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A Project Report On

**“Point of care quality improvement in process of quality assurance for effective
Immunization.**

IIHMR Delhi

By

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PG/21-23/085

Under the guidance of

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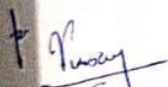
International Institute of Health Management Research

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CERTIFICATE

Dr. Riya Agrawal, affiliated with IHMR, Delhi, conducted a research project titled "Point of care quality improvement in the process of quality assurance for effective immunization: A Systematic Review" between March 10, 2023, and May 31, 2023. The study involved the collection of secondary data from reputable databases such as Pubmed, Google Scholar, and ProQuest. Following a thorough screening of titles, abstracts, and full texts, a total of 9 articles were deemed suitable for inclusion in the study. The extracted results focused on protocols, procedures, and drills, with a specific emphasis on resources that adhered to the recommended standards as highlighted in various studies.



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ABOUT THE ORGANIZATION



The International Institute of Health Management Research (IIHMR), New Delhi is allied to the 'Society for Indian Institute of Health Management Research' which was established in October 1984 under the Societies Registration Act-1958.

IIHMR-Delhi was setup in 2008 in response to the growing needs of sustainable management and administration solutions critical to the optimal function of healthcare sector both in India and in the Asia-Pacific region.

IIHMR Delhi are a leading institute of higher learning that promotes and conducts research in health and hospital management; lends technical expertise to policy analysis and formulation; develops effective strategies and facilitates efficient implementation; enhances human and institutional capacity to build a competent and responsive healthcare sector. There multi-dimensional approach to capacity building is not limited to academic programs but offers management development programs, knowledge and skills-based training courses, seminars/webinars, workshops, and research studies.

There four core activities are...

- Academic courses at masters and doctoral level in health and hospital management to meet the growing need of skilled healthcare professionals.
- Research that has high relevance to health policies and programs at national and global level.
- Continued education through management development programs and executive programs for working professionals to help them upgrade their knowledge and skills in response to the emerging needs of the industry.
- Technical consultation to the national and state-level flagship programs to address the gaps in planning as well as implementation.

Mission

IIHMR Delhi is an institution dedicated to the improvement in standards of health through better management of health care and related programs. It seeks to accomplish this through management research, training, consultation and institutional networking in a national and global perspective.

Vision

IIHMR is a premier institute in health management education, training, research, program management and consulting in the health care sector globally. The Institute is known as a learning organization with its core values as quality, accountability, trust, transparency, sharing knowledge and information. The Institute aims to contribute to social equity and development through its commitment to support programs aiming at poor and the deprived population.

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Date: Jun 2023

Dr. Riya Agrawal

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ABBREVIATIONS

QA: Quality Assurance

QI: Quality Improvement

RI: Routine immunization

UTD: Up- To- Date

PRISMA: Prisma Reporting Items for Systematic Reviews and Meta- Analyses.

LMIC: Low and middle-income country

WHO: World Health Organization

VEARS: Vaccine Adverse event reporting system.

CQI: Continuous Quality improvement

Title of the study: *Point of care quality improvement in Processes of quality assurance program for effective childhood immunization.*

Support: This study is not funded by any organization.

Trial Registration: Registered with PROSPERO (CRD42023421738) dated 16.05.2023

Abstract

Introduction:

The World Health Organization's expanded program of immunization, initiated in 1974, has successfully reduced the burden of vaccine-preventable diseases and introduced new vaccines. Quality assurance programs, including regular assessments and proper training, are essential to ensure the effectiveness of immunization services. Proper vaccine storage and handling, along with patient education on the importance of immunization, are crucial factors in maintaining vaccine efficacy. Additionally, the reporting of adverse events and monitoring and evaluation mechanisms help identify areas for improvement and ensure the success of immunization programs. Therefore, this study aims to investigate the impact of quality improvement in cold chain management on the effectiveness of childhood immunization.

Methods

This systematic review followed the PRISMA guidelines and protocol registered on the PROSPERO database. It focused on initiatives aimed at improving the quality of immunization

processes at the point of care in low- and middle-income countries (LMICs). The review included randomized controlled trials, cross-sectional studies, and grey literature published in English between 1991 and 2003. The key outcomes of interest were immunization coverage, immunization uptake, training and education related to immunization coverage, and medical records. Studies conducted in high-income countries, involving children older than two years, lacking data on the primary outcome, or not focusing on quality improvement and quality assurance for effective immunization were excluded. Comprehensive searches were conducted in various databases, and grey literature was obtained. Cross-referencing and consultation with senior members were also utilized for additional studies.

