and technical guides on syphilis testing during ANC were given. More details are presented in results chapter 6.

Figure 9: During onsite training in a rural health facility

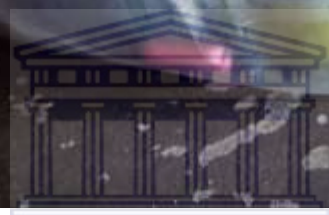


- Provision of rapid test and package for treatment

The selected facilities received syphilis test and kits for syphilis treatment.

The medicines for the kit were bought at the national central depot for essential medicines (CAMEG (Central d'achats des médicaments essentiels génériques)) and put in bags by the research team (see figure 9). The tests and all the materials were bought with representative distributor of Alere firm in Burkina Faso. Funds for the procurement were obtained through the scholarships received by the PhD student, notably ADDRf and TDR grant. The initial provision of rapid tests and ancillary supplies occurred on the same day, after the training. Thereafter, supplies were ordered by the research team and distributed to facilities by the health system's district management team.

Figure 10: Kit for syphilis treatment



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- Enrolment and screening of women

The intervention targeted pregnant woman aged 18 and over at first ANC visit. Women aged less than 18 years and not at their first ANC were excluded from the study. Participants under 18 years are not eligible because they are minors. For minors' participation, it would be necessary to obtain the permission of the parent or the legal tutor. For this, health worker should go to the house of the woman because most of them are not accompanied by the legal tutor (father or husband) for ANC. That mean the research would need to cover their transportation costs. We decided to limit the participation to women aged 18 and over.

Every eligible woman was offered the test when she was in the consultation room. If she agreed she signed consent and received the test. The decision to offer treatment was based on

test results. The treatment of positive pregnant women, who are not allergic to penicillin, is benzathine penicillin G, 2.4 million units intramuscularly as a single dose in accordance with Burkina Faso guidelines. Women who have an allergy to penicillin receive alternative treatment following the national guideline of erythromycin 500mg 1 tablet x 4 per day during 14 days + Polyvidone iodine. The treatment is available at the primary health facility because it is on the national list of generic medicines. Negative pregnant woman received counseling on STI prevention.

In Burkina Faso partner notification is on a voluntary basis. In the case of STI, the health worker gives advice to positive patient to inform his or her partner. The health worker is not allowed to contact partner without the agreement of the patient. For our study, the national legal framework was followed. This implied that pregnant women who tested positive for syphilis were free to inform her partner or not.

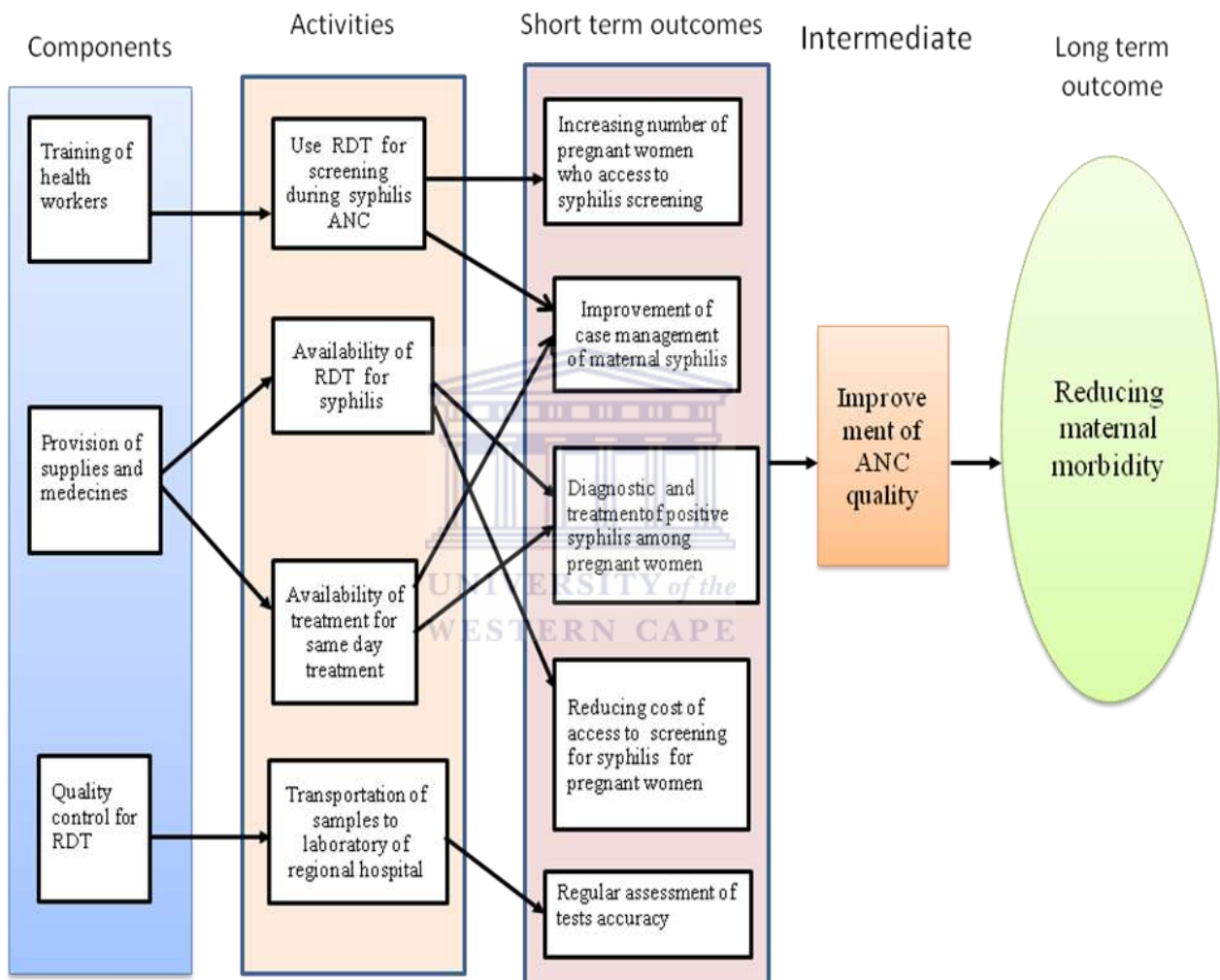
- Quality control and supervision

Every 20th negative and all positive women screened by rapid test were to have blood collected by venipuncture and sent to the laboratory of the regional hospital of Kaya, where RPR and TPHA were performed for the quality control. Transport of blood samples from the health facility to the laboratory was conducted by a health worker with an ice box. Transport costs were reimbursed. Supplies such as syringes, cryotubes were provided to health facilities and reagents (RPR and TPHA) and other supplies were provided to the laboratory. Regularly research team collected data from the laboratory staff.

For supervision, each health facility was visited once a month. A detailed checklist was elaborated for supervision. A separate register book for screened women was kept in each health facility. During supervisory visits, difficulties were discussed and patient register books were checked.

The conceptual model outlined in the figure below summarizes the components of the intervention.

Figure 11: Conceptual model of the intervention



3.4.3. Phase III: Evaluation

The evaluation consisted in identification of the potential effects of the intervention, the facilitators or barriers to implementation and estimating additional costs due to the intervention. Different methods were used.

For identifying potential effects of the intervention, at health facility a review of registers was undertaken. In each facility registers for rapid syphilis test were compiled. Data extracted from registers allowed estimating:

- Proportion of pregnant women who received a syphilis test
- Proportion of pregnant women being tested syphilis positive
- Proportion of pregnant women being tested syphilis positive and treated

Gestational date and demographic characteristics were also collected through register. Interviews with health workers (N =12) and district managers (N = 2) were conducted. Through these interviews perceptions of health workers on the intervention, potential effects, facilitators and barriers to implementation were explored.

A time motion study was conducted before and after the intervention in order to collect information on workload and time consumed. For this study, observation was held during ANC at health facility and all activities, resources used and time were recorded. Results from time motion were used for assessing the effect of the intervention on the length of ANC and costing health workers efforts. The details of this method are explained further in Chapter 7.

The additional costs of introducing rapid syphilis test were estimated from a provider's perspective. An incremental cost analysis looks at the cost of adding or implementing the additional intervention or program into existing services and does not estimate cost for

existing services (Fern Terris-Prestholt et al., 2011). The choice of this costing approach is twofold, first to provide evidence on costs for sustainability of the intervention and second to estimate how much the provider or decision maker should bear if they want to offer syphilis test for free to pregnant women coming for ANC visit. The costing approach was adapted from one used by Larson et al for syphilis diagnosis and treatment in Zambia (Larson et al., 2014). This costing approach is more adapted for estimating the cost per test using any technology. The details of the methodology used to estimate the incremental cost are discussed further in Chapter 7.

3.5. Validity

In research, different procedures can be used to enhance validity. In this study, key measures included drawing on validated approaches, and triangulation. Instrument and methods were based on previously published frameworks and approaches validated for African settings.

Triangulation was used for improving validity of our research. Mucchielli reports 5 types of triangulation (Mucchielli, 2009). In our study 3 types were used:

- Triangulation of methods: different methods were combined. The results from one method could be used as complementary of another one. Moreover different techniques such as in-depth interviews complemented by observations allowed corroborating results.
- Triangulation with researchers: other researchers such as our supervisors and co authors of articles were helpful in better understanding and interpreting the results. This work integrated work experiences from different researchers with various profiles (epidemiologist, biologist, anthropologist, statistician, health economist, and clinician).

- Triangulation through dissemination: different disseminations were used. Two workshops at district level allowed presenting results and discussing with local stakeholders. The doctoral seminar of the School of Public Health at UWC offered an opportunity to present the results and discuss them with professors and PhD students from the school.

3.6. Limitations

Resource constraints limited this intervention to a pilot study which has several limitations. The aim of this feasibility study is mainly to inform decision makers about the conditions of implementation and costs for sustainability of the intervention. Some data on health outcomes were collected but these findings should be interpreted cautiously given that this is a feasibility study with a small size (MRC, 2008). Moreover, the concept of feasibility may include dimensions such as legal, political, cultural, ethical and technical, which were not fully explored in this study.

Data are representative for pregnant women who attended ANC services in the study area and not all pregnant women. Although not all pregnant women who attended to ANC, in Burkina Faso over 80% of women have at least one ANC visit (DGISS, 2015).

This study enrolled women 18 years of age and older, as ethics procedures for informed consent or for assent to participate in research for youth under 18 are not yet commonly accepted in Burkina Faso, particularly in rural areas, and particularly for married women. This means that women under 18 who attend ANC were not included in the study, and that barriers specific to this age group may not have been taken into account.

During observations, the presence of the researcher could introduce potential changes in the behaviors of the health workers (the Hawthorne effect) (Fernald, Coombs, DeAlleaume,

West, & Parnes, 2012). This was limited because the researcher who conducted the observations was not medical personnel and the participants were aware of her background. The cost outcomes for testing for antenatal syphilis screening are context-dependent. In general, variations reflect differences in the epidemiology of the disease, treatment patterns and health system organization in urban and rural areas (Levin et al., 2007). Limitations due to the costing approach used were also highlighted. Using an incremental costing underestimated the general administrative nature borne by the health facility (particularly communications and office supplies). Moreover it is difficult to generalize results from this costing study (Fern Terris-Prestholt et al., 2011).

3.7. Ethical Concerns

This research was approved by the Senate Research Committee of University of Western Cape, the National Ethics Committee for Health in Burkina Faso and the Ethics Committee Review of the WHO. In addition, the study team obtained permission to conduct the intervention and research from the District authorities. Consent was obtained from pregnant women who received the test by health worker. They gave a witnessed signature or thumb-printed approval to participate. An information sheet explaining the purpose of the study, its potential benefits and risks was written by the researcher, in order for participants to understand what the study entailed prior to the signing of the consent form (see appendixes). The researcher in collaboration with the health workers took care to protect the confidentiality of the positive patients by following the national guideline regarding partner notification.

CHAPTER 4: Barriers to antenatal syphilis screening in Burkina Faso

This chapter (Paper I- published) presents the results of the situational analysis which emanated from phase I. Paper I responds to the subsidiary research question concerning the operational performance of the current antenatal syphilis screening program.

Paper I: Fadima Yaya Bocoum, Seni Kouanda, Christina Zarowsky, Barriers to antenatal syphilis screening in Burkina Faso, Pan Afr Med J. 2014; 17(Suppl 1): 12, 18 January 2014



INTRODUCTION

Despite several advances in treatment and management, syphilis remains a major public health problem. The World Health Organization (WHO) estimates that there are twelve million new cases of syphilis worldwide each year (World Health Organization (WHO), 2001). Ninety percent of syphilis cases occur in low income countries (World Health Organization (WHO), 2001) and the prevalence ranges from less than 1% to 10%. African studies show prevalence during pregnancy of 2% in Mali (WHO, 2007b), 3% in Nigeria (Taiwo, Adesiji, & Adekanle, 2007), 5% in Botswana (Romoren & Rahman, 2006), and 7.3% in Tanzania (Swai et al., 2006). In Burkina Faso, Kirakoya-Samadoulougou et al found a low prevalence of syphilis during pregnancy at national level but with important regional variations (Kirakoya-Samadoulougou et al., 2011). For instance, in Kaya District the prevalence was 7.5 in 2009 whereas in Ouagadougou it was 1% (CMLS/Santé, 2010).

Syphilis in pregnancy poses major health risks for the mother and the fetus and also increases the risk for HIV transmission (D. G. Walker & Walker, 2004). The World Health Organization (WHO) estimates that two million pregnant women each year are infected with syphilis globally (WHO, 2007b). The risk of vertical transmission could be up to 80% in early latent syphilis (WHO, 2007b). Approximately 1.2 million pregnant women with syphilis transmit the infection to their newborn every year (Kamb et al., 2010). It is estimated that 492 000 infants in sub-Saharan Africa die annually from congenital syphilis (Schmid, 2004) . In Tanzania, a clinic-based study found that a quarter of women with high-titer active syphilis infection had stillbirths compared with 1% among seronegative women (Watson-Jones et al., 2002).

Maternal syphilis is detectable by serological screening and entirely treatable with penicillin. Therefore, screening and treatment for syphilis has been recommended as a routine part of

antenatal care (Control Centers for Disease, 2002; WHO, 2001). In Burkina Faso, syphilis screening is recommended for premarital tests and during pregnancy (Ministère de la santé du Burkina Faso, 2010). Unfortunately, antenatal syphilis screening is often poorly implemented in many sub-Saharan African countries (S Gloyd et al., 2001). Currently, only 30% of women with syphilis are screened and treated in developing countries (The Lancet, 2012). The influence of health systems issues on timely prenatal syphilis screening has been observed in several countries, including Bolivia, Kenya and South Africa (Deperthes et al., 2004). In West African countries such as Burkina Faso, barriers to syphilis screening are understudied.

In this study, we sought to identify and understand barriers affecting health system performance for syphilis screening among pregnant women in Burkina Faso. Existing literature on syphilis screening among pregnant women suggests that antenatal care (ANC) is the cornerstone for the control of maternal syphilis. Thus, factors affecting attendance to ANC are likely to affect syphilis screening for pregnant women. We therefore explored various factors at policy, health provider, patient, and community levels that are likely to drive syphilis screening levels.

METHODS

Study design

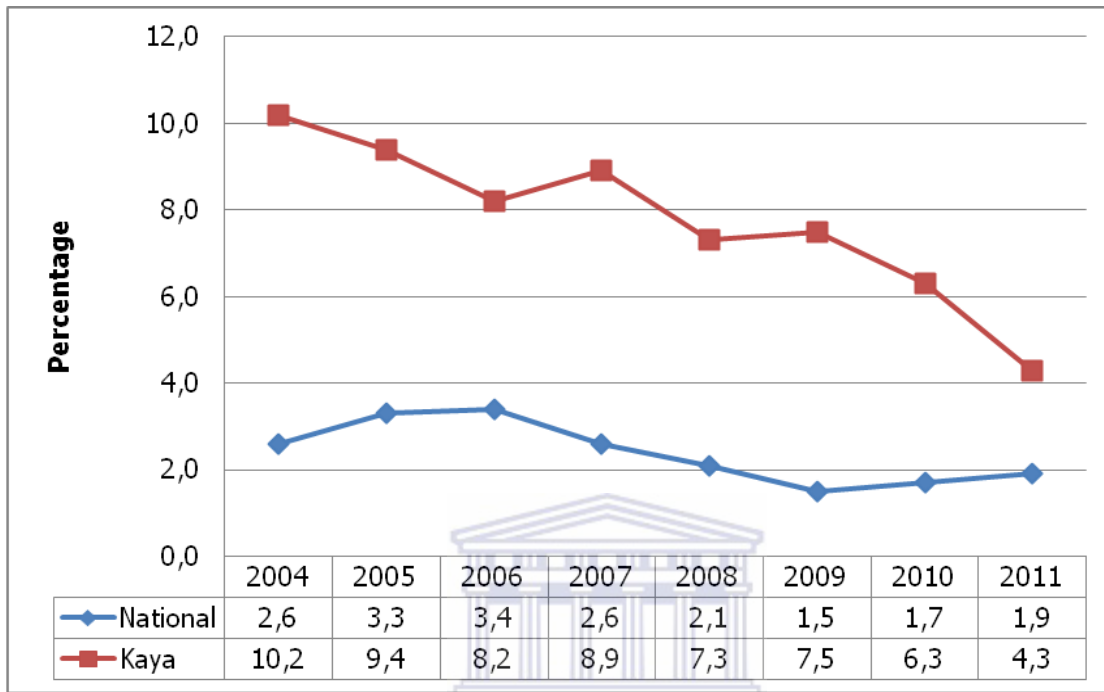
We conducted a Multilevel Assessment (MLA) (S. Hawkes et al., 2004) comprising of qualitative interviews and observations, as well as a review of existing data. For the latter, we assessed health information systems records, policy documents, service provider guidelines, training manuals, monitoring and evaluation reports and other relevant research reports and published literature. These data enabled us to investigate how the syphilis screening policy was implemented at facility level, the available indicators of its health outcomes, and any

documented barriers to its implementation to date. The in-depth interviews were held with health providers, district managers, facility managers, traditional healers, pregnant women, community health workers, and representatives of national and international Non Governmental Organizations (NGOs) which work on maternal and child health issues to explore barriers and constraints which affect the effective delivery of maternal syphilis screening. During data collection, the first author also observed interactions between health workers and clients in selected health facilities.

Study setting

The study was conducted in the Kaya health district, based in the central north region of Burkina Faso. Kaya district has 484 932 inhabitants, 40 primary health facilities and is a sentinel site for the national AIDS and STI control program. We conducted this research in Kaya District because of the high syphilis prevalence relative to the national average. Figure 1 presents the trend of syphilis prevalence among pregnant women from 2004 to 2009 in Kaya district and nationally. The study was nested in the Kaya Health and Demographic Surveillance System (Kaya HDSS), which was launched in 2007 by the Health Sciences Research Institute (IRSS). Kaya HDSS covers seven semi-urban areas and 18 villages of the district with a population of 48,131 inhabitants. In 2011, there were seven public primary health facilities that offered ANC, one faith-based health center and one regional hospital. The faith-based facility and the hospital did not offer ANC but their laboratories offer the *venereal diseases research laboratory* (VDRL) test and *Treponame pallidum hoemagglutination assay* (TPHA). One pharmacy offered a rapid test for syphilis. The health facilities selected for the study were all located within Kaya HDSS area.

Figure 1 Trends in syphilis prevalence from 2004 to 2011 in Burkina Faso. Source: report CMLS/Santé, 2010, 2011



Study population and sampling

The study population consisted of health providers, district managers, facility managers, traditional healers, pregnant women, community health workers, and NGO managers (Table 1). The healthcare providers included doctors, midwives, nurses, laboratory personnel, and pharmacists. Participants were purposively selected to capture a range of perspectives across different actors with varying roles and responsibilities. In each health facility, five pregnant women were approached as they queued to receive antenatal services and informed about the study. For those who consented, the interview was held at the end of their visit. Although we initially planned to have focus group discussions (FGDs) with pregnant women, the number of women available for the FGDs was too small because data collection occurred during the rainy season.

Table 1 : Study Sample

Group	Number and position
District managers	<ul style="list-style-type: none">- 1 pharmacist- 1 information systems specialist- 1 reproductive health specialist- Head of District- Head of regional laboratory
Health workers	<ul style="list-style-type: none">- 2 lab technicians- 4 midwives- 6 auxiliary midwives
Community health workers	<ul style="list-style-type: none">- 4 community care workers- 7 drug shop managers
NGO and private	<ul style="list-style-type: none">- 2 NGO managers- 1 midwife- 1 lab technician- 1 pharmacist
Facility manager	<ul style="list-style-type: none">- 7 (Primary health care center)
Community	<ul style="list-style-type: none">- 35 pregnant women- 4 traditional healers

Data collection

Data were collected using interview guides. Guides were adapted for each profile of respondent. The interview with pregnant women explored experiences of ANC, satisfaction with ANC, knowledge and perceptions of sexually transmitted infections (STIs) including syphilis, perceptions of existing point-of-care tests, opinion on the introduction of additional test. We sought to find out key informants' perception of ANC, management of STI during pregnancy, knowledge and perceptions of syphilis, barriers and constraints which affect the effective delivery of maternal syphilis screening, organizational and managerial issues, experience with point-of-care tests, and introduction of a rapid diagnostic test (RDT) for syphilis screening.

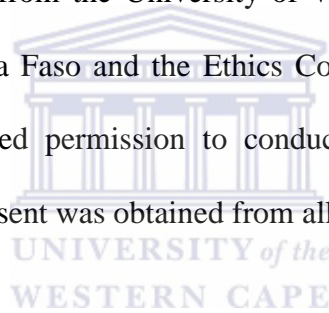
Data tools were pre-tested and appropriate modifications made before the final data collection. Data collection was conducted by the first author and two research assistants who are familiar with qualitative studies and have a social sciences background. Research assistants were trained on the study objectives, data collection tools, and processes before embarking on field data collection. Interviews with health providers, district managers, facility managers, and NGO managers were conducted in French while those with pregnant women, traditional healers and community workers were conducted in *Mooré* the local language. Appointments were made with community health workers, traditional healers, health providers, district managers, facility managers and NGO managers. All interviews were recorded using a digital recorder and files downloaded to a laptop the same day. Transcription was done by two transcribers. Interviews in *Mooré* were translated into French and transcribed.

Data analysis

Interviews were transcribed into a text program and then uploaded on Nvivo software. An analytical grid of key themes was developed based on the list of possible barriers in our conceptual framework, the objectives of the research and familiarization with the first few transcripts. Additional themes that emerged during the process of re-reading of transcripts were coded. Thematic content analysis was employed to systematically analyze the content of each theme.

Ethical issues

Ethical clearance was obtained from the University of Western Cape, the National Ethics Committee for Health in Burkina Faso and the Ethics Committee Review of the WHO. In addition, the study team obtained permission to conduct the research from the District authorities. Written informed consent was obtained from all participants.



RESULTS

Although the guidelines on the management of STIs recommend syphilis screening for all pregnant women, we found no information on the proportion of pregnant women routinely tested for syphilis at district, regional and national level. Our study findings highlight considerable weaknesses within operational systems for syphilis screening. In tracking a woman's journey from antenatal care (ANC) through to laboratory, the study documented several barriers at health provider and community levels.

Barriers at health provider level

The first barrier to routine syphilis screening among pregnant women was related to providers' perception that syphilis in pregnancy was not an important issue relative to other diseases. In addition, health workers also felt that syphilis prevalence was low because most women who undertook the test were seronegative. As one auxiliary midwife who had worked in an urban facility since 2009 stated, *"I have never found a positive test, all were negative."* Related to this, some health workers felt that syphilis was more prevalent in urban areas and thus, screening was more systematic in urban-based facilities. One district manager noted *"For syphilis screening it is not really systematic and I know that in urban facilities health workers prescribe it to all women but at rural facilities it is not systematic."* Overall, we noted an absence of interventions and information on maternal syphilis in the district.

The second barrier to routine syphilis screening among pregnant women was related to the availability of screening equipment, which was particularly a challenge for rural facilities. One facility manager in a rural-based facility noted that, *"I do not systematically prescribe syphilis test because we have no laboratory here."* A mapping of the facilities in the district indicated that three facilities (one public and two private) offered the syphilis test. All three facilities were urban-based. The public facility hosts the laboratory of the regional hospital and performs rapid plasma reagin (RPR) and Treponema pallidum particle agglutination assay (TPHA) tests. Between August 2011 and August 2012, this facility had performed 279 RPR tests and 260 TPHA tests. Among the two private that offered screening, one was a pharmacy offering a point of care test, while the second was a faith based facility offering the RPR and TPHA test. At the private pharmacy, only four clients had requested a syphilis test between June 2011 and June 2012. At the faith based facility, 50 RPR tests and 10 TPHA tests were performed between August 2011 and August 2012.

The third barrier was related to health workers' inability to communicate the need for syphilis screening to pregnant women. Health workers noted that it was difficult to convince women about the importance of screening for syphilis. This challenge was partly related to the need to collect multiple blood samples from women for an HIV test, as part of the PMTCT program, as well as for the syphilis test. According to one health worker, women did not understand the need for multiple blood tests: *"when we do an HIV test, you get a blood sample. We said that they need to go to the laboratory and have another blood test to know if they have other diseases, they said no, it is the same blood you got here and tested it is not necessary to have another sample."* Health workers acknowledged that they did not explain the importance of some of the examinations. For example, one manager in an urban-based facility noted that *"Most of the time it is a lack of communication at our level, we do not tell to the women the importance of some exams, why this prescription..."* The narratives from pregnant women corroborated this observation. One pregnant woman in a rural area stated *"One day the health worker took blood from my left finger but I did not know if it is HIV test or not ...) I don't know because until now they have said nothing."* The poor communication between health workers and pregnant woman may be related to the lack of routine training as the health workers stated that they had no specific training, except for a course on syphilis management during their professional training.

A fourth barrier was the fragmentation of services in a setting where geographic distance was already a barrier. Often women have to be referred to an external laboratory for the syphilis screening. According to health workers, many women live in rural areas and have to travel long distances to health facilities that offer screening services. One health worker commented, *"we observe that most women are from villages around Kaya, they walk from their house to our facility and we ask them to do the test the day after. The distance from their house to the laboratory is same to our facility. Thus the majority do not go."* We observed

that traveling from the nearest urban primary health facilities to the public laboratory would take about 1 hour by foot or 20 minutes by bicycle. Due to this situation, one urban health center had a lab technician who came to the facility to collect blood samples, but few women did the test.

Barriers at community level

The cost of the syphilis test was reported to be a barrier for many women. At the public laboratory, RPR and TPHA cost the equivalent of USD 2-3. The point of care test cost more in the pharmacy (USD 3) compared with the faith based facility (USD 2). Although the cost of syphilis tests in the public sector is subsidized by the government, many women are not screened because of the cost of the test. One auxiliary nurse stated *"There are women who keep the exam prescription until delivery because they said that they have no money for the exams."*

Our findings also indicate that a pregnant woman's husband or partner plays a key role in the decision to be screened for syphilis. Due to exemption of fees, women do not carry a lot of money when they go for their ANC visit. When they receive a prescription for additional medical examinations, such as the syphilis test, they have to go back home and get money from their husband. Sometimes, women need approval from their husbands as illustrated by this quote from a midwife in an urban facility, *"sometimes, until the delivery they (women) kept the prescription in their health card, when you ask them why, they explain that they gave it to the head of the family but he did nothing."*

Findings also show that poor knowledge about syphilis was also a potential barrier to testing. For example, although many women could describe the symptoms of sexually transmitted infections (STIs) (itches, pimples, and vaginal discharge), many were unaware about syphilis

or the consequences of untreated syphilis for the mother and child.

Finally, perceptions about syphilis also affected screening rates. In particular, the stigma surrounding sexually transmitted diseases was noted as a barrier to screening particularly in certain settings like pharmacies. One facility manager noted *"the pharmacy advertised and gave the prices but you know women, it is difficult for them to go to the pharmacy and do an exam related to sex. They prefer to go to the laboratory of the hospital if they have money because it is a public service."*

DISCUSSION

Syphilis screening is recommended for premarital tests and during pregnancy (Ministère de la santé du Burkina Faso, 2010). Although a policy that promotes syphilis screening in pregnant women exists in Burkina Faso, screening is very limited. Our findings identified several barriers to the uptake of syphilis screening among pregnant women in Burkina Faso.

Syphilis testing is largely dependent on the availability of adequate laboratory facilities (Tucker, Bu, et al., 2010). However, our results suggest that the fragmentation of services is key barrier to the uptake of syphilis screening. Health workers often have to refer women to external laboratories and many women, particularly those living in rural areas, have to travel long distances to access these laboratories. Other studies have also reported that long distances to screening facilities are associated with delay or failure to screen (Munkhuu, Liabsuetrakul, Chongsuvivatwong, Geater, & Janchiv, 2006; Yang et al., 2011). Our findings suggest the need to introduce a "one-stop" service point that including ANC, PMTCT and syphilis testing.

As highlighted in previous studies (Stephen Gloyd et al., 2007; Watson-Jones et al., 2005), we found that low motivation of healthcare workers to prescribe syphilis screening also

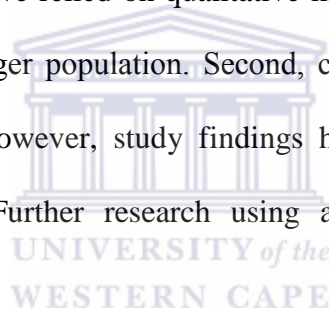
contributes to low screening. Although the need for continued antenatal screening for syphilis may be questionable in areas with low prevalence (Shakoor, 2004), health workers in the current study were not aware about the relatively high prevalence of syphilis in their district. Consequently, some health workers failed to prescribe the test. Trepka et al (Trepka, Bloom, Zhang, Kim, & Nobles, 2006) also found that a lack of provider awareness of the prevalence of syphilis was associated with inadequate provision of screening test in the United States. The absence of interventions to increase syphilis screening and the lack of information on maternal syphilis in the district shows also the low prioritization of the problem. Efforts to increase awareness about syphilis are therefore warranted in order to enhance syphilis screening levels.

The relatively high cost of screening, despite government subsidies, also prevents pregnant women from being screened for syphilis. The cost for testing was observed to range between \$2 and \$3 USD, a prohibitive cost in a country where 73% of population lives on less than \$2 a day (Worldbank, 2013) . The cost of screening is, therefore, a significant deterrent for many women particularly those who are financially dependent on their husband or partner. Women's financial dependency means that pregnant women's husbands or partners play a key role in the decision to be screened. Similar findings have been highlighted in previous studies (Adamu & Salihu, 2002; Simkhada, Teijlingen, Porter, & Simkhada, 2008) and underscore the need for male involvement in efforts to increase the uptake of syphilis screening among pregnant women.

