EXPANDED PROGRAMME FOR IMMUNISATION: REVIEW OF THE WESTERN CAPE DEPARTMENT OF HEALTH PUBLIC PRIVATE PARTNERSHIP

Student Name: Dr Jesse Werner

Supervisor names: Associate Professor Susan Cleary and Professor Andrew Boulle

Degree: Master of Medicine in Public Health Medicine

School of Public Health and Family Medicine

University of Cape Town

Declaration

The research reported is based on independent work performed by myself and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree to any other university. This work has not been reported or published prior to registration for the abovementioned degree.

This dissertation has been submitted to the Turnitin module (or equivalent similarity and originality checking software) and I confirm that my supervisor has seen my report and any concerns revealed by such have been resolved with my supervisor."

Name: Jesse Werner

Student number: WRNJES002

Signed by candidate

Signature:

Date:

23-04-2021

Dedication

I dedicate this work to my family and friends who have been an incredible support during this part of my life journey. To my husband Donfrey, thank you for all your encouragement and tremendous support. To my daughters Adina and Noah, you both have added immensely to my learnings during this season, thank you.

Finally, to my Lord Jesus, thank you for your continuous grace.

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Abstract

Background: The demand for healthcare services has been steadily increasing over the years whilst the health system is subjected to increasing resource limitations. The private sector has therefore, in various ways, including Public Private Partnerships, been viewed as a means to address these resource limitations. The Western Cape Department of Health has undertaken to expand the Expanded Programme for Immunisation as a Public Private Partnership. The programme aims to improve population health outcomes through increased vaccination coverage and service access. Benefits and challenges of such partnerships have been identified in various contexts. However, there is a significant research gap pertaining to public partnerships with for-profit entities, particularly in Sub-Saharan Africa.

Objectives: The study sought firstly to describe the socio-demographic characteristics of clients who utilised the Expanded Programme for Immunisation public private partnership services in the 2016/17 financial year. Secondly, to compare the socio-demographic characteristics of those using the Expanded Programme for Immunisation public private partnership services to those using the Expanded Programme for Immunisation services in Western Cape public sector facilities. Thirdly to describe the proportion of Expanded Programme for Immunisation public private partnership clients who have utilised public sector facilities for healthcare in the Western Cape. Finally, to describe the provincial health staff experiences of the service.

Methods: A descriptive quantitative cross sectional study and 12 semi- structured interviews were undertaken to fulfill the objectives of the study. The study population was clients who utilised the Western Cape Department of Health Expanded Programme for Immunisation services from April 2016 to March 2017 in the Western Cape Province. Convenience sampling of public private partnership clients was conducted which enabled the descriptive analysis whilst a random sample of public sector immunisation clients enabled the socio-economic status comparison to the public private partnership clients. Socio-economic status was analysed by reviewing the annual head of household income of clients estimated by client postal code. Western Cape Government staff were selected for interviews to gain insights into provinical staff experiences of the partnership. This was conducted by snowball sampling methods. Univariate analysis was conducted on data submitted by 80 private partners and thematic coding was used to analyse the staff interviews.

Results: The proportion of provincial Expanded Programme for Immunisation client visits attributable to the public private partnerships was approximately 12% in 2016/17. The 80 participating private partners provided almost 60, 000 vaccinations to 23,695 clients in the period of a year. The public private partnership appears to be accessed by users who are of similar socioeconomic status to the Expanded Programme for Immunisation clients accessing public sector facilities. Additionally, the small proportion (12.2%) of public private partnership clients having access to medical insurance further supports the findings of the similar socioeconomic profile of the two groups. 42.7% of public private partnership clients were found to have visited public sector facilities therefore suggesting that in the absence of the public private partnership they might otherwise have utilised the public sector to attain the service. Notwithstanding concerns around management and governance, the initiative is generally appreciated and supported by government stakeholders.

Conclusions and recommendations: The Western Cape Department of Health Expanded Programme for Immunisation public private partnerships operate at a scale that accounts for a meaningful proportion of the immunisation coverage and is utilised by clients of similar socio-economic status when compared to Expanded Programme for Immunisation clients accessing public sector facilities. The small proportion of public private partnership clients having access to medical insurance suggests public private partnership clients might otherwise have utilised the public sector in the absence of the partnership. Overall, the public private partnership has been appreciated by the Western Cape Department of Health staff and affords clients a degree of financial risk protection. Future research areas include an economic evaluation, a benefits incidence analysis and the describing barriers to uptake of the service from the perspective of stakeholders external to the Western Cape Department of Health.

Contents

List of Abbreviations

PPP	Public Private Partnership
WC	Western Cape
WCG: H	Western Cape Department of Health
EPI	Expanded Programme for Immunisation
LMIC	Low to Middle Income Countries
WHO	World Health Organisation
NPO	Non-profit Organisation
SES	Socio-economic Status
UHC	Universal Health Coverage
NHI	National Health Insurance
UCT	University of Cape Town
CI	Confidence Interval
N	Number

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Part A: Research Protocol

Summary

The Expanded Programme for Immunisation (EPI) is a health service initiative which aims to improve population health outcomes by decreasing mortality and morbidity related to infectious diseases. In an attempt to increase vaccination coverage and service access, the Western Cape Department of Health (WCG: H) entered into a number of Public Private Partnerships (PPPs) with various service providers including pharmaceutical retailers, baby wellness clinics as well as general practitioners operating in the private sector.

In the Western Cape (WC) immunisation services are rendered by private-for-profit, non-profit and public health care service providers. However, the bulk of population health services are delivered by the public sector (McIntyre & Ataguba, 2017). Public sector services can be further categorised into provincial and municipal facilities which provide immunisation services at primary health care level (Western Cape Department of Health, 2011).

The Business Development Unit is the directorate within WCG: H which supports district and subdistrict managers of the PPP and enables governance processes thereof. A total of 196 for-profit partners existed in the 2016/17 financial year. 29% of the providers were located in the rural districts; of which 55% are located in Eden, 21% are in the Winelands and 24% are located in the West Coast. There were no partners located in the Central Karoo and Overberg region. Of those located in the Metro district; 42% were located in the Southern-Western substructure, 25% located in Northern-Tygerberg substructure, 20% in Eastern-Khayelitsha and 13% in Klipfontein-Mitchells Plain substructures respectively.

This study aims to assess the demographic and socioeconomic profile of clients who utilise EPI PPP services from WCG: H for-profit partners. Additionally, the aim is to explore the WCG: H EPI staff experiences of the initiative. Findings from this research will inform policy decisions related to future as well as existing provincial PPP initiatives. A descriptive quantitative cross sectional study and semi-structured interviews will be used to achieve the study aims.

Introduction

1. Background

The South African Government has committed to addressing health service challenges which exist largely as a result of the country's history. Equity in health services has been addressed through legislation such as the National Health Act, 61 of 2003 (National Department of Health, 2004). Equity is further addressed in policy documents such as the Strategic Plan 2015/16 – 2019/20 (National Department of Health, 2015). This is in line with the Constitution's provision of access to healthcare for children (Constitutional Assembly, 1996). The EPI is one of the National health initiatives targeted to improve population health outcomes by decreasing

mortality and morbidity related to infectious diseases (Western Cape Provincial Department of Health, 2017).

In 2012 the first call for service, from WCG: H, was issued in the public domain with the goal of formalising and standardising EPI services rendered in partnership with the private sector (Western Cape Government, 2012). The PPP policy document was formulated in 2012 and detailed various operating procedures and the governance of state vaccine stock issued to private health care providers.

In an attempt to strengthen the EPI programme, the WCG: H formally entered the EPI public private partnership in March 2016 (Western Cape Department of Health, 2016). Prior to this, private partners received stock from the WCG: H. This stock was managed at a local level, mainly at medical depots, as reported by WCG: H stakeholders of the partnership. In an attempt to improve efficiencies and governance, the management of the partnership process was changed. A centralised management mechanism was adopted with official sign-off of the policy in 2016. Therefore, private partners with varying forms of agreements with managers of local medical depots were required to officially apply to be a partner in order to get access to free immunisation stock. Applications would be reviewed by the central management team and if the applicant successfully met the criteria to be a partner, only then would registration occur. Following this, the private partner would be able to access the stock available for the EPI PPP services. Therefore, the PPP contractual arrangements transitioned becoming increasingly formalised over time through the centralised management mechanism.

2. Significance

The EPI PPP initiative is thought to increase access and therefore utilisation of immunisation services in both the Metro and Rural districts. This enables the provincial targets related to vaccination coverage. Research conducted by Patouillard, et al.(2007), focused on for-profit organisations and included contract arrangements related to social marketing, pre-packaging of drugs, training, hygiene, supply chain, and maternity services. The study showed an increase in service utilisation within poorer communities. However, the quality of services was questioned as sub-optimal services were found to be provided by private partners. The authors further highlighted the research scarcity and related equity impacts of such initiatives. Further research into governance and management process related to these initiatives was therefore recommended.

The Business Development Unit has undertaken to various monitoring and reporting of the partnership. Although these processes have been adopted by the unit, population consumption of EPI PPP services from for-profit partners as well as the demographic and

socioeconomic profile of the population utilising the services have yet to be established. Furthermore WCG: H staff insights on the operational processes require further exploration.

3. Literature review

With the increasing demand for healthcare, in the context of a health system burdened with austerity measures, the private sector has been viewed by some countries as a means to address the resource gap (Ruckert & Labonté, 2014). PPPs have been considered instrumental for the ascertainment of effective country-wide health outcomes. With increasing attainment of these partnerships over the last few years, research has illustrated diverse collaborations between the private and public sector (Hernandez-Aguado & Zaragoza, 2016). Collaborations are seen to vary in purpose, design, composition and arrangement. With varying arrangements and partner roles for PPPs between and within developed and developing countries (Levin & Kaddar, 2011), research efforts to evaluate and compare their merit are often challenging (Hernandez-Aguado & Zaragoza, 2016). Numerous governments have however adopted a form or forms of these collaborations as a mechanism to strengthen their respective health systems (Björkma & Raman, 2015). The literature review will focus on the benefits of public private partnerships, vaccination coverage in South Africa and equity in vaccination coverage.

Benefits of Public Private Partnerships

Research has described benefits of public private partnerships in health to include improving access to care, quality of care, and enabling health system equity and efficiency (Björkma & Raman, 2015). Further benefits have been described by the World Health Organisation (WHO) as the improvement in a health system's ability to capitalise on the strengths and weaknesses of the public and private sector (WHO, 2017). This is operationalised through the pooling of resources, risk and competencies to improve the health of the public (Kula & Fryatt, 2014). Of importance, these benefits are not realised without paying attention to private sector governance, regulation and accountability (Björkma & Raman, 2015). The capacity of developing countries to ensure effective governance is however questionable (Ruckert & Labonté, 2014).

Vaccination Coverage in South Africa

In South Africa vaccination coverage is enabled by immunisation services rendered in both the private and public sector (McIntyre & Ataguba, 2017). However, there are significant challenges related to accessing data from the private sector due to sub-optimal reporting (Aung & Dlamini, 2017). In the 2016/17 financial year, the annualised coverage target for immunised children under 1 year in South Africa was 92%. The country managed to achieve

coverage of 82.3% (National Department of Health, 2017). Reasons for the lower coverage included national shortages of vaccinations which brought to light the health system challenges related to the EPI programme. When comparing low- and middle-income countries (LMIC), challenges further include the increasing gap in vaccination coverage (Ozawa, et al., 2016; Shen, et al., 2014). Within the WC immunisation coverage, for children under the age of a year, varied from 75% in the 2016/17 financial year to 82.9% in the 2018/19 financial period. For reasons similar to WCG: H, the national target of 92% was not achieved (Western Cape Government Department of Health, 2018).

