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One Dose of the Human Papillomavirus (HPV) Vaccine could be Sufficient

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Background

According to the Medical Research Council, cervical cancer which is caused by the sexually transmitted Human Papillomavirus (HPV), kills more South African women than any other cancer. Although there are over 150 types of HPV, about two thirds of cervical cancer are caused by two strains of the HPV, namely the HPV 16 and 18 strain. Before South Africa introduced a cervical screening policy, cervical screening was performed opportunistically, meaning it was generally done in family planning and antenatal clinics. The problem with this type of opportunistic screening was that it primarily reached younger women who were not the optimal target group because they normally experience significantly lower rates of cervical disease than older women. The South African government has since provided women with 3 Papanicolaou cytology tests (Pap tests) per lifetime, every 10 years, starting at age 30. Although this is a step forward for South African health care development, merely testing for cervical cancer will only indicate if a woman has cervical cancer but does not offer any prevention from the disease.

For this reason, in 2013/14 South Africa committed to provide free HPV vaccines to 9 and 10 year old girls in the poorest 80 percent of schools. HPV vaccines have been shown to be safe and highly effective against possible infection and also decreases ones chances of developing cervical cancer. The vaccine is only effective as a prophylaxis (preventative measure) and must be administered before exposure to HPV. It therefore follows that because HPV is a sexually transmitted disease, the ideal age for vaccination would be before sexual debut and as a result the vaccine has been approved to be administered to 9 and 10 year old girls in grade 4. The National Department of Health has embarked on a twice-yearly HPV vaccination programme, managed within the Integrated School Health Programme (ISHP), targeting grade 4 girls in public schools as of March 2014. This study will examine the rollout of the vaccine and possible cost savings that could be realised if a 1-dose schedule were implemented, as well as the effectiveness of the monitoring and reporting on the vaccination campaigns that have already been conducted.

HPV Vaccine Dosage

According to the World Health Organisation guidelines, 3 doses of the HPV vaccine must be given over a period of 6 months for it to be effective. After some research and

discussions with stakeholders, the Department of Health opted for a 2-dose vaccination, with a third dose to be given after 5 years because research at that time showed that 2 doses of the vaccine were just as effective as the 3 dose regimen if the 2 doses were given within a 6 month period. The decision was arrived at after various analyses revealed significant short-term cost savings for the Department if a 2 dose regimen was followed. The vaccine called Cervarix won the tender for provision to public schools. Eligible girls in South Africa have since been offered 2 doses of this bivalent vaccine which protects against the 2 main strains of HPV, 16 and 18. The vaccine has since been rolled out twice-yearly since the first dose which was administered in March and April 2014 and the second in September and October 2014.

More recent research has shown that a single dose of the HPV vaccine is just as effective in preventing cervical cancer as the two and three dose regimen. Two large vaccine trials published online in the Lancet Oncology supports this finding. According to the research conducted, it was found that the efficacy was the same regardless of the number of doses received. This emerging research is a critical finding because if the effectiveness of the vaccine were the same irrespective of the number of doses received, the Department can realise significant cost savings by reducing the dosage from 2 doses to 1 dose. Savings in terms of vaccine procurement, cold storage and the logistics of administering a second dose could assist the department to use these funds in other areas of importance. If 1 dose is indeed sufficient, it could also improve uptake and increase coverage since only 1 school visit per year would be necessary and departments would then have the option of increasing the number of schools participating in the campaign. This information is especially important in a developing country like South Africa where cost efficiencies are sought after. In addition to possible cost savings, the implications of administering the vaccine as a 1 dose regimen will be informative to decision makers in the public sector, as well as private health care providers, if the emerging research proves correct.

HPV Vaccination Process

Provincial education and health departments must collaborate on the process of administering the HPV vaccine. All participating schools are to prepare and make available the list of names of the grade 4 girls and all the consent forms and vaccination cards on the day of the HPV vaccination. It is understood that the grade 4 girls are

informed of the date of the HPV vaccination at least 3 days before the event. On the day of the vaccination the school is expected to provide the HPV vaccination team with a grade 4 class list and mark which girls are absent from school on that day. The returned consent forms for girls absent on the day of the vaccination must also be handed in with the class list to the HPV vaccination team.

