Ten Million Children Are Dying in the Poor World

David J. Fitch, dfitch@uvg.edu.gt,
Programa de Investigaciones en Ciencias Sociales
Departamento de Matemática, Universidad del Valle de Guatemala

ABSTRACT

This paper looks at a method used in evaluation work in International Health, e.g. to answer the question, has the goal of an 80% child vaccination rate been achieved? Statisticians concerned with the lives of children would pose a <80% null hypothesis, and if rejected would accept that the goal had been achieved. The method considered here poses a "null" hypothesis that the rate is ≥80%, rejecting it only if the chances of the rate not being at least 80% are very small, thus putting the lives of children at risk.

Keywords: LQAS, Valadez, USAID, Evaluation

Introduction

UNICEF estimates that ten million children under five die each year in the developing countries of the world. We could help reduce this number, both as statisticians and as concerned human beings. There is not enough time to speak very much of my observations over these past 16 years from my dual life – my life with neighbors in an indigenous Guatemalan village, and as a research professor. I will speak of two things - the first as a statistician and the second as a concerned human being. There is much overlap.

How are statisticians doing by all those grieving mothers? Well there are very few statisticians working in what is being called International Health (IH) or Global Health, almost none. One might say there is an anti-statistical bias in IH. I doubt if there are any ASA members in the Global Health Bureau of the United States Agency for International Development (AID) and there could be none within the NGOs and contractors they fund. So our question might be, of those people, not statisticians but people engaged in what we might consider statistical work – how are they doing? I am going to argue here - that because there is much support for an evaluation method that claims programs are successfully when in fact there is unacceptably little evidence for such - they are not doing well, nor are they knowledgeable enough to do well.

Lot Quality Assurance Sampling

Measles is a big killer of children - more than half a million in 2003. Let me relate my measles story. We were visiting a priest friend in a small town in Quiché. We were at supper when the church bell started to ring. I asked Benoit, "Why are you continuing to eat when the bell calls?" He replied, "Another child has died of measles. It rings most every day."

Measles will probably not spread within a community if the child vaccination rate is 80%. Thus it would be very useful to have a simple method to determine if this were the rate within a community of concern. Valadez has given a method which he seems to say does just that. He calls it a Lot Quality Assurance Sampling (LQAS) method. He writes (1991, p72) **"In a sample of 28 children from the catchment area of a Health Area, if nine or fewer have not received the target service, then classify the Health Area's coverage as adequate. Using this rule, managers will identify correctly areas with ≥80% coverage more than 95% of the time."** What this seems to say is obviously not correct as 19 vaccinated (9 unvaccinated) out of 28 is only 68%. What does he mean, and how does he reason? All kinds of people think his Lot Quality method is great. AID funded such evaluation work of Valadez for some 15 years. The very fine head of their Global Health Bureau in email exchanges said they were very pleased with Lot Quality – but that may have been because a CDC person seems to have been supporting it. Valadez's method is said, incorrectly, to be supported by a paper that gives a LQAS method that, contrary to the Valadez method, correctly evaluates child risks (Lemeshow, S, A, & Stroh, G, 1988). Valadez for years had a Harvard appointment and his book was published by Harvard University Press. He headed the evaluation efforts of a major, five year, AID contract. He now heads AIDS evaluation work at the World Bank. And he is the current chair of the International Health Section of the American Public Health Association. Receiving all these honors I must be wrong when I see his work as being confused. But what I really think is that all this shows the serious lack of statistical competence in International Health.

It is very difficult for me is to speak critically of a person, to say things that imply that the world's response to 10 million grieving mothers might just include snake oil salesmanship. We statisticians, happily, tend to be nice people. But for right now, let me be not nice, let me try my best to be with those mothers. And while I may sound as if I am critical of one person I am really trying to say that there is a general lack of statistical talent in

International Health, and that we in Statistics have not found a way of contributing. So please hear me, not as criticizing Valadez but rather of criticizing you and me. As I see it we carry a fair amount of responsibility for the very large number of easily preventable deaths because we haven't informed ourselves sufficiently about an area to which we could contribute – children dying – 10 million.