Result:

The systematic review followed PRISMA guidelines and screened 55 publications out of 60 initially identified records. After the full-text screening, 14 studies were included for qualitative synthesis. The studies focused on quality improvement initiatives in primary healthcare settings, pediatric clinics, and district administrative units in LMICs. These initiatives aimed to improve immunization coverage, uptake, training, education, cold chain management, adverse event reporting, and medical record review. The studies demonstrated that interventions such as training, supervision, monitoring, standardized guidelines, and local solutions led to increased immunization rates and improved quality of immunization services. Implementing quality improvement measures, such as record keeping improvements and staff training, also contributed to enhanced immunization rates.

Conclusion:

This systematic review highlights the significance of point-of-care quality improvement strategies in ensuring effective immunization. Collaboration with non-health stakeholders, data-driven approaches, QA management methods, and addressing data quality issues are vital for successful initiatives. Policymakers and healthcare practitioners can utilize these insights to enhance immunization coverage and deliver high-quality services.

Keywords: Quality improvement, Quality of care, Quality Assurance, Immunization, childhood.

INTRODUCTION:

Rationale: In 1974, the World Health Organization (WHO) initiated the expanded program of immunization to combat vaccine-preventable diseases (1,4). This program has been successful in reducing the burden of diseases such as diphtheria, pertussis, tetanus, polio, mumps, and measles, and has led to the introduction of new vaccines like the pneumococcal conjugate and rotavirus vaccines (3).

Immunization is one of the most successful public health measures to stop the spread of infectious illnesses (1). Programs for immunization are intended to protect against a variety of infectious diseases, some of which can be serious and even fatal (1). The level of care given to

vaccine recipients determines whether immunization programs are successful (1). Quality assurance is an essential aspect of care quality improvement (2). To guarantee that immunization services are of the highest caliber, healthcare facilities should have quality assurance programs in place. Regular assessments of vaccine administration methods, storage, and handling protocols, and patient education programs should all be a part of quality assurance programs (2). Training and education are two of the most important components of improving care quality. To guarantee that they have the skills and information required to deliver high-quality immunization services, healthcare workers must obtain proper training and education (1). The administration, storage, handling, and management of vaccines should all be covered in training courses on immunization. Additionally, it is crucial to give healthcare personnel regular training and education to make sure they are knowledgeable about the most recent immunization recommendations (1).

Proper vaccine storage and handling are critical to maintaining the effectiveness of vaccines (5). Vaccines must be stored at the correct temperature and handled correctly to ensure that they remain viable (5). Healthcare facilities must have proper refrigeration equipment and storage facilities to maintain the proper temperature of vaccines (5). Additionally, vaccines should be transported in temperature-controlled containers to ensure that they remain effective during transit (1,4). On the other hand, Patient education is crucial to make sure that people are aware of the value of immunization and the vaccines they are receiving (6). Patients should be informed about the vaccine they are receiving, any potential side effects and the significance of following the recommended immunization schedule (6). Information regarding diseases that can be prevented by vaccines as well as the advantages of immunization are equally crucial (6). An essential component of immunization services is vaccine administration. To ensure that vaccines are delivered properly, medical personnel must adhere to the suggested vaccination

delivery methods (7). This includes using the appropriate dosage, injection site, and needle size (7).

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program that collects and analyzes reports of adverse events following immunization (8,9). Healthcare professionals should report any adverse events following immunization to VAERS. The reporting of adverse events is essential to identify potential vaccine safety concerns and take appropriate measures to address them (8,9). The effectiveness of immunization programs must be ensured by monitoring and evaluation. To measure immunization coverage rates and pinpoint areas that can be improved, healthcare facilities should have monitoring and evaluation mechanisms in place (10). Data from monitoring and evaluation can be utilized to guide quality improvement efforts and pinpoint areas that may require more education and training (10).

The success of immunization programs depends on cooperation and coordination (10). To make sure that immunization services are coordinated and available to everyone who needs them, healthcare practitioners should collaborate with other healthcare providers, public health organizations, and local community groups (10).