Lack of knowledge about syphilis in the community was identified as a reason for not being screened. Most respondents at community level do not know the symptoms of syphilis nor its serious consequences for the unborn and born child. This misperception may be due to the lack of differentiation between STIs (L. Kleutsch, E. Rosser, H. Choi, J. Holley, 2009). Most

of STIs are recognized through symptoms and respondents do not realize that a STI could be asymptomatic. Community may also not perceive syphilis to be a problem because of its lack of visibility (Saloojee et al., 2004b). Low knowledge about syphilis might therefore pose a barrier to screening since pregnant women do not perceive the benefit of testing particularly for asymptomatic infections. As reported in a recent meta synthesis, many pregnant women did not feel the need to seek professional care when there is nothing wrong with their pregnancy (Finlayson & Downe, 2013). Efforts to enhance awareness of syphilis and other STIs are therefore recommended.

Our study findings should be interpreted in light of several limitations. First, because of the exploratory nature of the study, we relied on qualitative methods and therefore our findings cannot be generalized to the larger population. Second, community's perceptions reflected mostly health services users. However, study findings highlight potential barriers to the uptake of syphilis screening. Further research using a more representative sample is warranted.



CONCLUSION

Our study suggests that barriers such as distance to health facilities, cost of testing, and knowledge about syphilis among health workers and communities may limit screening levels and hinder the implementation of syphilis screening during pregnancy as recommended in national guidelines. Pregnant women often weigh the benefits of syphilis screening against the high direct and opportunity costs. Our results have several implications for efforts to improve screening levels. First, communication between health workers and clients needs to be improved in order to facilitate the acceptability of the test. Second, the introduction of point of care testing for syphilis during ANC may improve coverage of antenatal syphilis screening.

CHAPTER 5: Evaluation of the diagnostic performance and operational characteristics of four rapid immunochromatographic syphilis tests in Burkina Faso

In this chapter, the study reports the results of a comparative analysis of potential candidates for point-of-care rapid diagnostic tests for syphilis which might be integrated into the ANC package in Burkina Faso. This paper (Paper II – published) thus reports on the first step towards implementation of the intervention and addresses objective 4.

Paper II: Yaya Bocoum F, Ouédraogo HG, Tarnagda G, Kiba A, Tiendrebeogo, Simon Bationo F, Liestman B, Diagbouga, Serge Zarowsky, Christina Ouédraogo/Traoré R, Kouanda S: Evaluation of the diagnostic performance and operational characteristics of four rapid immunochromatographic syphilis tests in Burkina Faso. *Afr Health Sci* 2015, **15**.



INTRODUCTION

Syphilis in pregnant women remains a major public health problem. The World Health Organization (WHO) estimates that 90% of syphilis cases occur in low-income countries (WHO, 2007b). The prevalence in developing countries ranges from less than 1% to 10%. In a recent review among studies in 1990-2011, prevalence estimates were 4.5% (3.9%-5.1%) in East and southern Africa and 3.5% (1.8%-5.2%) in West and Central Africa (Chico et al., 2012). In Burkina Faso, prevalence in pregnant women is low, with notable regional variations (Kirakoya-Samadoulougou et al., 2011; Sombie et al., 2000). According to WHO estimates, each year, maternal syphilis is responsible for at least 50,000 spontaneous abortions or stillbirths and 500,000 premature births of babies infected with congenital syphilis or who have low birth weight (WHO, 2007b). However, rates of congenital syphilis are generally underestimated (Saloojee et al., 2004a). Congenital syphilis is an avoidable disease that prenatal testing and early treatment of infected pregnant women could eliminate (F Terris-Prestholt et al., 2003).

In response to this situation, the scientific and technical consulting group of the WHO's Department of Reproductive Health and Research adopted a strategy for the global elimination of congenital syphilis by 2015 (WHO, 2007b). Consequently, many countries have included syphilis testing as part of a minimum package of tests conducted during prenatal visits.

Unfortunately syphilis diagnosis in peripheral clinics (CSPSs) in Burkina Faso is conducted using a syndromic approach, while the majority of syphilis cases are asymptomatic. In hospital laboratories (Medical Centers with Surgical Services (CMA), regional hospitals (CHR), national hospitals (CHU)), testing is conducted with a *venereal diseases research laboratory* (VDRL) test or with a *Treponema pallidum hemagglutination assay* (TPHA) .

Although these tests present certain advantages in that they allow for the differentiation between an old or treated syphilis infection and active syphilis, as well as an analysis of treatment adherence, their use requires qualified personnel, laboratory equipment, and a source of electricity, which limits their utility to peripheral clinics (CSPSs).

Currently, there are several available specific, rapid syphilis tests that are simple to use and could be implemented in CSPSs. When compared to the diagnostic tests currently being used (VDRL and TPHA), rapid treponemic tests have several advantages, including the rapid availability of results (30 minutes) and the fact that their usage does not require electricity or highly qualified laboratory staff (WHO/TDR, 2006). Simultaneous point-of-care treponemal and non-treponemal are available with good performance (11) and are undergoing wide adoption for their benefits. However, despite reports of diagnostic performance provided by the manufacturers of rapid syphilis tests, data on test effectiveness and operational characteristics in the field remain limited in West Africa and non-existent in Burkina Faso. Against that background, we conducted a study to evaluate the diagnostic laboratory performance and operational characteristics of four rapid tests for *Treponema pallidum* available in Burkina Faso. The objectives of the study were; to assess the sensitivity and specificity of four on site rapid tests in comparison with *Treponema pallidum* haemagglutination assay (TPHA) as a gold standard and to evaluate the operational characteristics of the tests.

METHODS

Study populations

We evaluated rapid syphilis tests commercially available in Burkina Faso using archived serum samples and TPHA as the gold standard. Rapid syphilis tests were defined as

Treponema pallidum tests (i) capable of giving a result within 30 minutes and (ii) that could be used at service delivery points without any need for special storage or transport (WHO/TDR, 2006). Only rapid syphilis tests with market authorization in Burkina Faso (currently valid or in the process of renewing validity with the Ministry of Health) were considered. In total, four tests were selected. These were 1) *Accu-Tell® Rapid Anti-TP (Treponema pallidum / Syphilis)* (Accu Biotech Co Ltd, China), 2) *Alere™ Determine™ Syphilis TP* (Alere™ Médical Co Ltd, UK), 3) *Syphilis Cypress Diagnostics* (Cypress Diagnostics, Belgium), and 4) *SD Bioline syphilis 3.0* (Standard Diagnostics INC, Korea). The characteristics of the tests according to the manufacturers are listed in Table 1.



Table 1 Characteristics of the tests according to the manufacturers.

Characteristics	<i>Accu-Tell</i> [®] <i>Rapid Anti-TP</i>	Alere <i>Determine</i> [™] <i>Syphilis TP</i>	Cypress <i>Diagnostics</i> <i>Syphilis Quick test Diagnostics</i>	SD Bioline <i>Syphilis 3.0 test</i>
Manufacturer	Accu Biotech Co Ltd	Alere [™] Medical Co Ltd	Cypress Diagnostics	Standard Diagnostics INC
Product code	ABT-STD-B17	7D2443	353 Syphilis Quick Test	06FK11
Lot used	2011071312	14448k100	25094	32052
Type of antigen	Immunochromatographic TP Ag1, Ag2	Immunochromatographic Ag <i>Treponema pallidum</i>	Immunochromatographic Ag 17, 15 KDa <i>Treponema pallidum</i>	Immunochromatographic Ag recombinant pale (17, 15 kDa)
Specimen	Serum or plasma	Serum, plasma or whole blood	Serum, plasma or whole blood	Serum, plasma or whole blood
Time needed for results	15 minutes	15 minutes 24 hours maximum	5–20 minutes	5–20 minutes
Stable result	20 minutes	24 hours	20 minutes	20 minutes
Storage conditions	2–30°C	2–30°C	8–30°C	2–30°C

Blood samples were collected between November 2011 and June 2012 from blood donors at the Regional Blood Transfusion Center (CRTS) of Ouagadougou, Burkina Faso. A total of 120 serum samples were considered for the evaluation. There were 60 samples positive for syphilis (50 samples were TPHA and VDRL positive: active syphilis, and 10 were TPHA positive and VDRL negative: previous or primary case of syphilis) and 60 samples negative for syphilis (50 samples were TPHA negative and VDRL negative, and 10 were TPHA negative and VDRL positive). The comparative analysis was conducted in the laboratory of the Institut de Recherche en Science de la Santé (IRSS) in Ouagadougou, Burkina Faso.

For the evaluation of the operational characteristics, the study was conducted in a primary healthcare centre (CSPS) located in Ouagadougou the capital city of Burkina Faso. In total sixteen healthcare professionals (midwives, birth attendants, and auxiliary birth attendants) working in the maternity ward of an urban first-level healthcare were trained in the use of the four tests. Their seniority in the maternity ward was between 6 months and 18 years, although none had previously used a rapid syphilis test. However, they had used HIV and malaria rapid tests.

Sample collection

After obtaining the blood donor's consent, approximately 10 mL of blood was taken from the blood collection bag, put in a dry BD Vacutainer® tube (Becton, Dickinson and Company; USA) without anticoagulant and kept at +4°C for approximately four hours while waiting for the results of the syphilis test.

For the operational characteristics study, during the routine prenatal consultations, each healthcare worker used each rapid syphilis test on 5 pregnant women who consented to a

blood-draw by finger prick. A self-administered questionnaire was made available to the healthcare workers for the data collection. The operational characteristics were appreciated following: (i) the clarity of the manufacturers' pamphlets, mainly the description of use, in terms of level of comprehension, (ii) the complexity of technique, (iii) the length of time required to complete the entire testing process, (iv) the time of apparition of line result, and (v) the interpretation of result. For each criterion measures were defined.

The clarity of the manufacturer's pamphlets was appreciated regarding comprehension of the text if it was very clear, moderately clear or difficult to understand.

The complexity of technique was looked if the technique for utilization (from blood collection to the availability of the result) was complex (very difficult), moderately complex (difficult) or very easy in comparison with other rapid tests they had already used such as HIV test.

The length of time required for a test (from blood collection to the availability of the result) was compared to the duration of other rapid tests they had used following the modalities of long, equivalent or short duration.

The time for apparition of line result was compared to what was written in the pamphlet of each test. Finally the ease in interpretation of the result, in terms of visibility and readability of line result, was compared to other used rapid tests following the modalities of very easy or moderately easy to interpret. All these criteria were used to appreciate if a test has good operational characteristics or not.

Laboratory methods

After blood collection from blood donors, syphilis test was conducted by CRTS using the ARCHITECT Syphilis TP automated treponemal antibody test (Abbott Diagnostic, USA).

This is a two-step immunoassay for the qualitative detection of anti-TP antibodies in human serum or plasma. It uses chemiluminescent microparticle immunoassay (CMIA) technology with flexible dosage protocols called Chemiflex. The microparticles are covered with recombinant TP antigens (TpN15, TpN17, and TpN47). Once the syphilis status of the blood donor was determined by CRTS, we chose positive and negative samples for syphilis for our evaluation. At the end of the collection day, the samples were centrifuged at 3000 rpm for 10 minutes and then submitted to combined VDRL/TPHA (BIOLABO SA, France) testing in the serologic laboratory of the Institut de Recherche en Sciences de la Santé (IRSS) to confirm the syphilis status. After confirmation, the serum was aliquoted in two cryotubes of 2 mL, labeled, and stored at -20°C until beginning of the next stage of the evaluation. Hemolyzed samples were excluded.



The evaluation of the rapid syphilis tests performance was conducted at the laboratory of IRSS in July 2012 using the stock of serum samples from CRTS. The evaluation followed the manufacturers' instructions and used good laboratory practices. First the frozen serum samples were brought to ambient temperature before use. Then each test was used in series. To avoid the comparison of results between tests during the laboratory analysis, each rapid test was used on all samples before moving to the next test. There was a blind interpretation of test results, independent of the results of the reference test (TPHA). TPHA (BIOLABO SA, <http://www.biolabo.fr/pdfs/noticesFR/Syphilis>) was used as the gold standard (reference test). It is an indirect hemagglutination assay (IHA) for the identification of *Treponema pallidum* antibodies circulating in human plasma and regularly used for the diagnosis of syphilis in a laboratory.

3.7.1. Statistical data analysis

For each test, the laboratory evaluation results were compared to the reference test (TPHA) and categorized as true positive, false positive, true negative, or false negative. The data were entered with Epidata and analyzed using SPSS version 15 and R version 2-12.1. The performance characteristics, such as sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV), were calculated.

Ethical issues

The research protocol received the approval of the Health Research Ethics Committee (CERS), Ministry of Health, Burkina Faso.

RESULTS

Performance of diagnostic tests

A total of 120 samples were tested for the evaluation of the performance. The sensitivity of the tests was compared to the gold standard used (TPHA). Analysis of the sensitivity of the tests showed that *Alere DetermineTM syphilis TP* had the best sensitivity (93%) among the four selected rapid tests. Then in second position, *Cypress syphilis* and *SD Biotec Syphilis 3.0* with 90% followed. *Accu-Tell[®] Rapid Anti-TP* had the lowest sensitivity (78%). In terms of specificity, *Alere DetermineTM syphilis TP*, *Accu-Tell[®] Rapid Anti-TP* and *SD Biotec Syphilis 3.0* had the same result (98%), while *Cypress syphilis* had a specificity of 95% (Table 2).

Table 2 Results of the diagnostic performances of rapid syphilis tests.

	<i>Accu-Tell</i> [®] <i>Rapid Anti-TP</i> (Accu Biotech Co Ltd)	Alere Determine™ Syphilis TP (Alere™ Médical Co Ltd)	Cypress Diagnostics Syphilis Quick test (Cypress Diagnostics)	SD Bioline Syphilis 3.0 test (Standard Diagnostics INC)
Sensitivity				
(95% CI)	78% (66 - 87)	93% (84-97)	90% (79-95)	90% (80-95)
Specificity				
(95% CI)	98% (91-100)	98% (91-100)	95% (86-98)	98% (91-100)

CI = confidence interval

Operational characteristics of the four tests according to healthcare professionals

The results of the evaluation of the operational characteristics of the four tests by 16 healthcare professionals are summarized in Table 4. The pamphlet of the test was clearly comprehensible by 12 of the 16 respondents for *Accu-Tell*[®] *Rapid Anti-TP*, by 11 respondents for *SD Bioline syphilis 3.0*, by 9 respondents for *Cypress Diagnostics Syphilis Quick test*, and by 7 respondents for *Alere Determine™ syphilis TP*.

As a whole, the healthcare professionals judged the technique for utilization of the tests to be very easy. Indeed, of the 16 healthcare professionals who participated in the evaluation, 15

found *Cypress Diagnostics Syphilis Quick test* and *SD Bioline Syphilis 3.0* to be very easy to use, while 14 said the same for *Accu-Tell[®] Rapid Anti-TP* and *Alere DetermineTM syphilis TP*.

Overall, the time needed to obtain results was determined to be similar to other tests already used for HIV and malaria. Specifically, 10 respondents found *Alere DetermineTM syphilis TP* and *Cypress Diagnostics Syphilis Quick test* to be similar to the previously used tests, and approximately 50% found this for *Accu-Tell[®] Rapid Anti-TP* (9/16) and *SD Bioline syphilis 3.0* (8/16).

For the majority of respondents, the time required to obtain results matched the time indicated by the manufacturer for *Accu-Tell[®] Rapid Anti-TP*, *Cypress Diagnostics Syphilis Quick test* and *SD Bioline syphilis 3.0* (Table 4).

The interpretation of results was found to be very easy by 14 of 16 respondents for *Accu-Tell[®] Rapid Anti-TP* and *SD Bioline syphilis 3.0* and by 12 of 16 respondents for *Alere DetermineTM syphilis TP*. As for *Cypress Diagnostics Syphilis Quick test*, only 9 of 16 found the results to be easy to interpret.

Table 3 Operational characteristics of syphilis diagnostic tests.

Characteristics evaluated	Alere			
	<i>Accu-Tell</i> [®] <i>Rapid Anti-TP</i>	<i>Determine</i> [™] <i>Syphilis</i> <i>(Alere</i> [™] <i>Médical Co</i> <i>Ltd)</i>	<i>Cypress</i> <i>Diagnostics</i> <i>Syphilis</i> <i>Quick test</i>	<i>SD Bioline</i> <i>Syphilis 3.0</i> <i>test</i> <i>(Standard</i> <i>Diagnostics</i> <i>INC)</i>
Clarity of the test pamphlet	(n=16)	(n=16)	(n=16)	(n=16)
Difficult to understand	2	2	1	1
Moderately clear	2	7	6	4
Very clear	12	7	9	11
Complexity of technique	(n=16)	(n=16)	(n=16)	(n=16)
Complex	1	0	0	0
Moderately complex	1	2	1	1
Very easy	14	14	15	15
Time needed for performing	(n=16)	(n=16)	(n=16)	(n=16)
Long	0	4	0	0
Equivalent	9	10	10	8
Short	7	2	6	8
Time need for results	(n=16)	(n=16)	(n=16)	(n=16)
Time indicated in pamphlet	15	14	15	15

Time indicated plus 5 minutes	1	2	1	1
Ease of result interpretation	(n=16)	(n=16)	(n=16)	(n=16)
Moderately easy	2	4	7	2
Very easy	14	12	9	14

The realization of the tests requires the use of equipment not provided in the kit. Specific and non-specific equipment are needed. Specific equipment, such as capillary tubes with EDTA for *Alere Determine™ Syphilis TP* and pipettes for *Cypress Diagnostics Syphilis Quick test* and *SD Bioline syphilis 3.0 Accu-Tell®* are needed. *Rapid Anti-TP* does not require specific equipment. Non-specific equipment, including alcohol swabs and lancets, was required for the four tests. (Table 4)

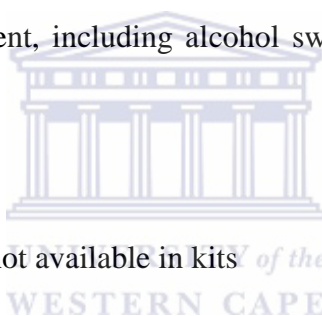


Table 4 Equipment required but not available in kits

		Alere	Cypress	SD	Bioline
		Determine™	Diagnostics	Syphilis 3.0 test	
	<i>Accu-Tell®</i>	Syphilis TP	Syphilis	(Standard	
	<i>Rapid Anti-</i>	(Alere™	Quick test	Diagnostics	
	<i>TP</i>	Medical Co Ltd)		INC)	
Specific		Capillary tube			
consumable		with EDTA	Pipette	Pipette	
Non-specific	Alcohol	Alcohol swab	Alcohol swab	Alcohol swab	
consumable	swab				
	Lancet	Lancet	Lancet	Lancet	

DISCUSSION

This is the first evaluation of the performance and the characteristics of commercially available rapid diagnostic syphilis tests for Burkina Faso, and it allows the identification of the test that is best adapted to the context of the country. To our knowledge, two of the tests, *Cypress Diagnostics Syphilis Quick test* and *Accu-Tell[®] Rapid Anti-TP*, were for the first time compared to other rapid tests for syphilis in West Africa.

All the tests used an immunochromatographic detection of anti-*Treponema pallidum* antibodies. These tests used one or more of several similar recombinant *Treponema pallidum* antigens, although their diagnostic performances in our study were different. With a sensitivity of 93%, *Alere DetermineTM Syphilis* was the most sensitive of the four rapid syphilis tests. It was followed by *SD Bioline Syphilis 3.0* and *Cypress Diagnostics Syphilis Quick test* (Se = 90%), with *Accu-Tell[®] Rapid Anti-TP* being the least sensitive (Se = 78%). In general, the four tests demonstrated a good diagnostic specificity for syphilis (95–98%). Taking into account the two diagnostic criteria of sensitivity and specificity, our study showed that *Alere DetermineTM Syphilis* was the best of the four evaluated tests (Se = 93%, Sp = 98%) followed by *SD Bioline Syphilis 3.0* (Se = 90%, Sp = 98%). The good diagnostic performance of these rapid tests compared to other tests has been reported in the literature (D Mabey et al., 2006; Montoya et al., 2006; Nessa et al., 2008; Tucker, Bu, et al., 2010) . However, few data exist regarding the performances of *Cypress Diagnostics Syphilis Quick test* and *Accu-Tell[®] Rapid Anti-TP*.

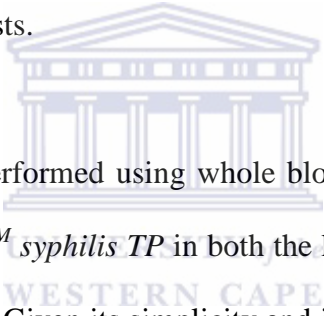
The performance of the tests was different than what was indicated in the manufacturers' pamphlets. Our results showed lower values than those reported for *Cypress Diagnostics Syphilis Quick test* (99.3% and 99.5%), *Alere DetermineTM syphilis TP* (100% with serum),

and *SD Bioline syphilis 3.0* (99.3% and 99.5%). The pamphlet for *Accu-Tell[®] Rapid Anti-TP* did not give any indication of performance. These data, which are crucial in the choice of diagnostic tests, are unavailable in the current published literature. This result calls into question the criteria used for obtaining market authorization from the Ministry of Health to sell rapid tests in Burkina Faso. Additionally, this result emphasizes the need to evaluate available tests on the local market to properly inform policy decision makers.

The performances of *Cypress Diagnostics Syphilis Quick test*, *Alere DetermineTM syphilis TP*, and *SD Bioline syphilis* in this study were in accordance with the threshold set by the WHO (WHO/TDR, 2006), which recommends a minimum sensitivity of 85% and a minimum specificity of 95%. The low sensitivity of *Accu-Tell[®] Rapid Anti-TP* (78%) when compared to the WHO threshold shows that this test is inappropriate for syphilis testing in Burkina Faso.

The sensitivities found for *Alere DetermineTM syphilis TP* and *SD Bioline syphilis 3.0* are below those found by Herring et al. (Herring et al., 2006b) using stored serum samples in Gambia (100%), Tanzania (96% and 94%), and South Africa (96% and 94%). However, their specificities are higher than those found by Herring et al. and Mabey et al. (D Mabey et al., 2006) and similar to the results obtained in China. This variation in performance could be explained not only by ambient storage conditions and use of the different tests but also by the use of fluorescent treponemal antibody, absorbed (FTA-ABS) as reference test and the type of specimen used. This study, whose objective was to evaluate rapid syphilis tests commercially available in Burkina Faso, used tests bought or received by intermediaries of local distributors. A direct order of rapid tests from the manufacturer would have permitted the traceability of the tests evaluated.

Regarding the evaluation of operational characteristics, no test was found to be easier to use than any other. We found all four tests to have very good operational characteristics. In fact, the majority of respondents found that the results were very easy to interpret, and the time required to use the tests was similar to that of existing tests for HIV and malaria. These results are corroborated by Herring et al. for *Alere DetermineTM syphilis TP* and *SD Bioline syphilis 3.0*. Other studies have also shown rapid diagnostic syphilis tests to be easy to use (Sabidó, 2009) but this criterion is not the most important in choosing a diagnostic test. Although perceived favorably by the healthcare professionals, the four test kits were missing equipment. This equipment, such as alcohol swabs, lancets, pipettes, and capillary tubes, is necessary to use the tests in the field. We recommend that the distributors include them in the kits to ensure correct use of the tests.



Of the four tests, three can be performed using whole blood. Studies have documented the performance of *Alere DetermineTM syphilis TP* in both the laboratory as well as in real-world situations (D Mabey et al., 2006). Given its simplicity and its good performance in our study, which is in agreement with data collected in previous studies by other research teams, *Alere DetermineTM syphilis TP* seems the best adapted to syphilis testing in Burkina Faso.

While our study presented the laboratory performance of these tests when used with serum samples, their performance with whole blood will be different (Siedner, Zapitz, Ishida, De La Roca, & Klausner, 2004). In addition, providing diagnostic tests to CSPSs would allow for the collection of more information on the effects of storage conditions on test performance when used in rural settings. Moreover, we did not evaluate the effects that additional infections, such as HIV or malaria, could have on the performance of these tests in real-world situations with whole blood.

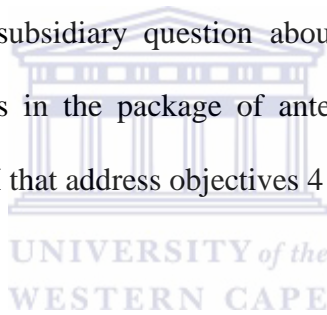
CONCLUSION

Rapid syphilis tests in limited-resource countries can help diagnose syphilis in CSPSs that, until now, have used a syndromic approach to STI diagnosis. Our study allowed us first to confirm the good performance of three of four rapid syphilis tests in Burkina Faso. Additionally, it allowed us to identify *Alere DetermineTM Syphilis TP* as the test that is best adapted to Burkina Faso. More research on the feasibility and acceptability of these rapid syphilis tests in first-level healthcare centers should allow for the effective implementation of the recommendation for systematic testing of pregnant women.



CHAPTER 6: Introducing an onsite antenatal syphilis screening in Burkina Faso: implementation and evaluation of a feasibility intervention tailored to a local context

Chapter 6 (Paper III- submitted) presents the process of development and implementation of the intervention and its outcomes notably the identification of the facilitators and barriers to the implementation of an antenatal syphilis screening at primary health facilities in Burkina Faso. Thus it responds to the subsidiary question about the facilitators and barriers to introduce the rapid syphilis tests in the package of antenatal care services. This chapter presents results of phase II and III that address objectives 4 to 7.



Paper III: - Fadima Yaya Bocoum, Grissoum Tarnagda, Fabrice Bationo, Justin R. Savadogo, Sarata Nacro, Séni Kouanda, Christina Zarowsky

Introducing onsite antenatal syphilis screening in Burkina Faso: implementation and evaluation of a feasibility intervention tailored to a local context,

Under review in BMC Health Services Research (manuscript ID: BHSR-D-15-00765)

Background

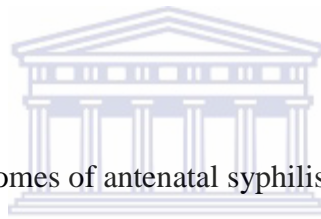
Syphilis in pregnancy poses major health risks for the mother and the fetus (Genc & Ledger, 2000) and also increases the risk of HIV transmission (D. G. Walker & Walker, 2004). The World Health Organization (WHO) estimates that two million pregnant women each year are infected with syphilis globally (WHO, 2007b). The risk of vertical transmission could be up to 80% in early latent syphilis (WHO, 2007b). Approximately 1.2 million pregnant women with syphilis transmit the infection to their newborn every year (Kamb et al., 2010). Each year, maternal syphilis is responsible for at least 50,000 spontaneous abortions or stillbirths and 500,000 premature births of babies infected with congenital syphilis or who have low birth weight (WHO, 2007b). In Burkina Faso, prevalence in pregnant women was 1.9% , with notable regional variations (PSSLS-IST, 2013). In 2011 in Kaya the prevalence was 4.3% whereas in Ouagadougou it was 2.1% (PSSLS-IST, 2013).

Maternal syphilis is detectable by serological screening and is entirely treatable with penicillin. Consequently, screening and treatment for syphilis has been recommended as a routine part of antenatal care in many countries (Control Centers for Disease, 2002; WHO, 2001). Unfortunately, antenatal syphilis screening is often poorly implemented in many sub-Saharan African countries (S Gloyd et al., 2001). The influence of health systems issues on prenatal syphilis screening has been documented in several countries, such as Bolivia, Kenya and South Africa (Deperthes et al., 2004). Yaya Bocoum et al. have documented constraints related to syphilis screening at primary health care facilities (CSPS) in Burkina Faso (Yaya Bocoum, Kouanda, & Zarowsky, 2014).

Syphilis screening in primary health care facilities during ANC in Burkina Faso is conducted using a syndromic approach, but the majority of syphilis cases are asymptomatic. Testing is

available at the hospital laboratories and conducted with a *venereal diseases research laboratory* (VDRL) test or with a *Treponema pallidum hemagglutination assay* (TPHA) which require qualified personnel, laboratory equipment, and a source of electricity, which limits their utility for primary health care facilities.

Currently, there are several available specific, rapid syphilis tests that are simple to use and could be implemented at primary health care settings (WHO/TDR, 2006). These rapid tests for syphilis screening are available in Burkina Faso, and four of them have had their performance and operational characteristics assessed (Yaya Bocoum, Ouédraogo, Tarnagda, Kiba, Tiendrebeogo, et al., 2015) . Unfortunately they are not widely adopted for ANC services.



Interventions to improve the outcomes of antenatal syphilis screening have been implemented in low and middle income countries where most congenital syphilis cases occur (Shahrook et al., 2013) . Although the advantages of introducing point of care testing for syphilis in antenatal care are well documented, there is little evidence on how to address the structural issues within the health system (S. Hawkes et al., 2011). A better understanding on how the interventions work in a range of settings and contexts is needed in order to overcome bottlenecks at health system level. When implementing any intervention, how – indeed whether – it works depends on elements of context such as socioeconomic background, health system structure and dynamics, and other factors (Campbell et al., 2007). It is with a view to better understanding the relationships between implementation and context that we developed and implemented an intervention focused on the integration of a rapid test for syphilis screening in the ANC services in primary health care facilities in Burkina Faso.

Revised UK Medical Research Council guidance on evaluating complex interventions (Craig et al., 2008) recommends describing the intervention and context and reporting on all stages of the process including feasibility evaluations.

The objectives of this study were to develop and describe the experience of a pilot integration of a rapid test for syphilis screening and its operational implementation into routine antenatal services in order to draw lessons for scaling up maternal syphilis screening in Burkina Faso.. This manuscript reports on the experience of implementing antenatal syphilis screening with a point of care test, the identification of barriers and facilitators to integrating this intervention into routine ANC in rural Burkina Faso. Finally its reports on the likelihood that point of care test for syphilis will become routinely incorporated in practice.

Study site – Kaya HDSS

The intervention was nested in the Kaya Health and Demographic Surveillance System (Kaya HDSS), located in the Kaya health district in the North Central region of Burkina Faso, 100 Km from Ouagadougou, the capital city. It covers seven urban areas and 18 villages of the health district. By the end of 2011, 64 480 inhabitants living in 10 587 households were being followed. The population is very young as 55.5% are under 20 years of age. The Mossi are the predominant ethnic group and Islam is the main religion (78.9%). The majority of the population of the HDSS (53.3%) has not attended school. Subsistence farming and livestock breeding are the two main occupations. Artisanal mining is also significant. Within Kaya HDSS, dirt roads and bush paths provide means of access to the villages. These roads present a challenge for users especially during the rainy season when there are floods (Kouanda et al., 2013).

Health facilities

Within Kaya HDSS, there are seven public primary health facilities that offer ANC, one faith-based health center and one regional hospital. The faith-based facility and the hospital do not offer ANC but their laboratories offer VDRL and TPHA tests for syphilis. In 2012, a pharmacy began offering a rapid test for syphilis but due to low demand they stopped selling the test.

All seven public primary health facilities, four urban and three rural, were selected for the intervention. All facilities have a maternity, dispensary and drug shop. There are 2 to 3 health workers staffing a rural facility compared to an average of 7 in urban facilities. Primary health care facilities are led by a state registered nurse and staffed by cadres including nurse, midwife, auxiliary midwife and outreach health workers. Nurses and midwives have formal training that includes syndromic STI case management.