To better understand things let us try to see how the Valadez, Lot Quality people reason. They tell us their method comes from a statistical method used in industry. I know very little of that literature but I do know that it includes what might be called health provider risks, and child risks. Provider risk would be the risk of concluding that those responsible for vaccinating children in the community had failed to reach an 80% goal when in fact they had been successful. So even if the chances of the providers having been successful are small, with provider risk concerns, they are considered successful unless there is strong reason to believe otherwise. Apparently in some industrial situations there is a reason for keeping such provider risks low and little child risk type concerns. Using this industrial method to evaluate child vaccination efforts, one proceeds as follows. Although the Valadez people don't describe their method in this way, in standard statistical terms, a null hypothesis, that the children of the community have been vaccinated at an $\geq 80\%$ rate is posed[1]. A sample of say 28 children is drawn from the community and the vaccination status of each is determined. With these data the null hypothesis is tested. Unless this hypothesis can be rejected at a confidence level more than 95%, the $\geq 80\%$ null hypothesis is accepted. The promotion of his Lot Quality method has rewarded Valadez handsomely, as noted above but only - as claimed here - because there is so little statistical competence in IH. People working with AID money in IH can use his method and claim success even when there is almost no real evidence of such. AID can claim in their reports to the Congress that the success rate in projects they have funded has been high. Valadez can keep "honest" by writing, with regard to some project evaluated with his method, that with finding 19 out of 28 vaccinated one would not reject the program area as failing to reach the 80% coverage target as this is supported at a confidence level of at least about 5%. "Everybody" is happy - but the children die.

Let us review, repeat things, a little less emotionally. In order to minimize provider risks it is concluded that they had met the 80% goal, as long this can be said with at least about a 5% confidence – the meaning of this to be considered in a moment. The consequences of defending one's work using provider risk analyses is that one would often conclude that community children were protected from measles when in fact they were not - that the community rate was actually less, perhaps far less, than 80%. So what may seem confused or incorrect, as for example the quote above, is at least partly understandable once we see that their reasoning may make sense if they are thinking about provider risks? Of course that's not the goal we would have where the concern is the lives of children. We want to see that it is child risks that are the concern. Now let us get into some details of elementary hypothesis testing. To answer the question, "Can we be reasonably confident that the child vaccination rate within a particular community is $\geq 80\%$?", we pose the null hypothesis, H_0: the vaccination rate is <80%, i.e. that the unvaccination rate is $\geq 20\%$, and we draw a sample, e.g. of 28 children from the community. Now if the community unvaccination rate is 20% we know from the binomial distribution that it is very unlikely that one or none of the 28 will be unvaccinated - the probability, as we see from Table 1, being .02. So if one or none of the 28 is unvaccinated – 27or 28 are vaccinated - H_0 is rejected and, H_1: the vaccination rate is $\geq 80\%$ is accepted. The confidence level by which H_0 is rejected can be thought of as about 1.00 – .02, i.e. .98. Hence finding 27 vaccinated we reject H_0 and accept H_1 with the confidence level of about .98. Now the probability of 9 of the 28 children not being vaccinated if the community rate is 80% is .96 as we see from Table 1. So with the reasoning that led us to reject H_0 with 98% confidence, with finding only 19 vaccinated (9 unvaccinated) we would "reject" H_0 and accept H_1 with a confidence of about 1.00 - .96 = .04, i.e. with essentially no confidence. Above and below I have written, or might be inclined to write, that the Valadez people say the vaccination rate is $\geq 80\%$ as long as there is at least a 5% chance that this is true. Please read such as concluding with as little as about 5% confidence that the rate is $\geq 80\%$. Note that Valadez's words here are, "managers will identify correctly areas with $\geq 80\%$ coverage more than 95% of the time." The impression one gets from this is quite different than the facts.

In a Robertson *et al* paper (1997) reviewing 34 studies they write that Lot Quality uses this standard procedure – e.g. testing a posed <80% null hypothesis and if rejected accepting that the child vaccination rate is $\geq 80\%$. But as we have seen the method used by Valadez is quite different. He poses, in effect, an $\geq 80\%$ null hypothesis which means he can, with his reasoning, conclude the child rate of 80% has been achieved even when the chances are slight. My guess is that few of the 34 studies listed in the article, at least if the goal was like 80%, use the hypothesis testing which is described in the article as the method actually used in Lot Quality studies reviewed. Rather they likely use the Valadez method. Library facilities are limited here in Guatemala. I look forward to time in the US National Library of Medicine (NLM) to

[1] Thanks to Paul Levy for this insight.

trace down some of these studies and see to what extent what I speculate is true. And I plan to attend meetings of the American Public Health Association in December, 2005. With Valadez the currently chair of the International Health Section I expect Lot Quality studies to be reported there. The deadline for getting this in the 2005 proceedings will be before I get a chance to search in the NLM for some of the 34 articles. I hope you will email me if you are interested in pursuing these things. I can share what further I've learned. I can hear about mistakes I have made, and can learn of your views.