Each grade 4 girl present will be given her own signed consent form and vaccination card before the vaccination session and then be sent to the vaccination information session. The girls that do not have permission for the vaccination have to be sent back to the classroom after the information session while girls that have consent to be vaccinated will proceed to the vaccination area. All girls that were vaccinated will be observed for 15 minutes by the HPV vaccination team before they are returned to class. After the vaccination, the consent forms have to be filed in the learners records by their school. The vaccination cards will be handed to each grade 4 girl to take home for safe keeping and class teachers are required to sign the HPV vaccination register after the vaccination session for their class.

HPV Training

Due to the HPV vaccine campaign being rolled out as a cross-department campaign involving both the Provincial Departments of Health and Education, various pre-HPV campaign training sessions have to be conducted. The vaccination campaign is delivered at schools and is therefore necessary for the schedule of delivery to meet both the requirements of the school calendar and the vaccine dose schedule. This requirement means that trainings have to be concluded before the scheduled first and second dose of the campaign. Standardised training material and practical exercises have to be reviewed by the entire HPV task team. Trainings on HPV have to be customised to school health team leaders, HPV vaccination team leaders, information officers, programme managers and coordinators. The data collection tools accommodate the collection of data in both the paper-based and electronic data capturing systems. To-date the NDoH has managed to successfully conduct all trainings but challenges have been experienced with the electronic data capturing devices that were used in the middle of the latest campaign in some provinces. As a result the NDoH is seeking to strengthen the information system in a standardised manner across all provinces by rolling out electronic data capturing

devices in all the provinces. Special task teams would then be required to configure all these devices and connect them to the national server.

There are many advantages to this method of capturing data, in that electronic devices are an easier way of inputting data that can be quickly consolidated in one place at a national level. It could also possibly improve data quality and it is also typically a fixed cost so the department would not outlay a large amount of funding for these items in the following financial years. The disadvantages are that the initial overhead costs would be very high in terms of procuring the actual electronic tablets, configuring them as well as developing the necessary software that would record the data. Extra training would also be required for users of the electronic devices and this training would be ongoing, depending on the frequency of technology and software programmes changes in the future. The risk of the electronic devices getting lost, stolen, broken or destroyed is very high and would mean a steady budget dedicated to repairing or purchasing a few more electronic devices each year.

As discussed above, if a 1 dose vaccination schedule were implemented instead of 2 doses, training on HPV will only be done once a year, just before the first dose and no follow up training will be needed after that. A reduction in the costs of keeping track of the vaccine data would also follow because there would only be one visit per school per year, and the school visit could be combined with the annual ISHP.

Performance Reporting on the HPV Vaccine

The current indicators the department uses to assess the performance for the HPV vaccination programme are inadequate in recording the success of the second dose of the vaccine being administered. According to the Departments annual report (Table 1.1), only the first dose outcome of the vaccine is published. Failure by the Department to report on the outcome of the second dose does not affirm the Departments efficiency in administering 2 doses of the vaccine but rather raises doubt as to whether it has successfully administered 2 doses of the vaccine to all eligible grade 4 girls that have already received the first dose. In addition the indicator records a deviation from the target and attributes it to vaccinating girls who had missed the first dose, during the second dose campaign run for the first time. This also implies that the department has a record of the second dose coverage but chose not to publish it. Secondly, many questions arise

regarding the monitoring and evaluation of the girls who were vaccinated for the first time, but not during the second campaign run. These include issues around keeping records of these deviations and if the campaign is run the next year, whether these girls received the second dose during the first campaign run. Traceability issues also arise if these girls transfer to another school.

The success of the programme in terms of uptake etc. will also result in distorted information if only the first dose vaccination campaign is published. Policy analysts seeking to assess the current HPV process will also be using partial information and therefore their analysis may not be an accurate depiction of the HPV campaign as a whole.