Considering Equity in Vaccination Coverage

Equity is defined by Braveman, (2014) as

> "The principle underlying a commitment to reduce—and, ultimately, eliminate—disparities in health and in its determinants, including social determinants" (Braveman, 2014, pg 5).

Consideration of equity in immunisation coverage should therefore inform initiatives supporting the national immunisation programme. Equity outcomes of for-profit partners have varied within populations and are seen to be dependent on the contextual factors. Therefore, some PPPs have not necessarily resulted in equal or equitable utilisation by all population groups (Lydon, Raubenheimer, Arnot-Krügerc, & Zaffran, 2014). More research is required to inform conclusions relating to the effect of EPI PPPs on equity in Sub-Saharan Africa (Antai, 2009; Bellamy, 2002; Patouillard, et al., 2007).

Motivation for the study

WCG: H has entered into EPI PPPs with various private stakeholders. Although PPPs have numerous resource implications for an already constrained public sector, in many developing countries PPPs have proven to increase access to services (Arsenault, et al., 2016). The EPI PPP has numerous resource implications for WCG: H which include financial, human and administrative support. The outcome of resource inputs and the extent to which it contributes toward the vaccination coverage targets in the EPI PPP programme requires further study.

Purpose

The purpose of the study is to inform and make recommendations for the WCG: H provincial EPI programme by conducting the review of EPI PPPs in WCG: H.

Aim

This study aims to assess the demographic and socio-economic profile of clients who utilise EPI PPP services from WCG: H for-profit partners. Additionally, the study aims to explore the WCG: H EPI staff experiences of the initiative.

Objectives

The objectives of the study are to:

- Describe the socio-demographic characteristics of clients that utilised EPI PPP services in the 2016/17 financial year;
- Compare socio-demographic characteristics of those using EPI PPP services to those using EPI services in WC public sector facilities;
- Describe the proportion of EPI PPP clients who visit public sector facilities in the Western cape; and
- Describe WCG: H staff experience of the EPI PPP service to identify challenges and succeses of the programme.

Methods

Definition of terms

Public Private Partnership: "A wide variety of ventures involving a diversity of arrangements, varying with regard to participants, legal status, governance, management, policy-setting prerogatives, contributions and operational roles. They range from small, single-product collaborations with industry to large entities hosted in United Nations agencies or private not-for-profit organizations" (WHO, 2017).

Non-profit organisation: "A business or organisation whose goal is helping the community and is concerned with money only as much as necessary to keep the organization operating" (Business Dictionary, 2019)

*For-Profit Organisation: "*A business or other organization whose primary goal is making money" (Business Dictionary, 2019)

Study design

A descriptive quantitative cross sectional study and semi-structured interviews will be conducted, as this design is most appropriate to achieve the study objectives. The study design will therefore include a quantitative component and an interview component. The latter will enable the staff experience of the programme to be described.

1. Quantitative Component

The description of for-profit partner clients having utilised EPI PPP services necessitates the quantitative component of the study.

1.1 Population

The study population was the children who utilised WCG: H EPI services from the beginning of April of 2016 to the end of March 2017. With the majority of the WC population residing in the Cape Metro, it is important to note its further subdivision into four substructures which include Southern-Western, Northern-Tygerberg, Eastern-Khayelitsha and Klipfontein-Mitchells Plain (Western Cape Government Department of Health, 2017).

1.2 Sampling

The sample will include clients who utilised EPI services provided by for-profit partners in the Rural and Metro health districts in the 2016/17 financial year. For-profit partners include private hospitals, pharmacy retailers, general practitioners and baby wellness clinics where services provided are driven by clinical nurse practitioners. Convenience sampling will be conducted.

Inclusion criteria:

Utilisation will be described through analysis of clients having attained EPI services from for-profit partners able to meet the following criteria:

- From the Metro and Rural districts in the 2016/17;
- Provide inpatient and/or outpatient health services;
- Submit data in an electronic format; and
- Willing to participate in the study, independent of the duration of the duration of EPI partnership with the WCG: H.

There are facilities which may not have electronic records which preclude them from participating in the study. No further information on partners unable to submit electronic data was collected. This is understood by the researcher to be a limitation. Reporting will include the proportion of for-profit partners having participated in the study.

Sample size estimate for estimating the socio-economic status (SES) differences in clients accessing WCG: H EPI PPP services versus government provided EPI services

The sub-analysis of the SES differences between clients having utilised the services from the for-profit private partners in comparison to those using WCG: H facilities will also be conducted. All for-profit partners meeting the inclusion criteria will be included in the sub-analysis. For the comparator, a simple random sample of clients attending WCG: H primary

health care facilities for EPI services will be drawn. The sample size will comprise of 5% of the live births from the beginning of April 2016 to the end of March 2017 and will be sourced from the WC Provincial Data Centre database.

For both groups SES will be estimated through determinining the average annual head-of-household income, by postal code, using income data from Census 2011 (median applied to income bands – excerpt in appendix 5). While this is a crude approach, it is necessitated owing to a lack of data indicating the in the sample. It is therefore assumed that clients reporting a particular postal code would have the mean head-of-household income from that postal code as per Census 2011. Although no precise estimates are available on the differences in SES estimates between the clients utilising the WCG: H facilities versus private partners, we hypothesise that the SES would be higher for the clients who utilise private partner services.

In order to be powered at 90%, to detect a 10% difference in the SES status of the independent groups (with annual head of household income estimated at R103 204 as per Census 2011), with equal numbers of clients in the PPP and public sector groups and a level of significance at 0.05; a minimum of 4206 client visits would need to be included in the PPP sample. In the sub-optimal case where the sample sizes are not met and smaller client numbers are available, an overall sample size of 788 could enable analysis with the study powered at 80%. This would be able to detect a 20% mean difference between the groups. We seek and expect to comfortably exceed 2000 clients based on preliminary information on data availability, therefore the study will most likely be adequately powered to address this potential challenge.

1.3 Instruments and data sources

Retrospective data sourced for the 12 months in the 2016/17 financial year will be obtained from the following sources:

- Private retail partner records submitted on an electronic database; and
- The WCG: H Provincial Health Data Centre

Analysis of the proportion of WCG: H EPI PPP client visits to public sector facilities will be conducted using the Data Centre database. The analysis will be restricted to the PPP client record having noted a visit at a government facility within the province three years prior or three years after their first record as a PPP client. Client identifiers will be utilised to ascertain the proportion of paediatric clients utilising services at WC municipal and provincially managed government facilities. Identifiers include:

- Client Name and Surname;
- Client Date of Birth; and
- Client Address.

The proportion of WCG: H EPI PPP client visits to public sector facilities will be restricted to government clinics within the province in keeping with the study objectives.

Variables

Data collected will yield the following tabulated variables post data anonymisation conducted by a trusted third party:

Table 1: Data elements requested from private partners

Field:
Client Name and Surname
Client age
Gender
Delivery facility
Suburb
Service provider name
Medical aid (Yes/No)
Date service received
Level of education of caregiver
Home language
Occupation of caregiver
Smoking status of caregiver
Number of children of caregiver
Marital status of caregiver
Immunisation catch up required (Yes/No)

Variables will include both categorical and numerical data and analysis will be conducted accordingly.

1.4 Data Analysis & Management

Secondary data will be sourced from the aforementioned sources. Data will undergo a process of linkage and de-identification by the University of Cape Town (UCT) School of Public Health and Family Medicine Health Intelligence Initiative, acting as the trusted third party.

Data Transfer

Password protected data will be transferred directly to the trusted third party via Lift Server or the UCT Filesender. The third party will receive, send and store the data in a secure access-controlled environment.

Data processing

The data will be treated at all times with absolute confidentiality and will not be shared or used for any other purpose except the data processing. The data processing will be undertaken only by specific analysts at UCT. Separation of clinical from identifying data at source will not be necessary in this case because the presence in the dataset is synonymous with having received immunization, which is the only clinical field of interest. Therefore, the process does not risk revealing any other clinical details related to the client. Keys for data re-identification will be stored in a high security environment until such time as they are permanently destroyed at study conclusion. The third party will similarly process the data of clients who have utilised services in the province. Standard data linkage approaches will be used to match records between the two datasets. The matched data will be linked and stripped of all identifying data prior to release to the researcher.

Dataset release

Final output of anonymised datasets will be transferred only to the researcher. Secure transfer with password protection will be used for output data at all times. Microsoft Excel and Word will enable storage of data once de-identified on the researcher's password protected computer.

Dataset deletion

The datasets provided and the output dataset will be deleted permanently by UCT at the end of December 2021.

Data Analysis and reporting

Reporting will be conducted at an aggregate level. Exploratory data analysis will be performed in order to detect and address errors or unexpected patterns within the data. Univariate analysis will be conducted for both categorical and numerical data. Numerical data description will include measures of central tendency or dispersion depending on the data distribution. Should the data not be normally distributed, the median and interquartile range will be described. Additionally, numerical variables will be explored using appropriate graphical representations. Categorical data will be explored using proportions and frequency tables.

Prevalence ratios will be used as the measure of occurrence. The data collated for the quantitative analysis will be analysed in Stata v.15 (2017).

2. Describing staff experiences of the programme

Semi-structured interviews will be conducted with WCG: H staff. These interviews will ultimately inform the aim by gaining insights into the WCG: H staff experiences of the successes and challenges in the WCG: H EPI PPP.

2.1 Participants and Sampling

Due to the resource constraints of the study the sampling method will be purposive. The study population is defined as staff with service delivery or management experience of the WCG: H EPI PPP. Non-probability snowball sampling will be conducted where 12 staff members will be recruited for study participation. Initial invites will be sent to managers based at the WCG: H Substructure Offices as well as managers from the Business Development Unit.

Inclusion Criteria:

WCG: H staff (all of whom are over the age of 18) that have more than 1 year work experience in the WCG: H EPI PPP programme will be included. Furthermore, participants are required to represent one or more of the following service components:

- WCG: H Cape Medical Depot;
- WCG: H Business Development Unit;
- WCG: H Pharmacy Service Managers; and
- EPI PPP Programme Coordinators.

2.2 Instruments and data sources

Questionnaire administration

Data related to this component of the study will be obtained using a semi-structured questionnaire administered by the interviewer (Appendix 3). All participants identified in the sampling strategy are anticipated to be fluent in English. The semi-structured interview will therefore be conducted in English only. Interviews be conducted either telephonically or face to face and each is estimated to take approximately 45 minutes. The interviewer will have experience and training in conducting interviews for the purpose of this research as offered by UCT.

Questionnaire development

The questionnaire has been developed by the researchers and investigators of the study. No names will be recorded on the questionnaire and participants will be assigned a number in order to maintain confidentiality.

The questionnaire has been adapted from the validated research tools utilised in the Critical Success Factors for Incident Management Partnerships report (Minnie, 2011) and Critical Elements of Routine Immunisation Programs study (Shen, Fields, & McQuestion, 2014). Questions have been adapted to the research context to enable dependability and validity. The semi-structured interview themes which the interview will cover include:

- Participant information;
- Goals and Policy;
- Management and Organisation;
- Human Resources;
- Information Management; and
- Operational Processes.

Further information on the detail of the questionnaire can be reviewed in Appendix 3.

2.3 Data Analysis

Primary data obtained from the semi-structured interviews will be transcribed using Microsoft Word and thereafter imported into One Note data management software programme. Data entry, triangulation and validation will take place on an ongoing basis during data collection. This information will be stored on the researcher's password protected computer. At the conclusion of the study, the data will be archived.