In brief, Quality improvement is essential to ensure that immunization services are effective. The above-mentioned topics give medical practitioners a framework for enhancing the level of care given to patients getting immunizations. Healthcare facilities may guarantee that immunization services are efficient, effective, and of good quality by putting these elements of care quality improvement into practice, so our study aims to investigate the quality improvement in the process of quality assurance for an effective childhood immunization.

OBJECTIVE:

- 1) To assess of the current evidence on the quality improvement in processes of quality assurance program for effective childhood immunization.
- 2) To identify the point-of-care continuous quality improvement (CQI) interventions in processes of Quality assurance for effective immunization.
- 3) To know the effect of quality improvement (QI) on immunization coverage in childhood.

Methods:

This systematic review adhered to the Preferred Reporting Item for Systematic Reviews (PRISMA) guidelines and protocol published on the PROSPERO database (CRD42023421738).

Inclusion Criteria:

In our study, we included randomized controlled trials, cross sectional studies, and grey literature that documented initiatives aimed at improving the quality of immunization processes at the point of care in low- and middle-income countries (LMICs)

We have defined effective immunization in terms of key outcomes like immunization coverage, immunization uptake, training and education related to immunization coverage, and medical records.

These studies were in the English language. We have included a study that shows that quality improvement leads to effective immunization including quality improvement in training, education, vaccine cold chain management, vaccine adverse event reporting event, and medical record review. Articles between 1991-2003 were included in the study.

Exclusion Criteria:

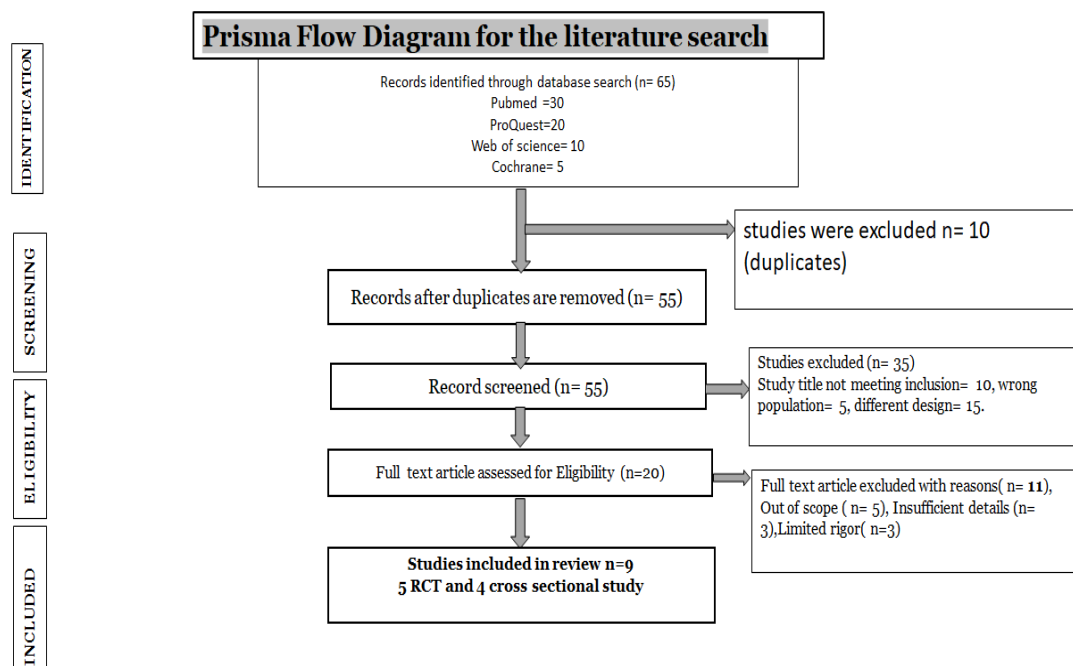
We excluded research conducted in high-income countries and studies involving children older than two years. Studies were also excluded if they lacked data on the primary outcome or if their main focus did not involve quality improvement and quality assurance for effective immunization. Also Study have Cohort and Case control design were excluded.

Literature Search:

We conducted a comprehensive search of the following databases: Pubmed, ProQuest, Web of Science, and the Cochrane database of randomized controlled trials and cross-sectional studies, covering the period from inception to 2023. Our search strategy utilized Boolean operators and relevant keywords pertaining to quality improvement (QI), quality assurance (QA), and effective immunization. Additionally, we obtained grey literature from the Library, focusing on quality improvement initiatives in low- and middle-income countries (LMICs). To augment

our research, we cross-referenced the bibliographies of included articles and consulted senior members for further studies.

