

Chapter TWO

A NEW CHAPTER

Man is a credulous animal, and must believe something; in the absence of good grounds for belief, he will be satisfied with bad ones.

Bertrand Russell

By allowing a flawed belief in vaccines to dominate our thinking, we have left ourselves open to all sorts of claims, prejudices, coercion, pressure, and restrictive laws. We have also allowed spurious reports and conclusions to be published, without proper scrutiny. One of these reports has been worked up over the past few years, and has taken the world by storm. We are destined to write another erroneous belief-chapter in our history books, unless we can acknowledge and correct it.

If you are not one to follow the news, you may have missed it. Others will have undoubtedly seen a stream of *good-news* stories over the past few years, such as:

Measles Deaths In Africa Plunge By 91%^{1,2}

There have been many versions of the theme; the percentage rates have changed over time. However, the bodies of the stories leave us in no doubt as to the reason for their headlines. Here are some direct quotes:

In a rare public health success story on the world's most beleaguered continent, Africa has slashed deaths from measles by 91 per cent since 2000 thanks to an immunization drive.

The Measles Initiative said Thursday that worldwide measles deaths fell from an estimated 757,000 to 242,000 between 2000 and 2006, a reduction of 68 per cent made possible by the remarkable gains in Africa, which cut fatalities from an estimated 396,000 to 36,000.

...."The clear message from this achievement is that the strategy works," said CDC director Dr. Julie Gerberding of the drive to vaccinate all children against measles before their first birthday and provide a second opportunity for measles vaccination through mass vaccination campaigns.

An ambitious global immunization drive has cut measles deaths...

Measles deaths in Africa have fallen as child vaccination rates have risen.

These stories represent a modern-day version of the *belief* which we discussed in the previous chapter. They are not merely *good-news* stories, but triumphant

1 Medical News Today 30Nov 2007; <http://www.medicalnewstoday.com/articles/90237.php>

2 UNICEF Joint press release; http://www.unicef.org/media/media_41969.html

overtures, seemingly offering up-to-date proof of the value of vaccines; strong images of a miracle transforming a world where death is common, into one where lives are saved. Sound familiar?

The stories have been faithfully repeated by all and sundry. The general media from the BBC and ABC, to the US Federal News, World Health, local papers, television shows, magazines, and medical journals have joined in.

Unbelievable results

However, there is something deeply disturbing about the stories, and it is not immediately apparent. The fact is: no-one knows how many people died of measles in Africa. No-one! Not last year and not ten years ago.

I will repeat that. **No-one** knows how many measles deaths have occurred in Africa. So, where did these figures come from? I will explain that in this chapter. In a nutshell, they were calculated on a spreadsheet, using a formula. You may be surprised when I show you how simple the method was.

We all believe these stories, because we have no reason to doubt them. The only people who would have questioned them were those who were aware that the deaths had not been counted. One of these was World Health Organisation (WHO) head of Health Evidence and Statistics, who reprimanded the authors of the original report (on which the stories were based) in an editorial published in the Bulletin of the WHO, as I will discuss shortly. Unfortunately, by then the train was already runaway. The stories had taken off virally through the worldwide media.

First, an overview of the formula. The authors looked at it this way: for every million vaccines given out, we hope to save 'X' lives. From that premise, we simply count how many million vaccines we gave out, and multiply that by 'X' to calculate how many lives (we think) we have saved. That is how the figures were arrived at.

| |
|---|
| IF |
| 1 million shots = 50000 lives saved |
| then... |
| 100 million shots = 5000000 lives saved |

The stories and the formula are both products of a deep belief in the power of vaccines; the same belief that Chapter One exposed. We think the stories report facts, but instead they report *hopes*.

The nuts and bolts

Hardly any of the willing participants in spreading the stories bothered to check where the figures came from, and what they meant. That was possibly understandable. Why would we need to check them? After all, they were produced by experts: respected researchers, and reputable organisations such as UNICEF, American Red Cross, United Nations Foundation, and the World Health Organisation.

However, I did check them. I checked because I knew the developing world wasn't collecting cause of death data that could provide such figures³. In fact, it is currently estimated that only 25 million of the 60 million deaths that occur each year are even registered, let alone have reliable cause-of-death information⁴. Sub-Saharan Africa, where a large proportion of measles deaths are thought to occur, still had an estimated death registration of only around 10%⁵ in 2006, and virtually no reliable *cause-of-death* data. Even sample demographic surveys, although considered accurate, were not collecting cause-of-death data that allowed for these figures to be reported. Simply put, this was not real data: the figures **had** to be estimates.

I was curious as to how the estimates were arrived at, so I traced back to the source—an article in *The Lancet*, written by a team from the *Measles Initiative*⁶. The article described the method used to create the figures presented in all of these stories. After reading the article, I realised the reports were not measles deaths at all. They were *planning estimates*, or *predictions*. In other words, they represented outcomes that the people at the Measles Initiative had *hoped* to achieve, through conducting vaccination programs.

Don't get me wrong. We all know that planning and predicting are very useful, even necessary activities, but it is obvious they are not the same as *measuring outcomes*.