Data captured in the participant interviews, will be analysed using thematic coding. The thematic coding strategy will be conducted through the analysis of participant perceptions of the challenges and successes of the WCG: H EPI PPP. Coding will be done manually in three cycles. The first will be based on pre-established codes as per the measurement tool, the second cycle will account for references external to codes identified by the measurement tool and the third will be the collation of codes into themes which inform the conclusions. A limitation to the analysis and confirmability is the lack of resources to enable independent data analysis.

2.4 Pilot Study

A pilot of the semi-structured interview tool will be conducted prior to initiating the study. It will be undertaken with 2 individuals, and will be performed in a manner reflecting the methods

used to describe the WCG: H staff experiences of the programme. One of these pilot interviews will be conducted telephonically and another interview conducted face to face.

The pilot study will assess the functionality and feasibility of the methods and procedures related to the questionnaire administration. Participants will have the opportunity to comment on the clarity of the questionnaire and offer suggestions for improvement. It will therefore enable assessment of the logistics and review of the tool based on challenges identified that may arise. The pilot study will allow the researchers to determine a more accurate representation of the time needed to complete data collection in the semi-structured interviews. After the pilot study has been conducted the necessary changes will be made to the research tool.

Validity and Reliability

Validity and reliability have been enabled as far as is possible with the aforementioned study design and methods. However, concerns of selection and information bias remain. Selection bias is realised due to the convenience and snowball sampling methods which will be conducted for the different components of the study. Furthermore, the PPP data is requested in electronic format. Although the number of providers using “paper-records” were described as minimal, this is a potential source of selection bias. Limitations to the confirmability and validity of the analysis for the interviews is the lack of resources to enable independent data analysis. Bias was however limited by ensuring the sample size is adequate. Methods including the use of a validated tool and data validation by various methods including triangulation of data from the semi-structured interviews further reduces potential bias.

Study limitations

The proportion of WCG: H EPI PPP clients with evidence of public sector visits will be conducted by the Data Centre. Accuracy of the analysis is based on the provision of adequate patient level data. Secondary data collected will be used for analysis of the proportion of WCG: H PPP clients having visited government facilities using client name, surname and date of birth. Therefore, the accuracy of the proportion of clients having visited public sector facilities is dependent on the quality of data inputs submitted by private providers. The client visits are however dependent on more than one data element, this increases the sensitivity of the analysis and therefore the accuracy of the estimated proportions. The researcher realises the estimation may be higher should the caregivers who are financially responsible for the child, having utilised the public sector services, were also analysed. Therefore, the proportion of clients may be higher if the analysis methods take this into account.

The crude data related to the use of Census 2011 annual head of household income to estimate SES is realised as a limitation of the study. However, given that data is sourced retrospectively it is not possible to include questions that would provide a better indication of the SES of these clients.

The semi-structured interviews will be limited to WCG: H staff having EPI PPP operations or management as part of their portfolio. Hence, the lens from which the EPI PPP programme is described is from the perspective of WCG: H staff only. It does not extend to include private partners and clients accessing or not accessing the service and therefore should not be generalised to all stakeholders. These limitations related to the scope of the study further highlight the need for further research related to the EPI PPP initiative in the WC.

Ethical Considerations

The protocol seeks to enable ethical approval sought from the UCT Human Research Ethics Committee.

Ethical and Regulatory Compliance

This study complies with the latest version of the Declaration of Helsinki (2008) as well as the Department of Health: Ethics in Health Research: Principle Structure and Processes (2004). Permission to engage with staff will be sought from the WCG: H: Health Research Committee, following approval by the UCT Health Research Ethics Committee.

Risks & Benefits

Risks to participants relate to confidentiality. This risk is mitigated by the anonymisation of data by a trusted third party as well as the processes described in the data analysis and management the study.

Although the study will not be of immediate benefit to the study participants, the insights gained will be imperative in the management of the EPI PPP initiative. Therefore, insights will enable future management decisions and consequently strengthen the WCG: H EPI PPP. Learnings from this initiative will add to the WCG: H institutional knowledge on WCG: H PPP staff experience and therefore potentially enable both effectiveness and efficiency in management and service operations. Furthermore, as there are resource implications to the WCG: H, learnings will enable more robust decision making and allocative efficiency at a departmental level. The study conducted requires no funding.

Respect for persons

Consent will be obtained from all staff members participating in the semi-structured interviews (Appendix 1, 2 & 3). Potential participants recruited will be informed that participation in the

study is entirely voluntary. Any individual approached will have the right to decline participation at any time. All subjects will be treated in a respectful and dignified manner and face to face interviews will be conducted in a private room. Breach of confidentiality will be further mitigated by the researcher not having access to named data through the use of a trusted third party. No incentives will be offered to encourage participation nor will the option to decline have any impact on the individual.

Conflicts of Interest

At the time of preparing the manuscript the researcher was a salaried employee of the WCG: H and a student at UCT.

Responsible Persons

Jesse Werner will be the researcher, (JW) Susan Cleary (SC) will co-supervise with Andrew Boulle (AB) who has the role of principal investigator. JW will conduct the interviews and will have access to the results of the questionnaires. The trusted party will provide only JW access to de-identified individuated data. JW is responsible for the design of the study, protocol submission, data collection, analysis and reporting. AB and SC will be involved in the report review process as well as presentation and dissemination of findings on various relevant fora.

Resources and logistical arrangements

Stationery will be provided by the WCG: H, other expenses will be the responsibility of the researcher (Table 2).

Table 2: Resources required for the study

Resource	Provider
Stationery	WCG: H
End Note data management software	WCG: H
Stata software Access	Access via UCT
Telephone with network for interviews	WCG: H
Petrol for travel to participants	Researcher
Computer	WCG: H

Logistical arrangements, as tabulated below, range from the period of February 2020 to April (Table 3).

Table 3: Logistical arrangement timelines

Activity	Proposed time period
Obtain UCT Human Research Ethics Committee Approval	February 2020- April 2020
Obtain Provincial and City of Cape Town Research Approval	April 2020
Data collation	May 2020
Staff interviews	May 2020
Data capturing and analysis	June-August 2020
Report compilation and dissemination	September –December 2020

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Part B: Background and Literature Review

Background

1. Research in context

The South African Government has committed to addressing health service challenges which exist largely as a result of the country's history. Although inequity remains a challenge throughout South Africa, efforts to mitigate inequity in health services has been undertaken through legislation such as the National Health Act, 61 of 2003 (National Department of Health, 2004) and further addressed in policy documents such as the Strategic Plan 2015/16 – 2019/20 (National Department of Health, 2015). This is in line with the Constitution's provision of access to healthcare for children (Constitutional Assembly, 1996). The Expanded Programme for Immunisation (EPI) is a global initiative undertaken to improve population health outcomes by decreasing mortality and morbidity related to infectious diseases.

Having realised the advantages of immunisations to public health, the World Health organisation introduced the EPI in 1974. The South African national policy for EPI is in keeing with the WHO EPI guidelines and immunisations are scheduled over various ages (National Department of Health, 2019). The aim of the programme is to provide vaccinations to all (World Health Organisation, 1980). However, the aim of the local programme is to "prevent death and reduce suffering from infections that can be prevented by immunisation of children and women" (Massyn, Dombo, Barron, & English, 2013) The Western Cape has instituted the programme to address childhood morbidity and mortality (Western Cape Provincial Department of Health, 2017).

The Western Cape Province comprises of six health districts namely the Cape Metro, West Coast, Central Karoo, Overberg, Eden and Winelands. Immunisation services are offered locally by private-for-profit, non-profit and public sector service providers. However, the bulk of population health services are delivered by the public sector (McIntyre & Ataguba, 2017). For-profit service providers include pharmaceutical retailers, private hospitals, baby wellness clinics as well as general practitioners operating in the private sector. In an attempt to increase vaccination coverage and service access, the Western Cape Department of Health (WCG: H) entered into a number of Public Private Partnerships (PPP) with various service providers.

In 2012 the first call for service, from the WCG: H, was issued in the public domain. The goal of the call was to formalise and standardise the EPI services rendered in partnership with the private sector (Western Cape Government, 2012). The PPP policy document was formulated in 2012 and detailed various operating procedures and the governance of state vaccine stock issued to private health care providers.

In an attempt to strengthen the EPI programme, and therefore improve efficiencies and governance, the WCG: H officially entered the EPI PPP in March 2016 (Western Cape Department of Health, 2016). The contractual arrangements between the partners transitioned becoming standardised and increasingly formalised over time. Prior to the formalisation process, private partners received vaccination stock from the WCG: H. This was managed at a local level, mainly at medical depots, as reported by WCG: H stakeholders of the partnership. General practitioners were reported as the predominant partners when the initiative commenced. With a change in PPP management and governance arrangements, stakeholders were required to officially undergo an application process in order to become a private partner. Applications would be reviewed by the WCG: H Business Development Unit and further reviewed if the applicant successfully met the application criteria. The next steps in the review process would be an assessment of the private partner ability to access and store the centrally managed vaccination stock. If the application was successful partners were registered and the WCG: H would make stock available to them at no cost.

2. Research significance

The Business Development Unit is the directorate employed within WCG: H to centrally manage and enable governance processes of the PPP (Western Cape Department of Health, 2016). The EPI PPP initiative is thought to increase access and therefore utilisation of immunisation services in both the Western Cape metro and rural districts. Therefore, it enables the provincial targets related to vaccination coverage.

Various monitoring processes of the WCG: H EPI PPP have been reported to be conducted. However, the demographic and socioeconomic profile of the population utilising the services has previously not been established. Furthermore, it is known that engaging staff subsequent to programme implementation is imperative in understanding programme successes and challenges (Lehmann & Sanders, 2007). This has not been undertaken previously for the WCG: H EPI PPP programme and therefore is another research gap. The gaps in data result in limitations in knowledge available to inform management effectiveness, process efficiencies, benefits and governance arrangements of the PPP.

Literature review

1. Objectives:

The objectives of the literature review are to explore the research available, prior to the initiation of the current study, pertaining to:

- Benefits and challenges of PPPs in developed and developing countries;
- Partner roles in vaccination related PPPs;
- Vaccination coverage in South Africa;
- The role of the private sector in contributing to the coverage rates in South Afrcia; and
- The extent of equity in PPPs globally.

2. Search strategy:

The databases made available through University of Cape Town were utilised to conduct the literature search strategy. Those chosen included PubMed, Africa Wide, Cochrane and EBSCO Host.

Search terms and keywords included “Public Private Partnerships”, Expanded programme for immunisation”, “vaccination”, “immunisation”, “effectiveness”, “coverage”, “benefits”, “advantages”, “successes”, “challenges”, “disadvantages”, “developed countries”, “developing countries”, “South Africa” and “Western Cape”. These were used in various combinations.

In addition to literature published online, related publications such as annual reports published by the Department of Health South Africa and the World Health Organisation as well as legislation related to the topic were included.

3. Inclusion criteria:

Literature published from 1996 was included in the review. Research papers that were included were peer-reviewed, published in English and ranged in study designs. Furthermore, the following criteria was utilised:

- Benefits and challenges of health-related PPPs locally and globally;
- Vaccination coverage in developed and developing countries;
- Determinants of effective immunisation programmes; and
- Population access and utilisation of immunisation programmes in developing countries.

4. Selection of Literature

Studies were included in the review after quality control of the abstracts was undertaken by the researcher. Papers which did not meet the inclusion criteria and were not related to one of the objectives of the literature review were excluded.

A total of 112 articles were found on the databases listed above. 38 articles were found to be duplications and were subsequently excluded. A further 20 articles were excluded based on the irrelevance of the titles and/or abstracts. 27 articles did not meet the inclusion criteria. After reading the full text of the articles, only 27 papers were included in the final literature review.

