Rapid assessment of the quality of services in rubella immunization provided through the primary health care service network in the Polonnaruwa district.

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Abstract:

Objective: To assess the quality of services in rubella immunization provided through Primary Health Care clinics at the divisional level using the Lot Quality Assurance Sampling method.

Methodology: A non-participant observation was carried out at 20 randomly selected clinics using Lot Quality Assurance Sampling (LQAS) method with a threshold level of a triage system of 80 and 50%. The-defective elements (clinics) needed to reject the lot and make improvements was six. Taking into account that not only rubella immunization is provided in a clinic, ten deliveries of rubella immunization in a clinic were studied with a triage system of 95 %, 75% (provider risk 1%, Consumer risk 23%). These repetitive activities were judged by LQAS 10:3 binary rules.

The study instrument was a pre-tested, structured observational checklist that comprised essential activities of vaccination referred to as **sub-systems**.

Results: In the subsystem "**sterility**", the hand washing procedure proved to be defective. . The maintenance of sterilization chart was found to be poor. Cold chain maintenance was extremely good and none of the related activities was found to be defective. The screening of eligible clients was poor. A register of eligible women for rubella immunization was not maintained in any of clinics supervised.

The register of immunization was completed after vaccination. In none of clinics were immunized clients totalled and categorized according to age groups at the end of sessions leading to inability to detect any unrecorded vaccinated client by

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comparing the number of vaccinations with the dosages of vaccines used and to calculate the vaccine wastage.

Conclusion: Apart from the defective activities already mentioned, overall quality of services was satisfactory in majority of essential activities.

Recommendations: It is essential to carry out regular supervisions to detect and modify substandard items by supervisory staff. Steps should be taken to improve documentation during and at the end of the clinic session.

Key Words: Quality, Rubella immunization, Lot Quality Assurance Sampling.

Introduction

Immunization is an effective means of prevention of childhood diseases and contributes significantly to reduce infant and childhood mortality. It is defined as one of the eight essential components of Primary Health Care (**PHC**) and one of the most cost effective public health measures. The expansion of the immunization coverage was a necessary and important step towards attaining the international goal of "**Health for All by the Year 2000**"(1).

In December 1989, **Universal Child Immunization (UCI)** status was declared in Sri-Lanka (2). Having reached high coverage, in addition to sustenance of the coverage over the years, there are new challenges in the future such as ensuring quality assurance in relation to immunization and paying special attention to areas with low coverage. Countries may also need to consider adding other vaccines to their schedules. The vaccination of women against rubella to prevent congenital rubella syndrome is such an example (3).

The program of rubella immunization was launched in Polonnaruwa district in December 1997. Since its introduction, ill effects and terminations of pregnancies associated with rubella immunization have been reported. Further, professionals have refused to offer immunizations to clients due to unreasonable fears of the ill effects of vaccination thus depriving clients of the potential benefits of rubella vaccination. Since the launch of the program, it has not been monitored or evaluated in a comprehensive manner. Therefore, it is highly appropriate that the quality of rubella immunization services provided through the Primary Health Care network be assessed within the district (4).

The present study is a component of a comprehensive evaluation of the rubella immunization program in the district with the objective of assessment of the quality of rubella

immunization services .It is hoped that the findings will provide information on service deficiencies and help program managers to plan strategies to overcome service deficiencies in relation to rubella vaccination in order to contribute a small step towards the goal of prevention of congenital rubella syndrome (CRS) in Sri Lanka.

Methodology

A descriptive study was carried out in the district to assess the quality of rubella immunization services using the quality control procedure based on *"Lot quality assurance sampling"* that provides simple, rapid and precise information to improve substandard items of supervision. Twenty clinics were randomly selected to apply the method. A threshold of a *triage system* for identifying priorities was defined with administrators and program managers' .The threshold levels selected were 80%, 50%.

The number of clinics needed to be studied to test the hypothesis that the number of clinics providing bad services is at 5% level was 20. If the defective elements (clinics) were to be > 6, the lot should be rejected, and improvements are needed. If the defective elements were found to be < 6, it is not an immediate priority for improvement.