The drugs for STI are standardized kits that are subsidized by the national committee for HIV and STI control. Every year kits are ordered by the national committee for HIV and STI control and supplied to the district for each facility. Frequently, drugs from these kits are expired or out of stock depending on the facility.

Syndromic STI case management and reference for laboratory test were used for syphilis screening in these facilities until the time of the intervention.

Methods

Design of the intervention

The main strategy of the intervention was the development and implementation of a decentralized model of syphilis screening among pregnant women. The components of this intervention included: (1) providing onsite training of health workers involved in ANC, (2) providing supplies and drugs to health facilities for diagnosis and treatment (3) implementing a quality control system, (4) and supervision and monitoring. Before the implementation a preparatory phase of formative research was undertaken.

Preparatory phase

A situation analysis and evaluation of health worker and community perspectives on syphilis screening was the first stage of this project (Yaya Bocoum et al., 2014) . An evaluation of the performance of four available onsite rapid syphilis tests in Burkina Faso was also conducted in order to select the test. The results of this evaluation are reported elsewhere (Yaya Bocoum, Ouédraogo, Tarnagda, Kiba, Tiendrebeogo, Simon Bationo, et al., 2015). The selected point of care test for syphilis was Alere TM Determine TM Syphilis TP (AlereTM Medical Co Ltd, UK). Before the implementation, the head of the health district received information on the objectives and procedures of the intervention.

A workshop was organized with health workers from each of the selected facilities. Participants were staff who regularly performed antenatal care. During the workshop, the importance of decentralizing antenatal syphilis screening, case management of syphilis positive cases, including treatment, counseling and the components of the intervention and a manual were presented. The treatment of positive pregnant women, who were not penicillin sensitive, was benzathine penicillin G, 2.4 million units intramuscularly immediately as a

single dose in accordance with Burkina Faso Ministry of Health (MOH) guidelines. In the national guideline the alternative treatment to penicillin is erythromycin 500mg 1 tablet 4 times per day during 14 days in addition to Polyvidone – iodine for ulceration.

Discussions about the eligibility criteria for women who would receive the test, the design of the intervention and the program manual were held during the workshop. The booklet-format manual was elaborated by the research team and included general information on syphilis, how to use of rapid diagnostic test (RDT) for syphilis, the purpose of the study, criteria for eligible women, obtaining consent, instructions for filling registers, and quality control.

There was no additional health educational campaign beside the routine health education organized by the facility or nongovernmental organization in the district.

Conceptual framework

We adapted and applied the Normalization Process Model (NPM) proposed by May et al (May et al., 2007). NPM focuses on the workability and integration of the components of an intervention in everyday health care practice and identifies conditions that need to be addressed in order to facilitate health intervention integration into routine care. It assists process evaluation in two ways. First, it allows identification and description of factors that have been shown to be important in promoting or inhibiting the implementation of interventions. Second, it provides a basis for assessing the likelihood that an intervention will become routinely incorporated in practice. We sought to identify barriers and facilitators for the introduction of a rapid test for syphilis screening among pregnant women and to understand the conditions under which such an intervention could become routinely incorporated in the antenatal care package.

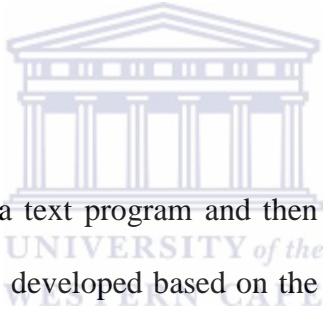
Data collection

Data were collected through qualitative and quantitative methods.

Interviews were conducted among health workers (n= 12) who used the point of care test for syphilis and district managers (n=2). We sought to explore health workers' opinions on organizational and managerial issues and their experience with point-of-care test for syphilis.

Non-participant observations were conducted during ANC visits. The aim was to observe how ANC was offered and how RDT was used. A researcher sat in the consultation room during ANC from the time a woman entered until the end of her consultation. Observations (n= 14 ANC 1 observed) included listening and asking questions as they arose out of observations in order to gain insight into what was observed.

Data analysis



Interviews were transcribed into a text program and then uploaded on Nvivo software. An analytical grid of key themes was developed based on the interview guide, the objectives of the research and familiarization with the first few transcripts.

Ethical considerations

This research was approved by the University of Western Cape, the National Ethics Committee for Health in Burkina Faso and the Ethics Committee Review of the WHO. In addition, the study team obtained permission to conduct the intervention and research from the District authorities. Consent was obtained from pregnant women who received the test by a health worker. They gave a witnessed signature or thumb-printed approval to participate. The consent process included an explanation of the study, its objectives, potential benefits and risks, confidentiality, and the voluntary nature of participation including the right to withdraw at any time.

Implementing and evaluating the intervention

Organizational issues

Seven health facilities participated in the intervention. Data were compiled from 6 facilities because one facility did not complete the record tools. The intervention was implemented in the maternity unit over 4 months in 4 facilities, 2 months and 1 month in 2 facilities. For these latter facilities, stock outs and lack of communication among staff were the main difficulties. The intervention was integrated into the existing package of antenatal care services at primary healthcare level of the district, using the available staff. Syphilis test was performed during ANC. In many cases, it was delivered at the same time as the HIV test. The health worker pricked a woman's finger once for a blood sample for both syphilis and HIV tests. In a few cases health workers pricked twice. There was no change in the organization of the health facilities and patient flow. The main complaint was the filling of the register for syphilis test. Health workers reported that there were many procedures and items to complete. In addition, some health workers highlighted an increase in the length of antenatal consultation. From our observations the difference in time between before and after the intervention was approximately 3 minutes.

Training

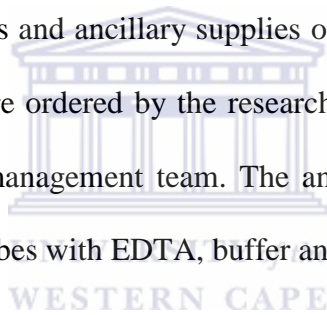
A one day on-site practical training was organized in each selected facility. The training was held in the maternity unit with all the staff available the day of the training. It covered the use of an onsite rapid syphilis test, filling of register book, case management of test-positive syphilis cases and quality control. After training, a simple manual, in French, was given to ensure standardization in screening and treatment for all trainees. In total 18 health workers such as midwife, auxiliary midwife and nurse received the training across 7 facilities. A

pharmacist working for IRSS laboratory and the lead researcher travelled to selected facilities to provide the training.

Health staff found the training interesting and useful mainly because it was a refreshment of their knowledge. They also appreciated the onsite session because this avoided absence of staff and benefited all staff simultaneously, although due to turn over of health workers, some did not receive training. Nonetheless, some of the staff who did not receive training performed the test.

Provision of supplies and drugs

The initial provision of rapid tests and ancillary supplies occurred on the same day, after the training. Thereafter, supplies were ordered by the research team and distributed to facilities by the health system's district management team. The ancillary supplies comprised cotton wool, lancets, gloves, capillary tubes with EDTA, buffer and alcohol.



In addition to the kits provided by the national committee for HIV and STI control, the research team provided kits that comprised benzathine penicillin, erythromycin and polyvidone- iodine. Each facility received 7 kits.

Case management and partner notification

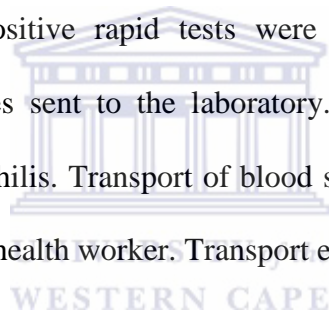
All eligible women were offered the syphilis test in the consultation room. Women at their first antenatal visit during the intervention period were eligible for the test. The decision to offer treatment was based on the point of care test result. Kits were available for treatment. All women diagnosed with syphilis were treated free of charge.

Women with syphilis were advised by the health worker to inform their partner or to invite them for a visit at the health facility without any letter or card of invitation. All health workers declared that partners did not respond to the invitation.

Quality control

All the seven facilities were involved in the quality control tests which were performed by the laboratory of the regional hospital located in Kaya. Supplies such as syringes, cryotubes were provided to health facilities and reagents (RPR and TPHA) and other supplies were provided to the laboratory.

Every 20th negative and all positive rapid tests were to be followed immediately by venipuncture with blood samples sent to the laboratory. RPR and TPHA were the gold standard for the diagnosis of syphilis. Transport of blood samples from the health facility to the laboratory was conducted by health worker. Transport expenditure was reimbursed.



In sum, only 4 facilities sent at least one sample to the laboratory of the regional hospital for control. In total 12 samples were sent. Among these samples 8 were positive and 4 negative. According to the laboratory record, 10 samples were appropriate for analyzing, the others were hemolyzed. There was no discordance between the rapid test results and TPHA one. The small number of samples sent for validation is due to misunderstanding of health workers about the 20th negative sample (some health workers misinterpreted the guidance as the 20th patient) and the system of reimbursement of transport costs.

Supervision and monitoring

For supervision, each health facility was visited once a month. A detailed checklist was elaborated for supervision. A separate register book for screened women was kept in each health facility. Records included the essential information as serial registration number, patient name, sociodemographic information, result of test, reasons for partner notification or non-notification. Supervision was perceived as important but not sufficient in some cases where staff did not follow the guidelines of the intervention despite many reminders. Supervision was also useful for supplies provision such as tests and treatment kits. In addition to visits to facilities, the team had monthly phone contact with the head of the maternity unit, with additional calls if there was any difficulty such as filling in the register, criteria for quality control or other issues. During supervisory visits, difficulties were discussed and patient register books were checked.



Effectiveness

Of 812 pregnant women who came for their first visit 39% were screened during the period (table 1). Rural facilities had higher coverage (66.8%) than the urban ones (25.6%). Among these screened women, 5.7% were positive.

Table 1: Percentage of pregnant women screened through the intervention

	Expected	Screened	%
CSPS rural 1	119	97	81.5
CSPS rural 2	63	40	63.5
CSPS urban 1	76	40	52.6
CSPS rural 3	83	40	48.2
CSPS urban 2	124	39	31.5
CSPS urban 3	347	61	17.6
Total	812	317	39.0

Barriers and facilitators

Interviews with health workers allowed collecting information on barriers and facilitators to introducing this new procedure into routine care.

Barriers

The perceived barriers were lack of training of all staff, workload, and lack of motivation.

Regarding lack of training for all staff as a barrier to introducing syphilis test, an auxiliary midwife in urban facility declared that “ *You have to train everybody, because we work together. It could happen that the person who received the training is absent. You are here and would like to work but you have to call the person to ask what to do. If you are with a pregnant woman, she will wonder if you know your work.*” The lack of training prevents health workers from performing new tasks. Moreover health workers without training will not be able to address questions raised by women during consultation.

Health workers found that the increase in workload is a barrier as illustrated by a midwife in charge of maternity unit in urban health facility “*People find that the workload is high with PMTCT here, malaria RDT there, with the filling of registers mainly with addition of PBF (Performance Base Financing), people find that the workload is too high.*” In fact the main complaint was the filling of the register for syphilis test. Staff felt that they already have many registers (4) and there was no need to add another. In addition, some health workers highlighted an increase in the length of antenatal consultation.

Another reported barrier was frequent stock-outs of consumables, which is also a source of demotivation. Consumables such as gloves and chase buffer were frequently claimed by health workers to be unavailable. The availability of chase buffer was crucial for the

continuity of the activity in the health facility. Gloves were also important but when there was no free stock health workers said that pregnant women are required to buy them at the pharmaceutical store of the facility. It becomes a barrier when woman does not have enough money to purchase gloves. Stock-outs of consumables were a common reason that health workers offered for not screening women.

Lack of supervision influences motivation of health workers to perform task. One nurse in charge of a rural facility declared: “ *if we start something without monitoring, at some point, staff will wonder if people who initiate the activity are interested in it. Thus there will be a demotivation for that activity*”.

Facilitators

All health workers found that offering the rapid test was a satisfying experience for them. Among facilitators, health workers cited political environment, ease of use and acceptability to pregnant women.

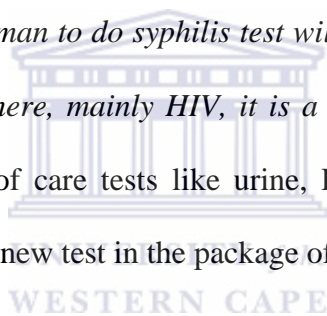


In terms of political environment, syphilis screening is officially part of the package of ANC in the guideline for ANC in Burkina Faso. In addition, there are new policies or reforms such as performance based financing (PBF) in which offering the full package of ANC is important. This is a good opportunity for implementation of syphilis screening as a routine activity as illustrated by this auxiliary midwife in rural facility “*With PBF, syphilis is part of [indicators that count in the evaluation]. If we get it (syphilis test), it will help us, we will gain points.*”

All health workers agreed that the rapid test was easy to use due to the similarity with the HIV testing. The comment of a midwife in an urban facility illustrated the ease of use: “*We*

did not face difficulties in performing testing as we did it for PMTCT, it is the same thing, we tick and collect blood, so it is the same thing. There was no difficulty because we received training for PMTCT.” In addition, some health workers declared that they received support from other colleagues who received training.

Acceptability to women is important to the success of an activity. There was a good acceptability of the test and the health workers recorded few refusals from women. Health workers were reported that women agree to testing because they would like to know more about their health status and protect their fetus. Moreover a nurse in charge of rural facility argued that *“HIV screening is already performed, women know that there are different tests at CSPS level. Thus, asking a woman to do syphilis test will not be a problem. They are used to the different tests we deliver here, mainly HIV, it is a routine.”* In other word, pregnant women have got used to point of care tests like urine, HIV or malaria test and this is a favorable factor for introducing a new test in the package of ANC.

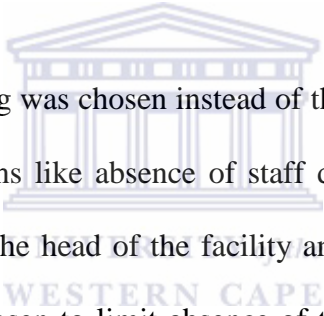


Discussion

The study demonstrated that it is operationally feasible and acceptable to staff to integrate a point of care test including rapid on-site syphilis testing and prompt treatment of syphilis cases at primary healthcare level in Kaya health district, Burkina Faso. It also highlighted implementation challenges and barriers to routine implementation that need to be addressed prior to rolling out the intervention.

In developing countries, one of the gaps in syphilis control in pregnant women is the access to syphilis testing at peripheral facilities. To address this challenge, a pilot model with a point of care test was designed and tested in Burkina Faso. This pilot model included different

components including onsite training, quality control and supervision. Decentralized models integrating a point of care for syphilis in ANC were designed and experimented in Low and Middle Income Countries (LMIC). These models were mostly implemented in Asia (Munkhuu, Liabsuetrakul, McNeil, et al., 2009; Tucker, Hawkes, et al., 2010), Latin America (P. J. García et al., 2013; S. G. García et al., 2007) and eastern and southern Africa (Bonawitz et al., 2015; Bronzan et al., 2007b; Elizabeth Glaser Foundation, 2011; Fleming et al., 2013; Watson-Jones et al., 2005). Few were implemented in West Africa (Dassah et al., 2015). Each model was adapted to the contextual health system and was feasible. This underlines the importance of contextual specificities in the implementation of health interventions and pilot studies.



In terms of training, onsite training was chosen instead of the usual off-site approaches. Off – site training has known limitations like absence of staff during training, small numbers of beneficiaries and that often it is the head of the facility and not front line workers who are targeted. Onsite training was chosen to limit absence of the staff from their facility and to offer a chance for all staff at maternity units to be trained to avoid the situation , common with off-site training as seen with HIV services, that staff who did not receive the training could use this to justify the non use of the rapid diagnostic test (Yaya Bocoum, Kouanda, Kouyaté, Hounton, & Adam, 2013) . Nonetheless some health workers complained about not having received training. Most of these were absent during the training session or had been newly appointed at the facility. It is important, in case of scale –up of the intervention, to plan refresher training and to explicitly include mechanisms for trained staff to train new or untrained staff. Those who performed the test without training reported that it was due to the similarity with HIV testing.

Case management of positive pregnant women was not reported to be a problem for health workers. The main challenge was partner notification. In most of the cases, the patients' husbands did not come to the facility as reported in many studies (Alam et al., 2010). This is one of the limits of patient driven notification and may be particularly challenging in patriarchal societies where polygamy is common, such as Burkina Faso. Further research might study constraints to partner notification in such contexts and develop a workable and acceptable partner notification model (McNutt & Coles, 2007).

With respect to the definition of integration of services understood as “the organization and management of health services so that people get the care they need, when they need it, in ways that are user friendly...” (World Health Organisation, 2008), integration of syphilis services was observed at ANC units in this study as a “one stop shop”. Rapid syphilis testing and treatment were delivered during ANC within the examination room. At the staff organization level, there was no specific additional mechanism put in place. Unfortunately, there were missed opportunities as not all the women who were eligible received test. Missed opportunities could be explained by insufficiently clear instructions, lack of financial incentives in a context where some health workers have come to expect financial incentives for adding new tasks (Israr, 2005; Ridde, 2010), increase in duration of consultation and high number of patients or workload as found by Zongo et al (Zongo, Ridde, & Haddad, 2013) in a study on utilization of RDT for malaria conducted in primary health care facilities in Burkina Faso.

The quality control was a challenging component because in the routine system the relationship between health workers at primary health facilities and lab personnel is limited to referral for laboratory tests that are not available at primary health facility. These cadres do

not really collaborate except during HIV serosurveillance surveys where health workers at health facility send blood samples. The laboratory does not conduct any routine supervision to validate rapid diagnostic tests that are delivered at the peripheral level. For the implementation of the quality control during our study, health workers received reimbursement for their transport depending on the distance. In two facilities where there were delays in reimbursement, the activity was stopped. This finding underlines that the issue of health workers' motivation in quality control needs to be properly addressed. In addition there is a need to implement a rigorous quality control, with regular supervision from laboratory personnel, in order to improve utilization of rapid diagnostic tests as a whole. The use of a rapid diagnostic test at level like primary health facility by non-lab personnel is a form of task shifting and needs supervision from lab personnel.

Most studies that documented syphilis screening programs did not pay particular attention to the workability and integration of the syphilis testing in ANC services. Our research identified facilitators and barriers that need to be addressed in order to facilitate integration of rapid test for syphilis into routine ANC services.

At the health worker level, respondents agreed that the rapid test for syphilis is easy to use because it is similar to HIV testing and is therefore compatible with their daily activities in ANC. The barriers to the full integration of the test are availability of consumables, filling of forms and lack of supervision. These factors - especially stock-outs of consumables - influence health workers' motivation to deliver the service. Due to lack of supplies, staff frustration was underlined in HIV services at peripheral facilities in Burkina Faso (Yaya Bocoum et al., 2013). Regular supply and supervision could help in maintaining motivation to deliver testing.

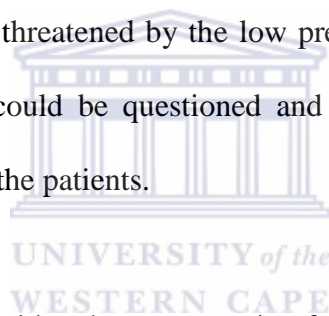
At the patient level, acceptability of testing is reported to be high. According to health workers, this high acceptability is due to their knowledge of existing testing such as HIV or malaria. The few refusals come from women who need prior agreement from their husband. However, the high acceptability hides constraints that oblige women to accept any service such as tests from health workers. From our observational survey of ANC, the interaction between health workers and pregnant women was unidirectional as Pembe et al. found (Pembe et al., 2010) . The health worker talks and the pregnant woman nods or answers to questions. In such a frame, a pregnant woman does not have an opportunity to refuse any offer from health workers. This situation is corroborated by findings from Malawi where rural Malawians perceive routine testing for HIV at antenatal clinics as compulsory to receive antenatal care (Angotti, Dionne, & Gaydosh, 2011). Moreover they found that constraining choice is likely when clients are women, rural and relatively uneducated compared to health personnel, as is the case in our study site. Although the situation helps staff in gaining high rate of acceptability of HIV testing and other services, the rights of clients may not be not fully respected.

Through the lens of the four factors of the Normalization Process Model (NPM), assessment of the likelihood that point of care test for syphilis will become routinely incorporated in practice was explored. These factors are interactional workability, relational integration, skill-set workability, and contextual integration.

In terms of interactional workability, the point-of care test for syphilis is both an opportunity to address a service gap and an opportunity to improve the standard of antenatal care. Health workers were aware that the current antenatal services did not provide optimal access to syphilis testing. This awareness could strengthen the willingness of health workers to

consider its implementation. So, there is congruence with operational needs (difficult access to syphilis test) and antenatal care practice.

Regarding relational integration, the dimension of confidence was explored. Health workers are confident in the reliability of the test and the utility of the test. Health workers did not show any reticence regarding the reliability of the results. The results from quality control reinforce the confidence in those results. Their perceptions of the reliability could be influenced by similarity with HIV test. From our knowledge, health workers had a good perception of the reliability of HIV except in some cases of indeterminate results. While reliability could be a promoting factor, the utility of the syphilis test could be also considered as such. However this could be threatened by the low prevalence. Where the prevalence is low the utility for routine test could be questioned and reduce the willingness of health workers to systematically test all the patients.



Skill-set workability could be considered as a promoting factor in relation to the capacities of the health workers to perform the test and there being no change required in the division of labour. The challenge posed by the intervention was the increase in workload due to filling the register and the increased perceived duration of consultation. The existing routine ANC register and ANC card do not allow for filling in information on syphilis testing. This would need to be addressed as filling in separate syphilis registers is a significant disincentive. The perceived extension of ANC consultation time could be addressed by sharing the results of observation survey (only 3 minutes additional time) and drawing attention to possible improvement of ANC service quality. Supervision of the work by both district managers and laboratory personnel could also mitigate the effects of the challenge.

Contextual integration is favorable at international and national levels. At the international level, the global initiative for the elimination of congenital syphilis, launched by WHO (WHO, 2007b), emphasized screening and treatment of pregnant women and their partners as a key component. At national level, policy and management of maternal care guidelines emphasize the importance of diagnosing and treating pregnant women for reproductive tract infections (RTIs). Moreover implementation of performance based financing with indicators concerning antenatal syphilis screening is a promoting factor. It could be argued that these initiatives provided a receptive international and local context for introducing point of care testing for syphilis in ANC services. Integration of point of care tests using available staff could contribute towards embedding this in to routine practice. The main challenge was the provision of supplies. Supply chains in Burkina Faso are known to have difficulties that often lead to stock out of consumables.

In summary the study identified a number of facilitators to potential normalization including congruence with professional practice, confidence in the reliability and utility, capacities for performing the test and no change at organizational level.

One of the limits of the study is that there was no baseline data on the percentage of women who had their syphilis test at the laboratory. Available data do not allow linking women and health facilities. Thus comparison between before and after coverage was not possible. But we assumed that the coverage was increased as found in other studies (Munkhuu, Liabsuetrakul, Chongsuvivatwong, McNeil, & Janchiv, 2009) . Another limitation is that we were not able to show impact as our main focus was feasibility.

Conclusion

In conclusion, point of care test for syphilis could be integrated in ANC at primary health facility in Burkina Faso. Nonetheless, barriers need to be addressed before scaling up. These barriers relate to staff motivation, which is negatively influenced by practical considerations such as stock-outs and the chore of filling in registers, inadequate supervision, and by some aspects perceived as unfair regarding training and incentives. Through the lens of NPM, point-of care test for syphilis is likely to be acceptable by health workers as routine service and incorporated as a normal practice, and may strengthen the quality of overall ANC services.



CHAPTER 7: Incremental costs of adding rapid syphilis test in to existing antenatal services at primary healthcare level in Burkina Faso

Chapter 7 (paper IV- submitted) answers questions about the costs for adding rapid diagnostic test for syphilis in antenatal care services. Paper IV emanated from phase III of the research.

Paper IV: Fadima Yaya Bocoum , Christina Zarowsky , Seni Kouanda ; Incremental costs of adding rapid syphilis test to existing antenatal services at the primary healthcare level in Burkina Faso. Under review in BMC Health Services Research (manuscript ID: BHSR-D-15-00773)



Introduction

Syphilis is a serious source of adverse pregnancy outcomes for both mother and infant (Di Mario et al., 2007; David Mabey & Peeling, 2011) and can also facilitate HIV acquisition and transmission (Mwapasa et al., 2006; Reynolds et al., 2006). Approximately 1.36 million pregnant women globally were estimated to have probable active syphilis (Newman et al., 2013). According to WHO estimates, each year, maternal syphilis is responsible for at least 50,000 spontaneous abortions or stillbirths and 500,000 premature births of babies infected with congenital syphilis or who have low birth weight (WHO, 2007b). However, rates of congenital syphilis are generally underestimated (Saloojee et al., 2004a). Congenital syphilis is an avoidable disease that prenatal testing and early treatment of infected pregnant women could eliminate (F Terris-Prestholt et al., 2003). Screening and treatment of pregnant women for syphilis remain cost-effective even when the prevalence is low (Kahn et al., 2014; Schmid, 2004; F Terris-Prestholt et al., 2003). Kuznik et al. found that screening in 43 sub-Saharan countries was highly cost-effective, with each DALY prevented on average costing only US\$11 (Kuznik et al., 2013). Despite its potential benefits, antenatal syphilis screening is often poorly implemented in many sub-Saharan African countries (S Gloyd et al., 2001). In many low resource settings, the traditional lab based diagnostic and syndromic approach have still ran with a low coverage due to number of barriers (Deperthes et al., 2004; The Lancet, 2012; Yaya Bocoum et al., 2014).

Currently point of care syphilis tests that are simple to use and with high accuracy compared to lab based diagnostic are available (Guinard et al., 2013; D Mabey et al., 2006; Tucker, Bu, et al., 2010). In Burkina Faso, these point-of-care tests are available but they have not been used by health workers at health facilities (Yaya Bocoum, Ouédraogo, Tarnagda, Kiba, Tiendrebeogo, Simon Bationo, et al., 2015). An intervention research project was

implemented on antenatal syphilis screening and treatment using a point of care test at peripheral health facilities. It included training of health workers, provision of supplies and drugs, supervision and offering testing and treatment for free to pregnant women coming for first ANC visit. This intervention has permitted pregnant women to receive syphilis testing as recommended by national ANC guidelines.

At the end of an intervention, issues such as the costs for replication, scaling-up or sustainability are usually raised by decision makers or program managers. An incremental cost analysis is required to answer such questions. An incremental cost analysis looks at the cost of adding or implementing the additional intervention or program to existing services and does not estimate cost for existing services (Fern Terris-Prestholt et al., 2011). The choice of this costing study is twofold, first to give evidence on costs for sustainability of the intervention and second to estimate how much the provider or decision maker should bear if they want to offer syphilis test for free to pregnant women coming for ANC visit. Moreover our study will contribute to fill the knowledge gap in low syphilis prevalence countries where lack of costing studies has deplored (Kuznik et al., 2013). This paper reports on an incremental cost analysis of the antenatal syphilis screening intervention we implemented in rural Burkina Faso.

Methods

Type of study

A cost analysis study in the frame of a pre post implementation intervention group with no comparison group was conducted.

Study settings

The intervention was nested in the Kaya Health and Demographic Surveillance System (Kaya

HDSS), located in the Kaya health district in the North Central region of Burkina Faso, 100 Km from Ouagadougou, the capital city.

Within Kaya HDSS, there were seven public primary health facilities that offered ANC, one faith-based health center and one regional hospital. The faith-based facility and the hospital did not offer ANC but their laboratories offered the *venereal diseases research laboratory* (VDRL) test and *Treponame pallidum hoemagglutination assay* (TPHA). tests for syphilis. All seven public primary health facilities, four urban and three rural, were selected for the intervention. All facilities have a maternity, dispensary and drug shop. There were 2 to 3 health workers staffing a rural facility compared to an average of 7 in urban facilities. Primary health care facilities were led by a state registered nurse and staffed by cadres including nurse, midwife, auxiliary midwife and outreach health workers. The drugs for STI were standardized kits that were subsidized by the national committee for HIV and STI control. Every year, kits were ordered by the national committee for HIV and STI control and supplied to the district for each facility. Frequently, drugs from these kits were expired or out of stock depending on the facility.

Unit costs for unscreened and screened woman

The costs for unscreened and screened woman were calculated from a government perspective at health facility level. The calculation of the cost depends on many pieces of information. We adapted the costing approaches developed by Larson et al for estimating cost of diagnosis and treatment of syphilis in Zambia (Larson et al., 2014) and cost of point-of-care testing (Larson et al., 2012).

The focus of this study was the cost of syphilis testing and treatment, as an additional service at public health facilities that already exist. Thus fixed cost such as costs of buildings and equipment (weigh scale, metric, blood pressure monitor, obstetrical stethoscope, tape

measure, table, and chair, etc.) were not relevant for the analysis.

Costs of daily startup were not relevant regarding the type of test which did not use resource for startup. Costs of quality control were not collected during the intervention. Costs for electricity and water were excluded because in majority of rural health facilities they used solar system for electricity and borehole water.

Of the components used in the approach of Larson et al, we selected 4 major inputs; (1) cost of test, (2) materials costs, (3) staff time and (4) salary cost.

In sum the unit costs for unscreened woman (before introducing of the rapid syphilis test) included:

- Material costs used for first ANC visit
- Salary cost estimated from staff mean time.

Material costs used for first ANC visit included gloves, cotton wool, alcohol, urine test, lancet, HIV test, chase buffer.

During ANC visit, multiple activities took place. One or more health workers could be involved in these activities and spent time with pregnant women. We conducted a non participant observation of time related activities which consisted of observation of each ANC consultation and recording of every activity, its duration and resources used.

Using a chronometer, time was recorded in minutes and seconds. For this study only time spent for first antenatal visit was used because syphilis test was performed only during this visit.

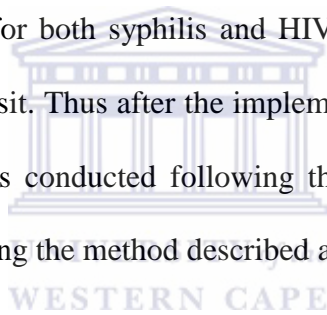
Using health worker time per ANC, staff costs per ANC were estimated. The full cost of salary and benefits was used for estimate. While there were potentially 260 working days in a year, the majority of employees in Burkina Faso worked less than this, due to national holidays, annual leave, and sick leave. Finally health workers worked on average 216 days per year. Using previous calculations, salary per day was estimated. Then with official 8

working hours, the salary per working hour was estimated.

The unit costs for screened woman (after introducing the rapid syphilis test) included:

- Material costs used for first ANC visit ;
- The rapid syphilis test cost;
- Materials cost for rapid syphilis test (chase buffer);
- Salary cost estimated from staff time used for conducting an ANC visit in addition to syphilis screening.

The rapid syphilis test and its materials (chase buffer) prices were drawn from the invoice of the company that supplied syphilis test during the intervention. Materials cost of lancet, alcohol, cotton wool and gloves were not added because health worker pricked a woman's finger once for a blood sample for both syphilis and HIV tests. Health workers completed rapid syphilis test during ANC visit. Thus after the implementation of the intervention, a non participant observation study was conducted following the same method described above. Salary cost was estimated following the method described above.