Background to Expanded Programme for Immunisation Public Private Partnerships

The demand for healthcare has been steadily increasing globally over the years. This increase in service demand adds to a burdened health system where numerous challenges such as governmental austerity measures and resource limitations exist. Therefore, the private sector has been viewed by some countries as a means to address the resource gap (Ruckert & Labonté, 2014).

Historically, the private sector has been perceived to be more responsive to the health care needs of developing countries and significant growth of the private sector has been identified in these regions (Kula & Fryatt, 2014). Studies have found the growth of the private sector to be linked to the public sector failures. In the context of the resource limitations, developed and developing countries have adopted various PPP arrangements (Chapman, 2014). However, more recently the private sector has had their quality of services provided questioned in numerous countries. Technical PPP programme quality challenges in LMIC are found to be linked to various conditions including sexually transmitted diseases, malaria and tuberculosis (Patouillard, Goodman, K, & Mills, 2007).

It is a known responsibility of governments to provide quality and efficient health services to the public. Services include numerous health programmes including the EPI (Shen, Fields, & McQuestion, 2014). Immunisations are known to be both a public and private good. Immunisations support the control of infectious diseases and the prevention of epidemics, thereby benefiting society as a whole (Toumi & Ricciardi, 2015). PPPs relating to vaccines are specific initiatives adopted with the objective to strengthen vaccination coverage in populations. Independent of whether there is a partnership process in place, immunisation programmes provide extensive health benefits at a relatively low cost. Globally, the majority of governments have committed to prioritising immunisation coverage. With resource constraints a challenge in many of these health systems, accessible and quality services remain a pertinent health system challenge (Levin & Kaddar, 2011).

In South Africa vaccination coverage is enabled by immunisation services rendered in both the private and public sector. However, the public sector is known to drive health services for the vast majority of the population (McIntyre & Ataguba, 2017). The private sector is estimated to account for approximately 12 to 19 percent of the South African vaccination coverage. This is based on for-profit private sector birth cohorts measured over time (Strachan M. , 2015). There are significant challenges related to accessing immunisation coverage data in the private sector including data not being readily available to key government stakeholders in the health system (Aung & Dlamini, 2017).

In the 2016/17 financial year, the annualised coverage target for immunisation under 1 year of age in South Africa was 92%. However, the country achieved coverage of 82.3% (National Department of Health, 2017). Reasons included national shortages of vaccinations bringing to light the health system challenges related to the EPI programme. These challenges further promote the increasing gap in vaccination coverage when comparing LMIC to developed countries (Ozawa, et al., 2016; Shen, et al., 2014). Within the Western Cape, immunisation coverage under 1 year has varied from 75% in the 2016/17 financial year, to 82.9% in the 2018/19 financial period. For similar reasons described by WCG:H, the national target of 92% was not achieved (Western Cape Government Department of Health, 2018). Furthermore, the demand for healthcare in the public sector renders health facilities overburdened adding to the service access challenge (Ataguba & McIntryre, 2012). With resource scarcities such as these, the private sector role as partner to the public sector has been considered instrumental in the ascertainment of effective country-wide health outcomes (Hernandez-Aguado & Zaragoza, 2016).

> The World Health Organisation (WHO) defines a public-private partnership for health as a:
>
> "wide variety of ventures involving a diversity of arrangements, varying with regard to participants, legal status, governance, management, policy-setting prerogatives, contributions and operational roles. They range from small, single-product collaborations with industry to large entities hosted in United Nations agencies or private not-for-profit organizations" (WHO, 2017, para, 2.).

With increasing attainment and study of PPPs over the last few years, research has illustrated diverse collaborations between the private and public sector (Hernandez-Aguado & Zaragoza, 2016). Contractual arrangements of PPP collaborations are seen to vary between and within developed and developing countries. Variances are noted with respect to purpose, design, and composition making research efforts to evaluate and compare their merit challenging (Hernandez-Aguado & Zaragoza, 2016; Levin & Kaddar, 2011). Numerous governments have

however adopted a form or forms of these collaborations as mechanism to strengthen their respective health systems (Björkma & Raman, 2015).

Benefits and challenges of PPPs

Research has described benefits of PPPs in health to include improving health access, quality of care as well as enabling health system equity and efficiency (Björkma & Raman, 2015) . The WHO further describes PPPs as having the potential to capitalise on the strengths and weaknesses of the public and private sector (WHO, 2017). This is achieved through the pooling of resources, risk and competencies to improve the health of the public (Kula & Fryatt, 2014).

In successful partnerships enablers of health system improvement were found to be the augmentation of resources and the opportunity for private sector regulation and accountability. Success of PPPs has been found to be correlated with the extent of effective regulation by the public sector (Björkma & Raman, 2015).

Kula and Fryatt's (2014), findings in South Africa linked PPP successes to an understanding of what the motivation of each partner was by the public sector. Furthermore, successes were found when both partner expectations were met. This created a culture of innovation and learning. Management commitment to close monitoring and evaluation of the partnership, whilst ensuring capacity and skills availability for contract management, were found to be additional determinants for PPP success.

There is limited evidence describing the improvement of health in poor populations through PPPs. More recently a systematic review has shown the majority of challenges to relate to poor strategic alignment, high transaction costs, poor democratic accountability and sub-optimal governance (Ruckert & Labonté, 2014). Research in developed and developing countries has found a lack of institutional capacity in design, contract management and monitoring to be common limitations to PPP success. As a result, although initiatives are implemented in good faith, few have shown favorable returns in improving health outcomes (Levin & Kaddar, 2011; Patouillard, et al., 2007).

Partner roles in EPI specific Public Private Partnerships

A literature review by Levin and Kaddar (2011), described variations in PPPs contractual agreements. Often governments were seen to provide vaccines, equipment and other supplies to private organisations. In LMIC the majority of PPPs related to vaccinations were found to exist in Asia, Africa, Latin America and Europe. The significance of their roles varied in the different countries. Although very few studies were available, in Europe the role of the private sector included vaccination training and social mobilisation (Levin & Kaddar, 2011). In many developing countries however, the private sector is a key provider of health services at the

level of the community and therefore contribute signficantly to the objectives of the EPI programmes namely:

- Decreasing the infection risk of the unvaccinated population by attaining herd immunity (Deogaonkar, Hutubessy, van der Putten, Evers, & Jit, 2012),
- Aversion of premature mortality, and
- Decreasing morbidity in children (Gavi, 2018; Kula & Fryatt, 2014).

The role of private-for profit service providers further extends beyond the frontline services due to their role as introducers of vaccinations into the market (UNICEF; WHO; World Bank, 2009). In South Africa the knowledge of partnership roles between the private and public sector remains limited. The partner roles and experience in PPPs which exist is poorly documented (Kula & Fryatt, 2014).

Equity in PPPs

The population able to access private for-profit organisations were found to be more likely to have higher educational levels and a higher family income (Levin & Kaddar, 2011). This therefore brings into question the private for-profit sectors ability to address the objective to decrease country-specific inequity in vaccination programmes.

> Equity in healthcare services is described by the World Health Organisation (2017), as
>
> "The absence of avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically" (WHO, 2017, para 1).
>
> Braveman (2014), underscores the aspect of commitment related to equity and described it as
>
> "The principle underlying a commitment to reduce—and, ultimately, eliminate—disparities in health and in its determinants, including social determinants" (Braveman, 2014, pg 5).

The South African Government has committed to addressing equity challenges that are largely as a result of the country's history. Equity in health services has been legislated through the National Health Act, 61 of 2003 and further addressed in the Strategic Plan 2015/16 – 2019/20 (National Department of Health, 2015). Specific reference to equity in immunisation services is also addressed in the aforementioned Strategic Plan in line with the Constitution's provision of free vaccination services for children (National Department of Health, 2017). The Global Alliance for Vaccines and Immunisations exists as a conduit, enabling public and private sector

partnerships for almost 2 decades. The goal is to increase immunisation coverage and decrease inequity in vaccination services globally (Gavi, 2018).

There is limited research and few evaluations conducted on the health outcomes related to equity in vaccination specific PPPs. A systematic literature review conducted by Nelson, et al. (2016), described the challenges related to equitable vaccination service delivery in developing countries. The authors noted scarcity of research in this area as a barrier to health systems improvement. The greatest challenge in generalising findings in the research relates to the scalability of successful interventions. This is due to context variations as well as variations in the supervision or regulation of PPPs (Nelson, Wallace, Sodha, Daniels, & Dietz, 2016).

Research conducted by Patouillard, et al. (2007), focused on for-profit organisations. PPPs included social marketing in health, pre-packaging of drugs, training, hygiene, supply chain and maternity service intitiatives. The study described an overall increase in utilisation of services in poorer communities. Independent of the arrangement between the parties, PPPs undertaken by non-profit organisations were found to increase equity by decreasing the disparities in access to vaccinations.

A study conducted in Nigeria explored the causes of childhood mortality and inequitable access to immunisation services. Authors suggested deficiencies in vaccine and equipment supplies to significantly contribute to high childhood mortality rates (Antai, 2009). A report by Bellamy (2002), described the factors associated with the inequities in Sub-Saharan Africa to be related to individual, community as well as systemic challenges. In the context of Nigeria these aforementioned factors were also found to be pertinent. Children of mothers with a higher SES and who have access to health services were more likely to have had their immunisations when compared to children of mothers of lower SES with less access to health services (Antai, 2009). Limitations in utilisation of vaccination services in South Africa have been correlated with low SES, lower education status, mothers who are aged 25-29 years, rural areas and children with more than three siblings (Fadnes, et al., 2011).

A systemic analysis conducted by Arsenault, et al., (2016) assessed the approaches to monitoring equity in vaccination coverage. It concluded that there were various considerations necessary in equity monitoring. The first was to define the population vulnerability through dimensions such as sex, age, race, ethnicity, migratory status, disability, maternal education, wealth status and geographical location. The dimensions utilised should be informed based on the research context. Consideration should further take into account measures of inequality which commonly include relative and absolute coverage measures. This approach should be utilised when the entire population is assessed. If not, they may generate imprecise estimates.

With this considered, equal coverage should ideally be the benchmark of vaccination coverage measures as this reflects government commitment to moral equality of persons and a right to health for all (Arsenault, et al., 2016).

Conclusion

Although vaccines are known to be one of the most effective measures in reducing childhood mortality and morbidity, immunisation coverage is often found to be sub-optimal in resource scarce countries in Sub-Saharan Africa (Levin & Kaddar, 2011). Many resource-constrained national governments, including the South African government (National Department of Health, 2015), have therefore adopted the EPI PPP service delivery model in an effort to honor their commitment to achieving vaccination targets (Kula & Fryatt, 2014). The private health sector has been deemed a valuable resource in the health system, increasing EPI service access in LMIC.

Although various PPP benefits have been identified in various contexts, sub-optimal governance is a significant challenge identified in PPPs (Ruckert & Labonté, 2014). PPPs have nevertheless been found to increase equity in various contexts (Kula & Fryatt, 2014; Levin & Kaddar, 2011). However, equal coverage should ideally be the benchmark of vaccination coverage measures within the population as this reflects a commitment by government to moral equality of persons and a right to health for all (Arsenault, et al., 2016).

More research pertaining to EPI PPPs in developing countries is recommended (Nelson, et al., 2016; Patouillard, et al., 2007), and these findings should be made widely available to add to the current disparate body of knowledge relating to vaccination specific PPPs in developing countries (Nelson, Wallace, Sodha, Daniels, & Dietz, 2016).

Motivation for the study

WCG: H has entered into EPI PPPs with various private stakeholders. Although PPPs have numerous resource implications for an already constrained public sector, in many developing countries PPPs have been proven to increase access to services (Arsenault, et al., 2016). The EPI PPP has numerous resource implications for WCG: H. These include financial, human and administrative support constraints. It is imperative that WCG: H reflect on the use of these resources to inform management effectiveness, process efficiencies, benefits, and governance arrangements of the PPP. The outcome of resource inputs, and the extent to which it contributes toward the vaccination coverage targets of the EPI programme, is further motivation for review of the initiative.