Table 1.1 HPV Indicator Measurement

Strategic Objective	Performance Indicator	Actual Achievement 2013/2014	Planned Target 2014/2015	Actual Achievement 2014/2015	Deviation from Planned Target to Actual Achievements for 2014/2015	Comments on deviation
To improve access to sexual and reproductive health services by expanding the availability of contraceptives	Couple year protection rate	42.50%	55% (8096666 of 14721211)	52.70%	-2.30%	Performance in 2014/15 increased compared to the previous financial year due to the introduction of a long acting reversible contraceptive, the subdermal implant. Note that this data element was not included in the DHIS and data on the use of the implant are added to the data from the DHIS
	Cervical cancer screening coverage	58.30%	60% (8716794 of 14527991)	54.50%	-5.50%	The policy guidelines are under review with the aim of providing clearer guidance on what constitutes the "gold standard" for CaCx (carcinoma of the cervix) screening, and to make the form of test more accessible nationally, including remote/ hard-to-reach sections of our communities. Women are often reluctant to have a Pap smear done, when offered the test by healthcare providers. The revised policy will also address and ensure improved efforts around heightening awareness and education among women of the importance of CaCx screening as a preventative measure.
	HPV 1st dose coverage	New indicator	70%	91.80%	21.20%	The high coverage is attributed to vaccination of learners with the first dose during the second round

Reporting on the outcome of the second dose of the vaccine is also probably more important than reporting on the first dose if one is determining whether the programme is performing well. The second dose generally reveals whether the learners who had received the first dose had also received the second dose within the stipulated 6 month period and whether their personal information had been properly captured and verified prior to the second dose. Failure to record, monitor and publish results on the second

dose vaccination process suggests that the department may be failing to properly account for the actual vaccine rollout.

Expenditure Analysis on the HPV Programme

Since the introduction of the HPV programme in 2014/15, the NDoH has been allocated R200 million in each financial year until 2018/19 for its implementation. Funding was initially allocated in the National Health Insurance indirect grant for the HPV vaccine component but from the 2018/19 financial year, all funding will be moved into a new direct Provincial Human Papillomavirus Vaccine Grant. The HPV vaccine is currently administered under the ISHP, however the department expects to shift the HPV administration and rollout to the provincial level from the national level. Funding is currently made available on the National Health Grant: Human Papillomavirus (Indirect Grant Component), as well as from the voted funds for the National Department under their Programme 3: HIV and AIDS, Tuberculosis, and Maternal and Child Health budget.

In 2014/15 R189.5 million was spent on the HPV vaccine programme. Spending decreased to R125.1 million in 2015/16, however this amount excludes the R32.8 million that had already been committed by the year end. The reason for the decrease in expenditure in 2015/16 was probably attributed to the department procuring more vaccines than they administered in the previous financial year, which they then used for that year. In the 2015/16 financial year, the department also utilised voted funding to pay for certain HPV related activities such as travel and transport, and compensation costs.

Table 1.2 Summary of expenditure and commitments made for the 2014/15 and 2015/16 financial years

	2014/15	2015/16
Compensation and contractors	2 603 615	12 479 580
Inventory (Incl. Vaccines)	177 045 656	112 814 253
Transport and travel	9 063 134	20 727 845
Training, venues and catering	111 518	3 983 263
Stationery, Printing and communication	679 429	4 068 195
Equipment (e.g. Electronic tablets)	-	3 345 424
Other expenses	-	556 642
Total Expenditure (incl commitments)	189 503 352	157 975 201

Table 1.2 above illustrates the spending already realised on the HPV vaccine campaign for both the first and second doses. The highest expenditure items include the procurement costs of the HPV vaccine, followed by travel and transport costs and compensation of employees, such as student and retired nurses that are hired by provinces. Invoices for the programme incurred at the provincial level of government are paid for by the NDoH. Electronic capturing devices at R2 000 each were procured to more precisely measure and electronically capture the learners that have been vaccinated for the first and second dose. This initial expenditure will enable the HPV programme to be better managed in terms of monitoring, reporting and data quality.

Costing the HPV Programme

The costing model based on the assumptions made illustrates that R330 per learner will be the approximate cost of procuring 2 doses of the vaccine. Based on the analyses R195.5 million is the total cost per year to administer a twice-yearly vaccination programme for 455 000 girls in Grade 4 in public schools across South Africa.