Unit costs for treatment

The recommended treatment at national level was benzathine benzyl penicillin (BBP) G, 2.4 million units intramuscularly as a single dose and for women who are allergic, the protocol is erythromycin 500mg 1 tablet, 4 times per day during 14 days. In each kit for treatment there was polyvidone- iodine for ulceration treatment. Cost was estimated for each treatment.

The unit costs for treatment with benzathine benzyl penicillin (BBP) G, 2.4 million included:

- The dose of BBP;
- Materials used for the injection (water, lidocaine or xylocaine, polyvidone-iodine, alcohol, cotton wool, syringe);
- Salary cost for staff time for the injection.

The unit costs for treatment with erythromycin included:

- Number of tablet of erythromycin.

The dose of BBP, materials for the injection, tablet of erythromycin prices were from the official list of consumables and essential medicines in public health facilities in Burkina Faso in 2014. For salary cost, we followed the same method as described above. However, during observation we did not meet enough pregnant women who tested positive (1 case). Thus we added an additional 5 minutes of time to prepare and complete one injection of penicillin as per Larson et al. (Larson et al., 2014).

Sampling

Data collection was held in primary health care facilities in the maternity unit. From 7 facilities that received the intervention, 4 facilities, 2 rural and 2 semi-urban, were selected and observed before and after the implementation of the intervention. For the purpose of this study, only prenatal services were analyzed.

Observations were conducted by a non medical researcher during one day scheduled for antenatal visits before and after the intervention. All consenting pregnant women coming for antenatal visit were observed the day of the survey. The researcher sat in the consultation room and reported all the information on a sheet during each antenatal consultation.

Data collection and analysis

Surveys were conducted before and after the implementation of the intervention respectively in 2012 and 2013. Data for staff time and materials were collected from observations of provider contacts with pregnant women.

Prices used in this analysis were from the official list of consumables and essential medicines in public health facilities in Burkina Faso in 2014 and the invoice from the company providing syphilis test during the intervention. Salary and benefits of health worker were

from the 2012 official salary grid and 2014 official benefits of public services. The salaries from 2012 grid were depreciated with gross domestic product (GDP) deflator for 2014 year (source: WDI, july 2015).

For analysis, only first antenatal visit observations were selected regardless the gestation time. Excel sheets were used for data entry and calculations. The information from each input were combined into final table that estimated the cost of unscreened , screened, screened and treated woman. Statistical means and standard deviation were calculated. Mean time for unscreened and screened woman was used for estimating salary cost for each type of health worker. For estimating salary cost we multiplied health worker salary per working hour by mean time for each activity (no test, testing, and BBP injection). Cost driver was also determined for each activity. Finally, costs were collected in CFA franc (XOF) and converted to US dollars (USD) using the average exchange rate for 2014 (494 CFA = 1USD) (OANDA, 2014).



Ethical considerations

This research was approved by the University of Western Cape, the National Ethics Committee for Health in Burkina Faso and the Ethics Committee Review of the WHO. In addition, the study team obtained permission from the District authorities before conducting the study. Written informed consents were obtained from pregnant women and health workers for observation during ANC. For pregnant women, they gave a witnessed signature or thumb-printed approval to participate. The consent process included an explanation of the study, its objectives, potential benefits and risks.

Results

Material costs per ANC

During observation, for each ANC, materials used were noted. For ANC 1, these materials include urine test, lancet and chase buffer for HIV test, cotton, alcohol, and 3 gloves. The total materials costs for ANC 1 without rapid syphilis test were 2.03 USD. HIV test was the cost driver which accounted for 80% of the total costs (table 1). When rapid syphilis test was added in ANC 1, the total materials costs were 3.90 USD (table 1). The main drivers costs were rapid syphilis test (45%) and HIV test (42%).

Table 1: Material costs per unscreened and screened woman

Item	Unit per woman	Cost per unit in 2014 XOF	Cost per woman in 2014 XOF	Cost per woman in 2014 USD
Urine test	1	29.4	29.4	0.06
Lancet	1	10.2	10.2	0.02
Cotton	1	15.0	15.0	0.03
Chase buffer	1	50.5	50.5	0.10
HIV test	1	808.4	808.4	1.64
alcohol	1	6.5	6.5	0.01
Gloves	3	26.9	80.6	0.16
Material cost per unscreened woman			1000.7	2.03
rapid syphilis test	1	875	875	1.77
chase buffer	1	50.5	50.5	0.10
Material cost per test			925.5	1.87
Material cost per screened woman				3.90

Cost of treatment

As outlined in table 2 the cost for treatment with BBP (1.11 USD) is lower than costs for treatment with erythromycin (4.47 USD). The driver cost in BBP treatment was lidocaine.

Table 2: Material cost per pregnant woman for syphilis treatment

Item	Unit per woman	Cost per unit in 2014 XOF	Cost per woman in 2014 XOF	Cost per woman in 2014 USD
Water for injection	2	34.4	68.8	0.14
Benzathine Benzyl penicillin 2.4 MU	1	128.59	128.59	0.26
Syringe	1	36.6	36.6	0.07
Alcohol	1	6.54	6.54	0.01
Cotton wool	1	14.99	14.99	0.03
Lidocaine	1	294.6	294.6	0.60
Erythromycin 500mg	60	36.79	2207.4	4.47
Polyvidone iodine	1	962.84	962.84	1.95
Cost of treatment with BBP			550.12	1.11
Cost of treatment with erythromycin			2207.4	4.47

Staff time

After observation, we found that health workers spend more time with pregnant woman when performing rapid syphilis test. As outlined in table 3, the average time for unscreened woman was 11 minutes and 14 minutes for screened woman.

Salary costs depend on cadre and location of health facility. Table 3 shows salary cost according to cadre and location. Salary in semi urban area varied from 0.93 to 0.53 USD and 0.77 to 0.48 USD in rural area. Salary costs for nurse and midwife in semi urban area are the

higher one and salary cost for auxiliary midwife in rural area is the lowest one. From observations, in semi urban facility 2 profiles of health workers were involved in ANC that included midwife and/ or auxiliary midwife. In rural facility there was auxiliary midwife or nurse.

Table 3 : Salary cost per activity

	Unit	Auxiliary midwife (semi urban)	Staff nurse/ midwife (semi urban)	Auxiliary midwife (rural)	Staff nurse/ midwife (rural)
Salary (including all benefits according to government policy)	USD/month	218.38	383.58	199.41	317.21
Salary per working hour	salary/hour working	1.52	2.66	1.38	2.20
Staff time per unscreened woman (mean time)	minute	11:28	11:28	11:28	11:28
Staff time per screened woman (mean time)	minute	14:01	14:01	14:01	14:01
Additional time for treatment with BBP injection	minute	05:00	05:00	05:00	05:00
Salary cost per unscreened woman	USD	0.27	0.48	0.25	0.40
Salary cost per screened woman	USD	0.35	0.61	0.32	0.51
Salary cost per BBP injection	USD	0.12	0.21	0.11	0.18

Full cost per pregnant woman attending ANC 1

Table 4 shows the full cost per pregnant woman attending ANC 1 before and after adding rapid syphilis test in ANC services.

The average cost for unscreened pregnant woman was 2.38USD (± 0.11) and the average cost for screened pregnant woman was 4.35 USD (± 0.14). Cost difference between unscreened

and screened woman was 1.97 USD. The main cost driver in screening was syphilis material costs. Syphilis device test accounted for 39% to 42% of the total costs and HIV device test accounted for 36% to 38%.

The average cost for screened and treated pregnant woman was 5.61 USD with BBP only and 8.81 USD for erythromycin treatment (table 4). Regarding cost difference between treatment with and without polyvidone iodine (used for ulcers), cost for polyvidone iodine increased the cost for screened and treated woman for about 22% to 36%. Costs varied also by health facility location and profile of health worker. The cost of personnel accounted for 11% to 19% of the total costs for unscreened woman and 8% to 13% for screened woman.

This cost was higher in semi urban facilities than in rural ones because of the number of health workers (on average 2 at semi urban facility) involved in ANC. For rural facilities where there was one health worker, either auxiliary midwife or nurse, the cost was higher with a nurse. In semi urban facility, the cost was higher when ANC was performed by 2 midwives.

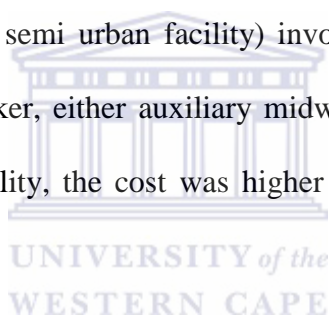


Table 4: Cost analysis of antenatal syphilis screening according to health worker profile and location

	Unit	Auxiliary midwife (semi urban)	Staff nurse/ midwife (semi urban)	Auxiliary midwife (rural)	Staff nurse/ midwife (rural)	Mean cost	SD
Total cost per unscreened woman	USD	2.30	2.51	2.27	2.42	2.38	0.11
Total cost per screened woman	USD	4.25	4.51	4.22	4.41	4.35	0.14
Total cost per treated with BBP injection	USD	1.23	1.33	1.22	1.29	1.27	0.05
Total cost per treated with erythromycin	USD	4.47	4.47	4.47	4.47	4.47	0.00
Total cost per	USD	5.48	5.84	5.44	5.70	5.61	0.19

screened and treated (BBP) woman							
Total cost per screened and treated (erythromycin) woman	USD	8.72	8.98	8.69	8.87	8.81	0.14



Discussion

In the national guideline for ANC 1 in Burkina Faso, screening for syphilis is recommended. However, syphilis testing is only available at laboratories, to which access is limited (Yaya Bocoum et al., 2014). Our intervention introduced a point of care test for syphilis in 7 health facilities in Kaya HDSS. The purpose of the study was to evaluate the incremental cost of integrating rapid syphilis test in ANC services.

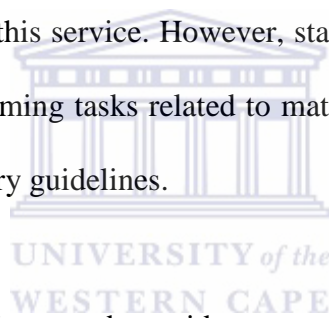
We first estimate the cost of ANC 1 visit before the introducing of rapid syphilis test. The mean cost was 2.38 USD of which 2.03 USD was for material (mainly HIV test) and 0.35 USD for health worker time. For ANC 1 with syphilis test the mean cost was 4.35 USD and material cost was 3.90 USD and 0.45 USD for health worker time. The incremental costs for adding syphilis test was 1.97 USD. Syphilis screening increased cost for ANC by about 83% on average. When comparing syphilis material costs with HIV material costs, the difference is not high (0.13USD) on the local market. The policy-relevant difference is that HIV material costs are currently covered by donors, whereas there is currently no donor offering to cover the costs of implementing syphilis screening as recommended in the national and international guidelines for ANC.

In Zambia, the cost to test one patient for syphilis was estimated at 3.10 USD (Larson et al., 2014) that is less than our findings. The difference in these results could be explained by the price of the test. In fact the test kit cost needed for syphilis testing (1.15USD) was less than our estimate (1.77 USD). The price depends heavily on the type of the test, the freight charges and taxes that vary from country to country. The cost for materials would be significantly lower if a less expensive test was used, or if the government subsidized prices of these devices, or if donors take it in charge as they do for HIV tests.

The incremental cost for adding rapid syphilis test in ANC represented 4% of per capita

healthcare spending in Burkina Faso and less than 1% of GDP per capita (717 USD in 2014). For defining a highly cost-effective intervention, a commonly accepted threshold of an Incremental Cost-Effectiveness Ratio (ICER) less than one times per capita gross national income was used (Marseille, Larson, Kazi, Kahn, & Rosen, 2015).

Other relevant findings are related to location of the facility and the staff availability and profile. At semi urban or urban facilities, the staff number is higher than rural facilities. In semi-urban and urban facilities ANC is generally conducted by two health workers, which explains the high staff costs. In contrast, in rural areas, generally ANC is provided by one health worker. Profiles also differ. In urban and semi urban facilities; a midwife and auxiliary midwife provide ANC whereas in rural facilities, an auxiliary midwife, nurse or itinerant health worker provided this service. However, staff such as itinerant health workers do not receive training for performing tasks related to maternal health, making it difficult to follow the national service delivery guidelines.



The interaction time between clients and providers was short. The mean duration was 13 minutes without syphilis test and 16 minutes with. This is lower than found in Tanzania by Pembe et al. (Pembe et al., 2010). Even if this reduces the cost of health worker time, the issue of quality of service delivery is raised when the estimated time for good quality focused ANC is 46 minutes, about half of which should be dedicated to counseling (von Both, Flessa, Makuwani, Mpembeni, & Jahn, 2006) . The interaction time also raised the issue of time for reading the results of HIV and syphilis tests. The required time for reading the results is 15 minutes. During observations all the health workers read the results before the adequate time. In sum, this study raises some questions about the quality of service delivery.

In terms of treatment, the costs vary between penicillin treatment and erythromycin treatment. Treatment with BBP was inexpensive in comparison with erythromycin treatment. Most of the women screened and treated during the intervention were not allergic to BBP thus BBP could be adopted as the main treatment as far as the risk of serious adverse reactions appears very low and does not outweigh its benefits (Galvao et al., 2013). During observations and discussions with health workers, they stressed that none of the women who were positive, had ulceration. That suggests the polyvidone- iodine was not useful as a significant component of the syphilis treatment kit. This questioned the reason to add this drug in the kit for syphilis when Grosskurth et al. argued that most ulcers are not due to syphilis or chancroid (Grosskurth, Gray, Hayes, Mabey, & Wawer, 2000). This could be explained by the fact that the kit is not specific to syphilis treatment but for any STI known with genital ulcers as symptom – yet the costs are attributed to the syphilis testing component of the program. We also found that health workers routinely use lidocaine to reduce injection pain, in line with their training but not accounted for in national policy . In the treatment kits (BBP) provided by the ministry of health, there was no lidocaine and supplies for injection (syringe and water for injection). These supplies had to be purchased by women who usually did not bring enough money for their ANC visit. Thus we recommend that the ministry of health could take it in charge, knowing that test-positive women requiring a painful benzathine penicillin injection are not many.

This study has some limitations. One of the limitations is the possible bias due to observation (Hawthorne effect). To mitigate this effect, the researcher who conducted observations was non medical personnel and health workers were informed. Thus they could act as usual and they seemed at their ease during the observation.

Another limitation is the components of the costs. We did not estimate the cost of quality control for positive case and training. These are components which need to be taken into account to maintain quality of services. Further studies could explore these costs.

A key limitation is that study addresses incremental cost for introducing rapid syphilis test in one particular area located in a high prevalence health district of Burkina Faso. The results from the study could not be extrapolated to the country. But the costing approach can be used for reassessing costs and performing cost effectiveness studies in other settings. Nonetheless the results could be used for budgeting related activities at the district level.

Conclusion

Our analysis suggests that integrating point of care testing for syphilis in ANC services is feasible at an incremental cost with variations. This incremental cost is modest in comparison with HIV test and the benefits to mothers, infants, and averted health costs from syphilis screening.

The variation in costs reflects differences in treatment patterns and the complexity of healthcare delivery systems in semi urban and rural areas with varying human resources capacities. In terms of priorities for sustainability, commodity management is key. With adequate supplies of tests, penicillin and other related supplies, health workers could perform their activities.

CHAPTER 8: Discussion, conclusions and recommendations

The main aim of the research presented in this thesis is to provide evidence about the feasibility and costs of introducing an on-site test for maternal syphilis into the package of antenatal care services in Burkina Faso. This evidence provides policy makers with information to take decisions that could improve practical responses for maternal and newborn health.

The thesis started by providing insight into the current practices of syphilis screening at antenatal services at primary health facilities. Then an appropriate onsite syphilis test adapted for peripheral facilities was determined among others available in Burkina Faso. The remainder of the thesis focused on the feasibility, effects and costs of the intervention on the health workers' work and the organization of services. In this chapter, conclusions and recommendations are distilled from these findings.

8.1. Discussion and contributions of this thesis

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8.1.1. Situational analysis of current antenatal syphilis program

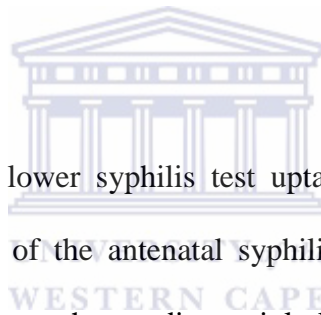
Antenatal syphilis screening is often poorly implemented in sub-Saharan countries (S Gloyd et al., 2001) , so it is important to first identify and understand barriers affecting health system implementation of syphilis screening among pregnant women in Burkina Faso. Chapter 4 explored barriers to antenatal syphilis screening in Kaya health district where

antenatal syphilis prevalence is high. Qualitative methods were used including in-depth interviews and observations in the Kaya health district. Participants were purposively selected to capture a range of perspectives across different actors with different roles and responsibilities.

In response to objective 1, (examining health workers' perspectives on strategies for managing antenatal syphilis screening) our findings suggest that antenatal syphilis screening is not a priority for health workers at ANC services. First, there is no indicator for monitoring progress of antenatal syphilis screening at district or national level that shows any political commitment. Second, health workers perceived that syphilis in pregnancy is not an important issue because most women who undertook the test were negative. Thus they do not perceive the burden of antenatal syphilis highlighted by statistics of sentinel surveillance.

The analysis of the operational performance of the current antenatal syphilis screening (objective 2) was challenging because we found no information on the proportion of pregnant women routinely tested for syphilis at district, regional and national level. However, organization of antenatal syphilis screening could be described and weaknesses were highlighted. The main weakness is the fragmentation of services because antenatal syphilis screening is through laboratory based tests. Laboratories are located in urban areas whereas majority of population live in rural areas. Health workers have to refer women to laboratories and many women, particularly those living in rural areas, have to travel long distances to access these laboratories. In other words, distance to laboratory is associated with delay or failure to screen. In rural areas health workers do not prescribe the test. This perspective was confirmed at district level. Overall the analysis of the current antenatal syphilis screening shows considerable weaknesses that contribute to low performance. Specific objective 3 (to

explore women's perceptions and costs related to syphilis screening) was also explored in chapter 4. Lack of knowledge about syphilis in the community was identified as a reason for not being screened. Most respondents from the community such as pregnant women, traditional healers and community health workers did not know the symptoms of syphilis nor its serious consequences for the unborn and born child. Thus they do not perceive the benefit of testing particularly for asymptomatic infections. ANC and related services such as PMTCT for HIV, and urine test are free for women in Burkina Faso. Although antenatal syphilis screening is part of essential screening in the national policy and management of maternal care guidelines, its cost is not subsidized as others. The cost for syphilis test was observed to range between \$2 and \$3 USD, a prohibitive cost in a country where 73% of population lives on less than \$2 a day.



All these factors contributed to lower syphilis test uptake among pregnant women. Our results highlight the weaknesses of the antenatal syphilis screening at both provider and community levels. In contrast, many other studies mainly look at one of these levels (Dassah et al., 2015; Deperthes et al., 2004; Fonck et al., 2001; Gharoro & Abedi, 2000; Hira et al., 1990) . The use of MLA was also an original contribution of this study to the literature on control of maternal syphilis in LMICs. The Multilevel Assessment (MLA) framework proposed by Hawke et al. allowed taking into account the perspectives of all key stakeholders as well as the contextual factors.

Together, these findings on the operational performance and barriers to uptake and integration of syphilis testing suggest that there is a need for improving current antenatal syphilis screening strategy. The overall situation presented in Paper I and reported in stakeholder dissemination workshops may stimulate decision makers' interest into finding

interventions that can help ensure the full implementation of the integrated ANC package described in policy guidelines but weakly implemented in practice. This situational analysis led to the design and implementation of an intervention that introduced a point of care syphilis test at primary health facilities.

Different stages were followed for the implementation of the intervention. Chapters 5 and 6 present these steps.

8.1.2. Assessment of point of care diagnostic test for syphilis

The first step was the selection of a point of care test through the evaluation of four point of care syphilis test. The objectives of the study were (i) to assess the sensitivity and specificity of four point-of care tests in comparison with *Treponema pallidum* haemagglutination assay (TPHA) as a gold standard and (ii) to evaluate the operational characteristics of those tests among health workers in a maternity unit. Our study found that Alere Determine™ Syphilis was the most sensitive of the four rapid syphilis tests evaluated. It was followed by SD Bioline Syphilis 3.0, Cypress Diagnostics Syphilis Quick test and Accu-Tell® Rapid Anti-TP, which was the least sensitive. The four tests demonstrated a good diagnostic specificity for syphilis (95–98%), and healthcare workers found them easy to use. Among the four tests, there are two for which no data was available in the international literature in terms of comparison with other tests. Our findings contributed new knowledge on the performance of the range of existing syphilis tests. Furthermore results provide practical evidence for decision makers when they are ready to select point of care test for syphilis for its integration in the health system as they did for HIV tests. Further research on point of care tests could explore the cross reactivity with other infectious diseases such as HIV or malaria.

Undertaking this assessment in the context of an operational intervention study highlighted that more than sensitivity and specificity are important in the choice of a test. Beyond technical issues, operational issues need to be assessed in order to know how it is likely to work in real settings, and the preferences of health workers must also be considered. In sum, regulatory authorities should supplement technical evaluations with an operational component (Palamountain et al., 2012).

8.1.3. Participatory process for intervention design and implementation

After selection of the test, a participatory approach with health workers of the study facilities was put in place in order to design the intervention. During a workshop, the different components of the intervention were presented and discussed with health workers and district managers. The objective was to agree on the model of the intervention and how to integrate its activities in the health system. The model was graphically represented in chapter 3.

The model was designed based on the existing infrastructure and resources of the health system and experiences of the participants because there was no formal framework for incorporating point-of-care in existing health system. Chapter 6 describes the different stages for designing and implementation of the intervention. Alongside the implementation phase of the intervention, various actors were involved. At the research team level, a multidisciplinary team was required that comprised biologists, pharmacists and social scientists. The implementation of a complex intervention required several competencies that are complementary alongside the intervention. In the field, the participatory approach was crucial at district and health facility level for the success of the intervention.

8.1.4. Feasibility of introducing point of care diagnostic for syphilis

In Kaya Health and Demographic Surveillance System (Kaya HDSS), all 7 primary health care facilities that offered ANC services were selected for intervention. Onsite training, provision of supplies and medicines, quality control and supervision were implemented in 2013. Facilities provided onsite rapid syphilis testing with immediate treatment for positive cases at ANC services.

The point of care test for syphilis was integrated into the existing package of antenatal care services at primary healthcare level of the district, using the available staff. It was delivered at the same time as HIV testing and other ANC services. The study showed that it is feasible to introduce point of care testing in ANC services at primary health facilities. But there are barriers that need to be overcome for the smooth implementation of the intervention.

The framework of Normalization Process Model (NPM) proposed by May et al. was adapted in order to identify factors that are barriers or facilitators (objective 7) for the introduction of rapid test for syphilis screening among pregnant women. Moreover, NPM allowed assessing the likelihood that point of care test for syphilis will become routinely incorporated in practice. Using NPM for assessing the likelihood of antenatal syphilis screening was the originality of this study. To our knowledge, it was the first time that NPM was used as a conceptual framework for such intervention. In the context of an abundance of trials that are more focused on clinical effectiveness rather than workability in real settings, NPM could be useful.

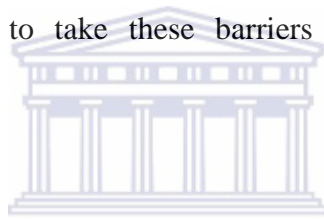
8.1.5. *Barriers to integration of point-of-care test for syphilis to ANC services*

The major reported barriers to the full integration of the test are stock out of consumables, filling of forms and lack of supervision. The main effect reported by health workers was the workload due to filling of registers and the duration of the consultation that was extended by about 3 minutes (objective 6).

Turnover and lack of communication between staff are also barriers that could explain why some women did not receive tests during the intervention. The lack of training evoked by newly appointed health workers and no or little information given by health workers who were aware of the intervention to other staff are the key points raised here. Other reasons highlighted by Zongo et al for not using malaria rapid diagnostic tests in Burkina Faso could be considered such as lack of financial motivation, the increase in duration of consultation and high number of patients or workload (Zongo et al., 2013) .

Even if the intervention is feasible, its implementation at a large scale could face barriers as highlighted by the experience of adding HIV tasks to routine care. From our HIV experience, we learnt that the way that a new task or intervention is introduced, is important. If it is introduced as a vertical program, particularly with separate additional funding, health workers could perceive it as a “project” in the sense of the so called “project mentality” described by Israr ((Israr, 2005). In the study reported here, there was a disconnect between the reported and observed acceptability and operational feasibility of incorporating point of care syphilis testing into ANC, and the low rate of actually testing eligible women. This disconnect and the comments reported regarding the need for 100% coverage in training suggest that “project mentality” may be a relevant concept here. “Project mentality” among

health workers, according to Israr, arises from direct incentives (perdiems) being paid to health workers who attend training or initial workshops, to motivate them to perform the tasks. This then leads to a situation where other staff cannot be motivated to perform the task even if they received onsite training (without per diem) through their colleagues. Consequently only health workers who receive perdiems will perform tasks, as these tasks are perceived as being additional to and not part of the normal responsibilities. This situation is one of the manifestations of the “acute perdiemitis” described by Ridde as one of the most prevalent illnesses that undermine African public health projects (Ridde, 2010). Of course, discussions of “project mentality” and “acute perdiemitis” must also take into consideration the actual salaries and living and working conditions of African health workers. It is important for decision makers to take these barriers into account before scaling up implementation.



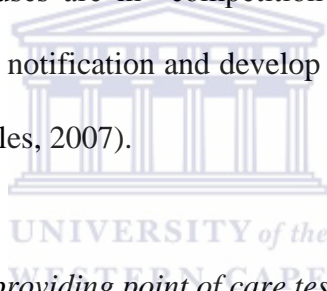
8.1.6. Facilitators to integration of point-of-care test for syphilis to ANC services

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At the health worker level, respondents reported that the rapid test for syphilis is easy to use because it is similar to HIV testing. At the patient level, acceptability of testing is perceived by health workers (and observed during our study) to be high due to their knowledge of existing testing such as for HIV or malaria. At the staff organization level, there was no particular organization that needs to be put in place for integration of syphilis testing in ANC (objective 6). The study identified a number of facilitators to potential normalization including congruence with professional practice, confidence in the reliability and utility, capacities for performing the test and no change at organizational level. In sum, the point-of-care test for syphilis is likely to be acceptable by health workers as a routine service and incorporated as a normal practice, if identified barriers are overcome.

8.1.7. Need for a functioning partner notification approach

One of the important issues that this study raises is partner notification especially for positive women. In most of the ANC visits reported and observed here, husbands did not accompany the women to the facility, in line with what has been reported in many studies (Alam et al., 2010; Dassah et al., 2015). These positive women may be at risk of re-infection because their partner could also have been positive. Reported barriers to partner notification are stigma associated with STIs, fear of violence and matrimonial conflict and fear of rejection (Alam et al., 2010; Díaz-Olavarrieta et al., 2007). These barriers are more strongly perceived in a context of polygamy where spouses are in “competition” for one man. Further research might study constraints to partner notification and develop a workable and acceptable partner notification model (McNutt & Coles, 2007).



8.1.8. Incremental costs for providing point of care test for syphilis during ANC

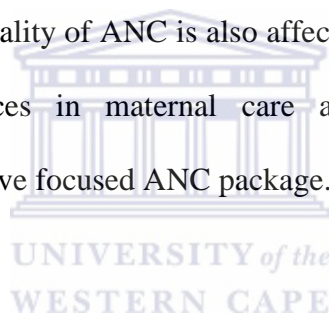
Introducing rapid syphilis testing in ANC services generates additional costs for the “provider” (government or the facility) in a scenario of sustainability of the intervention and free treatment for women. Chapter 7 addressed the focus of the objective 8, which was to estimate the incremental cost of the provision of the on-site test of syphilis for antenatal care services. The purpose of this study was to estimate the incremental costs of adding rapid syphilis test into first visit ANC from a provider’s perspective and identify the main cost drivers.

The main cost driver in screening is the material costs. There are cost variations due to health facility location and profile of health worker. Adding point of care test for syphilis in ANC

services is feasible at a modest incremental cost, comparable to the cost of HIV testing.

Most costing studies for syphilis tests have been conducted in high prevalence countries in Africa. There are few studies in low prevalence countries where Kuznik et al. deplored the lack of field data (Kuznik et al., 2013). This study contributed to fill this gap. Further research could explore cost for quality control or scaling up of the intervention.

The interaction time between clients and providers was, lower than what was observed in other studies but also lower than recommended for a focused ANC. The time motion study put in light weakness in the quality of testing performed by health workers at primary health facilities. This implies that the quality of ANC is also affected. That means there is a need to explore health workers practices in maternal care and assess barriers to the full implementation of a comprehensive focused ANC package.



8.2. Conclusions: contributions of this study to knowledge, policy and practice

Overall, the thesis contributes to knowledge about implementation of interventions related to maternal syphilis. The contribution is at different levels.

At the district level, although the district has one of the highest prevalence in the country, to our knowledge, there has been no study on maternal syphilis. Our study could contribute directly to the elaboration of an action plan by the district manager. Moreover, the costing analysis will contribute to budgeting.

At the national level, the literature, as presented in the section of literature review, is more focused on epidemiologic aspects thus this thesis contributes to filling the knowledge gap in terms of practical responses for controlling maternal syphilis. In addition, most health interventions are context specific. Examples from one country cannot simply be copied to another one. In that sense, the study offers evidence to national decision makers for evidence based and contextually appropriate decisions, as well as modeling an approach to developing and testing contextually relevant interventions.

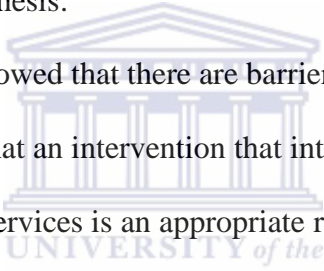
This study adopted a participatory approach that involved district managers, health workers and researchers. This reinforces collaboration between these stakeholders but also offers an opportunity to researchers to present their results to local actors who are able to take action.

At the international level, there is an important literature on syphilis especially on

interventions for maternal syphilis screening and treatment but studies from countries like Burkina Faso in Africa are few and they do not take a comprehensive, contextualized approach to both the technical and operational aspects of implementation in real-world settings. This thesis could motivate other research in similar contexts and could serve as a reference.