Research purpose, aim and objectives

This study aims to assess the demographic and socioeconomic profile of clients who utilise EPI PPP services from WCG: H for-profit partners. Additionally, the aim is to explore the WCG: H EPI staff experiences of the initiative.

The objectives of the study are to:

- Describe the socio-demographic characteristics of clients that utilised EPI PPP services in the 2016/17 financial year;
- Compare socio-demographic characteristics of those using EPI PPP services to those using EPI services in Western Cape public sector facilities;
- Describe the proportion of EPI PPP clients who have utilised public sector facilities for healthcare in the Western Cape; and
- Describe WCG: H staff experience of the EPI PPP service to identify challenges and succeses of the programme.

The 2016/17 financial year is chosen as this is the latest data available for the period of a year. The aims and objectives of the study have been developed with the purpose to inform and strengthen the WCG: H EPI PPP programme.

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Part C: Publication-Ready Manuscript

SOUTH AFRICAN MEDICAL JOURNAL

Reviewing the Expanded Programme for Immunisation Private Public Partnership in the Western Cape

J Werner,

Western Cape Government: Health and School of Public Health and Family Medicine,

University of Cape Town

Abstract

Background: The demand for healthcare services has been steadily increasing over the years whilst the health system is subjected to increasing resource limitations. The private sector has therefore, in various ways, including Public Private Partnerships, been viewed as a means to address these resource limitations. The Western Cape Department of Health has undertaken to expand the Expanded Programme for Immunisation as a Public Private Partnership. The programme aims to improve population health outcomes through increased vaccination coverage and service access. Benefits and challenges of such partnerships have been identified in various contexts. However, there is a significant research gap pertaining to public partnerships with for-profit entities, particularly in Sub-Saharan Africa.

Objectives: The study sought firstly to describe the socio-demographic characteristics of clients who utilised the Expanded Programme for Immunisation public private partnership services in the 2016/17 financial year. Secondly, to compare the socio-demographic characteristics of those using the Expanded Programme for Immunisation public private partnership services to those using the Expanded Programme for Immunisation services in Western Cape public sector facilities. Thirdly to describe the proportion of Expanded Programme for Immunisation public private partnership clients who have utilised public sector facilities for healthcare in the Western Cape. Finally, to describe the provincial health staff experiences of the service.

Methods: A descriptive quantitative cross sectional study and 12 semi- structured interviews were undertaken to fulfill the objectives of the study. The study population was clients who utilised the Western Cape Department of Health Expanded Programme for Immunisation services from April 2016 to March 2017 in the Western Cape Province. Convenience sampling of public private partnership clients was conducted which enabled the descriptive analysis whilst a random sample of public sector immunisation clients enabled the socio-economic status comparison to the public private partnership clients. Socio-economic status was analysed by reviewing the annual head of household income of clients estimated by client postal code. Western Cape Government staff were selected for interviews to gain insights into

provinical staff experiences of the partnership. This was conducted by snowball sampling methods. Univariate analysis was conducted on data submitted by 80 private partners and thematic coding was used to analyse the staff interviews.

Results: The proportion of provincial Expanded Programme for Immunisation client visits attributable to the public private partnerships was approximately 12% in 2016/17. The 80 participating private partners provided almost 60, 000 vaccinations to 23,695 clients in the period of a year. The public private partnership appears to be accessed by users who are of similar socioeconomic status to the Expanded Programme for Immunisation clients accessing public sector facilities. Additionally, the small proportion (12.2%) of public private partnership clients having access to medical insurance further supports the findings of the similar socioeconomic profile of the two groups. 42.7% of public private partnership clients were found to have visited public sector facilities therefore suggesting that in the absence of the public private partnership they might otherwise have utilised the public sector to attain the service. Notwithstanding concerns around management and governance, the initiative is generally appreciated and supported by government stakeholders.

Conclusions and recommendations: The Western Cape Department of Health Expanded Programme for Immunisation public private partnerships operate at a scale that accounts for a meaningful proportion of the immunisation coverage and is utilised by clients of similar socio-economic status when compared to Expanded Programme for Immunisation clients accessing public sector facilities. The small proportion of public private partnership clients having access to medical insurance suggests public private partnership clients might otherwise have utilised the public sector in the absence of the partnership. Overall, the public private partnership has been appreciated by the Western Cape Department of Health staff and affords clients a degree of financial risk protection. Future research areas include an economic evaluation, a benefits incidence analysis and the describing barriers to uptake of the service from the perspective of stakeholders external to the Western Cape Department of Health.

Background and Objectives

With the increasing demand for healthcare, in the context of a health system burdened with austerity measures, the private sector has been viewed by some countries as a means to address the resource gap (Ruckert & Labonté, 2014). Public Private Partnerships (PPPs) have been considered as instrumental for the ascertainment of countrywide health outcomes. There has been an increase in the number and study of PPPs over the last few years and research has illustrated diverse collaborations between the private and public sector (Hernandez-Aguado & Zaragoza, 2016). The private sector, and partnerships between the public sector and the private sector, are service aspects of mixed health systems which need to be harnessed in order to reach Universal Health Coverage (UHC) which is the goal of health systems (Clarke, et al., 2019).

The National Health Insurance (NHI) is a financial tool which South Africa has undertaken to implementing. It foregrounds the principles and objectives of UHC to enable quality and efficiencies in service delivery. Furthermore, it is intended to decrease inequity in health service access. Within the NHI financing mechanism, health services will be purchased from service providers in the public and private sector through various governance arrangements. Services include primary health care in which the Expanded Programme for Immunisation (EPI) is included (National Department of Health , 2019).

In South Africa, vaccination coverage is enabled by immunisation services rendered in both the private and public sector (McIntyre & Ataguba, 2017). The EPI is a national initiative, which aims to improve population health outcomes by decreasing mortality and morbidity related to infectious diseases (Western Cape Provincial Department of Health, 2017). In an attempt to strengthen the EPI programme, the Western Cape Department of Health (WCG: H) officially entered a PPP in March 2016 (Western Cape Department of Health, 2016).

The PPP initiatives contribute to the objectives of the broader EPI programme, namely:

- Decreasing the infection risk of the unvaccinated population by attaining herd immunity (Deogaonkar, Hutubessy, van der Putten, Evers, & Jit, 2012),
- Aversion of premature mortality, and
- Decreasing morbidity in children (Gavi, 2018; Kula & Fryatt, 2014).

The WCG: H EPI PPP initiative affords clients the ability to access immunisations, as per the EPI schedule, from private partners. The initiative is thought to increase access to immunisations in both the Metro and Rural districts enabling the provincial targets related to vaccination coverage. Private partners are provided with vaccination stock by the provincial

government (subject to availability and budgetary constraints related to the vaccinations in the department). Although immunisations are provided to partners at no cost, clients are charged an administrative fee established as part of the agreement between the partners and WCG: H. Any amendments to the pricing structure require approval by the WCG:H. The processes related to the partnership term, targets, order, delivery, management of medical supplies and reporting lines is detailed in the memorandum of understanding existing between the partners. The contractual arrangements and stock management have transitioned over time. The partnerships were initially managed by the medical depots with the predominant partners reported as general practitioners. The partnership became increasingly formalised over time with management transitioning from a decentralised to a centralised management mechanism. In the 2016/17 financial year, the WCG:H PPP's contribution to the total vaccination services provided by WCG: H EPI was 11.8% (120,101 vaccinations). This a meaningful proportion of the total (1,020,824) vaccinations provided by the WCG: H and its EPI partners.

It is unknown if those utilising the service would otherwise have sought immunisation services in the public sector thereby alleviating the public sector health facilities service burden. Clients affordability of private care and whether the they are utilising the PPP service for cost savings are also unknown. Furthermore, the programme's contribution to decreasing equity in population coverage and the demographic profile of the population using these partner EPI services have yet to be established.

The objectives of the study were therefore to describe the socio-demographic characteristics of clients that utilised EPI PPP services in the 2016/17 financial year, to compare socio-demographic characteristics of those using EPI PPP services to those using EPI services in Western Cape public sector facilities, to describe the proportion of EPI PPP clients who have utilised public sector facilities for healthcare in the Western Cape and to describe the WCG: H staff experience of the EPI PPP service. The 2016/17 financial year was chosen as that was the latest data available for the period of a full year at the time of initiating the study.

Acknowledgements

Acknowledgement is extended toward the Programme Impact and Evaluation component of the Western Cape Health Intellingence Unit, the Business Development Unit and other stakeholders who enabled the research process.

Conflicts of Interest and funding sources

At the time of preparing the manuscript, the researcher was a salaried employees of the WCG: H and a student at the University of Cape Town. No funding sources were necessary for the research process.

Methods

A descriptive quantitative cross sectional study and semi- structured interviews were undertaken to meet the objectives of the study.

Quantitative Study Methods

Multiple sampling methods were applied to the study population to fulfill the objectives of the study. The study population was the children who utilised WCG: H EPI services from the beginning of April 2016 to the end of March 2017.

Convenience sampling of PPP clients was conducted which enabled the desriptive analysis of population demographics. The analysis of SES was based on the postal code of the geographic area in which they lived. The convenience sample was sampled from EPI PPP providers from the Rural and Metro districts contracted in the partnership in the 2016/17 financial year who were able to submit the requested data as per the protocol. All for-profit partners who consented to the study and provided data in the electronic format were included as participants. No further information on partners unable to submit electronic data was collected. For the comparison to SES of PPP clients, a simple random sample of clients attending WCG: H primary health care facilities for EPI services was drawn. The latter sample included 5% of those born during the 2016/17 financial year (estimated at 572, 878) and data was sourced from the Western Cape Provincial Health Data Centre database. The database provides consolidated patient-level data (Boulle, et al., 2019).

For both groups SES was estimated through determinining the average annual head-of-household income, by postal code, using income data from Census 2011 (median applied to income bands – excerpt in appendix 5). While this is a crude approach, it was necessitated owing to a lack of data indicating the SES in the sample. It was therefore assumed that clients reporting a particular postal code would have the mean head-of-household income from that postal code as per Census 2011. To ensure an adequately powered study, the sample size for the SES comparison was calculated using the Chi-squared function to compare means between groups. In order to be powered at 90%, to detect a 10% difference in the SES status of the independent groups with equal numbers of clients in the PPP and public sector groups and a level of significance at 0.05; a minimum of 4, 206 clients were needed in the PPP sample overall.

The estimation of the number of clients who utilised EPI PPP services and who visited municipal and provincial government managed facilities was conducted using the Data Centre database. The estimation was restricted to the PPP clients having recorded a visit at a government facility within the province three years prior or three years after their first record as a PPP client. Client identifiers utilised to ascertain the proportion of children linked to Western Cape provinicial and municipal managed health facilities included the child's:

- Name;
- Surname;
- Date of birth; and
- Address.

Categorical data was explored using prevalence proportions, frequency tables and 95% confidence intervals (CI). As the data had a skewed distribution, the median has been described in the resultls and discussion. The data collated for the quantitative analysis was analysed in Stata v.15 (2017).

WCG: H Staff interviews:

Non-probability snowball sampling was conducted for participant recruitment. In order to elicit themes regarding the staff experience of the WCG: H EPI PPP initiative, a purposive sample of 12 staff members in both rural and metro subdistricts were interviewed by the researcher using a semi-structured questionnaire. All participants identified in the sampling strategy were interviewed in English. Two interviews were conducted telephonically due to interviewee availability or preference. The remainder were conducted face to face. Ten of the twelve staff members were managers either at provincial or subdistrict level. Pharmacy service managers at health facilities were also included. The remaining interviewees were information management staff located at WCG: H subdistrict offices. Interviews were conluded after twelve participants had participated in interviews as data saturation was achieved.