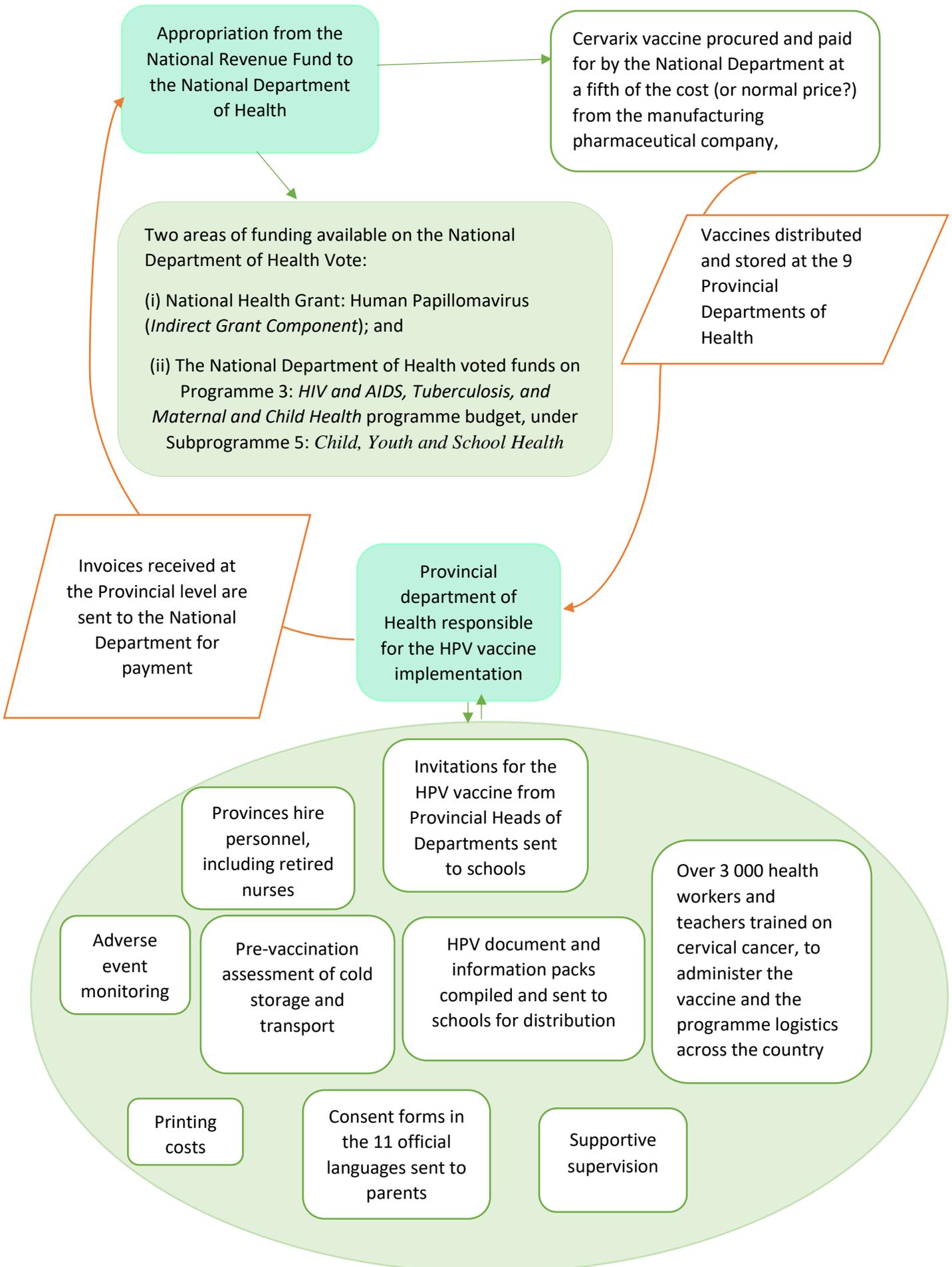
A costing for a 1 dose vaccine was also done and the estimated cost of the vaccine rollout will be R99.8 million. This amount is roughly half the cost of a 2 dose vaccine. It is therefore apparent that significant cost savings can be achieved by administering a 1 dose HPV vaccine. Since the main costs in administering the programme is the HPV vaccine, travel and transport and compensation of employees, it was assumed that these costs will be halved with a 1 dose schedule, since they are not fixed costs.

Monitoring and Reporting on the HPV programme

The reporting on the success of the HPV vaccine only shows vaccine coverage for the first and second dose. The main impact of the vaccine however will only be seen in about 2 to 4 decades, as the girls that were vaccinated in 2014 pass through the ages where cervical cancer incidence is highest. Therefore from 2034 onwards, South Africa should see a dramatic drop in the rate of cervical cancer incidence.