Cont...



Data Extraction and Analysis:

Three reviewers (R.A., R.C.) conducted the screening of titles and abstracts, while two reviewers (R.A., T.G.) performed the full-text screening. Any disagreements were resolved through discussions involving a third reviewer. The selected studies, the full-text screening, underwent quality assessment using the Modified SIGN checklist.

Two reviewers (R.A., R.C.) extracted the data, focusing on a predefined outcome established by the team in consultation with senior members. The Outcome included the following: health worker training, patient education, medical record registry, immunization uptake, cold chain

management, coordination, and collaboration in the team. Quality and risk of bias were assessed by 2 reviewers using a pilot appraisal tool that included indicator from the JBI(Joanna Brigg's tool).

Quality tools were scored in low, medium, and high-level articles. All the included studies were categorized and agreed upon the methodological approaches to Quality improvement for increasing immunization coverage and processes of quality assurance to improve immunization.

A summary of the analysis was conducted in Microsoft Excel to report the impact of QI interventions across the studies. Where the relevant data were not reported for the predefined outcome, article were not included for syntheses.

Risk of bias assessment:

Five studies were assessed using the JBI critical appraisal tool for randomized controlled trials (RCTs). Among these, two studies met all thirteen criteria, two studies met nine of the thirteen criteria, and one study met five of the thirteen criteria. All five studies fulfilled the RCT criteria 1, 2, and 3. Four studies met the criteria for number 4. Only two studies fulfilled the criteria for number 5, three studies met the criteria for number 6, and four studies met the criteria for numbers 7, 8, 9, and 10. All five studies fulfilled the criteria for number 11, four studies met the criteria for number 12, and two studies met the criteria for number 13.

Four studies were assessed using the JBI critical appraisal tool for cross-sectional studies. None of the studies met all the criteria, one study met all seven criteria, two studies met all six criteria, and one study met all six criteria. All the studies fulfilled the cross-sectional criteria 1, 2, and

3. Three studies met the criteria for number 4. Only one study fulfilled the criteria for number 5, and no study fulfilled the criteria for number 6. Three studies fulfilled the criteria for numbers 7 and 8.

Result

Overview of Included Literature:

In the database searches, a total of 60 records were initially identified, with 55 publications undergoing title and abstract screening after removing duplicates. From these, 20 articles were selected for full-text screening, along with one grey literature record. Among the 21 articles assessed during full-text screening, two were out-of-scope, three lacked sufficient detail, and two had limited rigor. Ultimately, 14 studies were included for qualitative synthesis. Many of these studies involved multifaceted interventions.

The search results indicated that 9 studies addressed the research question regarding immunization. Out of these, Five studies were randomized controlled trials, and four studies were observational studies.

The included studies spanned the years 1991 to 2018 and focused on implementing QI initiatives primarily in urban and rural healthcare settings. The sites included primary healthcare settings (seven studies), pediatric primary care clinics (one study), and district units (one study)

Features initiatives:

The studies included in the review focused on assessing quality improvement (QI) initiatives in primary healthcare settings. These initiatives encompassed various quality assurance management methods such as training and supervision, effective practices and management of medical records, designing and implementing sustainable programs for immunization, utilizing multiple approaches, and developing and disseminating standardized guidelines to determine patient and family needs.

Regarding QI initiatives in pediatric care clinics, the studies examined the improvement of immunization delivery. The interventions included utilizing medical records to track immunization status, enhancing parent contact information, and reducing missed opportunities for provider education.

One of the studies explored QI initiatives in a district administrative unit with the goal of enhancing safe and effective immunization. The study emphasized the importance of local solutions and QI strategies to strengthen routine immunization practices within the health unit.

Outcome:

Primary health setting:

In a primary healthcare setting in a rural area, a study by **Zeitz et al. 1993** ⁽²¹⁾ found that providing three days of training, supervision, and two months of monitoring in quality assurance and management resulted in an increase in reported cases of a specific disease. Another study conducted by **Harder et al. in 2018** ⁽¹⁹⁾ focused on 20 primary care practices and implemented a quality improvement project for

seven months among children aged 29-33 months. The study demonstrated that immunization coverage increased across all age groups over the course of three years.

Furthermore, a study by **Nicholas et al. 1991** ⁽²⁰⁾ to assessed the impact of the PRICOR program on immunization activities in nine developing countries. The program provided technical assistance to managers to improve the quality of immunization services. The study revealed that the rate of vaccination completion among children aged 12-23 months increased from 66% to 84%.