We do have the Valadez book, where one of the 34 studies is reported. They carried out Lot Quality surveys in 60 Health Areas. Adequate coverage was defined as 80%. On the bases of survey findings each Health Area was classified as adequate or not adequate. This classification was done, not using the correct method described in the Robertson *et al* article, but rather in the manner as noted here. Samples of 28 children in each area were drawn. An $\geq 80\%$ null hypothesis was in effect posed. If 19 or more were found to be vaccinated it was accepted that the rate was $\geq 80\%$. My guess is that this is how Lot Quality was used in all of the studies. Correct procedures do seem to have been used in estimating means and variances for the 60 Health Area population. But the goal of getting estimates for each area, the Lot Quality announced goal, seems to have been abandoned.

I'd say that the facts, to the extent that they are facts, can lead us to conclude that WHO and USAID people are motivated in their bureaucratic settings to give methods which might seem to yield accurate community estimates from small samples. They either know little statistics, or if they know the correct statistics – such as are given in the first paragraph, page 200 of the Robertson *et al* paper – choose not to use them nor to challenge the flawed Valadez reasoning as such would be unpopular with the IH community that wants something simple, something that will likely allow them to conclude that their project has been a success, and wants to think they have done a good job.

The non-statistician, eager to believe a health effort has been successful may well believe that Valadez is saying his 9 of 28 unvaccinated rule can be used to answer positively the question, "Can one conclude with 95% confidence that the rate in the community sampled is $\geq 80\%$?" But although Valadez seems to be saying this, i.e., his Lot Quality method is one for examining child risks, when it is not, he does at times imply, more or less clearly that what he writes is only correct from a provider risk perspective. For example he wrote in an email of 1/29/04 to the head of the Global Health Bureau of USAID that with finding 19 of 28 children vaccinated "one would not reject the program area as failing to reach the 80% coverage target". There are two ways in which what he has written are "true". As noted above, with finding 19 out of 28 vaccinated if one rejected a <80 null hypothesis and accept a $\geq 80\%$ hypothesis, it would be only at a confidence level of about 5%, i.e. with essentially no confidence. The second defense of what he writes, as noted in other places here, is to observe that with finding 19 of 28 vaccinated, 80% would fall within a 95% confidence interval, and thus with provider risks concerns an 80% hypothesis would not be rejected. (Note that the smaller the sample the more likely one, with this reasoning, would be able to conclude that the 80% goal had been achieved.) Neither reasoning satisfies our concerns about protecting children from the killer measles. But he seems to have hidden his reasoning sufficiently so that the Assistant Administrator, head of the Global Health Bureau of the United States Agency for International Development, with no one statistically knowledgeable on her staff, did not – nor have others in IH seen the danger in his method for the lives of children. Sadly statistics is little known or honored in International Health.

Let's look at the quote again. **"In a sample of 28 children from the catchment area of a Health Area, if nine or fewer have not received the target service then classify the Health Area's coverage as adequate. Using this rule, managers will identify correctly areas with $\geq 80\%$ coverage more than 95% of the time."** Valadez seems to be saying that to determine, with normal statistical procedures, whether or not the child vaccination rate in a community is 80%, one can take a sample of 28 children. If 9 or fewer of the 28 have not been vaccinated then a manager can conclude, with 95% confidence, that the community population vaccination rate is 80%. This is not true and a careful reading of what he has written indicates that if challenged he may claim that he is saying something different. Let's look at two possibilities of how he might explain such a claim.

1. He writes **"Using this rule, managers will identify correctly areas with 80% coverage more than 95% of the time."** It can be read as saying that his Lot Quality method would, if we separated areas into two groups - those where the coverage is $\geq 80\%$, and those where the coverage is less than 80% - that his method would correctly identify areas within the $\geq 80\%$ group, as areas with a vaccination rate of $\geq 80\%$, more than 95% of the time. This is true, but if this is how we are to read what he writes it is not helpful. It gives no clue as to how those $\geq 80\%$ coverage areas are to be separated from those where the coverage is less. So this reading does not give a rational for his claim.

2. How are we to read, "**will identify correctly areas with 80% coverage"**? We see from column 4, row 9 of Table 1. that with 9 of 28 unvaccinated the probability of an 80% hypothesis being true is .09, i.e.>.05, so it would

not be rejected. It appears as if an area is identified as with **"80% coverage"** by using a provider risk hypothesis, and since the probability of this 80% hypothesis being true is >.05, the hypothesis is not rejected, and the "**80% coverage"** hypothesis is accepted. Since such conclusions, with provider risk reasoning is that children have been protected when there is only a small chance that this is true, we would not like to see an evaluation of a child vaccination program, or any health program, carried out in this way.