The HPV vaccine rollout has also contributed to indirect shorter term benefits for the health sector, such as strengthening the relatively weak pubescent and adolescent health systems in South Africa.

Funding Flow:



Human Papilloma Virus (HPV) vaccine Logframe

National Department of Health

Impacts	Towards the realisation of a long and healthy life for all South Africans		
Indicator / Measure	Increase in the life expectancy rate and reduction in cervical cancer cases reported for all female South Africans	Life expectancy reports and surveys	People die of natural causes
Data source	ENE, Annual report	ENE, Annual report, Stats SA data	Stats SA data
Direct impact of HPV Vaccine	Reduction in the incidence of cervical cancer		
Indicator / Measure	Coverage of cervical cancer screening coverage per year	Hospital records, clinical reports	Women over 30 years of age receive 1 Pap test every 10 years
Data source	ENE, Annual report	National and Provincial Departments of Health	Provincial Departments of Health
Outcomes	HPV vaccine coverage		
Indicator / Measure	No. of grade 4 girls vaccinated and no. of schools covered	HPV vaccination register	All students eligible for the vaccine will receive it
Data source	NDoH Strat Plan 2015/16-2019/20, NDoH Annual Report	NDoH Annual Report	Individual HPV vaccination cards
Outputs	Grade 4 girls in the poorest 80 percent of public schools receive 2 doses of the HPV vaccine within 6 months		
Indicator / Measure	All eligible girls receive the HPV vaccine during the first and second dose campaign	100 percent attendance and participation on the day of date of the vaccination	No eligible girl will be absent from school
Data source	NDoH quarterly reports	Attendance register	Attendance register
Process / Activities	Refining of HPV vaccination policy	Develop implementation plan for the HPV vaccination rollout for both doses	Cost the HPV programme
Process / Activities	The HPV vaccination team receive relevant training regarding the various areas of the HPV vaccination process	Vaccination consent forms and information packs are sent to parents	Consent forms are signed and returned timeously to each school
Process / Activities	Administer the first HPV vaccine dose in March/April	Accurately capture data on electronic tablets	Keep a record of the girls that receive the first vaccine dose
Process / Activities	Administer the second HPV vaccine dose in September/October	Accurately capture data on electronic tablets	Ensure the girls that received the first dose, also receive the second dose within the 6 month period
Inputs	Procurement and cold storage of the HPV vaccines	Expenditure invoices sent to the national department for payment to be made	Adequate HPV programme funding in future years
Inputs	Retired nurses, student nurses and contractors hired	Employment contracts awarded	No skills shortages and prices remain stable
Responsibility	PR3: HIV and AIDS, TB, Maternal & Child Health	PR3: HIV and AIDS, TB, Maternal & Child Health	PR3: HIV and AIDS, TB, Maternal & Child Health
	National Department of Health		
Current Programme Elements	Develop / refine HPV policy	Refine HPV implementation strategy	Cost HPV implementation strategy
Location of budget	PR3: HIV and AIDS, TB, Maternal & Child Health	PR3: HIV and AIDS, TB, Maternal & Child Health	PR3: HIV and AIDS, TB, Maternal & Child Health

Concluding comments and findings of the research

- 1) The doses discussed, measured and published in all departmental documents is the first dose only.
- 2) Keeping track of age qualification could be a problem in cases where some learners have been held back from progressing to the next grade or miss the vaccine because they moved to another school.
- 3) Consent forms not returned to the school in cases of child headed households will mean that some eligible girls may miss the opportunity to get vaccinated.
- 4) A school's role and responsibility is not defined clearly in policy documentation. It seems that the NDoH and Provincial Health departments carry out the process almost entirely on their own.
- 5) Girls that miss the first vaccine can get it during the second phase but there is no clear direction given as to how they receive the second dose and whether it is within the 6 month period. This calls into question the supposed urgency for the vaccine to be administered twice within a 6 month period.
- 6) One dose of the vaccine could be just as effective in protecting against cervical cancer as 2 or 3 doses. This information suggests that a 1 dose schedule should be further evaluated.
- 7) Savings from a 1 dose regimen can be made instead of a 2 dose regimen. If one dose is sufficient, it could reduce vaccination and administration costs as well as improve uptake. This is especially important in less developed regions of the world where more than 80 percent of cervical cancer cases occur.