8.3. Recommendations

Even though this was a pilot study, some tentative recommendations for decision makers can be made from the findings in the thesis:

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- The situational analysis showed that there are barriers to access to antenatal syphilis screening. This suggests that an intervention that introduces point of care test for syphilis at antenatal care services is an appropriate response (especially with a dual HIV/syphilis test which is the most advanced technology that was not available during my study) and could serve as an entry point for improving ANC quality and more widely strengthen the health system.
 - In addition to an intervention at health facility level, community based interventions that increase awareness of STI and health needs among the populations are needed to stimulate health care demand.
 - In designing intervention, it is important to consider both the reported views of stakeholders for a successful implementation.
 - The study identified a number of specific implementation challenges that should be addressed prior to scale-up of such an intervention (including clearer instructions to

staff to ensure testing of all eligible women and quality control of appropriate numbers of positive and negative tests), in addition to barriers that require interventions at the policy level (such as per diems, registers, supervision, and quality control as discussed below)

- Quality control system for rapid diagnostic tests is essential for ensuring that results delivered to clients are accurate and reliable. A quality control strategy is a key component that should be put in place for any rapid diagnostic test such as malaria, HIV or syphilis.
- The study found that most positive women had no symptoms such as genital ulcers that need using Polyvidone- iodine, thus there is a need for revision of treatment regimens but also strategies for STI screening during pregnancy.
- This study has demonstrated that rapid syphilis test could be introduced into ANC services. Further studies are required to develop comprehensive packages with other tests and cares that will strengthen the primary health care system.

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**Appendix 1 : Interview Guide for Health
workers**



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Guide for health workers

INTRODUCTION:

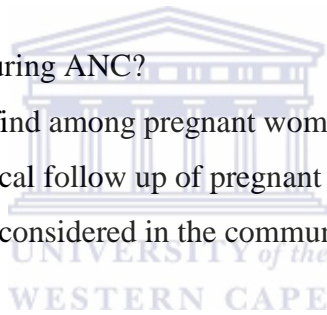
[Information and consent]

Perception on ANC

1. Explain what is the content of ANC in your facility?
2. Do you have priority in ANC activities?
3. What difficulties are you face during ANC?

Management of STI

4. How do you screen STI during ANC?
5. What kind of STI do you find among pregnant women?
6. How do you manage medical follow up of pregnant women with a STI?
7. How a patient with STI is considered in the community?



Management of syphilis

8. How do you screen syphilis during ANC?
9. What are means of transmission of syphilis?
10. What do you consider signs and symptoms of syphilis?
11. What are the different phases of syphilis?
12. What means of prevention against syphilis do you know?
13. What are the causes and effects of syphilis?
14. Do you systematically prescribe VDRL test during ANC to pregnant women? Why?
15. What kind of difficulties are you face with this prescription?
16. Explain how do you manage a pregnant woman suffer from syphilis?

Experience with RDT

17. Describe your experience with RDT for malaria, HIV and others?
18. How these tests were introduced in your daily practice?
19. How do you appreciate the process of introducing of these tests?
20. What are the effects of these tests in your daily practice?
21. What type of difficulties are you facing in the use of these tests?
22. What effects do you observe on patients, utilization of services?
23. What kind of collaboration do you have with lab technicians?
24. How do you appreciate this collaboration?
25. What do you think about task shifting from tests lab to point of care test using by less qualified staff?
26. What category of health workers have to be involved in the use of RDT ?

Introduction of RDT for syphilis screening

27. What do you think about the introduction of a new RDT for syphilis screening in Burkina Faso ?
28. What could be the barriers to the introduction of a new RDT ?
29. What are the opportunities/ factors in favor to the introduction of a new point of care test In Burkina Faso ?
30. What are your suggestions for the availability of the new point of care test to pregnant women ?
31. What suggestions do you have for gaining adhesion of pregnant women to this test?
32. What are the important steps in the introduction of new point of care test in health system?
33. Who will be the main actors to involve in the process of introduction of a new point of care test in Burkina Faso?
34. What kind of information would you need about a new point_of care test?
35. What kind of information would you think people in your community need about a new point of care test?
36. What could be your contribution in the introduction of a new point of care test in your community?
37. Do you have any suggestions about the introduction of a new point of care test?



**Appendix 2 : Interview Guide for policy
makers**

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Guide for policy makers

INTRODUCTION:

[Information and consent]

Context

1. What do you think about the prevalence of STI and syphilis in Burkina Faso/ kaya district?
2. Do you think that there are other health priorities than syphilis ?
3. What strategies were implemented in order to control STI and syphilis for pregnant women in Burkina Faso ?
4. How do you appreciate the implementation of syphilis screening for pregnant women ?

Implementation

5. Who are donors involve in the funding of syphilis screening in Burkina Faso?
6. What type of research program do you know in Burkina Faso?
7. Who are people involve in maternal syphilis screening?
8. Who are people involve in the supply of reagents, and medicines?
9. What are the difficulties you are face in the implementation of the strategy?
10. What requirements do you think need to be filling in order to optimize the strategy?

Knowledge about RDT

11. What are the type of point of care tests use in Burkina Faso?
12. What do you think about point of care test?
13. What are the advantages and the disadvantages of point of care test in Burkina Faso ?

Introduction of RDT

14. What do you think about the introduction of a new point of care test for syphilis in burkina Faso ?
15. What are the barriers to the introduction of a new point of care test In Burkina Faso ?

16. What are the opportunities/ factors in favor to the introduction of a new point of care test In Burkina Faso ?
17. What are your suggestions for the availability of the new point of care test to pregnant women ?
18. What are the important steps in the introduction of new point of care test in health system?
19. Who will be the main actors to involve in the process of introduction of a new point of care test in Burkina Faso ?
20. What are the main requirements for the success of the process of introduction?
21. What would cause you to motivate in supporting the introduction of a new point of care test in Burkina Faso?
22. What kind of support could you give to the success of the initiative?
23. Do you have any suggestions about the introduction of a new point of care test in Burkina Faso?





**Appendix 3 : Interview Guide for
pregnant women**

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Guide for pregnant women

INTRODUCTION:

[Information and consent]

Knowledge on STI and syphilis

1. What types of STI do you know?
2. What types of STI do you often find in your community?
3. What do you consider signs and symptoms of STI and syphilis?
4. What are the causes of STI and syphilis? How do STI and syphilis transmit?
5. Who are more at risk for STI and syphilis?
6. What are the effects of STI and syphilis on people who are infected?
7. How do you do to prevent from getting STI and syphilis?
8. When people suffer from STI or syphilis what does he/she do?
9. What kind of STI traditional healer could take care?
10. How do traditional healers take in charge STI in your community?
11. What are your appreciations on traditional healer's work?
12. What kind of STI could be care at health facility?
13. How do health workers take in charge STI in your community?
14. What are your appreciations on health worker's work?

Knowledge on TDR

15. What do you think about point of care test?
16. Based on your experience, what are the advantages of point of care test?
17. Based on your experience, what are the disadvantages of point of care tests?

Introduction TDR

If a new point of care is available for syphilis screening

18. What kind of information would you need about a new point of care test?
19. What influences you to have access to the new point of care?
20. What might keep you from getting new point of care test?

21. How much are you able to pay for this test?
22. Who do you prefer to deliver you the test and the results of the test?
23. What would be the best place for you to get the new point of care test?
24. Which people will be at priority to access to the new point of care test?
25. What other questions might people in your community have about a new point of care test?
26. Do you have any suggestions about the introduction of a new point of care test?



Appendix 4 : Sheet for observation



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Observation sheet for ANC

Sheet N° :					
Date :					
CSPS :					
Round :					
Total number of health worker :					
Profile of health worker :					
Time at beginning :			time at end :		
Type of ANC (1,2,3,4),	number and profile of health worker	Activities	Materials used	Duration	Observations



Appendix 5 : Ethical approvals



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**OFFICE OF THE DEAN
DEPARTMENT OF RESEARCH DEVELOPMENT**

20 September 2011

To Whom It May Concern

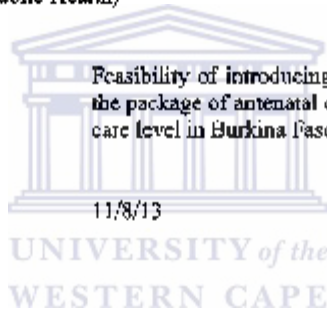
I hereby certify that the Senate Research Committee of the University of the Western Cape has approved the methodology and ethics of the following research project by:
Ms F Bocoam (School of Public Health)

Research Project:

Feasibility of introducing onsite test for syphilis in the package of antenatal care at rural primary health care level in Burkina Faso.

Registration no:

11/8/13



*Ms Patricia Jorlas
Research Ethics Committee Officer
University of the Western Cape*

Private Bag X17, Bellville 7535, South Africa
Tel: +27 21 959-2946/9
Fax: +27 21 959 3170
Website: www.uwc.ac.za

DELIBERATION N° 2011-11-75

1. TITRE DE LA RECHERCHE

«Faisabilité et acceptabilité du dépistage de la syphilis en consultation prénatale par l'utilisation de test rapide au Burkina Faso »

2. REFERENCE DU PROTOCOLE

Version n° 3 du 17 octobre 2011.

3. DOCUMENTATION

- Protocole de l'étude,
- Fiche d'information,
- Fiche de consentement

4. REFERENCE DU DEMANDEUR

Investigateurs principal : Dr Seni KGUANDA, MD, PhD médecin épidémiologiste de l'Institut de Recherche en Sciences de la santé (IRSS) 03 BP 7192 Ouagadougou 03, tel : 00226 50 33 56 84

Co-investigateurs

- YAYA BOCOUM Fadima, Sociologue, Economiste de la santé
- Dr OULDRAOGO Gautier, pharmacien biologiste de l'Institut de Recherche en Sciences de la santé (IRSS)

5. SITES DE LA RECHERCHE

CSPS ruraux et urbains du district sanitaire de la ville de Kaya

6. DATE DE LA DELIBERATION

10 novembre 2011

7. ELEMENTS EXAMINES

- Conception scientifique et conduite de la recherche ;
- Soins et protection des participants à la recherche ;
- Protection de la confidentialité des données du participant à la recherche ;
- Processus de consentement éclairé ;
- Budget de la recherche.

8. OBSERVATIONS

Néant

9. AVIS DU COMITE

Avis favorable

10. RESERVES

Néant

11. RECOMMANDATIONS

Néant



Ouagadougou, le 10 novembre 2011

UNIVERSITY of the
WESTERN C





WHO ERC
Review Summary

Protocol ID: RPC525
Country: Burkina Faso
Protocol Title: Feasibility of introducing onsite test for syphilis in the package of antenatal care at rural primary health care level in Burkina Faso
WHO Responsible Staff Member: Launois, P.
Responsible Unit: IER/TDR
Meeting Date: NIL

Dear Dr. Launois, P.,
Please find the review summary of the Protocol "Feasibility of introducing onsite test for syphilis in the package of antenatal care at rural primary health care level in Burkina Faso", which was submitted to the Secretariat on 26/06/2012. This proposal underwent Expedited Review.

- The outcome of the review is provided below. When responding, please submit the following:
1. A cover memorandum that addresses your responses, POINT BY POINT, to each of the queries in sections A and B.
Section C contains Suggestions to improve the proposal but there is no obligation to follow them.
 2. An Amended protocol including the responses in bold, highlighted or in track changes. The protocol should include all relevant documentation (ICF, study instruments, peer review, etc.) even if already submitted.

Please note that comments in the introductory paragraph are meant for the WHO Responsible Staff Member, though you may decide to share them with the PI.

PLEASE RESPOND TO THIS REVIEW SUMMARY WITHIN A THREE MONTH PERIOD, OR PROVIDE THE ERC SECRETARIAT A VALID JUSTIFICATION FOR THE DELAY.

The ERC reviewed this proposal and considered that it would be important to provide further information on some topics of the proposal and to further address some technical aspects. This would allow for a better understanding of the study and a comprehensive assessment of the ethical component of the protocol. Please find the specific comments below.

A. Amendments (Response and change required)

This section includes queries and comments on your protocol, study instruments or the informed consent form for which the ERC requires your response and where relevant, appropriate amendments to the protocol, study instruments or the informed consent.

1. Protocol
 - 1.1. Please provide an amended proposal specifying the version number and/or date on each page.
 - 1.1. Please provide more information on the control arm, including (but not limited to) how will enrollment and recruitment occur, how will the participants receive syphilis testing, how will they be followed up, what data will be recorded for them.
 - 1.2. Under section 4.5.2 it is specified "The selected facilities will be provided with syphilis test and package for syphilis treatment through the routine procedure". Please specify whether there is a rapid test currently available in Burkina Faso that meets the study criteria for use/inclusion (sensitivity between 85 and 95% and specificity of 95% at least, detailed notice in French, simple to use, use of whole blood and time of availability of result).
 - 1.3. The objectives of the study include an analysis of the operational performance of the current maternal syphilis screening and treatment. Please discuss how the operational performance will be assessed before on site testing is rolled out.


ERC Secretariat



Protocol ID: RPC525 /Meeting Date: NIL

Review Summary (contd)

- 1.4. While it is appropriate to assess the feasibility of on-site screening in a high prevalence district, the investigators will need to consider what might be operational differences in low prevalence areas especially as they consider cost. It would be worthwhile acknowledging as a study limitation, the fact that the study will only be conducted in a high prevalence area. Please discuss how findings in Kaya district can be extrapolated to other parts of Burkina Faso.
- 1.5. In section 4.5 it is specified "...The study will comprise three phases; the first to assess the performance of the current ANC in detecting maternal syphilis...". However, under section 4.5.1 it is specified "In order to understand the viewpoints and expectations of all major stakeholders, a comprehensive approach will be adopted. The phase 1 will include policy and situation analyses that will explore health system and client perspectives". It seems that they are two different phases with different methodologies to achieve different objectives. Please discuss and harmonize.
- 1.6. Under section 4.4 it is specified "All the facilities located in KADESS will be selected for the study". However, it would be pertinent to specify "All 7 primary health facilities which offer ANC in KADESS". Please modify.
- 1.7. In response to a question raised by the ERC Secretariat, the Principal Investigator has stated "A letter of invitation will be sent to the responsible of the selected facility in order to identify the health workers that are motivated to participate to the training workshop and the study". Since all health workers providing ANC will be invited to take part in the study, it seems that all of them should undergo training. If not, this may impact on the consistency of the intervention provided and would affect the results of the study. Please discuss.
- 1.8. Eligible participants are women 18 years and older. Please justify the exclusion from the study of younger pregnant women. It seems that they should have the opportunity to be tested and treated and, in that case, the necessary protections for minors who are pregnant will apply.
- 1.9. The ICF specifies under "Procedures and Protocol": "You will be asked to provide a sample of blood (1 tablespoon). The blood will be taken with finger stick and you will get the results of the test within 20 minutes. [If quality control: After completing your test, we would like to save any left-over blood for quality control. Your blood sample will be frozen and will be stored with a number assigned to it instead of your name. The number will be linked to your name. The sample will be transported to a laboratory for testing. The results of this test will be told you.] If your result is positive, you will receive the treatment of your condition according to national guidelines."
 - 1.9.1. The information in brackets is unclear. Since 10% of the samples will undergo quality control, please specify how it will be determined to whom this information should be provided.
 - 1.9.2. Under 4.5.2 it is specified that the decision to offer treatment will be based on the results of the rapid test. However, the ICF specifies that treatment will be based on the results of the left-over blood tested at the laboratory. Please specify what will be done in the case of discordant results and include this information in the consent document.
 - 1.9.3. Blood samples will be frozen, stored and then transported to the laboratory from the field. Please specify how these samples will be transported to ensure that they are still suitable for re-testing.
- 1.10. Women who screen positive for syphilis and who are potentially allergic to penicillin will be referred to local district hospitals. Please specify the appropriate alternative to penicillin for these women and confirm that hospitals have the treatment protocols and access to appropriate medicines.
- 1.11. In relation to the previous point, please specify the cost implications to women who test positive for syphilis (e.g. out of pocket expense for women who receive the POC testing, will they be required to pay for treatment, etc.). This should also be explicit in the informed consent.
- 1.12. On page 21 of 100 it is stated that partner notification will be recorded. Please include the legal framework regarding partner notification in Burkina Faso and discuss the implications for women who may test positive for syphilis. The consent documents should reflect this information so that women fully understand the implications of screening.
- 1.13. Please describe how key informants will be identified and invited to take part in the study (who will identify and contact them, how, where, and when the FGDs will take place, how long they will last, etc.).



Protocol ID: RPC525 / Meeting Date: NIL

Review Summary (contd)

- 1.14. Only 10 semi-structured interviews will be conducted among national or regional key informants. Please comment on whether the data gathered from them will allow for generalization of results. If not, this should be stated as a study limitation.
- 1.15. A focus group discussion guide specifically for traditional healers is included in the protocol. Please provide a description on how they will be identified and selected (who will identify and contact them, how, where, and when the FGDs will take place, how long they will last, etc.).
- 1.16. On section 4.5.1.1 it is specified "FGD will be held with pregnant women in order to assess knowledge and perceptions of syphilis". However, the FGD guide contains several questions about experiences and satisfaction of antenatal care. Please clearly specify the objective(s) of the FGDs and modify the study instrument accordingly.
- 1.17. On section 4.5.1.2 it is specified:
- 1.17.1. "Client exit interviews will be conducted with consenting client after the consultation. It will focus on the quality of receiving care and the content of the consultation. All consenting clients for the day of the survey will be interviewed in each health center". Since personal and confidential information will be asked, please specify where the exit interviews and the individual interviews will be conducted as to ensure privacy and confidentiality. Please include this information on the consent documents.
- 1.17.2. "Every consenting woman will be received in the consultation room where she will sign consent and receive the on-site syphilis test. This statement seems to assume that women will consent to the study. However, women may or may not agree to take part in the study. Please modify the wording to clearly state that women will be involved in the consent process.
- 1.18. Please specify whether human resources costs will be included in the economic evaluation. If not, then list this as a study limitation.
- 1.19. The budget of \$10,000 seems little to cover the full scope of the work. Please discuss whether it is realistic to complete the project within this amount.

2. Study Instruments

- 2.1. The focus group guide does not include anything on costs. The investigators can consider including some discussion of these implications.

3. Informed Consent Forms

- 3.1. Please submit the consent form for traditional healers.

ICF for Pregnant Women enrolled for testing:

- 3.2. Please address points 1.8, 1.9, and 1.14.1 listed above.
- 3.3. Under "Introduction" it is specified "am doing a study on the disease syphilis which is very common in this district". It seems that there are no recent data to affirm that "syphilis is very common". This statement could be understood differently by different people. Please modify.
- 3.4. The study objective is presented as "The present study will assess if it is possible to do early detection of maternal syphilis by providing an onsite test that give results in 20 minutes". However, this does not seem to be the objective of the study. Please clearly explain participants what the study intends to find out.
- 3.5. Under "Purpose of research" please modify the word "gestation" as it is a technical word that may be difficult to understand.
- 3.6. Please specify that testing for syphilis is part of the routine recommended ANC and that the only difference is that this is POC testing.
- 3.7. Please specify that POC testing is a proven technique and the study is being done to see how it can be implemented in Burkina Faso.



Protocol ID: RPC525 /Meeting Date: NIL

Review Summary (contd)

- 3.8. Under "Voluntary participation" it is specified "If you choose not to participate in this research project, you will offer the care that is routinely offered in this health facility, and we will tell you more about it later". In order to decide whether to take part in the study, potential participants should be fully informed. All information related to the study should be provided before making the decision and not after. Please modify.
- 3.9. Under "Duration" the phrase "During that time, it will not be necessary for you to come to the health facility" may be misinterpreted (e.g. you do not need to come for the rest of your pregnancy). Please modify.
- 3.10. The need for and implications of partner notification need to be presented as part of the informed consent process.
- 3.11. The information sheet should describe what is expected from the participant and should also describe in general terms, the type of questions that the participant will be expected to respond to. On the Certificate of Consent (Part 2):
- 3.12. The phrase "I promise to keep the information in this study confidential" should be deleted.
- 3.13. The phrase "I consent to give my blood" should be better elaborated (e.g. I agree to provide a blood sample to be stored).

B. Clarifications (Response required but change may not be required)

This section includes queries on your protocol, study instruments or the informed consent form for which the ERC requires a clarification, and it may not be mandatory for you to make changes to your protocol. Please consider the comments of the ERC and determine if you believe change is needed. If no change is made, the ERC will consider the response. If the judgement of the ERC is that a change should occur, the ERC will promptly notify you.

1. Protocol

- 1.1. On section 4.3 it is specified "Since 2007, IRSS has implemented a health and demographic surveillance system..." Please clarify whether syphilis data is collected by the surveillance system and whether data from 2007 is the latest available from the sentinel surveillance system. E

2. Study Instruments

NIL

3. Informed Consent Forms

NIL

C. Suggestions

This section consists of suggestions for alternative scientific or technical approaches or methods for conducting the research but which do not raise critical, ethical issues. These are meant to be helpful to investigators and are presented as suggestions for you to consider incorporating into a revised protocol. No response from you is required for any comment in this section. If, however, you do make changes to the protocol as a result of these suggestions, please submit the revised protocol to the ERC.

- 1. Figure 1 and 2 (page 11 of 100) states that the data is for year 2009. However, the source is 2008. Please correct.



Protocol ID: RPC525 /Meeting Date: NIL

Review Summary (contd)

Based on the above comments, the Committee has the following recommendation(s) for this proposal:

- The proposal is *Approved as submitted*. No modifications are required.
- The proposal is *Conditionally Approved; requires amendments and/or clarifications*. Final approval is contingent upon an adequate response by the Principal Investigator, to the satisfaction of the reviewers or the Chair on behalf of the ERC.
- The proposal is *Not approved; requires additional information and/or rewriting*. A revised version of the proposal should be re-submitted by the WHO responsible staff member as a new submission to the ERC for re-review by Committee.
- The proposal is *Rejected*. The proposal is ethically unacceptable, for the reasons stated above. The Principal Investigator may submit a new proposal that takes into consideration the ethical issues raised by the Committee. If you do not agree with the Committee's assessment, please feel free to submit an appeal to the Chair of the ERC, through the Secretariat.

NOTE: Final Approval of the Proposal is contingent upon submission of the following:

- Local ethics approval(s)
- Other relevant documents

The ERC would like to receive a copy of the recommendations of the local ethics committee when available.

IMPORTANT

1. Any changes to the proposal or to the attachments (informed consent/ study instruments etc.) should be approved by ERC before being implemented.
2. The approval for this proposal is valid for a period of one year only.
3. Please resubmit this proposal for a Continuing Review at least 2 months before the next re-approval period.



UNIVERSITY of the WESTERN CAPE

Chairperson R. Johnson

Date 6 July 2012

Name: Ronald Johnson/Michelle Gayer

FINAL APPROVAL	FOR THE SECRETARIAT
<p>Amendments and Clarifications to the proposal have been reviewed. The protocol (Version: <u>3</u> Date: <u>August 2012</u>, informed consent Forms (Dated: <u>-</u>) submitted on <u>11.09.2012</u> are approved by the ERC.</p>	<p>Amendments and Clarifications to be reviewed: <input type="checkbox"/> Electronically by ERC <input type="checkbox"/> by Primary reviewers <input type="checkbox"/> by Secretariat</p> <p>Amendments approved / Clarifications accepted on Local ERC approval(s) obtained on <u>20/09/2012</u> Relevant Documents submitted on <u>NA</u> Comments: <u>NA</u></p>
<p>Chairperson <u>R. Johnson</u> Name <u>R. Johnson</u> Date <u>12 Sept 2012</u></p>	<p>Signature <u>Abubakar</u> Date <u>12/09/2012</u></p>

ERC Secretariat

**Appendix 6 : Informed consent form for
individual interview**



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INFORMED CONSENT FORM FOR INDIVIDUAL INTERVIEW

Principal Investigator : Seni KOUANDA

Organization : Institut de recherche en science de la santé

Sponsors: ADDR/TFDR/ LTG grant /IRSS

Title: Feasibility of introducing onsite test for syphilis in the package of antenatal care at rural primary health care level in Burkina Faso

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction

I am XXX, working for IRSS organization. I am doing a study on the disease syphilis which is very common in this district. I am going to give you information and invite you to be part of the research. If you have questions, you can ask them at anytime to me or to the principal investigator.

Purpose of the research

Syphilis is a sexual transmitted infection with a serious source of adverse pregnancy outcomes. If left untreated, maternal syphilis infection has significant medical, economic, and societal consequences. African Policy makers, programme managers and health professionals are faced with complex choices on how best to detect early maternal syphilis. The present study will assess the feasibility to integrate syphilis point-of-care diagnostic test in the package of antenatal care in order to guide decision makers on the best approach to adopt for maternal syphilis screening and treatment. We want to know more about local health practices, how you manage syphilis in your day to day practice with pregnant women because this knowledge might help us to learn how to better control syphilis in this community.

Type of Research Intervention

This research will involve your participation in an interview that will take about 45 minutes.

Participant Selection

You have been identified as someone who can provide useful information for this study because we feel that your experience as a health provider can contribute much to our understanding and knowledge of local health practices.

Voluntary Participation

Your participation in this research is entirely voluntary. You may or may not decide to take part. It is your decision. The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.

Procedures

During the interview, I will sit down with you in a comfortable place. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential, and no one else except the research team will access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tapes will be destroyed when the study ends. Your name will not be recorded, and no name will appear in any presentations or reports. The information you give us will not in any way be used against you or your family.

Duration

The research takes place over one year in total. During that time, we will visit you two times for interviewing you at the situation analysis and the end of the intervention. Each interview will last for about 45 minutes.

Risks

The questions asked during interviews concerns mainly programme based information that is largely information in the public domain. These are questions which are commonly asked during regular in depth programme evaluations. Opinions will be asked regarding STI management policy, in particular maternal syphilis; identify the barriers and constraints which affect the

effective delivery of STI services and particularly maternal syphilis screening, supervision, monitoring, the perceptions of rapid diagnostic test (RDT), patients, and use of RDT.

Benefits

You will not benefit directly from this study. By sharing your views, you are giving your leaders information they need to make decisions about people's health.

Reimbursements

You will not be provided any incentive to take part in the research.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

Do you agree to take part in this study?

Who to Contact

If you wish to ask questions later, you may contact any of the following:

Dr. Seni Kouanda, Principal Investigator, at 50 33 35 94.

This research has been reviewed and approved by the Burkina Faso Comité d'éthique de recherche en santé (CNEERS). This committee reviews research studies to help protect participants. If you have any questions about your rights as a research participant you may contact:

The chairman, Comité national d'éthique pour la recherche en santé (CNEERS), Ministère de la Santé, 03 BP 7009, Ouagadougou 03, Burkina Faso, phone number: 50 32 41 59.

Part II: Certificate of Consent

The study has been described to me in language that I understand and I freely and voluntarily agree to participate in this study. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way. I promise to keep the information in this study confidential.

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.

I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

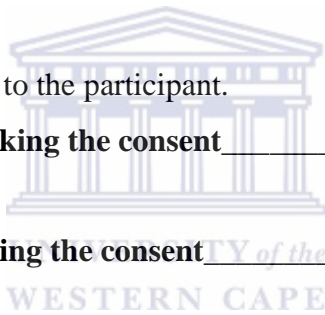
A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent _____

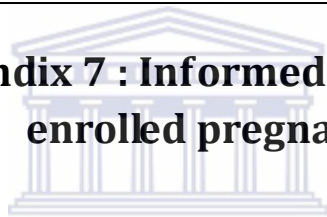
Signature of Researcher /person taking the consent _____

Date _____

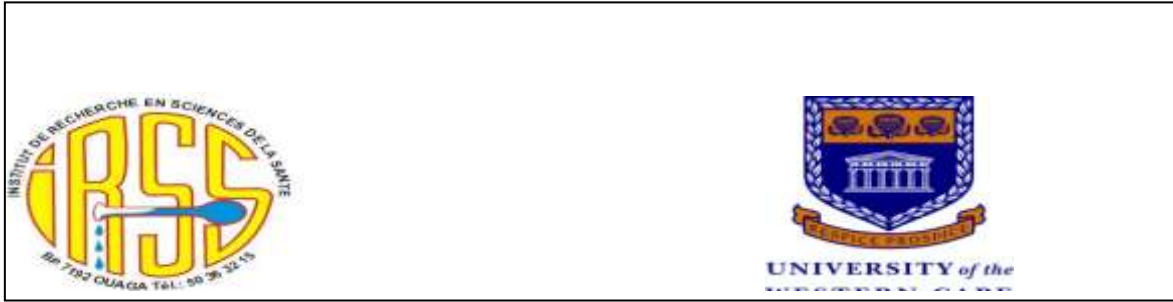
Day/month/year



**Appendix 7 : Informed consent form for
enrolled pregnant woman**



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INFORMED CONSENT FORM FOR PREGNANT WOMAN ENROLLED FOR TESTING

Principal Investigator : Seni KOUANDA

Organization : Institut de recherche en science de la santé

Sponsor : ADDR/ADR/TDR/ LTG grant /IRSS

Title: Feasibility of introducing onsite test for syphilis in the package of antenatal care at rural primary health care level in Burkina Faso

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I am XXX, working for IRSS organization. I am doing a study on the disease syphilis which is very common in this district. I am going to give you information and invite you to be part of the research. If you have questions, you can ask them at anytime to me or to the principal investigator.

Purpose of the research

Syphilis is a sexual transmitted infection with a serious source of adverse pregnancy outcomes like miscarriage and stillbirth. If left untreated, maternal syphilis infection can be transmitted to child during pregnancy and cause abnormal growth of child. Transmission most commonly takes place after 4 months of gestation. This is why it is important to have early detection of the infection. For the moment the detection is performed at laboratory. We would like to implement

an intervention in which a test will be possible in the health facility without a laboratory.

Type of Research Intervention

The present study will assess if it is possible to do early detection of maternal syphilis by providing an onsite test that give results in 20 minutes. You will be asked to provide a sample of blood (1 tablespoon). The blood will be taken with finger stick and you will get the results of the test within 20 minutes. If your result is positive, you will receive medicines.

Participant selection

We are inviting all pregnant women who attend clinic for first ANC and are unless 18 years old to participate in the research.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offer the care that is routinely offered in this health facility, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Procedures and Protocol

You will be asked to provide a sample of blood (1 tablespoon). The blood will be taken with finger stick and you will get the results of the test within 20 minutes. [If quality control: After completing your test, we would like to save any left-over blood for quality control. Your blood sample will be frozen and will be stored with a number assigned to it instead of your name. The number will be linked to your name. The sample will be transported to a laboratory for testing. The results of this test will be told you.]. If your result is positive, you will receive the treatment of your condition according to national guidelines. This means that you will be given a single dose of benzathine penicillin G 2.4 million units intramuscularly. If you have allergy to penicillin you will be referred to the district hospital for an appropriate treatment. If your result is negative, you will receive advice on STI prevention.

Duration

The research takes place over one year in total. During that time, it will not be necessary for you

to come to the health facility. Your participation in this experiment will take approximately 20 minutes for the blood draw and the waiting of the result.

Side Effects

This test cannot have some unwanted effects. But the treatment could give you allergy. If so we may stop the use of the drug and referred you to the district hospital.

Risks

The risks associated with this study are slight discomfort from the blood draw.

Benefits

You will not be paid to participate in this study. If the result of your test is positive, you will receive treatment for free. If your result is negative, you will receive advice on STI prevention.

Reimbursements

You will not be provided any incentive to take part in the research.

Confidentiality

The results of your sample will be used for research purposes only. We will keep the information about your result confidential. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key.

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the care that is routinely offered in this health facility.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

Do you agree to take part in this study?

Who to Contact



If you wish to ask questions later, you may contact any of the following:

Dr. Seni Kouanda, Principal Investigator, at 50 33 35 94.