Initial invites were sent to managers from the provincial subdistricts and the Business Development Unit. The inclusion criteria enabled the purposive sampling method. Participant selection was WCG: H staff (all of whom are over the age of 18) that are stakeholders of the programme and represent the following:

- WCG: H Cape Medical Depot;
- WCG: H Business Development Unit;
- WCG: H Pharmacy Service Managers; and
- EPI PPP Programme Organisers and Managers.

The questionnaire was adapted from validated research tools utilised in the Critical Success Factors for Incident Management Partnerships report (Minnie, 2011) and the Critical Elements of Routine Immunisation Programs study (Shen, Fields, & McQuestion, 2014). Questions were adapted to the research context to enable dependability and further refined after a pilot on two interview subjects was conducted.

The semi-structured interview themes included:

- Goals and Policy;
- Management and Organisation;
- Human Resources;
- Information Management; and
- Operational Processes.

Data obtained was transcribed using Microsoft Word and thereafter imported into One Note software programme by the researcher. Data entry, validation, reconciliation and triangulation took place on an ongoing basis from the start of the data collection period until all data had been entered onto the data handling software. Data analysis was conducted utilising a thematic coding strategy undertaken in three cycles.

Identifiers utilised to ascertain the proportion of paediatric clients linked to WC government facilities were provided to a trusted third party and a linked anonymized dataset was made available to the researcher. The research protocol was approved by the University of Cape Town Human Research Ethics Committee (HREC 113/2019) and research ethical standards outlined in the Helsinki Declaration were followed (World Health Organisation, 2000). The risks to study participants were minimal and no incentives were provided to participants. Participation was voluntary and all participants provided informed consent.

Personnel

The researcher role was undertaken by Dr Jesse Werner (JW) , with Associate Professor Susan Cleary undertaking the role of co-supervision with Professor Andrew Boulle as principal investigator. JW developed the protocol and conducted the interviews, data analysis and report compilation.

Results

There were 196 WCG: H partners in the 2016/17 period, of whom 57 (29%) were located in rural districts. The remainder were located in the Cape Metro district. Of the total, 80 partners (40.8%) were successfully recruited for participation. These partners submitted data on 23,695 clients, having had 59,487 partner visits in 2016/17, indicating approximately 2.5 visits per

client to EPI PPP services. The PPP sample represents approximately 50% of the entire (120,101) PPP client visits in the Western Cape in the 2016/17 period. Further detail on client characteristics is described in Table 1. Missing data for all paediatric clients receiving services are noted as unknown in all tables.

Table 1: Descriptive characteristics of clients utilising WCG: H EPI PPP services

Client characteristics	**Totals** (N=23695 clients)
Gender (N, %)	
Male	11326 (47.8)
Female	10663 (45.0)
Unknown	2441 (10.2)
Age in Months (Median; IQR)	7 (2.0-18)
Access to health insurance by client geographic residence (N, %) (%; (% access unknown by geographic location))	
Western Cape	2305 (12.2)[1]
Cape Winelands	454 (12.0)[2]
Cape Metro	1544 (11.5)[3]
Eden	307 (22.6)[4]
West Coast	0 (0.0)[5]
****EPI Service Received (N, %)**	
Birth	1130 (1.9)
Six weeks	11897 (20)
Ten weeks	15466 (26)
Fourteen weeks	12909 (21.7)
Nine months	9280 (15.6)
Eighteen Months	5830 (9.8)
Six years	2261 (3.8)
Twelve years	714 (1.2)
Service utilisation by residing district (N, %)	
Cape Winelands	4192 (17.7)

Proportion of data where client access is unknown (%):

[1]Western Cape: 25.6
[2] Cape Winelands: 10.4
[3] Cape Metro: 4
[4] Eden: 1
[5] West Coast: 0

Utilisation of PP services located within client district location	*3224 (76.9)*
Utilisation of PP services located external to client district location	*968 (23.1)*
Cape Metro	18054 (76.2)
Utilisation of PP services located within client district location	*14082 (78.0)*
Utilisation of PP services located external to client district location	*3972 (12.0)0*
Eden	1372 (5.8)
Utilisation of PP services located within client district location	*1290 (94.0)*
Utilisation of PP services located external to client district location	*82 (6.0)*
West Coast	7 (0.0)
Utilisation of PP services located within client district location	*7 (100)*
Utilisation of service by private partner category (N; %)	
Pharmacy retail chain store	19524 (82.4)
Local retail pharmacy	617 (2.6)
Women and child health centre	2322 (9.8)
Paediatrician	569 (2.4)
General Practitioner	521 (2.2)
Hospital	142 (0.6)

*(**N=59,487 number of total client visits)*

The majority of clients did not have access to health insurance with 12.2% of the overall sample noted to have health insurance as described in Table 1. The district with the greatest proportion of clients with access to health insurance is Eden as 22.6% (332 clients) of its population were found to have health insurance in the study. Although the proportion of PPP clients residing in the Metro who had access to health insurance was 11.5%, the number of clients was highest with 2014 clients having access to health insurance.

Table 2 below compares the sample mean and median annual head-of-household income category for the rural and metro subdistricts measured in South African rands. Table 2 describes the SES differences at district and subdistrict level. The majority of clients residing in subdistricts located in the Metro were noted to have a median annual household income category of R57,300 in comparison to the majority of clients residing in rural subdistricts whose median annual household income category was noted as R28,900. The sample-wide comparison depicts the median annual household income as equal for both the clients utilising

services in the public sector and for those utilising PPP services. Income inequality within geographic areas is noted by the variance in the mean and median.

Table 2: Socio-economic description of clients using EPI services from the PPPs and Western Cape public sector health facilities

Geographic location	***Clients using public sector EPI services (N=4743)***		***Clients using EPI PPP services (N=23695)***	
	N (%)	***Annual household Income Median (^^Mean)***	***N (%)***	***Annual household Income Median (^^Mean)***
Western Cape	*4743 (100)*	*57300 (63835)*	*23695 (100)*	*57300 (49075)*
****Cape Winelands District***	*877 (18.5)*	*28900 (29645)*	*15.8 (3744)*	*28900 (28900)*
Breede Valley	*194 (4.1)*	*28900 (28900)*	*95 (0.4)*	*28900 (28900)*
Drakenstein	*299 (6.3)*	*28900 (30415)*	*2769 (11.8)*	*57300 (57064)*
Langeberg	*33 (0.7)*	*28900 (42265)*	*0 (0)*	
Stellenbosch	*299 (6.3)*	*28900 (32450)*	*829 (3.5)*	*57300 (57300)*
Witzenberg	*52 (1.1)*	*28900 (28900)*	*24 (0.1)*	*28900 (28900)*
****Eden***	*669 (14.1)*	*28900 (39088)*	*1469 (6.2)*	*28900 (28900)*
Bitou	*38 (0,8)*	*57300 (44162)*	*379 (1.6)*	*28900 (28900)*
George	*213 (4.5)*	*57300 (57300)*	*332 (1.4)*	*28900 (28900)*
Hessequa	*66 (1.4)*	*28900 (30797)*	*0 (0.0)*	
Kannaland	*19 (0.4)*	*57300 (54311)*	*0 (0.0)*	
Knysna	*62 (1.3)*	*57300 (43717)*	*260 (1.1)*	*28900 (28900)*
Mossel Bay	*133 (2.8)*	*28900 (34086)*	*332 (1.4)*	*28900 (28900)*
Oudtshoorn	*138 (2.9)*	*28900 (35239)*	*166 (0.7)*	*28900 (28900)*
****West Coast***	*294 (6.2)*	*57300 (55381)*	*640 (2.7)*	*57300 (57300)*
Cederberg	*109 (2.3)*	*57300 (57300)*	*0 (0.0)*	
Matzikama	*81 (1.7)*	*57300 (50287)*	*284 (1.2)*	*28900 (31661)*
Saldanha	*157 (1.1)*	*57300 (57300)*	*356 (1.5)*	*57300 (57300)*
****Cape Metro***	*2481 (52.3)*	*57300 (87050)*	*17534 (74)*	*57300 (52568)*

Eastern	*308 (6.5)*	*28900 (50470)*	*3151 (13.3)*	*57300 (57300)*
Khayelitsha	*89 (10.3)*	*28900 (45040)*	*1635 (6.9)*	*28900 (42559)*
Klipfontein	*104 (2.2)*	*28900 (28900)*	*1279 (5.4)*	*57300 (57300)*
Mitchells Plein	*237 (5.0)*	*57300 (53408)*	*0 (0)*	
Northern	*2 (95)*	*115101 (120565)*	*2938 (12.4)*	*57300 (57300)*
Tygerberg	*133 (2.8)*	*57300 (74734)*	*1976 (8.3)*	*57300 (51374)*
Southern	*337 (7.1)*	*57300 (97439)*	*806 (3.4)*	*28900 (28900)*
Western	*313 (6.6)*	*57300 (88694)*	*4407 (18.6)*	*57300 (48612)*
^Tygerberg Eastern	*465 (9.8)*	*57300 (57300)*	*1351 (5.7)*	*28900 (32247)*

*(^^Mean derived from sample weighted average based on postal code; ^Postal code noted to appear in two subdistricts therefore subdistricts combined; * Districts comprising of subdistricts: noted below)*

As shown in Table 3, a total of 10,118 (42.7%) PPP clients had visited public sector facilities. The district with the highest number of clients with evidence of public sector visits was the Cape Metro. Of the 10,118 clients, the medical insurance status was known for 6,749 clients (67.7%). The majority of clients having visited public sector facilities, whose medical insurance status was known, did not have medical insurance (73.3%). The district with the highest number of clients known to have medical insurance was the Cape Metro. The extent of medical insurance benefits (i.e. comprehensive cover versus a more limited 'hospital plan') was not available for analysis. This in line with the scope of the objectives.

Table 3: Residential and Medical Insurance status of clients with evidence of public sector visits

Client characteristics (N; %)	**Sample Total** (N=23695)	
Clients with evidence of public sector visits per district	**N: 10118**	**Proportion of clients not linked per district (%)**
Cape Winelands	2003	8.4
Cape Metro	7366	31.1
Eden	749	3.1
West Coast	0	0.0
Clients who used public sector services with access to medical insurance	**N: 10118**	**Proportion of clients where access to health insurance is unknown (%)**
Cape Winelands	0	0.0
Cape Metro	376	5.1
Eden	1	0.1
West Coast	0	0.0

The themes and opportunities elicited from the staff interviews are noted in table 4 below.

Table 4: Describing the opportunities to strengthen the EPI PPP as per the staff interview findings

Theme	Opportunity
Policy and population access	Policy to detail clear objectives of the PPP with the target population for which access should be prioritised clearly stipulated Enforcement and improved regulation of policy enactment
Communication	Stakeholder engagement could be improved through succinct communication of policies. Improve strategic and operational process through increased collaboration between subdistrict/ district management teams and the directorate employed to manage and ensure governance processes of the PPP Increase population and potential partner awareness
Resource constraints	Resource gaps were noted in the following service domains: - Legal advisory team; - Monitoring and evaluation; - Private partner audits and training. Stock shortages are both a National and WCG: H are a challenge.
Roles and Responsibilities	Clarity in roles related to partner training and audits is required
Monitoring and Evaluation	Enable efficient data reconciliation of the various data sources Strengthen data integration and data flow Review of the current tools and ensure electronic tools made available to stakeholders to enable efficient and effective management of the partnership.