The service delivery was studied, taking into account that rubella immunization was not the only service provided in a clinic. Therefore, it was decided to study 10 deliveries of rubella immunization in a clinic. The triage system used was 95 %, 75% (provider risk 1%, Consumer risk 23%) A specificity of 99 % was preferred to ensure that resources were used to improve clinics that really need improvement.

Non-repetitive activities were marked as adequate or not, by using a binary rule. Repetitive activities were judged by LQAS 10:3 binary rules. More than three defective components were considered to be substandard per clinic. The presence of more than six such defective subsystems for 20 clinics was considered a failure, which needed immediate attention.

A pre-tested, structured observational checklist that comprised essential activities of vaccination referred to as *sub-systems* which include infection control procedures (sterilization), maintenance of cold chain, screening of eligible clients, vaccination technique and maintenance of records were used in non-participatory observation to assess the quality of immunization services. The purpose of the visit was explained but the rubella component was not revealed to the clinic staff to minimize the *Hawthorne effect.*

Results

Results of the non-participatory observation are given below.

Table 1. Assessment of sterilization procedures in relation to rubella immunization (n=20, d=6)

Component	No of failed clinics	Substandard / Standard
1.Availability of steam sterilizers	03	Standard
2 washing of all equipment with soap & water	00	Standard
3 Separate packing of plungers & barrels of syringes and needles correctly in the sterilizer, placement of the forceps in the sterilizer, placement of the forceps in the sterilizer and pouring water to the marked level	00	Standard
4 Covering of the sterilizer when water starts to boil and boiling for 20 minutes	00	Standard
5 Instruments are not inserted into sterilizer after boiling starts	00	Standard
6Availability & maintenance of sterilizing chart	10	Substandard
7 washing hands before immunization	20	Substandard
8 Use of separate syringe & needle for each vaccination	00	Standard
9 Keeping syringes & needles sterile & using a forceps to pick-up syringes and needles	00	Standard
10 Aseptic technique in handling to put the barrel, plunger & needle together, filling & emptying (No touch technique)	03	Standard

Tab 2. Assessment of cold chain maintenance in provision of rubella immunization at clinics in Polonnaruwa (n=20, d=6)

Component	No of failed clinics	Substandard Standard
1.Vaccine is carried in a vaccine carrier	00	Standard
2 Lid is closed during transport	00	Standard
3 Specified number of ice packs are present	00	Standard
4 Ice packs stand on its edges, not flat on each other	00	Standard
5 Diluent is also kept in the vaccine carrier	00	Standard
6 Vaccine carrier is kept away from direct sunlight and heat	00	Standard
7 Only one vial is taken at a time	00	Standard
8 Vials are kept away from direct sunlight at heat	00	Standard
9 Opened vials are kept in a cup of ice water	00	Standard

Table 3. Assessment of the screening of clients eligible for rubella vaccination (n=20, d=6)

Component	No of failed clinics	Substandard Standard
1.A history of previous rubella immunization is inquired	01	Standard
2 Pregnancy is excluded	00	Standard
3 Primary or secondary immunodeficiency is excluded	20	Substandard
4 Use of immunosuppressive drugs is excluded	20	Substandard
5 A history of systematic hypersensitivity to Neomycin and egg protein is excluded	20	Substandard

Table 4. Assessment of the technique of immunization (n=20, d=6)

Component	No of failed clinics	Substandard Standard
1.Label on the vaccine vial was checked	00	Standard
2 Entire diluent is drawn into the syringe vaccine is reconstituted by transferring diluent to vaccine vial, vaccine pellet is completely dissolved.	00	Standard
3 A dose of 0.5 ml is taken to the syringe	00	Standard
4 Vaccine is given subcutaneously (angle of 45⁰ to the skin)	00	Standard
5 Before injecting aspiration is done to exclude access to a blood vessel.	18	Substandard
6. Vaccine is injected slowly, pressure applied, needle withdrawn	00	Standard

Table 5. Assessment of the documentation of immunization (n=20, d=6)