This research has been reviewed and approved by the Burkina Faso Comité d'éthique de recherche en santé (CNER). This committee reviews research studies to help protect participants. If you have any questions about your rights as a research participant you may contact:

The chairman, Comité national d'éthique pour la recherche en santé (CNER), Ministère de la Santé, 03 BP 7009, Ouagadougou 03, Burkina Faso, phone number: 50 32 41 59.

PART II: Certificate of Consent

The study has been described to me in language that I understand and I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way. I promise to keep the information in this study confidential. I consent to give my blood sample.

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____

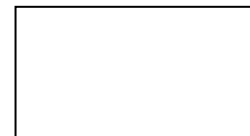
AND

Thumb print of participant

Signature of witness _____

Date _____

Day/month/year



Statement by the researcher/person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Day/month/year



Appendix 8: Supervision tools



UNIVERSITY *of the*
WESTERN CAPE

BURKINA FASO

**CENTRE NATIONALE DE LA RECHERCHE SCIENTIFIQUE ET
TECHNOLOGIQUE (CNRST)**

INSTITUT DE RECHERCHE EN SCIENCES DE LA SANTE



03 BP7192 Ouagadougou 03,

Tel : (00226 50) 363215 / 335684/ 333594

**Faisabilité et acceptabilité du dépistage de la syphilis en
consultation prénatale par l'utilisation de test rapide au Burkina
Faso**

FICHE DE SUPERVISION MEMSUELLE



Supervision n°.....

Date de la supervision.....

Nom du Centre de santé (site) :

Appendix 9: Register for enrolled woman



BURKINA FASO

CENTRE NATIONALE DE LA RECHERCHE SCIENTIFIQUE ET
TECHNOLOGIQUE (CNRST)

INSTITUT DE RECHERCHE EN SCIENCES DE LA SANTE



03 BP7192 Ouagadougou 03,

Tel : (00226 50) 363215 / 335684/ 333594

**Faisabilité et acceptabilité du dépistage de la syphilis en
consultation prénatale par l'utilisation de test rapide au Burkina**

Faso

REGISTRE DE SUIVI DES FEMMES ENCEINTES

Date : /_/_/_/_/_/_/

Code Centre de santé (site) : -----

DEMANDE DE CONSENTEMENT

PART II: déclaration de consentement éclairé

J'ai été invitée à participer à l'étude sur le dépistage de la syphilis après avoir reçu toute les informations nécessaires pour m'éclairer sur les objectifs de l'étude. J'ai compris les informations qui m'ont été données et je décide de participer de façon libre et volontaire. Mes questions ont reçues des réponses et mon identité sera sauvegardée. J'ai compris que je peux me retirer à tout moment de l'étude sans raison et cela n'affectera en rien mon suivi. Je promets de respecter la confidentialité des informations sur l'étude que j'aurais en ma possession. Je marque mon accord pour participer à l'étude. Par conséquent, j'autorise l'agent de santé à me faire une prise de sang pour le test de dépistage.

Nom de la Participante _____

Signature de la Participante _____

Date _____

Si illettré

J'ai été témoin que la fiche d'information et la déclaration de consentement éclair ont été lues à la participante et qu'une opportunité de poser des questions a été offerte à cette dernière. Je confirme que la participante a donné un consentement libre et volontaire.

Nom du témoin _____ *ET* **empreinte de la participante**

Signature du témoin _____

Date _____

Déclaration de la personne recueillant le consentement

Je confirme que la participante a eu l'opportunité de poser toutes les questions concernant l'étude et que j'ai donné des réponses du mieux que j'ai pu. Je confirme que la participante a donnée un consentement libre et volontaire sans aucune pression.

Une copie du consentement a été remise à la participante.

Nom de la personne recueillant le consentement _____

Signature de la personne recueillant le consentement _____

Date _____

Non, je refuse de participer → /_/_

Pourquoi ?.....
.....

Si Oui attribuer un numéro d'inclusion suivant l'ordre séquentiel.

NUMERO D'INCLUSION (Pour celle ayant donné leur consentement) : /_/_/_/

ENTRETIEN D'INCLUSION

Date d'inclusion ou de CPN1 _____

I. Données socio-démographiques de la patiente

101. CODE CPN DE LA FEMME : /_/_/_/_/_/_/_/_/

102. Age : Date de naissance : lieu de résidence :

.....

105. Situation matrimoniale : Marié (vie en couple monogame) : /_/

Marié (foyer polygame) : /_/ Célibataire : /_/ Divorcée/séparée : /_/ Veuves :
/_/

106. Niveau d'instruction : Non scolarisée: /_/ Primaire : /_/ Secondaire /_/
Supérieur /_/

107. Profession :

.....

II. Historique de la grossesse et antécédent gynécologique

201 : Age de la grossesse /_/_/ mois. H.U /_/_/ cm nombre de geste :.....

203. Avez -vous déjà eu un avortement spontané ou provoqué : Oui /_/ Non : /_/

204. Parité : Nombre de naissances vivantes : Nombre
d'enfants vivants.....

III. DEPISTAGE DE LA SYPHILIS

501. Test réalisé : Oui /_/ Non /_/

502. Résultats du test de dépistage :

a. Résultat du test initial: Positif : /_/ => Traiter et faire un prélèvement pour le contrôle de qualité
Négatif : /_/

Invalide ou Douteux: /_/ => répéter le test sur place avec la permission de la patiente et reporter le résultat en
bas.

b. Résultat du test répété (2) : Positif : /_/ => Traiter et faire un prélèvement pour le contrôle de qualité

Négatif : /_/ Invalide/Douteux : /_/=> faire un prélèvement pour le contrôle qualité ou référer au CHR

IV. CONSEIL POST-TEST ET ANNONCE DES RESULTATS A LA PATIENTE

Quelque soit le résultat du test, rassurer la patiente avant de lui annoncer ses résultats.

Poser la question : Nous vous avons dit que lorsque le test est positif, il sera souhaitable que vous informiez votre (vos) partenaires sexuels pour qu'ils viennent se faire traiter. Acceptez-vous de l'informer et de le faire venir au centre médical la semaine prochaine pour le traitement ?

Oui je vais l'informer : /_/ Oui, mais donner moi une invitation pour lui : /_/

Non : /_/ Pouvez vous nous donner la raison ?

Absent du village : /_/

Je ne peux pas lui parler de cela : /_/

Nous ne sommes plus ensemble : /_/ Autres : /_/ Préciser.....

V. TRAITEMENT POUR LES PATIENTES POSITIVES AU TEST DE DEPISTAGE ET/OU PRESENTANT DES PLAIES SUR LES ORGANES GENITAUX

601. Avez-vous déjà présenté des éruptions cutanées ou une allergie suite à l'administration d'un médicament (pénicilline surtout) ?

Oui : /_/ De quel médicament s'agit-il ?..... (Demander à voir son carnet de santé). Si suspicion d'allergie à la pénicilline, référer la femme au CMA pour prise en charge.

Non : /_/ Administrer le traitement a ou b ci-dessous selon le cas.

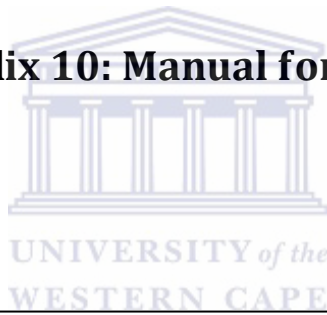
602 : Traitement administré :

- a. Benzathine Benzyl Pénicilline (BBP) 2,4MUI IM, 1 injection :/_/
- b. Ery 500 mg 1 cp x 4/j pdt 14j + Polyvidone Iodée solution 10% :.. /_/

NB : a. Pour test de dépistage positif uniquement

b. Pour présence de plaie, ulcération génital +/- test positif.

Appendix 10: Manual for training





**Faisabilité et acceptabilité du dépistage de la syphilis en consultation
prénatale par l'utilisation de test rapide au Burkina Faso**
MANUEL DE FORMATION DES AGENTS DE SANTE POUR LA REALISATION
DES TESTS RAPIDES DE LA SYPHILIS

Dr Gautier Ouédraogo, pharmacien biologiste

Dr Grissoum Tarnagda, pharmacien

IRSS, 50 33 35 94

INTRODUCTION

Ce manuel doit être soigneusement étudié et utilisé comme référence sur le terrain quand vous vous posez des questions concernant la façon de procéder pour effectuer toutes les tâches impliquées dans la procédure des tests.



Avant de proposer le test à votre client, rassurez-vous que tout le matériel nécessaire pour votre travail est disponible.

CARACTÉRISTIQUES GÉNÉRALES

Dans le cadre de cette enquête intitulé **“faisabilité et acceptabilité du dépistage de la syphilis en consultation prénatale par l’utilisation des tests rapide au Burkina Faso”**, des prélèvements de sang seront effectués auprès des femmes enceintes pour pratiquer le test de la syphilis. Ce manuel décrit les procédures que vous devez suivre pour harmoniser les pratiques, mais aussi assurer la qualité et la sécurité de votre travail sur le terrain.

Contexte et justification

La transmission de la syphilis demeure une source importante d’effets sur l’issue des grossesses et également un cofacteur important dans la transmission du VIH dans les pays en développement. Selon les estimations de l’OMS, la syphilis maternelle est chaque année responsable d’au moins 500 000 avortements spontanés ou mortinaissances, tout comme de la naissance de 500 000 enfants prématurés atteints de syphilis congénitale ou présentant une insuffisance pondérale à la naissance. Or, la charge que représente la syphilis congénitale est encore généralement sous-estimée. La syphilis congénitale est une maladie évitable que le dépistage prénatal et le traitement précoce des femmes enceintes infectées permettraient d’éliminer. En réponse à cette situation, Le groupe consultatif scientifique et technique du Département OMS Santé et recherche génésiques (RHR) a approuvé une stratégie pour l’élimination mondiale de la syphilis congénitale d’ici 2015.

Cette stratégie se base sur 4 piliers. L’un de ses piliers est d’assurer le dépistage et le traitement des femmes enceintes et de leurs partenaires. Ainsi de nombreux pays ont inclus le dépistage de la syphilis dans un paquet minimum d’examen à effectuer lors des visites prénatales. Pour cela il est nécessaire que les tests diagnostiques soient accessibles aux populations les plus affectées.

La technique de test de dépistage de la syphilis dans cette enquête consiste à prélever par piqûre au bout du doigt des gouttes de sang et à le déposer dans une cassette de test rapide qui

vous donnera le résultat en 20 minutes.

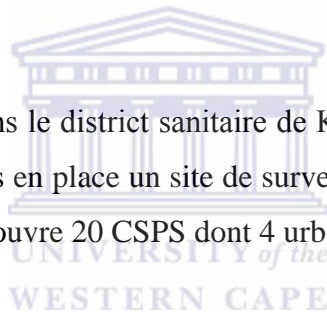
Les résultats de ces tests seront également remis sur place, et la femme sera prise en charge au service de santé si le test est positif.

1.1.1 But de l'étude

Cette recherche a pour but de contribuer à l'élimination de la syphilis en fournissant des évidences scientifiques à l'intention des décideurs sur la faisabilité (pratique, acceptabilité, et coût) du dépistage de la syphilis par les tests rapides au niveau des structures périphériques de soins.

1.1.2 Les sites de l'étude

Les CSPPS seront sélectionnés dans le district sanitaire de Kaya où l'Institut de Recherche en Sciences de la Santé (IRSS) a mis en place un site de surveillance démographique et de santé (KaDESS) depuis 2007. Le site couvre 20 CSPPS dont 4 urbains situés dans la ville de Kaya.



Généralités sur la maladie

3.7.2. Aspects cliniques

➤ Clinique

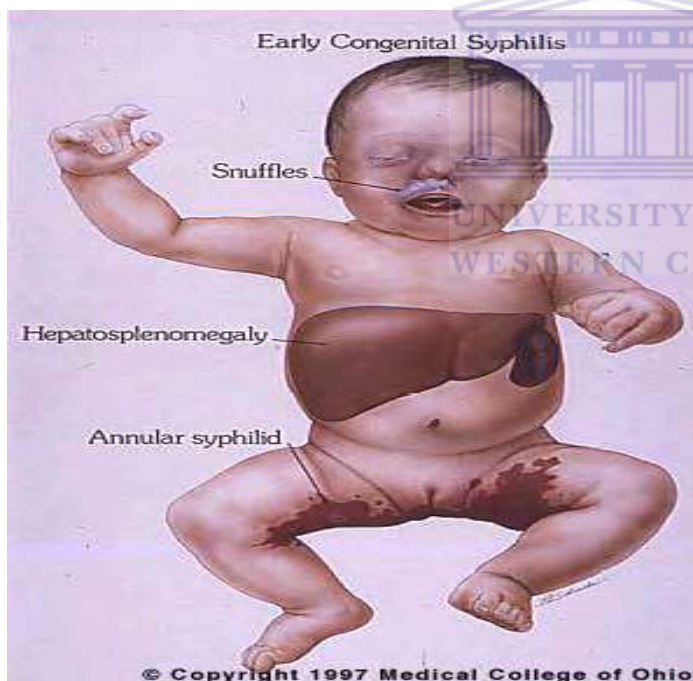
[Dr Thomas Perpoint Hôpital de la Croix Rousse Service de Maladies Infectieuses, Lyon]

Incubation # 3 semaines (10 à 90 j)

• Primaire :

- Chancre et adénopathies = complexe primaire
- Chancre unique (2/3), indolore, base indurée..., cicatrisation spontanée en 3 à 5 semaines (1- 3 sem. Sous traitement)
- Adénopathie satellite inguinale uni ou bilatérale unique ou multiple
- Chancres génitaux,
 - Homme : sillon balano-préputial, méat, prépuce (phimosis), hampe

- Femme : grandes lèvres (géant), petites lèvres (nain), vagin (rare), col
- Chancres extra-génitaux : lèvres, amygdales, anus



Syphilis Congénitale
 Contamination in
 utero,
 2ème trimestre

- Jetage nasal
- Hépatosplénomégalie
- Lésions cutanéomuqueuses et osseuses

- Secondaire : (contagiosité +++)
- Précoces :
 - Roséole (macule de 1 à 3 mm, tronc paumes et plantes...)
 - Plaques muqueuses : érosions superficielles, contagion +++
 - Alopécie
- Tardives :

- Syphilides : papules squameuses, tronc, régions génitales, mains, pieds
- polyAdp, AEG

3.7.3. Aspects biologiques

Principes pour l'interprétation de la sérologie de la syphilis

1. Au stade primaire le diagnostic de certitude repose sur la recherche de TP au microscope à fond noir (positif dans 30 à 50% des cas), pas de valeur au niveau buccal.
2. Les 2 tests utilisés pour le diagnostic sont le TPHA et le VDRL
3. Au tout début du chancre le TPHA et le VDRL peuvent être négatifs (3-7 premiers jours du chancre)
 1. Au stade de syphilis secondaire les 2 tests sont toujours positifs (exceptionnelles neg)
 2. Un VDRL positif isolé n'est pas synonyme de syphilis
 3. La surveillance sérologique après traitement repose sur le VDRL quantitatif
 4. Aucun test actuel ne permet de différencier une syphilis d'une tréponématose non vénérienne
 5. Interprétation des résultats avec la clinique (contact clinicien-biologiste) +++

Fausses sérologies de la syphilis, VDRL + isolé

Causes infectieuses

Bactériennes: lèpre, tuberculose, leptospirose, borréliose, scarlatine...

Virales: varicelle, oreillons, MNI, hépatite, rougeole, VIH

Parasitaires: trypanosomiase, paludisme

Causes non infectieuses

Grossesse, Toxicomanie IV, Hépatopathie chronique, Gammopathie monoclonale, Lupus

Syndrome des anticardiolipides, Cancers...

3.7.4. Aspects thérapeutiques

Le traitement de la syphilis selon le protocole national de prise en charge des IST correspond à celui de l'ulcération génitale. Il consiste à traiter, le chancre mou et l'herpès génital par l'un des Kits UG :

- Kit UG1 : Benzathine Benzyl Penicilline 2,4 millions UI en IM unique + Polyvidone iodée solution à 10%

- Kit UG2 (si allergie, femme enceinte ou allaitante)
Erythromycine 500 mg 1cp 4 fois par jour pendant 14 jours + Polyvidone iodée solution à 10%

ORGANISATION DU TEST

Pour pouvoir prélever les échantillons de sang, chaque personnel de santé chargée de réaliser le test, aura reçu une formation spéciale pour le prélèvement du sang. Le consentement des femmes sera recueilli avant procéder au prélèvement. Les données socio-anthropométriques (âges, poids, situation matrimoniale), les données sur la grossesse en cour (âge de la grossesse, date probable d'accouchement), les antécédents gynéco-obstétricaux (nombre de grossesses vivantes, nombre de mortinaissances, nombre d'avortement spontanés,...) seront recueillis à l'inclusion. Après le recueil de ces données de base, une explication du déroulement du test sera donnée à la femme suivie d'une prise de sang capillaire (au bout du doigt) pour le dépistage rapide et instantané de la syphilis. Le test étant rapide et instantané (maximum 30 minutes), les résultats seront remis à la femme tout en prenant soins de lui en donner la signification et la conduite à tenir. **En cas de positivité du test, un prélèvement sanguin veineux sera fait dans un tube sec sans anticoagulant avant l'administration du traitement et chez chaque 20 ième cas négatif de chaque site pour le contrôle de qualité ultérieure par le Laboratoire du CHR.**

Concernant le test auprès des femmes enceintes, les agents trouveront ci-dessous la liste des tâches principales qu'ils devront effectuer :

- Identifier toutes les femmes qui sont éligibles pour le test ;
- Obtenir le consentement éclairé de la femme enceinte et enregistrer les informations concernant la femme dans le registre de suivi des femmes.
- Prélever un échantillon de sang capillaire pour chaque femme enceinte et effectuer le test de la syphilis en utilisant le test rapide Syphilis.
- Enregistrer le résultat du test sur la fiche de suivi de la femme;
- Informer la femme du résultat de l'examen sur la syphilis;
- Prescrire le traitement pour les femmes ayant un test positif à la syphilis.

Dans les sections suivantes de ce document vous trouverez la description détaillée des procédures et les directives que vous devrez suivre pour mener à bien ces tâches.

Formation des personnels de santé

Votre formation pour apprendre à effectuer le test de la syphilis comprendra des cours théoriques et pratiques qui vous donneront la capacité nécessaire de pratiquer ce test sur le terrain.

Durant la première phase de la formation, nous reverrons ensemble toutes les sections de ce manuel. Vous apprendrez comment choisir les femmes éligibles, comment enregistrer les informations concernant le test dans le registre ou comment procéder pour le prélèvement des échantillons, le test, etc.

Durant la seconde phase de cette formation, nous organiserons des simulations pour les tests de la syphilis au cours desquels vous vous entraînerez à prélever les échantillons de sang parmi vos collègues en formation.

Au cours de la session de formation, il vous faudra étudier soigneusement ce manuel, en prenant des notes et en écrivant les questions que vous vous posez. Posez toutes les questions que vous vous posez à n'importe quel moment ; cela vous permettra d'éviter de faire des erreurs sur le terrain. Vous pouvez apprendre beaucoup les uns des autres en posant des questions et en relevant les éventuelles difficultés que vous pourrez rencontrer.

Supervision

La formation est un processus continu. L'observation et la supervision sur le terrain constituent une partie du processus de la formation et de la collecte des données. Le coordinateur de l'enquête pour les tests biologiques jouera un rôle très important en continuant votre formation et en assurant la qualité des données de l'enquête. Il devra:

- Contrôler la qualité de votre pratique des tests et la qualité de vos résultats
- Aider à résoudre les problèmes que vous pourriez rencontrer sur le terrain.

Une équipe de supervision effectuera une fois par mois la tournée des centres de santé concernés par l'étude. Chaque CSPS sera doté d'un code.

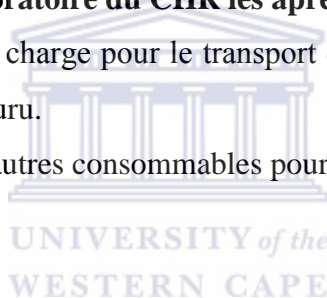
Contrôle de qualité

Le contrôle de qualité des résultats des tests sera assuré par le laboratoire du CHR de Kaya. Il va s'inspirer du système de sérosurveillance pour le VIH. Le laboratoire sera chargé d'analyser les échantillons qui seront acheminés par les CSPS. Chaque 1/20 des cas négatifs et tous les cas positifs seront analysés pour confirmation. Un point focal sera désigné au sein du laboratoire du CHR de Kaya pour le suivi de l'étude.

Les CSPS seront dotés de consommables (tubes et aiguilles de prélèvement sanguin, garrot) pour les prélèvements sanguins. **Un prélèvement veineux sera effectué sur toute femme avec un résultat positif et sur chaque 20ème femme avec un résultat négatif. Les prélèvements seront conservés dans un tube sec au réfrigérateur à une température de 2 à 4°C au niveau du CSPS en attendant leur acheminement au laboratoire du CHR où ils seront centrifugés et testés. La collecte des échantillons dans les CSPS se fera deux fois par semaine (le Lundi et le Jeudi). Chaque CSPS devra se charger de transporter les échantillons collectés au laboratoire du CHR les après midi entre 15h et 17h.**

Les CSPS recevront une prise en charge pour le transport des échantillons jusqu'au CHR en fonction du nombre de Km parcouru.

Le CHR sera doté des réactifs et autres consommables pour effectuer les tests en laboratoire.



MATÉRIEL ET ÉQUIPEMENT POUR EFFECTUER LES TESTS

Dans cette section, vous trouverez une description détaillée des divers instruments et équipement que vous utiliserez pour effectuer les tests de la syphilis. Des détails supplémentaires sont présentés dans le document concernant la description du déroulement de la procédure des tests.

Matériel et équipement pour effectuer la piqûre au doigt

Les gouttes de sang capillaire utilisées pour le test de la syphilis seront prélevées au doigt. L'équipement et le matériel suivants (Figure 12) seront utilisés pour effectuer la piqûre au doigt :

- *Gants jetables en latex non poudrés* : ils sont utilisés pour réduire le risque de contamination par le sang. Les gants doivent être portés par l'agent de santé et par quiconque qui participe à un prélèvement sanguin.



Figure 12: Matériel pour effectuer les piqûres au doigt

- *Tampons alcoolisés* : ils sont utilisés pour nettoyer la peau avant d'effectuer la piqûre au doigt.

- *Compresse de gaze stérile ou simple coton* : elles sont utilisées pour essuyer les premières gouttes de sang pour stimuler le flux sanguin.

- *Pansements adhésifs* : Après le prélèvement sanguin, il faut appliquer un pansement sur l'endroit de la piqûre pour éviter qu'une infection ne se produise.

- *Lancettes (rétractables)* : La lancette est un dispositif d'incision automatique, jetable utilisé pour piquer le bout du doigt ou le talon. Elle est spécialement conçue pour s'adapter à la surface de la peau, réduisant ainsi l'indentation de la peau. En appuyant sur le déclencheur, on libère rapidement une lame chirurgicale qui se rétracte automatiquement. L'angle de la lame est réglé de façon à ce que le débit sanguin soit au maximum et que le mouvement de la lame soit si rapide qu'il ne peut être vu.

Le test : Matériel pour le test de la syphilis

L'équipement suivant est utilisé pour le test de la syphilis:

- Cassette du test syphilis unitaire (dans une pochette)
- Flacon de réactif du test
- Pipette ou micro tubes capillaire avec EDTA
- Marqueur/crayon pour étiquetage

REPLISSAGE DES QUESTIONNAIRES ET DES AUTRES DOCUMENTS POUR LES TESTS

En tant que agents, vous êtes chargés d'enregistrer les informations qui seront utilisées pour suivre les résultats des tests.

Cette section a pour objectif de passer en revue les tâches suivantes:

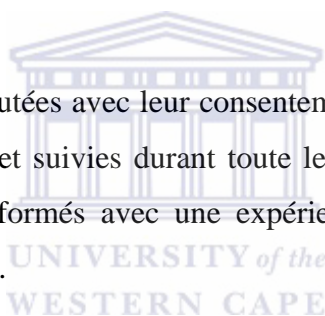
- Identification des sujets éligibles ;
- Obtention du consentement éclairé pour le test ;
- Enregistrement les informations concernant les résultats des tests dans le cahier.

Les activités spécifiques nécessaires à la réalisation de ces tâches sont décrites ci-dessous

Identification des sujets éligibles

Recrutement des femmes

Les femmes enceintes seront recrutées avec leur consentement dans les formations sanitaires retenues dès leur première CPN et suivies durant toute leur grossesse. Le recrutement sera assuré par des agents de santé formés avec une expérience dans la prise en charge des grossesses au niveau périphérique.



L'inclusion effective dans l'étude

L'inclusion effective dans l'étude sera précédé par l'information de la femme des objectifs et du déroulement de l'intervention à l'issue de laquelle elle décidera librement de sa participation.

Critères d'inclusion

- Femme enceinte reçue en première consultation prénatal (**toute femme en CPN 1**) pour la grossesse en cours
- **Femme enceinte âgée d'au moins 18 ans**
- Femme acceptant de participer à l'étude

Critères de non inclusion

- Femmes enceinte ayant déjà bénéficié d'une consultation prénatale pour la grossesse en cours *car le test de la syphilis fait partie des examens prénataux obligatoires qui doit être prescrit dès la première consultation prénatale.*
- *Femme enceinte âgée de moins de 18 ans*
- Femme refusant de participer à l'étude

Obtention du consentement éclairé pour le test

L'une des tâches principales de l'agent sera d'expliquer l'objectif de ce test aux femmes éligibles, en vue d'obtenir leur consentement éclairé avant de commencer à effectuer les tests sanguins. Pour permettre aux femmes de fournir un consentement éclairé sur leur participation au test, des formulaires de consentement comportant des explications sur la nature des tests et une demande d'autorisation seront administrés avant d'effectuer les prélèvements sanguins pour ces tests. Ces déclarations sont appelées des déclarations de consentement éclairé.

Dans tous les cas, vous devez inscrire la réponse à la demande de consentement éclairé avant d'effectuer le prélèvement sanguin d'une femme.

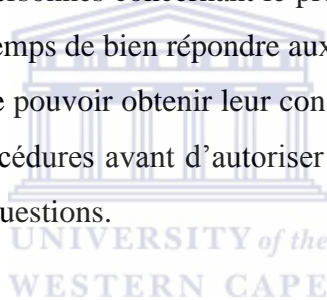
Vous devez signer la fiche de consentement pour attester que vous avez lu la déclaration aux femmes et que vous avez enregistré leur(s) réponse(s) de manière exacte.

Les points suivants sont des points importants dont il faut se souvenir quand on cherche à obtenir le consentement éclairé pour effectuer les tests :

- 1) **Lire la déclaration de consentement à chaque personne telle qu'elle est exactement formulée dans la fiche.** Quand vous recevez votre patiente et quand vous commencez à parler, vous pouvez discuter de manière informelle des points qui figurent dans la déclaration de consentement éclairé. Cependant, avant de commencer à effectuer le test d'un sujet, vous devez lire la déclaration de consentement telle qu'elle est exactement formulée dans le formulaire. Si vous vous apercevez que la personne trouve la déclaration répétitive, expliquez-lui/elle que vous êtes tenu de lire

cette déclaration de manière formelle pour que les personnes bénéficient de toutes les informations appropriées.

- (2) **Lisez clairement et de manière intelligible les déclarations de consentement éclairé.** Entraînez-vous à lire les déclarations de consentement éclairé pour être capable de les lire facilement sur un ton naturel. Éviter de les lire sur un ton monocorde ou en prenant un rythme trop rapide pour qu'elles puissent être comprises.
- (3) **Ne jamais prélever le sang d'une femme sans au préalable avoir obtenu le consentement.**
- (4) **Ne jamais essayer d'obtenir un consentement par la force ou la coercition.** Vaincre les craintes des personnes concernant le prélèvement sanguin exige du tact et de la patience. Prenez le temps de bien répondre aux questions et soucis des personnes qui sont hésitantes, afin de pouvoir obtenir leur consentement. Certains sujets peuvent souhaiter discuter des procédures avant d'autoriser les tests. Répondez patiemment à tous ceux qui posent des questions.



Enregistrement des informations concernant les tests pour les femmes éligibles.

Les résultats des tests seront enregistrés sur le cahier. Ce cahier mis à votre disposition est détenu par votre responsable de la maternité.

Fournir les résultats du test de la syphilis

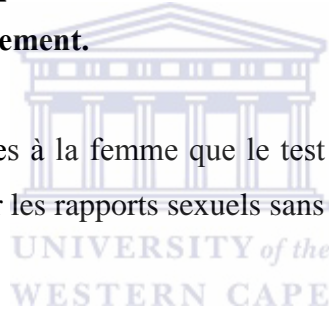
Après avoir effectué le test, vous donnerez pour chaque femme ayant effectué le test les résultats. En donnant les résultats verbalement, expliquez brièvement ce que les résultats du test du sujet signifient.

Résultat négatif : Dites à la femme que le résultat est négatif, et que l'examen fait aujourd'hui n'a pas trouvé de germes de la syphilis dans son sang. Vous pouvez lui conseiller les rapports sexuels sans risque notamment la fidélité.

Résultat Positif : Dites à la femme que le test est positif à la syphilis, mais cela n'est pas grave parce qu'elle aura un traitement pour guérir et protéger son enfant. Il peut s'agir d'une infection ancienne, mais par mesure de précaution, nous allons lui administrer le traitement. Conseillez-lui des rapports sexuels protégés (port du préservatif) et expliquez-lui l'intérêt de faire traiter son (ses) partenaire (s) sexuel (s).

NB : Il n'est pas nécessaire de réaliser le test chez le partenaire. Un résultat négatif chez celui-ci pourrait entraîner des problèmes dans le couple. Pour ce faire, dites au partenaire que l'infection peut ne pas se manifester chez l'homme mais se manifester chez la femme. Un résultat positif au test utilisé ne veut pas dire que l'infection est en cours, cela peut être une infection ancienne, guérie, mais par mesure de précaution, surtout avec l'enfant à naître, il sera mieux qu'il se fasse traiter. Expliquez-lui l'intérêt de se faire traiter et lui proposer l'administration du traitement.

Résultat douteux/Invalide : Dites à la femme que le test n'a pas pu déterminer un résultat précis. Vous pouvez lui conseiller les rapports sexuels sans risque notamment la fidélité.



PROCÉDURES GÉNÉRALES POUR PRÉLEVER DES GOUTTES DE SANG CAPILLAIRE

Le prélèvement de la goutte de sang capillaire peut être effectué sur la surface palmaire de l'extrémité du doigt. Les paragraphes suivants concernent la description détaillée des différentes étapes pour effectuer le prélèvement de gouttes de sang capillaire à partir du doigt.

Étape 1 : Préparation générale

- a) Si possible, trouvez un endroit à l'intérieur pour être en privé. De même, il est souhaitable que l'endroit soit pourvu d'une table ou d'un autre « meuble » ayant une surface plate sur

laquelle vous pourrez étaler vos fournitures. Un lit ou un matelas doivent être disponibles au cas où un sujet viendrait à s'évanouir et devrait s'allonger.