Participants represented were staff located at various levels of the health system including Information Management, Subdistrict Offices, Rural District Office, Business Development Unit, Cape Medical Depot and Pharmacy Services. There was convergence of views with respect to the findings of monitoring and evaluation policy, communication and resource constraints. Clarification of roles and responsibilities of stakeholders was a theme which emerged only from subdistrict managers. Although there was divergence of views pertaining to the partnership being successful, there was agreement by WCG: H staff that the benefits of the partnership are deemed to outweigh the challenges. This rationale was motivated by the aggregate population health gains of immunisation coverage resulting in a decrease in childhood morbidity and mortality.

The EPI PPP was considered by the participants as client-centered. Services provided by private partners are deemed more accessible with the option of service utilisation outside standard working hours. Furthermore, the partners were deemed to deliver a more efficient service as caregivers who accompany clients are able to get back to work timeously without waiting in long queues, which are often a challenge in WCG: H facilities.

Quality, as set out by the memorandum of understanding, was questioned and improved governance of the partnership deemed necessary. Quality challenges identified through ad hoc audits conducted by some staff included a lack of valid reporting of stock utilisation and waste by partners. Furthermore, partner inflation of administrative fees charged to clients was described as a challenge.

Communication of the “Call for service”, inviting potential partners to apply to render WCG: H EPI services, was described to be on numerous media platforms. However, the effectiveness of the communication used requires review to enable optimal service reach to the target population in all districts. This sub-optimal communication results in a lack of awareness of the partnership both by potential partners and by the clients’ caregivers whom the initiative is targeted toward. Suggestions made to strengthen communication include a revision of messaging to ensure it resonates with the target audience. This must be supported by public sector facility staff being informed of the local EPI PPP service providers in order to communicate the service options to public sector clients. Although the benefits of the partnership were appreciated by all, the initiative was deemed as onerous by some managers, being described as an additional burden to the workload of WCG: H staff.

Discussion

A meaningful proportion of the total provincial volume of vaccines are issued by EPI private partners. This highlights the importance of the EPI private partner role in the health system, in keeping with previous research relating to PPPs (Kula & Fryatt, 2014; Ruckert & Labonté, 2014). The majority of services are rendered by pharmacy retail chain stores. This transitioned over time with the majority of EPI PPP services reported to have been provided by general practitioners in the initial years of the partnership. Almost half the WCG:H private partner EPI clients had evidence of attendance at public sector health service facilities. The patient profile of the clients utilising services from private partners is not obviously advantaged relative to clients utilising services from public sector facilities. Although there were concerns around governance and management of the partnership, WCG: H staff expressed appreciation for the PPP and the initiative was described as being beneficial, contributing to a decrease in provincial childhood morbidity and mortality.

Exploring client SES in the EPI programme

The overall marginal differences between the SES comparison of EPI PPP clients and clients having received EPI services in public sector facilities, suggests the initiative provides service access to clients who are not more socio-economically advantaged relative to clients utilising the public sector for EPI services. Additionally, the small proportion of PPP clients having access to medical insurance further supports the findings of the similar socio-economic profile of the two groups. As the majority of PPP clients did not have access to medical insurance, in the absence of the partnership, PPP clients would otherwise be required to pay out of pocket for EPI services received. This reveals the client subsidization function of the PPP and the potential role the private sector can play in supporting the public sector health system. Therefore, the PPP has the benefit of affording clients a degree of financial risk protection through partnerships with local government, this in keeping with research conducted many years ago (Xu, et al., 2007)

Client health seeking behavior

WCG: H EPI PPP client health seeking behavior spans both the private and public sector. A high proportion of WCG: H EPI PPP clients (42%) were found to have visited public sector facilities within the Western Cape. Study findings suggest EPI PPP clients might otherwise have sought healthcare from provincial public sector facilities had the PPP initiative not been in place. The partnership therefore partially alleviates the client burden on the public sector.

The study did not account for the proportion of caregivers, who are financially responsible for the child, having utilised the public sector services. Therefore, the proportion of clients may be higher if the analysis methods had taken this into account.

Of further interest was the considerable proportion of clients noted to receive EPI services outside of their residing district. This was noted in the majority of the districts including the Cape Metro, despite almost 75% of partners found to be geographically located in the Cape Metro health district. Client health seeking behavior is known to be both multi-faceted and complex encompassing principles such as access, supply and demand (Scheffler, Visagie, & Schneider, 2015). Consideration of these principles, along with data quality and other components of information management, are fundamental in the interpretation of these results.

Programme monitoring and governance

Information management and programme monitoring were deemed to be conducted in a haphazard way with sub-optimal data integration and flow to support programme monitoring. The challenge related to information management is a consistent finding in many private partnerships existing in developing countries, including South Africa. Efficiency in service provision and governance therefore require strengthening of information and management reporting systems (Björkma & Raman, 2015; Kula & Fryatt, 2014).

Policy enactment by partners was reported by key stakeholders as sub-optimal with challenges pertaining to quality provided by the private partners noted. Although these findings require further exploration, service quality has been raised as a potential challenge in many PPPs. The potential quality gaps of concern identified in this study are therefore congruent with findings of Lydon, et al., (2014) and Patouillard, et al., (2007) where technical service quality challenges were found to be linked to private partners offering health services in numerous countries.

Community Awareness

Community awareness of the EPI PPP service was described by staff as an important factor for initiative success. The lack of awareness was believed to limit the uptake of EPI PPP services by clients and potential private partners. Community awareness efforts were suggested to be supported by public sector facility staff being informed of the local EPI PPP service providers. They would therefore have the ability to share with clients the alternative options clients have to receive EPI services in the health system to enable improved access

to the service. These recommendations are congruent with the WHO, where all aspects of the health system need to be accounted for in order for the health system to have an effective actionable health response. This to encourage continuity of care between the private and public sector as a model for service delivery (WHO, 2007).

Strengths and limitations

The insights gained from the WCG: H staff, although valuable, do not comprehensively describe all the stakeholder experiences of the initiative as the client and private provider experience of EPI PPP implementation have not been accounted for in the study. The scope of this study was further limited to describing the WCG: H EPI PPP related to for-profit partners in the 2016/17 financial year and hence did not explore the non-profit partner contribution to the EPI PPP programme in this period. Further limitations of this study include insights of the service quality offered by private partners and a lack of information to improve the estimation of private partner clients who seek health services in the public sector.

The use of the Census 2011 data to inform client SES is a further limitation. In effect, we have assumed that clients living in a particular postal code area would have the mean SES of that area, as per Census 2011. This approach was necessitated by a lack of any other income data for this study. Because of this, we have considered data on client utilisation of public sector facilities as well as medical insurance status in order to strengthen findings.

The sample inclusion criteria required partners to submit data via an electronic database and additional selection bias was the result of the convenience sample and missing data. However, the response rate was reassuring at 40% of providers, and the sample comprised 50% of all the PPP client visits occurring in the 2016/17 financial year.

The explorative nature of the study serves to inform future research areas pertaining to the topic. Future research areas include studies of partners using paper-based information systems and exploration of barriers to uptake of the service from the client and service provider perspective. An economic evaluation and a benefit incidence analysis of the programme would be of value to further strengthen health service models such as these.

Demonstrating the importance of the EPI private partner role in the health system, in keeping with previous research relating to PPPs (Kula & Fryatt, 2014; Ruckert & Labonté, 2014), this study affords the opportunity for increased engagement between all stakeholders in both the rural and the metro districts and serves as an opportunity to improve policy. Therefore, it should inform service models locally and nationally as countries progress towards UHC.

Furthermore, the study provides an opportunity to continue dialogue on service improvement with WCG: H EPI PPP stakeholders.

The Western Cape population is heterogenous and the governance and management history of the partnership renders the findings specific to local context. Therefore, these results are to be considered with caution in other settings. The results should however be reflected on, considering the local context, to inform immunisation programme design and management.

Conclusion

The WCG: H EPI PPP operates at a scale that accounts for a meaningful proportion of the province's immunisation coverage, thereby increasing access to services in the population. It appears to be accessed by users who are of similar SES when compared to EPI clients accessing public sector facilities. Furthermore, the small proportion of PPP clients having access to medical insurance suggests that some PPP clients might otherwise have utilised the public sector in the absence of the partnership. The contractual arrangement of the partnership affords clients a degree of financial risk protection decreasing potential out-of-pocket expenditure for clients accessing the service from the private partners. Notwithstanding concerns around management and governance, the initiative is generally appreciated and supported by key government stakeholders.

The explorative nature of the study serves to inform future research areas pertaining to EPI PPPs. Future research areas include an economic evaluation, a benefits incidence analysis and a description of the barriers to uptake of the service from the perspective of stakeholders external to WCG: H.

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Part D: Appendices

Appendix 1: Participant information sheet form

You are being invited to take part in research relating to the Western Cape Department of Health

(WCG: H) Expanded Programme for Immunisation (EPI) public private partnership (PPP). A**s a** key stakeholder, you are being invited to participate to offer your perspective. These findings will help to inform and strengthen the EPI efforts in the province.

What is this evaluation all about?

WCG: H has entered into a PPP with various private stakeholders with respect to the EPI programme. This initiative was implemented in accordance the Constitution's provision for free immunisation for children. These PPPs have numerous resource implications for WCG: H which include amongst others financial, human, administrative support. PPPs have been proven to increase access to services in many developing countries and the outcomes of the PPP in the Western Cape require further assessment to inform management decisions with regard to strengthening the EPI programme. Therefore the requirement for the research was established

What is required of you?

It is requested that you reflect on the successes and challenges relating to the following areas of the WCG:H EPI PPP prior to the interview:

- Management and Organisation of the partnership;
- Operational Processes;
- Resources required for the partnership
- Stakeholder relationships; and
- Information Management.

Your participation will involve you taking part in a semi-structured interview pertaining to the WCG: H EPI PPP. The interview process is estimated to take approximately 45 minutes.

Please also note that while the interview is anonymous and your participation is voluntary with the intention to enable strategic and operational planning and better health outcomes relating to the EPI within the province. Furthermore should you wish to no longer participate for any reason, there will be no penalties or any costs incurred if you choose to withdraw from the study.

Who do I contact if I have any questions about the study?

If you have any further questions, please contact Dr Jesse Werner on 021 483 9057 or jesse.werner@westerncape.gov.za.

Appendix 2: Participant Consent Form

I consent to participation in this semi-structured interview and to having it digitally recorded (audio), where the interviewer chooses to do so. I understand that this session is being held as part of a review of the WCG: H EPI PPP.

I understand that the session will be conducted with both personal and professional integrity and that any information I provide is done so in confidence. I understand that statements made in this session will not be reported with my name, job title, address or any other details that may be used to personally identify me.

I am assured that the interview will be conducted in an impartial manner and that the findings will be presented in a manner that balances the strengths and weaknesses of the various issues.

I concede that the purpose of the interview and the intended use of the findings have been adequately explained to me. I have understood the information contained in this consent form, and I have been given the opportunity to ask questions about the interview session.

I am assured that should I wish, I may withdraw from participating at any time and there will be no penalties incurred.

Consent given: (please tick)

Yes	No

Participant Name _____

Signature _____

Date _____

Appendix 3: Semi Structured Questionnaire

Interview tool for researcher

Participant information

1. Division/ sub-directorate/ directorate name/Partner:
2. Years of service in current area of work:
3. If partner years' operating in partnership

Goals and Policy

4. What is your understanding and thoughts on the goals of the partnership?

   _____

5. Opinion on achievement of the goals?

   _____

6. What are your thoughts on data policy, standards and guidelines related to the partnership?

   _____

   Suggestions for improvement?

   _____

Management and Organisation

7. What are your thoughts on the management of the partnership

   _____

   What are your suggestions for improvement?