Study conducted by **Omoleke et al. 2017** ⁽²²⁾ data quality assessments were conducted in health facilities in **Nigeria**(22). The assessments, carried out through semi-structured questionnaires, showed that only 20-40% of children were fully vaccinated at the appropriate age, while 60-70% were either partially vaccinated or not vaccinated(22). However, through **quality improvement initiatives that focused on educating and raising awareness among mothers and caregivers, routine immunization rates could be improved.**

Another Cross-sectional study conducted by **Mavimbe et al. 2005** ⁽²⁴⁾, involving a sample size of **seven** health facilities in Mozambique(24). It was observed that supervisors primarily focused on tally sheets rather than the immunization rate. The study suggests that **by implementing effective quality improvement measures such as improving record keeping** and providing staff training, the immunization rate can be enhanced.

In Uganda, a study by **Omaswa et al. in 1997** ⁽²⁵⁾ revealed that the implementation of quality improvement initiatives, such as increased morale among district health team members, improved patient satisfaction, and greater involvement of local government in district health committees' decisions, led to increased immunization uptake and decreased maternal mortality.

Finally, a study conducted by **Manyazewal et al. in 2018** ⁽⁴⁾ in Ethiopia collected data from 781 government health sector participants. The study demonstrated that after the implementation of technical support, training, and supportive supervision interventions, vaccine coverage significantly improved. Pentavalent coverage increased from 63.6% to 79.3% ($P = 0.0001$), measles coverage

increased from 62.5% to 72.8% ($P = 0.009$), BCG coverage increased from 62.4% to 73.5% ($P = 0.0001$), and PCV coverage increased from 65.3% to 81.0% ($P = 0.02$).

Pediatric primary care clinic:

A study conducted in a pediatric clinic focused on reducing missed opportunities for immunization and improving efficacy. Study by **Daley et al. in 2004** ⁽³⁰⁾ also conducted in a pediatric clinic, the researchers found that the immunization up-to-date (UTD) rates significantly increased for different age groups. For 7-11 month olds, the UTD rate increased from 21% before the quality improvement (QI) project to 52% after ($P < .0001$). Similarly, for 12-18 month olds, the rate increased from 16% before QI to 44% after ($P < .0001$). For 19-25 month olds, the rate increased from 18% before to 33% after ($P < .001$). These improvements were attributed to the utilization of chart prompts, provider education, and provider reminders as part of the quality improvement initiatives.

In a study by **Bazo et al. in 2015** ⁽²³⁾, a Microsystems Quality Improvement Approach was implemented in five health units. The approach involved various strategies such as implementing RI (Routine Immunization) registers, providing Child Health Cards, monitoring, cross-training staff, changing staffing patterns, establishing predictable outreach schedules, and organizing meetings between health system leaders and community leaders. The study demonstrated that these interventions led to increased vaccination rates in three out of the five health units and the improvements were sustained even five months after the intervention.

Discussion:

This systematically conducted a review to study the association between Point of care quality improvement in processes of quality assurance and effective immunization of children under 2 years children. A total of nine studies with findings from different countries Nigeria, Africa, Vermont, Mozambique, Uganda, and Ethiopia. The differences in the study methodologies precluded us from combining the study findings.

The findings from the reviewed studies highlight the importance of implementing point-of-care quality improvement initiatives as part of the process of quality assurance for effective immunization. Despite the dramatic improvements in immunization coverage observed in the 1990s in the United States, certain groups, particularly children in poor urban areas, have been left behind. Traditional interventions recommended to improve vaccination rates have not always been effective in addressing the pockets of under-immunization in these specific populations.

One notable approach that has shown promise is the involvement of non-health stakeholders, such as civic and political leaders, in the assessment of immunization data. The study by John Snow International demonstrated that when districts and health facilities actively share routine immunization data with local leaders, it can lead to the mobilization of local resources. This involvement has resulted in initiatives like purchasing gas cylinders to fuel refrigerators and motorcycles to improve the delivery of routine immunization services. Such collaborations between the health sector and non-health stakeholders can contribute to the success of quality improvement efforts.