- b) Passez en revue le matériel et vérifiez le nombre de femmes éligibles. Après avoir établi le nombre de femmes à tester, sortez l'équipement approprié (Tableau 2). **Il vous faut tout le matériel à portée de mains avant de commencer à prélever les échantillons de sang.**

Tableau 2 : Équipement et fournitures nécessaires
Pour la piqûre au doigt

Lancettes rétractables
Gants en caoutchouc
Tampons alcoolisés
Compresse de gaze stérile
Pansement (Sparadrap)

Pour le test de la syphilis

Test rapide Alere Détermine syphilis

- c) Lavez-vous soigneusement les mains avec de l'eau et du savon puis séchez-les ; **mettez des gants** avant de commencer à effectuer le prélèvement sanguin.
- d) Décrivez à la femme la procédure de prélèvement exacte et ce qu'elle peut faire pour vous aider durant le prélèvement.
- e) Aussi, faites preuve d'un calme rassurant quand vous commencez à prélever le sang. Rappelez-vous que pour diminuer l'anxiété des sujets, il est important de prendre un air amical et de faire en sorte d'établir un climat de confiance.

Étape 2 : Sélection et préparation du lieu de ponction

a) Le prélèvement sera généralement plus facile si vous vous asseyez du côté opposé à la main du sujet. Par exemple, si vous voulez prélever le sang de la main gauche, placez-vous à la droite du sujet.

b) Utilisez le troisième ou le quatrième doigt pour prélever le sang (Figure 2). N'utilisez pas un doigt avec une cicatrice,

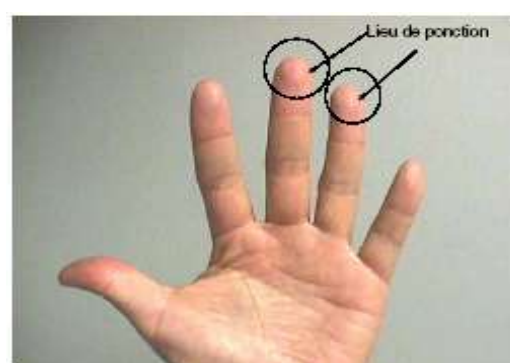


Figure 2: Doigts à utiliser pour le prélèvement

une blessure ou une entaille, une infection, un œdème, une difformité, des boutons ou des callosités. **N'utilisez pas un doigt auquel la femme porte une bague parce qu'elle peut gêner le flux du sang au bout du doigt.**

c) Si l'extrémité est froide, réchauffez la peau en la frottant à l'endroit où la ponction sera effectuée. Cela améliorera la circulation sanguine en diminuant la proportion de liquide du tissu et facilitera le prélèvement de l'échantillon.

d) Nettoyez la peau avec un tampon alcoolisé. Si la peau est très sale, prenez un nouveau tampon. Laissez l'alcool sécher à l'air. **Ne soufflez pas sur le lieu de ponction pour sécher l'alcool car des bactéries pourraient s'y incruster.**



e) Assurez-vous que la lancette est facilement à portée. Pour ce travail, vous utiliserez les lancettes dont la lame mesure 2,25 mm.

Étape 3 : Piquer le doigt

a) Retirez la protection blanche de l'ouverture de la lame en la tordant d'abord à 360° et ensuite en la tirant. **N'enlevez pas la protection de l'ouverture de l'aiguille sans la tordre au préalable**, cela pourrait empêcher l'aiguille de percer la peau.

b) **Assurez-vous que le doigt se trouve en dessous du cœur du sujet pour augmenter le flux du sang vers le doigt.** En décrivant un mouvement circulaire avec le pouce, appuyez doucement sur le doigt à partir de la jointure supérieure vers le bout. Cela stimule la circulation sanguine vers le lieu de ponction.

c) Quand votre pouce atteint le bout du doigt, maintenez une pression légère. Placez la lancette perpendiculairement à l’empreinte digitale sur la **surface palmaire au bout du doigt, soit au centre ou légèrement sur le côté. Évitez l’extrémité du doigt ou les côtés extérieurs à l’empreinte digitale parce qu’il y a un risque d’atteindre l’os sous-jacent.** .

d) Utilisez la lancette pour piquer la peau en plaçant la surface de l’ouverture de la lame contre le lieu de ponction et appuyez sur le déclencheur (Figure 4). Le bout de la lame s’éjecte à travers l’ouverture, causant une micro-incision dans la peau et se rétracte immédiatement dans le dispositif. Lorsque vous piquez la peau, vous coupez ainsi à travers le lieu de ponction pour permettre au sang de former des bulles et de l’empêcher de circuler dans les sillons des empreintes digitales.



Figure 4: Utiliser la lancette pour piquer le doigt

e) La lancette doit être mise de côté pendant le test. Après le test, la lancette doit être placée dans un sac à déchets dangereux avec le reste du matériel utilisé pour le prélèvement de sang.

Étape 4 : Prélèvement de(s) échantillon(s) de sang

a) Lorsque le sang apparaît, utilisez une compresse de gaze stérile pour essuyer la première goutte de sang (Figure 5). **La seconde goutte sera utilisée pour le test.**

b) Si le sang s’arrête de couler avant qu’une quantité suffisante n’ait été prélevée, la procédure de ponction de la peau peut être répétée après que la femme ait

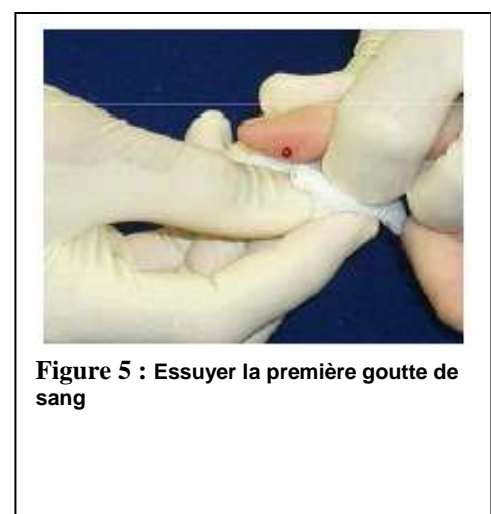


Figure 5 : Essuyer la première goutte de sang

donné son consentement pour une ponction à un doigt différent en respectant les procédures décrites aux étapes 1 à 3. **Ne réutilisez aucun instrument/ matériel utilisé lors du premier test.**

REALISATION DU TEST RAPIDE DIAGNOSTIC SEROLOGIQUE DE LA SYPHILIS PAR LE TEST RAPIDE ALERETM DETERMINETM SYPHILIS TP

Mode opératoire

Préparation du test

- Ramener réactif et échantillon à la température de la salle 30 minutes avant utilisation
- Sortir le nombre de tests à utiliser de leur pochette (**Une fois la protection plastique retirée chaque test, le dosage doit être effectué dans les 2 heures**)
- Réaliser le test à la température de la salle

Mode opératoire

- 1- Enlever la protection plastique de chaque test
- 2- Distribuer 50 µl de sang total à l'aide de micro pipette ou tube capillaire sur la zone de dépôt de l'échantillon (symbolisé par la flèche).
- 3- Attendre que le sang soit absorbé par la zone de dépôt, puis distribuer **une goutte de tampon de fixation** sur la zone de dépôt de l'échantillon.
- 4- Attendre 15 minutes (maximum : 24 h)
- 5- Lire le résultat

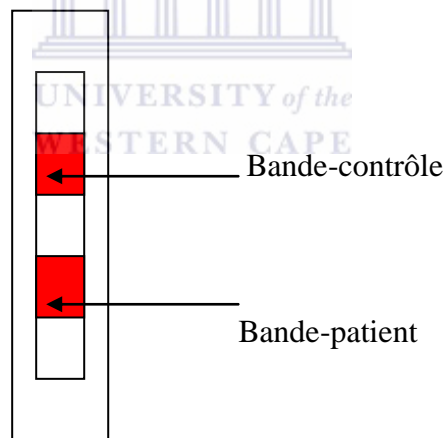
3-4-5 interprétation et validation des résultats

Le test est validé lorsqu'une bande rouge apparaît dans la zone « contrôle »



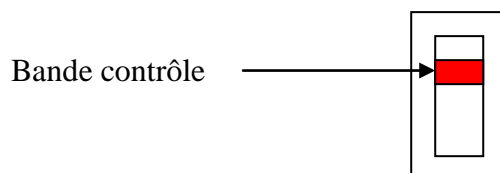
a- *résultat positif (deux barres)*

Apparition de bandes rouges dans la fenêtre-contrôle et dans la fenêtre-patient (une bande par fenêtre) sur la bandelette. Toute couleur rouge visible dans la fenêtre-patient doit être interprétée comme un résultat positif.



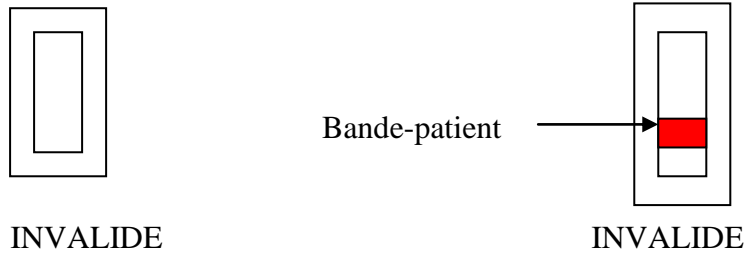
b- *Résultat négatif*

Apparition d'une bande rouge dans la fenêtre-contrôle. La bande rouge de la fenêtre-patient n'apparaissant pas.



c- *Résultat non valide*

Absence de bande rouge dans la fenêtre-contrôle. Le test doit être recommencé.



Stopper le saignement au lieu de ponction

- a) Après le prélèvement sanguin, essuyez le sang qui s'écoule du lieu de ponction avec une compresse de gaze stérile.
- b) Après avoir vérifié que le sang ne coule plus, prenez un pansement adhésif et placez-le sur le lieu de ponction.

Se débarrassez des déchets bio-médicaux

Mettez tous les déchets bio-médicaux (comme les lancettes, les tampons alcoolisés, les compresses et les gants) dans un sac à déchets destiné à collecter tous les déchets bio-médicaux qui doivent être éliminés. En fin de journée, éliminer ces déchets selon les procédures décrites.

PRECAUTIONS A PRENDRE POUR LE PRELEVEMENT DES ECHANTILLONS

Cette section traite des précautions les plus importantes que les agents doivent observer quand ils effectuent des prélèvements d'échantillons sanguins, pour se protéger eux-mêmes ainsi que les sujets qui se prêtent au test contre les blessures ou les infections qui peuvent se transmettre et pour éviter de contaminer les prélèvements.

Précautions universelles en prélevant les échantillons

Cette section traite des précautions universelles que les agents doivent observer quand ils effectuent des prélèvements pour les tests de la syphilis et. Les agents chargés du prélèvement sanguin pour les tests doivent prendre des précautions pour prévenir l'exposition parentérale, dermique et des muqueuses aux infections transmises par le sang, comme l'hépatite B ou le Virus de l'Immuno déficience Humaine (VIH). Pour se conformer aux précautions universelles, les directives suivantes doivent être suivies pour éviter de contracter ces infections qui peuvent se transmettre par le sang¹.

- **Portez des gants.** Les gants empêchent votre peau et les membranes muqueuses d'être en contact avec le sang du sujet. Les gants doivent être portés pendant le prélèvement du sang pour les tests de la syphilis jusqu'à ce que l'échantillon soit prélevé et que tous les déchets aient été évacués. À ce moment-là, les gants utilisés doivent être considérés comme des déchets bio-dangereux. Une nouvelle paire de gants doit être utilisée avec chaque sujet. **Ne jamais réutilisez de gants!**
- Évitez les blessures perforantes. Les gants permettent de se protéger de la contagion sanguine qui peut se produire à la suite de contact avec la peau, qu'elle soit intacte ou non, mais ils ne permettent pas d'éviter les blessures perforantes causées par des instruments utilisés pour les piqûres au bout du doigt. Les lancettes rétractables qui sont utilisées par les agents réduisent les risques de blessures pénétrantes.

Les lancettes ne doivent pas être utilisées à des fins autres que piquer le doigt pour prélever le sang pour les tests de la syphilis. Les lancettes ne doivent pas être cassées ou détruites par curiosité ou pour des raisons qui n'ont rien à voir avec les prélèvements. Immédiatement après la fin du test, les lancettes doivent être placées dans un sac pour les déchets bio-dangereux résistant aux piqûres.

Si un accident se produit, toute partie de la peau contaminée ou ayant été en contact avec le sang, doit être immédiatement lavée.

¹ Pour les précautions universelles concernant les agents pathogènes qui se transmettent par le sang, voir les directives du U.S. Centers for Disease Control and Prevention et les standards de l'U.S. Occupational Safety and Health Administration (OSHA).

- **Ne jamais manger ou boire au cours des prélèvements.** Comme manger, boire ou se maquiller peut être cause de distraction pendant la procédure, cela n'est pas autorisé pendant les tests.
- Se débarrasser correctement de tous les déchets biodangereux. Après utilisation, tout équipement qui a été en contact avec le sang doit être placé dans un sac à déchets biodangereux

Faites attention à bien ramasser **tous les déchets** des tests **avant** d'en commencer un nouveau.

Après avoir terminé les tests de tous les sujets éligibles, vérifiez bien l'endroit où vous avez effectué les tests pour être sûr de n'avoir pas laissé traîner de déchets. Attachez bien le sac pour éviter que quelque chose ne puisse tomber.

N'oubliez pas que vous êtes responsable de l'évacuation des déchets. Ne donnez jamais le sac à une personne qui n'est pas un membre de l'équipe pour le jeter. Si un des autres membres de l'équipe vous aide à vous débarrasser des déchets, assurez-vous qu'il a compris qu'il doit jeter lui-même le sac et ne pas le donner à quelqu'un d'autre.

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Règles particulières à observer au cours des prélèvements pour les tests De la syphilis

Il y a un certain nombre de règles particulières que l'agent doit observer au cours des prélèvements pour les tests de syphilis. Ces règles comprennent :

- **Ne jamais « traire » le doigt.** L'agent doit appliquer une faible pression en utilisant son pouce, son index et son majeur pour faire un « bourrelet » au site de ponction. Cela rendra plus poreux le tissu conjonctif sous-jacent à la peau et permettra au sang capillaire de couler plus facilement après l'incision.
- **Ne jamais mélanger l'alcool avec le sang.** L'alcool utilisé pour nettoyer le lieu de ponction peut se mélanger au sang et causer des erreurs de lecture du taux

d'hémoglobine. Pour éviter ce problème, il faut essuyer et attendre que le doigt soit complètement sec avant d'effectuer la ponction.

- **Obstruction du flux sanguin.** Il est important de bien tenir le doigt pour permettre l'accumulation de sang dans le lieu de ponction. Il ne faut cependant pas le tenir trop serré car cela peut obstruer le débit sanguin vers le doigt.

Concernant le **test de la syphilis**, les règles suivantes sont particulièrement importantes :

- **Ne pas ouvrir le test unitaire sans être sûr de l'utiliser dans les 30 minutes qui suivent.**
- **Ne jamais toucher les cercles de dépôt de l'échantillon sur la cassette test. Evitez de toucher la zone à l'intérieur** des cercles de dépôt de sang sur le test, avant le prélèvement.
- **Protéger les cassettes de test des contaminations.** Ne laissez jamais de l'eau ou autre élément contaminant entrer en contact **avec la cassette de test** avant l'utilisation.



REJET DES DECHETS BIO-DANGEREUX

Tout matériel qui entre en contact avec le sang (par exemple, lancettes, tampons alcoolisés, gazes et gants, etc.) est considéré comme dangereux, c'est-à-dire dangereux pour les autres êtres humains. Il est très important d'éliminer correctement ces déchets biomédicaux de façon adéquate pour empêcher la transmission des maladies transmissibles par le sang, telles que l'hépatite B et le VIH..

A la fin des tests de chaque sujet, tous les déchets bio-dangereux qui ont été produits pendant la procédure du test doivent être placés dans un sac poubelle, pour « déchets biodangereux ».

PREMIERS SOINS EN CAS D'ACCIDENT D'EXPOSITION AU SANG

Exposition percutanée

En cas de blessure par du matériel contaminé par du sang, ou à la suite d'un contact entre une blessure cutanée et du sang ou un fluide corporel :

- laisser saigner la blessure, nettoyer immédiatement la blessure et la peau qui l'entoure à l'eau et au savon, puis rincer ;
- désinfecter la blessure et la peau qui l'entoure avec un des produits suivants :
 - de l'alcool à 70% *pendant 5 minutes.*
 - une solution de chlore 12° chlorométrique *pendant 5 minutes,*
(diluée à 1/10ème, 0,1% de chlore actif)

ou

- polyvidone iodée 10% (Bétadine) *pendant 5 minutes,*

ou

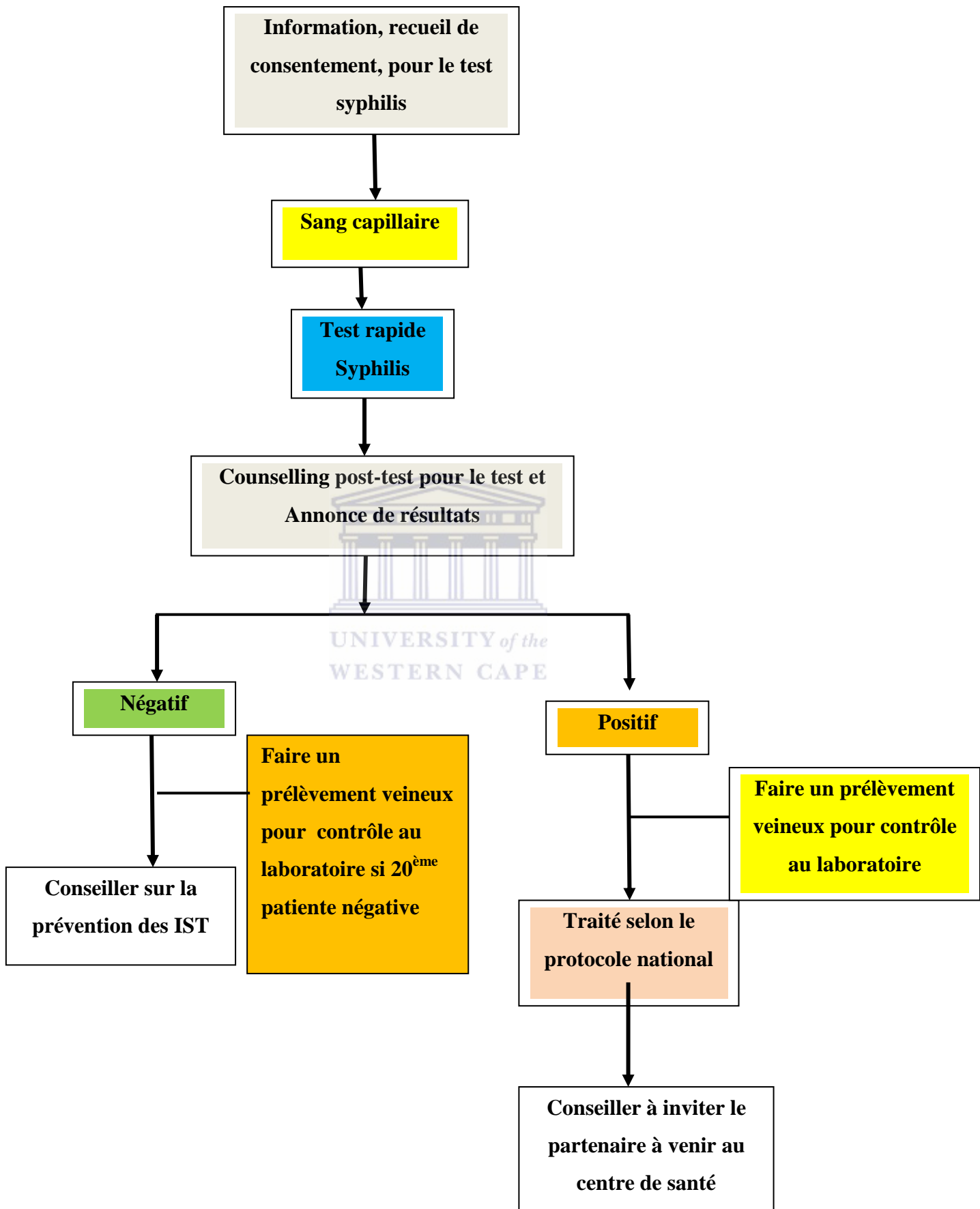
La chlorhexidine cetrimide étant active contre le VIH mais sans effet contre le VHB n'est pas recommandée pour les personnes qui ne sont pas vaccinées contre le VHB.

Exposition affectant les yeux ou des membranes muqueuses

Rincer immédiatement la zone exposée au moyen d'une solution saline isotonique pendant 10 minutes ou passer l'œil sous le robinet d'eau courante. Des gouttes oculaires antiseptiques peuvent également être appliquées sur les yeux exposés. Si aucune de ces solutions n'est disponible, utiliser de l'eau propre.

**APRES TOUS CES PREMIERS SOINS REALISABLES IMMEDIATEMENT,
CHERCHER A ENTRER EN CONTACT DANS LES 24 HEURES AVEC UNE
FORMATION SANITAIRE DE REFERENCE POUR UNE MEILLEURE PRISE EN
CHARGE**

Schéma récapitulatif



**Appendix 11: Original version of articles
published**



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Research

Barriers to antenatal syphilis screening in Burkina Faso

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Introduction: Despite advances in treatment and management, syphilis remains a major public health problem in Burkina Faso. Syphilis in pregnancy poses major health risks for the mother and the fetus and also increases the risk for HIV transmission. Despite its potential benefits, antenatal syphilis screening is often poorly implemented in many sub-Saharan African countries. The purpose of the study is to identify and understand barriers affecting health system performance for syphilis screening among pregnant women in Burkina Faso.

Methods: We conducted in-depth interviews and observations in the Kaya health district, Burkina Faso. Participants were purposively selected to capture a range of perspectives across different actors with different roles and responsibilities. Seventy-five interviews were conducted with health providers, district managers, facility managers, traditional healers, pregnant women, community health workers, and Non-Governmental Organizations (NGO) managers. Interviews were transcribed and organized into codes and categories using NVivo software.

Results: Participants identified multiple barriers at health providers and community levels. Key barriers at provider level included fragmentation of services, poor communication, low motivation for prescription, and low awareness of syphilis burden. Cost of testing, distance to laboratory and lack of knowledge about syphilis were identified as barriers at community level.

Conclusion: The study highlights barriers such as distance, cost of testing, and knowledge about syphilis. The introduction of point of care testing for syphilis could be an entry point for improving coverage of antenatal syphilis screening.

Cite this article: Fadima Yaya Bocoum, Seni Kouanda, Christina Zarowsky. Barriers to antenatal syphilis screening in Burkina Faso. Pan Afr Med J. 2014;17(Supp 1):12

Key words: Screening, syphilis, barriers, antenatal, Burkina Faso

Permanent link: <http://www.panafrican-med-journal.com/content/series/17/1/12/full>

DOI: 10.11694/pamj.supp.2014.17.1.3423

Received: 28/09/2013 - **Accepted:** 09/12/2013 - **Published:** 18/01/2014

This article is published as part of the supplement "Promoting health research in Africa: research from emerging African scholars in health"

Supplement sponsored by African Population and Health Research Center

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Introduction

Despite several advances in treatment and management, syphilis remains a major public health problem. The World Health Organization (WHO) estimates that there are twelve million new cases of syphilis worldwide each year [1]. Ninety percent of syphilis cases occur in low income countries [1] and the prevalence ranges from less than 1% to 10%. African studies show prevalence during pregnancy of 2% in Mali [2], 3% in Nigeria [3], 5% in Botswana [4], and 7.3% in Tanzania [5]. In Burkina Faso, Kirakoya-Samadoulougou et al found a low prevalence of syphilis during pregnancy at national level but with important regional variations [6]. For instance, in Kaya District the prevalence was 7.5 in 2009 whereas in Ouagadougou it was 1% [7].

Syphilis in pregnancy poses major health risks for the mother and the fetus and also increases the risk for HIV transmission [8]. The World Health Organization (WHO) estimates that two million pregnant women each year are infected with syphilis globally [2]. The risk of vertical transmission could be up to 80% in early latent syphilis [2]. Approximately 1.2 million pregnant women with syphilis transmit the infection to their

newborn every year [9]. It is estimated that 492 000 infants in sub-Saharan Africa die annually from congenital syphilis [10]. In Tanzania, a clinic-based study found that a quarter of women with high-titer active syphilis infection had stillbirths compared with 1% among seronegative women [11].

Maternal syphilis is detectable by serological screening and entirely treatable with penicillin. Therefore, screening and treatment for syphilis has been recommended as a routine part of antenatal care [12,13]. In Burkina Faso, syphilis screening is recommended for premarital tests and during pregnancy [14]. Unfortunately, antenatal syphilis screening is often poorly implemented in many sub-Saharan African countries [15]. Currently, only 30% of women with syphilis are screened and treated in developing countries [16]. The influence of health systems issues on timely prenatal syphilis screening has been observed in several countries, including Bolivia, Kenya and South Africa [17]. In West African countries such as Burkina Faso, barriers to syphilis screening are understudied.

In this study, we sought to identify and understand barriers affecting health system performance for syphilis screening among pregnant

women in Burkina Faso. Existing literature on syphilis screening among pregnant women suggests that antenatal care (ANC) is the cornerstone for the control of maternal syphilis. Thus, factors affecting attendance to ANC are likely to affect syphilis screening for pregnant women. We therefore explored various factors at policy, health provider, patient, and community levels that are likely to drive syphilis screening levels.

Methods

Study design

We conducted a Multilevel Assessment (MLA) [18] comprising of qualitative interviews and observations, as well as a review of existing data. For the latter, we assessed health information systems records, policy documents, service provider guidelines, training manuals, monitoring and evaluation reports and other relevant research reports and published literature. These data enabled us to investigate how the syphilis screening policy was implemented at facility level, the available indicators of its health outcomes, and any documented barriers to its implementation to date. The in-depth interviews were held with health providers, district managers, facility managers, traditional healers, pregnant women, community health workers, and representatives of national and international Non Governmental Organizations (NGOs) which work on maternal and child health issues to explore barriers and constraints which affect the effective delivery of maternal syphilis screening. During data collection, the first author also observed interactions between health workers and clients in selected health facilities.

Study setting

The study was conducted in the Kaya health district, based in the central north region of Burkina Faso. Kaya district has 484 932 inhabitants, 40 primary health facilities and is a sentinel site for the national AIDS and STI control program. We conducted this research in Kaya District because of the high syphilis prevalence relative to the national average. Figure 1

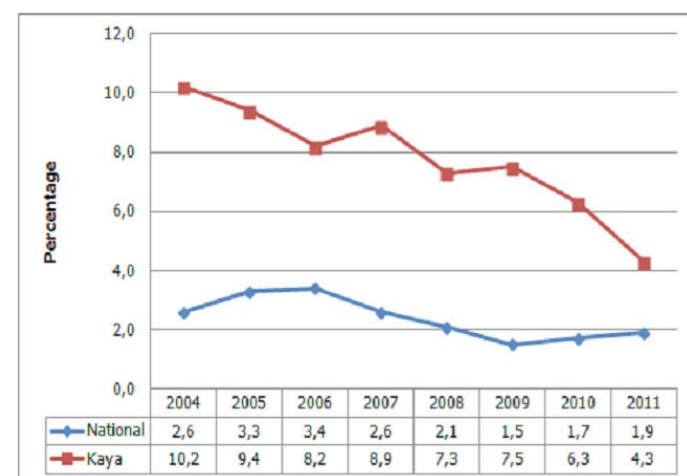


Figure 1
Trends in syphilis prevalence from 2004 to 2011 in Burkina Faso. Source: report CMLS/Santé, 2010, 2011

presents the trend of syphilis prevalence among pregnant women from 2004 to 2009 in Kaya district and nationally. The study was nested in the Kaya Health and Demographic Surveillance System (Kaya HDSS), which was launched in 2007 by the Health Sciences Research Institute (IRSS). Kaya HDSS covers seven semi-urban areas and 18 villages of the district with a population of 48,131 inhabitants. In 2011, there were seven public primary health facilities that offered ANC, one faith-based health center and one regional hospital. The faith-based facility and the hospital did not offer ANC but their laboratories offer the venereal diseases research laboratory (VDRL) test and Treponema pallidum haemagglutination assay (TPHA). One pharmacy offered a rapid test for syphilis. The health facilities selected for the study were all located within Kaya HDSS area.

Study population and sampling

The study population consisted of health providers, district managers, facility managers, traditional healers, pregnant women, community

health workers, and NGO managers (Table 1).

Table 1: Study Sample	
Group	Number and position
District managers	1 pharmacist
	1 information systems specialist
	1 reproductive health specialist
	Head of District
	Head of regional laboratory
Health workers	2 lab technicians
	4 midwives
	6 auxiliary midwives
Community health workers	4 community care workers
	7 drug shop managers
	2 NGO managers
NGO and private	1 midwife
	1 lab technician
	1 pharmacist
Facility manager	7 (Primary health care center)
Community	35 pregnant women
	4 traditional healers

The healthcare providers included doctors, midwives, nurses, laboratory personnel, and pharmacists. Participants were purposively selected to capture a range of perspectives across different actors with varying roles and responsibilities. In each health facility, five pregnant women were approached as they queued to receive antenatal services and informed about the study. For those who consented, the interview was held at the end of their visit. Although we initially planned to have focus group discussions (FGDs) with pregnant women, the number of women available for the FGDs was too small because data collection occurred during the rainy season.

Data collection

Data were collected using interview guides that were adapted for each profile of respondent. The interview with pregnant women explored experiences of ANC, satisfaction with ANC, knowledge and perceptions of sexually transmitted infections (STIs) including syphilis, perceptions of existing point-of-care tests, opinion on the introduction of additional test. We sought to find out key informants' perception of ANC, management of STI during pregnancy, knowledge and perceptions of syphilis, barriers and constraints which affect the effective delivery of maternal syphilis screening, organizational and managerial issues, experience with point-of-care tests, and introduction of a rapid diagnostic test (RDT) for syphilis screening.

Data tools were pre-tested and appropriate modifications made before the final data collection. Data collection was conducted by the first author and two research assistants who are familiar with qualitative studies and have a social sciences background. Research assistants were trained on the study objectives, data collection tools, and processes before embarking on field data collection. Interviews with health providers, district managers, facility managers, and NGO managers were conducted in French while those with pregnant women, traditional healers and community workers were conducted in Mooré the local language. Appointments were made with community health workers, traditional healers, health providers, district managers, facility managers and NGO managers. All interviews were recorded using a digital recorder and files downloaded to a laptop the same day. Transcription was done by two transcribers. Interviews in Mooré were translated into French and transcribed.

Data analysis

Interviews were transcribed into a text program and then uploaded on Nvivo software. An analytical grid of key themes was developed based on the list of possible barriers in our conceptual framework, the objectives of the research and familiarization with the first few transcripts. Additional themes that emerged during the process of re-reading of transcripts were coded. Thematic content analysis was employed to systematically analyze the content of each theme.