   _____

Human Resources

8. What are your thoughts on the staff capacity and resource successes and or challenges of this partnership

   _____

9. What are your thoughts on the partner roles and responsibilities

_____

10. What are your thoughts on the partner values and attitudes

_____

Stakeholder Information Management

11. What are your thoughts on the communication by partners

_____

12. What are your thoughts on the information systems and information management by partners

_____

What are your suggestions for improvement?

_____

Operational Processes

13. What are your thoughts on the operational processes related to this partnership

_____

14. What are your thoughts on the resource/ stock required for the partnership (stock/cold chain)

_____

15. Do you think that this model of service is sustainable? Why or why not?

Appendix 4: SAMJ Research Submissions: Instructions to authors

Guideline word limit: 4 000 words

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important clinical question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

Select figures and tables for your paper carefully and sparingly. Use only those figures that provided added value to the paper, over and above what is written in the text.

Do not replicate data in tables and in text.

Structured abstract

- This should be 250-400 words, with the following recommended headings:
- **Background:** why the study is being done and how it relates to other published work.
- **Objectives:** what the study intends to find out
- **Methods:** must include study design, number of participants, description of the intervention, primary and secondary outcomes, any specific analyses that were done on the data.
- **Results:** first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
- **Conclusion:** must be supported by the data, include recommendations for further study/actions.
- Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors.
- Do not include any references in the abstracts.

Here is an example of a good abstract.

Main article

All articles are to include the following main sections: Introduction/Background, Methods, Results, Discussion, Conclusions.

The following are additional heading or section options that may appear within these:

- Objectives (within Introduction/Background): a clear statement of the main aim of the study and the major hypothesis tested or research question posed.
- Design (within Methods): including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.
- Setting (within Methods): level of care, e.g. primary, secondary, number of participating centres.
- Participants (instead of patients or subjects; within Methods): numbers entering and completing the study, sex, age and any other biological, behavioural, social or cultural factors (e.g. smoking status, socioeconomic group, educational attainment, co-existing disease indicators, etc)that may have an impact on the study results. Clearly define how participants were enrolled, and describe selection and exclusion criteria.
- Interventions (within Methods): what, how, when and for how long. Typically for randomised controlled trials, crossover trials, and before and after studies.
- Main outcome measures (within Methods): those as planned in the protocol, and those ultimately measured. Explain differences, if any.

Results

Start with description of the population and sample. Include key characteristics of comparison groups.

Main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.

Do not replicate data in tables and in text.

If presenting mean and standard deviations, specify this clearly. Our house style is to present this as follows:

E.g.: The mean (SD) birth weight was 2 500 (1 210) g. Do not use the ± symbol for mean (SD).

Leave interpretation to the Discussion section. The Results section should just report the findings as per the Methods section.

Discussion

Please ensure that the discussion is concise and follows this overall structure – sub-headings are not needed:

Statement of principal findings

Strengths and weaknesses of the study

Contribution to the body of knowledge

Strengths and weaknesses in relation to other studies

The meaning of the study – e.g. what this study means to clinicians and policymakers

Unanswered questions and recommendations for future research

Conclusions

This may be the only section readers look at, therefore write it carefully. Include primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article.

General article format/layout

Accepted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction, which will delay publication.

General:

Manuscripts must be written in UK English.

The manuscript must be in Microsoft Word format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes).

Please make your article concise, even if it is below the word limit.

Qualifications, ***full*** affiliation (department, school/faculty, institution, city, country) and contact details of ALL authors must be provided in the manuscript and in the online submission process.

Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.

Include sections on Acknowledgements, Conflict of Interest, Author Contributions and Funding sources. If none is applicable, please state ‘none’.

Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dL).

Litres is denoted with an uppercase L e.g. 'mL' for millilitres).

Units should be preceded by a space (except for % and ºC), e.g. '40 kg' and '20 cm' but '50%' and '19ºC'.

Please be sure to insert proper symbols e.g. µ not u for micro, a not a for alpha, b not B for beta, etc.

Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160.

Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'

Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.

If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the *only* exception. Please DO NOT use fill, format lines and so on.

SAMJ is a generalist medical journal, therefore for articles covering genetics, it is the responsibility of authors to apply the following:

- Please ensure that all genes are in italics, and proteins/enzymes/hormones are not.

- Ensure that all genes are presented in the correct case e.g. TP53 not Tp53.

**NB: Copyeditors cannot be expected to pick up and correct errors wrt the above, although they will raise queries where concerned.

- Define all genes, proteins and related shorthand terms at first mention, e.g. ‘188del11’ can be glossed as ‘an 11 bp deletion at nucleotide 188.’

- Use the latest approved gene or protein symbol as appropriate:

Human Gene Mapping Workshop (HGMW): genetic notations and symbols

HUGO Gene Nomenclature Committee: approved gene symbols and nomenclature

OMIM: Online Mendelian Inheritance in Man (MIM) nomenclature and instructions

Bennet et al. Standardized human pedigree nomenclature: Update and assessment of the recommendations of the National Society of Genetic Counselors. J Genet Counsel 2008;17:424-433: standard human pedigree nomenclature.

Appendix 5: Census 2011 Income Band Reference Table (Excerpt)

SubPlace_NAME/code	No incom	R 1 - R 48	R 4801 - R 9600	R 9601 - R 19 600	R 19 601 - R 38 200	R 38 201 - R 76 400	R 76 401 - R 153 800	R 153 801 - R 307 600	R 307 601 - R 614 400	R 614 001 - R 1 228 80	R 1 228 801 - R 2 457 6	R 2 457 601 or more	Unspecifi	SubPlace_NAME	MainPlace_CODE	MainPlace_NAME
177003 Formosa State Forest	-	-	-	-	-	-	-	-	-	-	-	-	-		177003	Formosa State Forest
177003001 Formosa State Forest SP	-	-	-	-	-	-	-	-	-	-	-	-	-	Formosa State Forest SP	177003	Formosa State Forest
177004 Uniondale	86	32	63	195	266	213	144	82	28	6	1	1	-		177004	Uniondale
177004001 Uniondale SP	86	32	63	195	266	213	144	82	28	6	1	1	-	Uniondale SP	177004	Uniondale
177005 Haarlem	29	19	34	145	201	98	42	22	5	1	-	-	-		177005	Haarlem
177005001 Haarlem SP	29	19	34	145	201	98	42	22	5	1	-	-	-	Haarlem SP	177005	Haarlem
177001 Swartberg State Forest	-	-	-	-	-	-	-	-	-	-	-	-	-		177001	Swartberg State Forest
177001001 Swartberg State Forest SP3	-	-	-	-	-	-	-	-	-	-	-	-	-	Swartberg State Forest SP3	177001	Swartberg State Forest
177001002 Swartberg State Forest SP1	-	-	-	-	-	-	-	-	-	-	-	-	-	Swartberg State Forest SP1	177001	Swartberg State Forest
177001003 Swartberg State Forest SP2	-	-	-	-	-	-	-	-	-	-	-	-	-	Swartberg State Forest SP2	177001	Swartberg State Forest
177006 George	3169	475	897	3067	4780	5629	5020	4135	2577	677	172	104	1		177006	George
177006001 George SP4	-	-	-	-	-	-	-	-	-	-	-	-	-	George SP4	177006	George
177006002 Denneoord	237	9	10	39	95	215	328	338	200	29	7	6	-	Denneoord	177006	George
177006003 Fernridge	31	1	-	4	4	11	26	43	27	19	3	4	-	Fernridge	177006	George
177006004 Campher's Drift	32	-	-	6	11	22	36	56	56	28	2	6	-	Campher's Drift	177006	George
177006005 Glen Barrie	49	-	1	5	7	12	31	42	49	18	7	2	-	Glen Barrie	177006	George
177006006 Heatherlands	30	4	3	18	34	51	88	112	132	67	13	4	-	Heatherlands	177006	George
177006007 Heather Park	164	2	8	19	37	108	279	282	228	64	15	8	-	Heather Park	177006	George
177006008 Blanco	333	71	104	316	438	400	342	294	149	43	12	8	-	Blanco	177006	George
177006009 Fancourt Golf Estate	4	-	-	-	-	2	5	8	8	10	11	3	-	Fancourt Golf Estate	177006	George
177006010 Kingswood Golf Estate	15	-	-	2	6	13	32	64	53	51	6	6	-	Kingswood Golf Estate	177006	George
177006011 King George Park	5	-	1	3	6	37	60	55	45	12	-	1	-	King George Park	177006	George
177006012 George Central	84	2	7	79	135	222	237	187	63	5	5	3	-	George Central	177006	George

Appendix 6: Ethics approval

UNIVERSITY OF CAPE TOWN

HUMAN RESEARCH ETHICS COMMITTEE
24 JUN 2020
HEALTH SCIENCES FACULTY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.06.2021
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	29/6/2020

Note: Please note that incomplete submissions will not be reviewed.
Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.
Please clarify your plan for research-related activities during COVID-19 lockdown

Comments to PI from the HREC
We are currently in the data analysis and report writing therefore Covid-19 has no bearing on the study

Principal Investigator to complete the following:

1. Protocol Information

Date (when submitting this form)	23/06/2020		
HREC REF Number	113/2019	Current Ethics Approval was granted until	30.06.2020
Protocol title	Expanded Programme for Immunisation: Review of a Public Private Partnership		
Protocol number (if applicable)	N/A		
Are there any sub-studies linked to this study?	No		
If yes, could you please provide the HREC Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.	N/A		
Principal Investigator	Prof Andrew Boulle		
Department / Office Internal Mail Address	University of Cape Town, School of Public Health CIDER: Faculty of Health Sciences School of Public Health, University of Cape Town		

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

1.1 Does this protocol receive US Federal funding?		No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? **Note:** Any annual approvals for **Full Committee** review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-enquiries@uct.ac.za)		

If yes in 1.2 please complete section 1.3 below for invoicing purposes	
1.3 Annual Approval for **full committee** review	- R 3450 (inclusive of vat)
For invoicing purposes, please provide:	
Sponsor's name	N/A
Contact person	
Address	
Telephone number	
Email Address	

2. List of documentation for approval

3. Protocol status (tick ✓)

☐	Open to enrolment
☐	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
X	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	N/A
Number of participants enrolled, since last HREC Progress report (continuing review)	N/A
Additional number of participants still required	N/A

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	N/A

6. Cumulative summary of participants

Total number of participants who provided consent	N/A
Number of participants determined to be ineligible (i.e. after screening)	
Number of participants currently active on the study	
Number of participants completed study (without events leading to withdrawal)	
Number of participants withdrawn at participants' request (i.e. changed their mind)	
Number of participants withdrawn by PI due to toxicity or adverse events	
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
• De-identified data has been received. • Linkage has been identified at approximately 20% • Descriptive statistics are in process • Further analysis is to be completed in the next few weeks

8. Protocol violations and exceptions (tick ✓ all that apply)

X	No prior violations or exceptions have occurred since the original approval
☐	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

9. Amendments (tick ✓ all that apply)

X	No prior amendments have been made since the original approval
☐	Prior amendments have been reported since the last review and have already been approved
☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).
Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
N/A

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
☐ Yes	☐ No	☐ Not applicable
If yes, please describe:		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?		
☐ Yes	☐ No	X Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
☐ Yes	☐ No	X Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.					
Agency Name		Report attached	☐ Yes	☐ No	☐ Not applicable
		DSMB report attached	☐ Yes	☐ No	☐ Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
☐ Yes	X No

If yes, please explain:

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
☐	Increased
☐	Decreased
X	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.
N/A

13. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	X No
If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	

14. Signature

My signature certifies that the above is complete and correct.			
Signature of PI		Date	23/06/2020

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Signatures Removed