Zeitz et al.'s study emphasized the significance of employing quality assurance (QA) management approaches to enhance primary healthcare (PHC) services in Nigeria and other underdeveloped nations ⁽²¹⁾. These methods can be instrumental in enhancing the quality of PHC infrastructure where it exists to some extent. Implementing QA management methods can address gaps in service provision, contributing to improved immunization coverage and overall healthcare delivery.

The study by Nicholas et al. emphasizes the significance of data-driven solution strategies. By analyzing data, the researchers developed a solution strategy that focused on promoting vaccination at every opportunity, training nurses using national immunization modules, conducting informal sessions to discuss coverage rates, and intensifying supervision of health workers ⁽²⁰⁾. These interventions targeted

both the service delivery level and community organization, demonstrating the need for multifaceted approaches to enhance immunization rates.

The study conducted by Manyazewal et al. further supports the effectiveness of quality improvement interventions in improving vaccination coverage ⁽⁴⁾. Following the implementation of various interventions, significant improvements were observed in pentavalent, measles, BCG, and PCV coverage. Although the increase in full vaccination coverage was not statistically significant, the process indicators showed consistently high performance across all regions. These findings highlight the potential of quality improvement initiatives in achieving positive outcomes in immunization programs.

However, challenges related to data quality were identified in the studies by Omoleke et al. and Mavimbe et al. Discrepancies in immunization reports and over-reporting from administrative coverage data indicate poor data quality at the local government level ^(22,24). Efforts should be directed toward improving data quality among immunization stakeholders as it has direct implications for disease prevention and control efforts.

Conclusion:

Findings from this systematic review underscore the importance of implementing point-of-care quality improvement strategies as part of the quality assurance process for effective immunization. Collaboration with non-health stakeholders, utilization of data-driven solution strategies, implementation of QA management methods, and addressing data quality issues are all crucial components of successful quality improvement initiatives. These findings provide valuable insights for

policymakers and healthcare practitioners seeking to enhance immunization coverage and ensure the delivery of high-quality immunization services.

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Table1: Publications report documenting Point of care quality improvement in processes of quality assurance for effective immunization.						
S.No.	Report	Setting	Topic	Measurement	outcome	Study design
1.	Zeitz et al, 1993 ⁽²¹⁾	Primary health care setting in a rural area. Nigeria	To improve quality in PHC system.	Quality assurance management method like training and supervision.	With use of quality assurance there has been an increase in reporting cases of disease.	RCT
2.	Bazos et al, 2015 ⁽²³⁾	Health unit, Africa	Local solutions to strengthen the Routine immunization.	Microsystem Routine Immunization System	Three of five HUs significantly increased the number of vaccines administered. All improvements were sustained 5 months post-intervention.	RCT
3.	Harder et al, 2018 ⁽¹⁹⁾	Primary health care setting. vermont	Quality improvement project on immunization coverage	Medical record review	Immunization coverage is increased over the 3 years in all age group.	Cross sectional study
4.	Nicholas et al, 1991 ⁽²⁰⁾	Primary health care setting of low developing countries	Continuous quality improvement in less developed countries.	Designing and implementing sustainable programs for immunization and multiple areas	Rates of vaccination completion among children 12- 23 months rose from 66% to 84%.	RCT
5.	Omoleke et al, 2017 ⁽²²⁾	Health facilities Nigeria. Nigeria	Routine immunization data quality	WHO data quality assurance and Routine immunization tool	With the use of QI the immunization rate is improved.	Cross sectional study
6.	Mavimbe et al, 2005 ⁽²⁴⁾	Health facilities Mozambique	Data quality for immunization	Practices on record keeping, reporting and the support mechanism	Use of record keeping and support mechanism increases the immunization rate.	Cross-sectional study
7.	Omaswa et al, 1997 ⁽²⁵⁾	. Primary health care facilities Uganda	Development and dissemination of standards or guidelines, determining the needs of patients and their families.	Quality management method	Quality assurance programme raised awareness of the importance of the quality of health services, both at the central and the district level.	Cross sectional study
8.	Manyazewal et al, 2018 ⁽⁴⁾	Health facilities and health department, Ethiopia	Improve the national immunization program.	Continuous quality improvement interventions	Vaccination coverage improved significantly	RCT
9.	Daley et al, 2004 ⁽³⁰⁾	Pediatric primary care clinic, Poor area of US.	Quality improvement in immunization delivery	Increase the use of medical records, improve the parent contact information, reduced missed opportunities to provider education.	Immunization up to data rates for 7-11-month-olds increased from 21% before the QI project to 52%	RCT

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