We can see an error in reasoning in what we might call a **"Valadez's rule"** for identifying areas with 80% coverage. I don't find that it is clearly stated anywhere. It is a rule he seems to be trying to give his reader, trainee, without her or him recognizing that it is flawed. It goes as follows. For a given sample size drawn from a population where the unvaccination rate is 20%, determine the minimum unvaccinated number of children one will find, with repeated sampling, at least 95% of the time. For sample sizes of 28 this number as we see from the 96% in column three is 9, i.e., 19 vaccinated. Then in evaluating a vaccination effort, if one draws a sample of 28 children, and finds 19 or more of these children vaccinated, his rule seems to be that one can conclude that the rate in the community from which the sample was drawn, is ≥80%. Apparently to convince trainees that this is true, he has them draw samples from a bag with 80 green marbles and 20 red ones (www.dec.org/pdf_docs/PNACN935.pdf). Then if, in evaluating a vaccination effort one finds 19 vaccinated in a sample of size 28, one can apparently conclude the rate is 80% with 95% confidence. But if this is his reasoning - or the impression that one gets - it is reasoning of the type, if A then B, implies if B then A. It is false reasoning. It is a fact that, if the population rate is 80%, one will find 19 or more vaccinated 96% of the time, as we see in column three. But one can not conclude from this fact, that if 19 or more of 28 are vaccinated, the population rate is at least 80%. If John shot the President then John had a gun, does not imply that if John had a gun then John shot the president. I am beginning to believe that Valadez knows all of this and is letting the International Health community believe that finding 19 vaccinated means that they can conclude with 95% confidence that a vaccination rate is ≥80%. The tragedy is that the IH people have not seen the relevance to their mission of statistics. They have not done the hard work needed to learn the statistics necessary in order to carry out well the mission they have chosen. And let me add, a reason for this is likely that they find they can get money from USAID without knowing relevant statistics. My experience with AID suggests that were an NGO to include sound statistical reasoning in a grant application, it would have a negative effect.

Number un-vaccinated	Probability of this number	Probabilities for testing the null hypothesis that the rate is	
		<.80	≥.80
0	0.00	0.00	1.00
1	0.01	0.02	1.00
2	0.05	0.06	0.98
3	0.10	0.16	0.94
4	0.15	0.31	0.84
5	0.19	0.50	0.69
6	0.18	0.68	0.50
7	0.14	0.82	0.32
8	0.09	0.91	0.18
9	0.05	0.96	0.09
10	0.02	0.99	0.04
11	0.01	1.00	0.01
12	0.00	1.00	0.00
13	0.00	1.00	0.00

Table 1. Probabilities and cumulative probabilities from the binomial distribution for numbers unvaccinated of samples of 28 children, given that the unvaccinated rate is .20, i.e. the vaccination rate in the community is 80%.

Careful consideration of this **Valadez's rule** shows that it again is a rule for testing provider risks. Perhaps he knows this but is not saying it - trying to leave the impression that the rule allows one to decide whether or not children have been protected against measles, i.e. the community rate is $\geq 80\%$. My anger is out of thinking of those mothers - and I find my anger is especially likely to come when something is implied that is not true. For me it's worse than lying. Let's consider some things in Table 1. Entries in column three are the probabilities of the number of unvaccinated children being the row number or less that one would expect to find in a sample of 28 if the population unvaccinated rate is 20%, such as the .96 probability we see for 9 or fewer unvaccinated children found in column three, row 9. With row 9 identified as the first row, going down, where the column three entry is >.95, note that the column four entry is .09, which is the first column four entry >.05 going up - the smallest probability in the column by which a $\geq 80\%$ provider risk null hypothesis would not be rejected, and presumably accepted. Let us note something here that may have troubled a reader. The two probabilities, .96 and .09 don't add to 1.00 as one might well think they should. The reason is that the .05 probability of the number unvaccinated being exactly 9 is included in both the probability for testing the null hypothesis that the rate is <.80, and that it is $\geq .80$ – columns three and four. So Valadez has his reader, his trainee, consider the fact that if a population's unvaccinated rate is .20 one would expect to find in samples of 28, 9 or fewer unvaccinated 96% of the time. From this fact he seems to want one to believe that if 28 children are sampled from a community and if 9 or fewer of the sample are unvaccinated that one can say with at least 95% confidence that the child vaccination rate in the community is at least 80%. But the probability for testing an 80% null hypothesis is not the .96, identified by finding 9 of 28 unvaccinated, but rather the .09 in the same row as the .96, but column four. If our concern were provider risks we would not reject the null hypothesis that the population rate is $\geq 80\%$ as the probability by which we might reject this null hypothesis is greater than .05. But basing a conclusion, in effect, on a 5% chance that children are protected from this dangerous disease is no answer. Let's hope that those concerned with saving children's lives will, in the near future, begin working with people that understand these things.