Component	No of failed clinics	Substandard Standard
1.A completed rubella immunization record is issued to each client after vaccination	00	Standard
2 A rubella immunization register is maintained at the clinic	00	Standard
3. Register of women eligible for rubella is available	20	Substandard
3 Name, age, marital status, method of family planning used or adopted, date of vaccination, batch number of the vaccine & address of the client are recorded in the immunization register.	02	Standard
4 Total number of immunization carried out are noted according to the age groups at the end of each immunization sessions	18	Substandard
5 Information from the rubella immunization register is taken into the clinic summary	18	Substandard

Discussion

The quality of rubella immunization services was assessed using the Lot Quality Assurance Sampling (**LQAS**) method considering its simplicity and rapidity. The method has the advantage that this

method can be applied to either small or large populations using a small sample size.

In repetitive activities such as vaccination, a high specificity was preferred to ensure that among detected defective elements, false positives were minimal (high positive predictive value). By ensuring a high specificity, the program manager is able to divert his attention to improve substandard items, which really need inputs thus avoiding unnecessary diversions of scarce resources (cost, training efforts, time requirement for the task etc.) to false positive items. Low sensitivity may cause high false negatives. This can be avoided by regular supervisions that help to detect false negatives in subsequent supervisions.

There is only a small likelihood that a misclassification of an inadequate as an adequate during one round of supervision will be misclassified during a second round. By increasing number of supervision rounds, the error decreases by a greater amount. Subsequently, it is vital to conduct frequent supervisions to minimize consumer risk. Although the high specificity is achieved at the cost of low sensitivity, experts believe that this trade-off is worthwhile, when resources should be invested in activities that really need reform (5). One limitation of the study is the Hawthorne effect. However, since wide ranges of activities were assessed, substandard activities detected will be a clearer area for improvement, although PHM performs better than usual.

The first subsystem consisted of **"sterility"**. The hand washing procedure proved to be defective. In every clinic, they washed hands only at the beginning of the clinic session. When immunization activities were to be resumed after every cessation, washing of hands was not adhered to. Maintenance of a sterilization chart is required to ensure 20 minutes of boiling. The maintenance of this chart was found to be poor in the study.

Cold chain maintenance was extremely good and none of the related activities was found to be defective.

The screening of eligible clients was poor. Public Health Midwives were keen to exclude pregnancy but other contraindications were not excluded. Circulars, which contained contraindications to immunization, have been issued with regard to immunization. This had been clearly explained in the orientation program.

A register of eligible women for rubella immunization was not maintained in any of the clinics supervised. The register of immunization was completed after vaccination. In none of clinics were immunized clients totalled and categorized according to age groups at the end of the session. Had this been performed, any unrecorded vaccinated client would have been detected by comparing the number of vaccinations with the dosages of vaccines used. Not adhering to totalling at the end of the day leads to under reporting if any vaccinated clients are left unrecorded. It leads to inability to calculate vaccine wastage as well. Despite the defective activities already mentioned, overall quality of services was satisfactory.

Recommendations

It is essential to carry out regular supervisions by supervisory staff to detect and modify substandard items. As a few deficiencies were observed in record keeping at the clinic, steps should be taken to improve documentation during and at the end of the clinic session.

Acknowledgements

References

1. Sokhey J. Universal immunization programme: data at a glance. India: Ministry of Health and Family welfare; 1985-86

2. Ministry of Health and Womens Affairs. Declaration of Universal Child Immunization status in Sri Lanka (Sinhala version). Colombo, Sri-Lanka 1989:6-12

3. World Federation of Public Health Organizations. Immunization. Washington: WFPH; 1984

4. Wijesinghe PR. Evaluation of Rubella immunization programme in Polonnaruwa district.Dissertation submitted for the degree of MSc to the PGIM of the University of Colombo, Sri Lanka 1999

5. Valadez JJ. Assessing child survival programmes in developing countries,Testing Lot Quality Assuarance Sampling. Boston, Massachusetts: Harvard School of Public Health; 1991:131-5