Ethical issues

Ethical clearance was obtained from the University of Western Cape, the National Ethics Committee for Health in Burkina Faso and the Ethics Committee Review of the WHO. In addition, the study team obtained permission to conduct the research from the District authorities. Written informed consent was obtained from all participants.

Results

Although the guidelines on the management of STIs recommend syphilis screening for all pregnant women, we found no information on the proportion of pregnant women routinely tested for syphilis at district, regional and national level. Our study findings highlight considerable weaknesses within operational systems for syphilis screening. In tracking a woman's journey from antenatal care (ANC) through to laboratory, the study documented several barriers at health provider and community levels.

Barriers at health provider level

The first barrier to routine syphilis screening among pregnant women was related to providers' perception that syphilis in pregnancy was not an important issue relative to other diseases. In addition, health workers also felt that syphilis prevalence was low because most women who undertook the test were seronegative. As one auxiliary midwife who had worked in an urban facility since 2009 stated, "I have never found a positive test, all were negative." Related to this, some health workers felt that syphilis was more prevalent in urban areas and thus, screening was more systematic in urban-based facilities. One district manager noted "For syphilis screening it is not really systematic and I know that in urban facilities health workers prescribe it to all women but at rural facilities it is not systematic." Overall, we noted an absence of interventions and information on maternal syphilis in the district.

The second barrier to routine syphilis screening among pregnant women was related to the availability of screening equipment, which was particularly a challenge for rural facilities. One facility manager in a rural-based facility noted that, "I do not systematically prescribe syphilis test because we have no laboratory here." A mapping of the facilities in the district indicated that three facilities (one public and two private) offered the syphilis test. All three facilities were urban-based. The public facility hosts the laboratory of the regional hospital and performs rapid plasma reagin (RPR) and Treponema pallidum particle agglutination assay (TPHA) tests. Between August 2011 and August 2012, this facility had performed 279 RPR tests and 260 TPHA tests. Among the two private that offered screening, one was a pharmacy offering a point of care test, while the second was a faith based facility offering the RPR and TPHA test. At the private pharmacy, only four clients had requested a syphilis test between June 2011 and June 2012. At the faith based facility, 50 RPR tests and 10 TPHA tests were performed between August 2011 and August 2012. The third barrier was related to health workers' inability to communicate the need for syphilis screening to pregnant women. Health workers noted that it was difficult to convince women about the importance of screening for syphilis. This challenge was partly related to the need to collect multiple blood samples from women for an HIV test, as part of the PMTCT program, as well as for the syphilis test. According to one health worker, women did not understand the need for multiple blood tests: "when we do an HIV test, you get a blood sample. We said that they need to go to the laboratory and have another blood test to know if they have other diseases, they said no, it is the same blood you got here and tested it is not necessary to have another sample." Health workers acknowledged that they did not explain the importance of some of the examinations. For example, one manager in an urban-based facility noted that "Most of the time it is a lack of communication at our level, we do not tell to the women the importance of some exams, why this prescription..." The narratives from pregnant women corroborated this observation. One pregnant woman in a rural area stated "One day the health worker took blood from my left finger but I did not know if it is HIV test or not ...) I don't know because until now they have said nothing." The poor communication between health workers and pregnant woman may be related to the lack of routine training as the health workers stated that they had no specific training, except for a course on syphilis management during their professional training.

A fourth barrier was the fragmentation of services in a setting where geographic distance was already a barrier. Often women have to be referred to an external laboratory for the syphilis screening. According to health workers, many women live in rural areas and have to travel long distances to health facilities that offer screening services. One health worker commented, "we observe that most women are from villages around Kaya, they walk from their house to our facility and we ask them to do the test the day after. The distance from their house to the laboratory is same to our facility. Thus the majority do not go." We observed that

traveling from the nearest urban primary health facilities to the public laboratory would take about 1 hour by foot or 20 minutes by bicycle. Due to this situation, one urban health center had a lab technician who came to the facility to collect blood samples, but few women did the test.

Barriers at community level

The cost of the syphilis test was reported to be a barrier for many women. At the public laboratory, RPR and TPHA cost the equivalent of USD 2-3. The point of care test cost more in the pharmacy (USD 3) compared with the faith based facility (USD 2). Although the cost of syphilis tests in the public sector is subsidized by the government, many women are not screened because of the cost of the test. One auxiliary nurse stated "There are women who keep the exam prescription until delivery because they said that they have no money for the exams."

Our findings also indicate that a pregnant woman's husband or partner plays a key role in the decision to be screened for syphilis. Due to exemption of fees, women do not carry a lot of money when they go for their ANC visit. When they receive a prescription for additional medical examinations, such as the syphilis test, they have to go back home and get money from their husband. Sometimes, women need approval from their husbands as illustrated by this quote from a midwife in an urban facility, "sometimes, until the delivery they (women) kept the prescription in their health card, when you ask them why, they explain that they gave it to the head of the family but he did nothing."

Findings also show that poor knowledge about syphilis was also a potential barrier to testing. For example, although many women could describe the symptoms of sexually transmitted infections (STIs) (itches, pimples, and vaginal discharge), many were unaware about syphilis or the consequences of untreated syphilis for the mother and child.

Finally, perceptions about syphilis also affected screening rates. In particular, the stigma surrounding sexually transmitted diseases was noted as a barrier to screening particularly in certain settings like pharmacies. One facility manager noted "the pharmacy advertised and gave the prices but you know women, it is difficult for them to go to the pharmacy and do an exam related to sex. They prefer to go to the laboratory of the hospital if they have money because it is a public service."

Discussion

Syphilis screening is recommended for premarital tests and during pregnancy [14]. Although a policy that promotes syphilis screening in pregnant women exists in Burkina Faso, screening is very limited. Our findings identified several barriers to the uptake of syphilis screening among pregnant women in Burkina Faso.

Syphilis testing is largely dependent on the availability of adequate laboratory facilities [19]. However, our results suggest that the fragmentation of services is key barrier to the uptake of syphilis screening. Health workers often have to refer women to external laboratories and many women, particularly those living in rural areas, have to travel long distances to access these laboratories. Other studies have also reported that long distances to screening facilities are associated with delay or failure to screen [20, 21]. Our findings suggest the need to introduce a "one-stop" service point that including ANC, PMTCT and syphilis testing.

As highlighted in previous studies [22, 23], we found that low motivation of healthcare workers to prescribe syphilis screening also contributes to low screening. Although the need for continued antenatal screening for syphilis may be questionable in areas with low prevalence [24], health workers in the current study were not aware about the relatively high prevalence of syphilis in their district. Consequently, some health workers failed to prescribe the test. Trepka et al [25] also found that a lack of provider awareness of the prevalence of syphilis was associated with inadequate provision of screening test in the United States. The absence of interventions to increase syphilis screening and the lack of information on maternal syphilis in the district shows also the low prioritization of the problem. Efforts to increase awareness about syphilis are therefore warranted in order to enhance syphilis screening levels.

The relatively high cost of screening, despite government subsidies, also prevents pregnant women from being screened for syphilis. The cost for

testing was observed to range between \$2 and \$3 USD, a prohibitive cost in a country where 73% of population lives on less than \$2 a day [26]. The cost of screening is, therefore, a significant deterrent for many women particularly those who are financially dependent on their husband or partner. Women's financial dependency means that pregnant women's husbands or partners play a key role in the decision to be screened. Similar findings have been highlighted in previous studies [27-28] and underscore the need for male involvement in efforts to increase the uptake of syphilis screening among pregnant women.

Lack of knowledge about syphilis in the community was identified as a reason for not being screened. Most respondents at community level do not know the symptoms of syphilis nor its serious consequences for the unborn and born child. This misperception may be due to the lack of differentiation between STIs [29]. Most of STIs are recognized through symptoms and respondents do not realize that a STI could be asymptomatic. Community may also not perceive syphilis to be a problem because of its lack of visibility [30]. Low knowledge about syphilis might therefore pose a barrier to screening since pregnant women do not perceive the benefit of testing particularly for asymptomatic infections. As reported in a recent meta synthesis, many pregnant women did not feel the need to seek professional care when there is nothing wrong with their pregnancy [31]. Efforts to enhance awareness of syphilis and other STIs are therefore recommended.

Our study findings should be interpreted in light of several limitations. First, because of the exploratory nature of the study, we relied on qualitative methods and therefore our findings cannot be generalized to the larger population. Second, community's perceptions reflected mostly health services users. However, study findings highlight potential barriers to the uptake of syphilis screening. Further research using a more representative sample is warranted.

Conclusion

Our study suggests that barriers such as distance to health facilities, cost of testing, and knowledge about syphilis among health workers and communities may limit screening levels and hinder the implementation of syphilis screening during pregnancy as recommended in national guidelines. Pregnant women often weigh the benefits of syphilis screening against the high direct and opportunity costs. Our results have several implications for efforts to improve screening levels. First, communication between health workers and clients needs to be improved in order to facilitate the acceptability of the test. Second, the introduction of point of care testing for syphilis during ANC may improve coverage of antenatal syphilis screening.

Competing interests

The authors declare no competing interests.

Authors' contributions

All the authors have contributed to this study in ways that comply to ICMJE authorship criteria. All the authors have read and approved the final version of this manuscript.

Acknowledgements

We thank participating staff in Kaya district, NGOs, private facilities Community Care givers and research participants. This research was partially funded by an African Doctoral Dissertation Research Fellowship award offered by the African Population and Health Research Center (APHRC) in partnership with the International Development Research Centre (IDRC) and the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR). The data reported here were collected as part of a dissertation study conducted by the first author.

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PAMJ is an Open Access Journal published in partnership with the African Field Epidemiology Network (AFENET)



Evaluation of the diagnostic performance and operational characteristics of four rapid immunochromatographic syphilis tests in Burkina Faso

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Abstract

Background and objective: Little information is available on the rapid diagnostic testing for syphilis in Burkina Faso. The objectives of the study were (i) to assess the sensitivity and specificity of four on site rapid tests in comparison with *Treponema pallidum* haemagglutination assay (TPHA) as a gold standard and (ii) to evaluate the operational characteristics of those tests among health workers in a maternity unit.

Methods: Four rapid syphilis tests commercially available in Burkina Faso were evaluated using archived serum samples and *Treponema pallidum* hemagglutination assay (TPHA) as the gold standard. Blood samples were collected between November 2011 and June 2012 from blood donors at the Regional Blood Transfusion Center of Ouagadougou. The sensitivity and specificity of the tests were calculated. Evaluation of operational characteristics such as clarity of pamphlet, complexity of technique, duration, was conducted in a first-level healthcare center with health workers in maternity unit.

Results: Alere Determine™ Syphilis was the most sensitive of the four rapid syphilis tests evaluated. It was followed by SD Bioline Syphilis 3.0, Cypress Diagnostics Syphilis Quick test and Accu-Tell® Rapid Anti-TP, which was the least sensitive. The four tests demonstrated a good diagnostic specificity for syphilis (95–98%), and healthcare workers found them easy to use.

Conclusions: The study allowed confirming the good performance of three of four rapid syphilis tests in Burkina Faso. More research will be conducted to assess the feasibility of introducing selected rapid tests for syphilis in antenatal care services.

Keywords: syphilis, rapid test, performance, Burkina Faso

DOI: <http://dx.doi.org/10.4314/ahs.v15i2.8>

Introduction

Syphilis in pregnant women remains a major public health problem. The World Health Organization (WHO) estimates that 90% of syphilis cases occur in low-income countries¹. The prevalence in developing

countries ranges from less than 1% to 10%. In a recent review among studies in 1990-2011, prevalence estimates were 4.5% (3.9%-5.1%) in East and southern Africa and 3.5% (1.8%-5.2%) in West and Central Africa². In Burkina Faso, prevalence in pregnant women is low, with notable regional variations^{3,4}. According to WHO estimates, each year, maternal syphilis is responsible for at least 50,000 spontaneous abortions or stillbirths and 500,000 premature births of babies infected with congenital syphilis or who have low birth weight¹. However, rates of congenital syphilis are generally underestimated⁵. Congenital syphilis is an avoidable disease that prenatal testing and early treatment of infected pregnant women could eliminate⁶.

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In response to this situation, the scientific and technical consulting group of the WHO's Department of Reproductive Health and Research adopted a strategy for the global elimination of congenital syphilis by 2015¹. Consequently, many countries have included syphilis testing as part of a minimum package of tests conducted during prenatal visits.

Unfortunately syphilis diagnosis in peripheral clinics (CSPSs) in Burkina Faso is conducted using a syndromic approach, while the majority of syphilis cases are asymptomatic. In hospital laboratories (Medical Centers with Surgical Services (CMA), regional hospitals (CHR), national hospitals (CHU)), testing is conducted with a venereal diseases research laboratory (VDRL) test or with a *Treponema pallidum* hemagglutination assay (TPHA). Although these tests present certain advantages in that they allow for the differentiation between an old or treated syphilis infection and active syphilis, as well as an analysis of treatment adherence, their use requires qualified personnel, laboratory equipment, and a source of electricity, which limits their utility to peripheral clinics (CSPSs).

Currently, there are several available specific, rapid syphilis tests that are simple to use and could be implemented in CSPSs. When compared to the diagnostic tests currently being used (VDRL and TPHA), rapid treponemal tests have several advantages, including the rapid availability of results (less than 30 minutes) and the fact that their usage does not require electricity or highly qualified laboratory staff⁷. Simultaneous point-of-care treponemal and non-treponemal are available with good performance¹¹ and are undergoing wide adoption for their benefits. However, despite reports of diagnostic performance provided by the manufac-

turers of rapid syphilis tests, data on test effectiveness and operational characteristics in the field remain limited in West Africa and non-existent in Burkina Faso. Against that background, we conducted a study to evaluate the diagnostic laboratory performance and operational characteristics of four rapid tests for *Treponema pallidum* available in Burkina Faso. The objectives of the study were; to assess the sensitivity and specificity of four on site rapid tests in comparison with *Treponema pallidum* haemagglutination assay (TPHA) as a gold standard and to evaluate the operational characteristics of the tests.

Methods

Study populations

We evaluated rapid syphilis tests commercially available in Burkina Faso using archived serum samples and TPHA as the gold standard. Rapid syphilis tests were defined as *Treponema pallidum* tests (i) capable of giving a result within 30 minutes and (ii) that could be used at service delivery points without any need for special storage or transport⁷. Only rapid syphilis tests with market authorization in Burkina Faso (currently valid or in the process of renewing validity with the Ministry of Health) were considered. In total, four tests were selected. These were 1) Accu-Tell® Rapid Anti-TP (*Treponema pallidum* / Syphilis) (Accu Biotech Co Ltd, China), 2) Alere™ Determine™ Syphilis TP (Alere™ Médical Co Ltd, UK), 3) Syphilis Cypress Diagnostics (Cypress Diagnostics, Belgium), and 4) SD Bioline syphilis 3.0 (Standard Diagnostics INC, Korea). The characteristics of the tests according to the manufacturers are listed in Table 1.

Table 1 Characteristics of the tests according to the manufacturers.

Characteristics	<i>Accu-Tell® Rapid Anti-TP</i>	<i>Alere Determine™ Syphilis TP</i>	<i>Cypress Diagnostics Syphilis Quick test Diagnostics</i>	<i>SD Bioline Syphilis 3.0 test</i>
Manufacturer	Accu Biotech Co Ltd	Alere™ Medical Co Ltd	Cypress Diagnostics	Standard Diagnostics INC
Product code	ABT-STD-B17	7D2443	353 Syphilis Quick Test	06FK11
Lot used	2011071312	14448k100	25094	32052
Type of antigen	Immunochromatographic TP Ag1, Ag2	Immunochromatographic Ag <i>Treponema pallidum</i>	Immunochromatographic Ag 17, 15 KDa <i>Treponema pallidum</i>	Immunochromatographic Ag recombinant pale (17, 15 kDa)
Specimen	Serum or plasma	Serum, plasma or whole blood	Serum, plasma or whole blood	Serum, plasma or whole blood
Time needed for results	15 minutes	15 minutes 24 hours maximum	5–20 minutes	5–20 minutes
Stable result	20 minutes	24 hours	20 minutes	20 minutes
Storage conditions	2–30°C	2–30°C	8–30°C	2–30°C

Blood samples were collected between November 2011 and June 2012 from blood donors at the Regional Blood Transfusion Center (CRTS) of Ouagadougou, Burkina Faso. A total of 120 serum samples were considered for the evaluation. There were 60 samples positive for syphilis (50 samples were TPHA and VDRL positive: active syphilis, and 10 were TPHA positive and VDRL negative: previous or primary case of syphilis) and 60 samples negative for syphilis (50 samples were TPHA negative and VDRL negative, and 10 were TPHA negative and VDRL positive). The comparative analysis was conducted in the laboratory of the Institut de Recherche en Science de la Santé (IRSS) in Ouagadougou, Burkina Faso.

For the evaluation of the operational characteristics, the study was conducted in a primary healthcare centre (CSPS) located in Ouagadougou the capital city of Burkina Faso. In total sixteen healthcare profession-

als (midwives, birth attendants, and auxiliary birth attendants) working in the maternity ward of an urban first-level healthcare were trained in the use of the four tests. Their seniority in the maternity ward was between 6 months and 18 years, although none had previously used a rapid syphilis test. However, they had used HIV and malaria rapid tests.

Sample collection

After obtaining the blood donor's consent, approximately 10 mL of blood was taken from the blood collection bag, put in a dry BD Vacutainer® tube (Becton, Dickinson and Company; USA) without anticoagulant and kept at +4°C for approximately four hours while waiting for the results of the syphilis test.

For the operational characteristics study, during the routine prenatal consultations, each healthcare worker used each rapid syphilis test on 5 pregnant women who con-

sented to a blood-draw by finger prick. A self-administered questionnaire was made available to the healthcare workers for the data collection. The operational characteristics were appreciated following: (i) the clarity of the manufacturers' pamphlets, mainly the description of use, in terms of level of comprehension, (ii) the complexity of technique, (iii) the length of time required to complete the entire testing process, (iv) the time of apparition of line result, and (v) the interpretation of result. For each criterion, measures were defined. The clarity of the manufacturer's pamphlets was appreciated regarding comprehension of the text if it was very clear, moderately clear or difficult to understand.

The complexity of technique was looked if the technique for utilization (from blood collection to the availability of the result) was complex (very difficult), moderately complex (difficult) or very easy in comparison with other rapid tests they had already used such as HIV test. The length of time required for a test (from blood collection to the availability of the result) was compared to the duration of other rapid tests they had used following the modalities of long, equivalent or short duration. The time for apparition of line result was compared to what was written in the pamphlet of each test. Finally the ease in interpretation of the result, in terms of visibility and readability of line result, was compared to other used rapid tests following the modalities of very easy or moderately easy to interpret. All these criteria were used to appreciate if a test has good operational characteristics or not.

Laboratory methods

After blood collection from blood donors, syphilis test was conducted by CRTS using the ARCHITECT Syphilis TP automated treponemal antibody test (Abbott Diagnostic, USA). This is a two-step immunoassay for the qualitative detection of anti-TP antibodies in human serum or plasma. It uses chemiluminescent microparticle immunoassay (CMIA) technology with flexible dosage protocols called Chemiflex. The microparticles are covered with recombinant TP antigens (TpN15, TpN17, and TpN47). Once the syphilis status of the blood donor was determined by CRTS, we chose positive and negative samples for syphilis for our evaluation. At the end of the collection day, the samples were centrifuged at 3000 rpm for 10 minutes and then submitted to combine VDRL/TPHA (BIOLABO SA, France) testing in the serologic laboratory of the Institut de Recherche en Sciences de la Santé (IRSS) to confirm the syphilis status. After confirmation, the serum was aliquoted in two cryotubes of 2 mL, labeled, and stored at -20°C until

beginning of the next stage of the evaluation. Hemolytic samples were excluded.

The evaluation of the rapid syphilis tests performance was conducted at the laboratory of IRSS in July 2012 using the stock of serum samples from CRTS. The evaluation followed the manufacturers' instructions and used good laboratory practices. First the frozen serum samples were brought to ambient temperature before use. Then each test was used in series. To avoid the comparison of results between tests during the laboratory analysis, each rapid test was used on all samples before moving to the next test. There was a blind interpretation of test results, independent of the results of the reference test (TPHA). TPHA (BIOLABO SA, <http://www.biologo.fr/pdfs/noticesFR/Syphilis>) was used as the gold standard (reference test). It is an indirect hemagglutination assay (IHA) for the identification of *Treponema pallidum* antibodies circulating in human plasma and regularly used for the diagnosis of syphilis in a laboratory.

Statistical data analysis

For each test, the laboratory evaluation results were compared to the reference test (TPHA) and categorized as true positive, false positive, true negative, or false negative. The data were entered with Epidata and analyzed using SPSS version 15 and R version 2-12.1. The performance characteristics, such as sensitivity and specificity were calculated relative to the reference standard TPHA results obtained for each serum specimen.

Ethical issues

The research protocol received the approval of the Health Research Ethics Committee (CERS), Ministry of Health, Burkina Faso.

Results

Performance of diagnostic tests

A total of 120 samples were tested for the evaluation of the performance. The sensitivity of the tests was compared to the gold standard used (TPHA). Analysis of the sensitivity of the tests showed that Alere Determine™ syphilis TP had the highest sensitivity (93%) among the four selected rapid tests. The sensitivity of Cypress syphilis and SD Bioline Syphilis 3.0 was 90%. Accu-Tell® Rapid Anti-TP had a sensitivity of 78%. In terms of specificity, Alere Determine™ syphilis TP, Accu-Tell® Rapid Anti-TP and SD Bioline Syphilis 3.0 had the same result (98%), while Cypress syphilis had a specificity of 95%. (Table 2)

Table 2 Results of the diagnostic performances of rapid syphilis tests.

	<i>Accu-Tell® Rapid Anti-TP</i> (Accu Biotech Co Ltd)	Alere Determine™ Syphilis TP (Alere™ Médical Co Ltd)	Cypress Diagnostics Syphilis Quick test (Cypress Diagnostics)	SD Bioline Syphilis 3.0 test (Standard Diagnostics INC)
Sensitivity (95% CI)	78% (66 - 87)	93% (84-97)	90% (79-95)	90% (80-95)
Specificity (95% CI)	98% (91-100)	98% (91-100)	95% (86-98)	98% (91-100)

CI = confidence interval

Operational characteristics of the four tests according to healthcare professionals

The results of the evaluation of the operational characteristics of the four tests by 16 healthcare professionals are summarized in Table 3. The pamphlet of the test was clearly comprehensible by 12 of the 16 respondents for *Accu-Tell® Rapid Anti-TP*, by 11 respondents for SD Bioline syphilis 3.0, by 9 respondents for Cypress Diagnostics Syphilis Quick test, and by 7 respondents for Alere Determine™ syphilis TP.

As a whole, the healthcare professionals judged the technique for utilization of the tests to be very easy. Indeed, of the 16 healthcare professionals who participated in the evaluation, 15 found Cypress Diagnostics Syphilis Quick test and SD Bioline Syphilis 3.0 to be very easy to use, while 14 said the same for *Accu-Tell® Rapid Anti-TP* and Alere Determine™ syphilis TP. Overall, the time needed to obtain results was determined to be similar to other tests already used for HIV and malaria. Specifically, 10 respondents found Alere Determine™ syphilis TP and Cypress Diagnostics Syphilis Quick test to be similar to the previously used tests, and approximately 50% found this for *Accu-Tell*

® Rapid Anti-TP (9/16) and SD Bioline syphilis 3.0 (8/16).

For the majority of respondents, the time required to obtain results matched the time indicated by the manufacturer for *Accu-Tell® Rapid Anti-TP*, Cypress Diagnostics Syphilis Quick test and SD Bioline syphilis 3.0 (Table 3).

The interpretation of results was found to be very easy by 14 of 16 respondents for *Accu-Tell® Rapid Anti-TP* and SD Bioline syphilis 3.0 and by 12 of 16 respondents for Alere Determine™ syphilis TP. As for Cypress Diagnostics Syphilis Quick test, only 9 of 16 found the results to be easy to interpret.

The realization of the tests requires the use of equipment not provided in the kit. Specific and non-specific equipment are needed. Specific equipment, such as capillary tubes with EDTA for Alere Determine™ Syphilis TP and pipettes for Cypress Diagnostics Syphilis Quick test and SD Bioline syphilis 3.0 *Accu-Tell®* are needed. *Rapid Anti-TP* does not require specific equipment. Non-specific equipment, including alcohol swabs and lancets, was required for the four tests.

Table 3 Operational characteristics of syphilis diagnostic tests.

Characteristics evaluated	<i>Accu-Tell® Rapid Anti-TP</i> (n=16)	Alere Determine™ Syphilis TP (Alere™ Médical Co Ltd) (n=16)	Cypress Diagnostics Syphilis Quick test (n=16)	SD Bioline Syphilis 3.0 test (Standard Diagnostics INC) (n=16)
Clarity of the test pamphlet	(n=16)	(n=16)	(n=16)	(n=16)
Difficult to understand	2	2	1	1
Moderately clear	2	7	6	4
Very clear	12	7	9	11
Complexity of technique	(n=16)	(n=16)	(n=16)	(n=16)
Complex	1	0	0	0
Moderately complex	1	2	1	1
Very easy	14	14	15	15
Time needed for performing	(n=16)	(n=16)	(n=16)	(n=16)
Long	0	4	0	0
Equivalent	9	10	10	8
Short	7	2	6	8
Time need for results	(n=16)	(n=16)	(n=16)	(n=16)
Time indicated in pamphlet	15	14	15	15
Time indicated plus 5 minutes	1	2	1	1
Ease of result interpretation	(n=16)	(n=16)	(n=16)	(n=16)
Moderately easy	2	4	7	2
Very easy	14	12	9	14

Discussion

This is the first evaluation of the performance and the characteristics of commercially available rapid diagnostic syphilis tests for Burkina Faso, and it allows the identification of the test that is adapted to the context of the country. To our knowledge, two of the tests, Cypress Diagnostics Syphilis Quick test and *Accu-Tell® Rapid Anti-TP*, were for the first time compared to other rapid tests for syphilis in West Africa.

All the tests used an immunochromatographic detection of anti-Treponema pallidum antibodies. These tests used one or more of several similar recombinant Treponema pallidum antigens, although their diagnostic performances in our study were different. With a sensitivity of 93%, Alere Determine™ Syphilis was the most sensitive of the four rapid syphilis tests. It was followed by SD Bioline Syphilis 3.0 and Cypress Diagnos-

tics Syphilis Quick test (Se = 90%), with *Accu-Tell® Rapid Anti-TP* being the least sensitive (Se = 78%). In general, the four tests demonstrated a good diagnostic specificity for syphilis (95 – 98%). Taking into account the two diagnostic criteria of sensitivity and specificity, our study showed that Alere Determine™ Syphilis had higher diagnostic performance than the four evaluated tests (Se = 93%, Sp = 98%) followed by SD Bioline Syphilis 3.0 (Se = 90%, Sp = 98%). The good diagnostic performance of these rapid tests compared to other tests has been reported in the literature¹⁰⁻¹³. However, few data exist regarding the performances of Cypress Diagnostics Syphilis Quick test and *Accu-Tell® Rapid Anti-TP*.

The performance of the tests was different than what was indicated in the manufacturers' pamphlets. Our results showed lower values than those reported for Cypress Diagnostics Syphilis Quick test (99.3% and

99.5%), Alere Determine™ syphilis TP (100% with serum), and SD Bioline syphilis 3.0 (99.3% and 99.5%). The pamphlet for Accu-Tell® Rapid Anti-TP did not give any indication of performance. This data, which is crucial in the choice of diagnostic tests, is unavailable in the current published literature. This result calls into question the criteria used for obtaining market authorization from the Ministry of Health to sell rapid tests in Burkina Faso. Additionally, this result emphasizes the need to evaluate available tests on the local market to properly inform policy decision makers.

The performances of Cypress Diagnostics Syphilis Quick test, Alere Determine™ syphilis TP, and SD Bioline syphilis in this study were in accordance with the threshold set by the WHO⁷, which recommends a minimum sensitivity of 85% and a minimum specificity of 95%. The low sensitivity of Accu-Tell® Rapid Anti-TP (78%) when compared to the WHO threshold shows that this test is inappropriate for syphilis testing in Burkina Faso.

The sensitivities found for Alere Determine™ syphilis TP and SD Bioline syphilis 3.0 are below those found by Herring et al.¹⁴ using stored serum samples in Gambia (100%), Tanzania (96% and 94%), and South Africa (96% and 94%). However, their specificities are higher than those found by Herring et al. and Mabey et al.¹³ and similar to the results obtained in China. This variation in performance could be explained not only by ambient storage conditions and use of the different tests but also by the use of fluorescent treponemal antibody, absorbed (FTA-ABS) as reference test and the type of specimen used. This study, whose objective was to evaluate rapid syphilis tests commercially available in Burkina Faso, used tests bought or received by intermediaries of local distributors. A direct order of rapid tests from the manufacturer would have permitted the traceability of the tests evaluated.

Regarding the evaluation of operational characteristics, no test was found to be easier to use than any other. We found all four tests to have very good operational characteristics. In fact, the majority of respondents found that the results were very easy to interpret, and the time required to use the tests was similar to that of existing tests for HIV and malaria. These results are corroborated by Herring et al. for Alere Determine™ syphilis TP and SD Bioline syphilis 3.0. Other studies have also shown rapid diagnostic syphilis tests to be easy to use¹⁵ but this criterion is not the most important in choosing

a diagnostic test. Although perceived favorably by the healthcare professionals, the four test kits were missing equipment. This equipment, such as alcohol swabs, lancets, pipettes, and capillary tubes, is necessary to use the tests in the field. We recommend that the distributors include them in the kits to ensure correct use of the tests.

Of the four tests, three can be performed using whole blood. Studies have documented the performance of Alere Determine™ syphilis TP in both the laboratory as well as in real-world situations¹³. Given its simplicity and its good performance in our study, which is in agreement with data collected in previous studies by other research teams, Alere Determine™ syphilis TP seems to be adapted to syphilis testing in Burkina Faso. While our study presented the laboratory performance of these tests when used with serum samples, their performance with whole blood will be different¹⁶. In addition, providing diagnostic tests to CSPSs would allow for the collection of more information on the effects of storage conditions on test performance when used in rural settings. Moreover, we did not evaluate the effects that additional infections, such as HIV or malaria, could have on the performance of these tests in real-world situations with whole blood.

Conclusion

Rapid syphilis tests in limited-resource countries can help diagnose syphilis in CSPSs that, until now, have used a syndromic approach to STI diagnosis. Our study allowed us first to confirm the good performance of three of four rapid syphilis tests in Burkina Faso. Additionally, it allowed us to identify Alere Determine™ Syphilis TP as the test that is adapted to Burkina Faso. More research on the feasibility and acceptability of these rapid syphilis tests in first-level healthcare centers should allow for the effective implementation of the recommendation for systematic testing of pregnant women.

Acknowledgements

This research was partially funded by an African Doctoral Dissertation Research Fellowship award offered by the African Population and Health Research Center (APHRC) in partnership with the International Development Research Centre (IDRC) and the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) received by Fadima Yaya Bocoum for her PhD.

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