And a comment. I see no advantage in using the binomial distribution – a discrete distribution – over the usual and more efficient confidence interval method for testing a provider risk hypothesis that the vaccination rate is 80%., and the reader will note that I have gone back and forth between the two approaches. Perhaps it is an advantage to those promoting the Valadez type LQAS method in that, binomial distribution probabilities being less familiar; problems with the method are more difficult to see. With 18 of 28 vaccinated the CI is .340-.832, i.e. .80 is in the interval. Valadez now suggests sample sizes of 19. Here with 11 vaccinated the CI is .335-.823. With 11 of 19 found vaccinated the population rate is just as likely to be 34% as it is to be 82%, giving no good reason to believe children are protected.

Let me say something more, about corruption, something that often also depends on implying things that are not true. We have a very fine and courageous minister of education. A few months ago she reported to the press that she had found, that of the 74,000 people receiving a monthly teacher pay check, 16,000 didn't teach. The money was a pay off for supporting a winning presidential candidate. AID supports education in Guatemala. Why didn't, during a previous administration, they say to the minister, you clean up your act - which will make some $30 million available - and we will add $20 million. With $50 million we can do a lot for that which is most needed for the country's development – education. I fear the reason is that a typical minister would say, "No" and the donor, if she kept to her threat, would not be able to spend her money. Spending money is of large importance to a bureaucrat. The more money she spends the more important she is, the more rapidly will she will be promoted. Unfortunately people in a donor organization, because it could be to their advantage, may seek to work within the network of corruption here. Procedures can be bypassed, things can get done. Promoting one's career may take priority over helping Guatemala. There are a lot of fine people in International Health but the concern here is that there are few professionals in areas of statistics. Professionals are more likely, I believe, to ask if an expenditure would likely achieve some goal, and less likely to rationalize the expenditure of money. They would be more inclined to ask, "What is the evidence?" I also believe professionals are less likely to promote corruption. And an ASA member would certainly not come to our meetings and try to sell the method we just reviewed.

Some Concluding Remarks

1. Valadez's stated concern to get estimate for particular communities as to whether the child vaccination rate is 80% is understandable but not practical due to the large number of children that would have to be sampled.

2. His substitution of provider risks - from an industry application - for child risks, allows much smaller samples but puts children at risk.

3. Since standard hypothesis testing is not feasible, the challenge is to develop decision rules as to where to put health efforts based on feasible statistics.

4. The evaluation of new health programs is important but donor organizations need to strengthen themselves statistically if they are to help. AID, for example is very weak, as are their contractors. And with such expertise they would have not have spent their millions on Lot Quality.

5. With regard to Millennium Development Goal grant applications, a country that has experimentally evaluated and found successful those health programs for which they seek funds will be more likely to have their grant application accepted – another reason for us getting involved in International Health.

6. As grants will not be made where corruption is severe, donor organizations can help countries develop if they will act so as to reduce corruption.

7. Someone statistically knowledgeable might well have one of two reactions in reading of AID funded evaluation studies. Likely the most typical would be - when methods are not clearly spelled out - to assume that reasonably correct methods were used. But from one knowing of the reputation in Washington of USAID, the reaction might well be, "One can not expect good work of the agency." Washington is full of statisticians, many very good ones, and the Washington Statistical Society is much respected within the statistical community. But no one from the donor agencies participates. We observed who, in order to get a promotion went to USAID, and saw that their standards were low. My plea is to recognize the level of work in International Health and to work for improvements. Children's lives are in the balance.

8. I trust that it is clear that my concern here is only to make the case that the IH community, accepting Valadez's LQAS as a method – in so far as it does – as one that allows one to conclude with 95% confidence that the child vaccination rate is 80% or more when e.g., 19 of a sample of 28 children are found to be vaccinated, shows that much of this community lacks the statistical competence needed, in some situations, to save children's lives.

9. Where 9 of 28 children are unvaccinated we can have very little confidence that the community rate is $\geq 80\%$. Valadez shows however that here, i.e. where 9 or fewer of 28 are unvaccinated, we can have about 95% confidence that the rate is $\geq 50\%$. But at a 50% rate children of a community are not protected of dying of measles, so this is not relevant to the concerns of the present paper.

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