The title of the original report from the Measles Initiative reads, "*Has the 2005 measles mortality reduction goal been achieved? A natural history modelling study.*"⁷ The authors took one and a half pages to explain how *natural history modelling* applied here. I will simplify it in about ten lines. I realise that in doing so, some may accuse me of editorial vandalism, however I assure you what follows captures the essence of the method. The rest is detail. If you are interested in confirming this, I urge you to read the original article for that detail. Here we go... the formula at the heart of the stories:

My interpretation of the Measles Natural History Modelling Study (2007)

1. Open a blank spreadsheet
2. Enter population data for each year from 2000 to 2006
3. Enter measles vaccine coverage for each of the years also

3 Jaffar et al. Effects of misclassification of causes of death on the power of a trial to assess the efficacy of a pneumococcal conjugate vaccine in The Gambia; *International Journal of Epidemiology* 2003;32:430-436
<http://ije.oxfordjournals.org/cgi/content/full/32/3/430>

4 Save lives by counting the dead; An interview with Prof Prabhat Jha, *Bulletin of the World Health Organisation* 2010;88:171–172

5 Counting the dead is essential for health: *Bull WHO* Volume 84, Number 3, March 2006, 161-256
<http://www.who.int/bulletin/volumes/84/3/interview0306/en/index.html>

6 Launched in 2001, the Measles Initiative is an international partnership committed to reducing measles deaths worldwide, and led by the American Red Cross, CDC, UNICEF, United Nations Foundation, and WHO. Additional information available at <http://www.measlesinitiative.org>

7 Wolfson et al. Has the 2005 measles mortality reduction goal been achieved? A natural history modelling study; *Lancet* 2007; 369: 191–200 Available from http://www.measlesinitiative.org/mi-files/Reports/Measles%20Mortality%20Reduction/Global/Wolfson%20Lancet2007_Measles_Mortality_Reduction.pdf

4. Assume all people develop measles if not vaccinated
5. Assume vaccination prevents 85-95% of measles cases
6. Calculate how many measles cases were 'prevented' each year (using the above figures)
7. Calculate how many measles **deaths** were 'prevented' each year (using historical case-fatality ratios)

There, simple. As you can see, this is a typical approach if we are *modelling*, for predictive purposes. Using a spreadsheet to predict outcomes of various plans helps us set targets, and develop strategies. When it comes to evaluating the result of our plan however we need to go out into the field, and measure what happened. We must never simply return to the same spreadsheet. But this is precisely what the Measles Initiative team did. And the publishing world swallowed it—hook, line and sinker.

As mentioned earlier, WHO Health Evidence and Statistics head, Dr Kenji Shibuya, saw the problem with this method. Writing editorially in the Bulletin of the WHO, under the title “*Decide monitoring strategies before setting targets*”, Shibuya had this to say⁸:

Unfortunately, the MDG⁹ monitoring process relies heavily on predicted statistics.

*The same applies to monitoring progress in major disease interventions. For example, the assessment of a recent change in measles mortality from vaccination is mostly based on statistics predicted from a set of covariates such as the number of live births, vaccine coverage, vaccine effectiveness and case-fatality ratios. It is understandable that estimating causes of death over time is a difficult task. However, that is no reason for us to avoid measuring it when we can also measure the quantity of interest directly; otherwise the global health community would continue to monitor progress on a spreadsheet with limited empirical basis. **This is simply not acceptable.** (emphasis mine)*

This mismatch was created partly by the demand for more timely statistics (i.e. on an annual basis) from their users and partly by a lack of data and effective measurement strategies among statistics producers. Users must be realistic, as annual data on representative cause-specific mortality are difficult to obtain without complete civil registration or sample registration systems.

If such data are needed, the global health community must seek indicators that are valid, reliable and comparable, and must invest in data collection (e.g. adjusting facility-based data by using other

8 Kenji Shibuya. Decide monitoring strategies before setting targets; Bulletin of the World Health Organization June 2007, 85 (6) <http://www.who.int/bulletin/volumes/85/6/07-042887/en/index.html>

9 MDG – Millennium Development Goals, to be discussed shortly in this chapter.

representative data sources).

Regardless of new disease-specific initiatives or the broader WHO Strategic Objectives, the key is to focus on a small set of relevant indicators for which well defined strategies for monitoring progress are available. Only by doing so will the global health community be able to show what works and what fails.

In simple terms, Shibuya was saying:

- We know it is difficult to estimate measles deaths, but
- You should have tried, because you attracted a lot of interest
- Instead, you simply went back to the same spreadsheet you used to make the plan—and that is unacceptable!
- If you want to make a claim about your results, you need to measure the outcomes and collect valid data
- Until you do, you cannot say whether your plan has 'worked'

Unfortunately, by the time Shibuya's editorial was published, the media had already been trumpeting the stories for more than a year, because the Measles Initiative team announced their news to a waiting media before subjecting it to peer-review. So, without scientific scrutiny, the stories were unleashed into a world hungry for good news, especially concerning the developing world. The result... the reports were welcomed, accepted, and regurgitated to a degree where official scrutiny now seems to have the effect of a drop in a bucket.

The question of who was responsible for this miscarriage of publishing justice plagued me for a while. Was it the architects of the original report? Or was it the robotic section of our media (that part that exists because of a lack of funds for employing real journalists) who spread the message virally to every corner of the globe, without checking it?

The original Lancet report was correct in a sense. Its title was "*Has the 2005 measles mortality reduction goal been achieved? A natural history modelling study.*" It asked a question, and attempted an answer via modelling on a spreadsheet. The authors had no real data to go on, yet the world was waiting on a progress report. If you read the report, you will find it seems to say *we've done a lot of vaccinating, and on paper our model suggests we may have already achieved our target.* When we look at the media reports we see a much more confident message. One quote which really stands out in the stories is from former director of the United States Centers for Disease Control (CDC).

"The clear message from this achievement is that the strategy works," said CDC director Dr. Julie Gerberding

What strategy works? Is she talking about modelling on a spreadsheet? Or, using the predictions in place of *real* outcomes? More recent reports from the Measles

Initiative indicate the team are continuing with this deceptive approach. In their latest report¹⁰, it is estimated 12.7 million deaths were averted between 2000-2008. All were calculated on their spreadsheet, and all were attributed to vaccination, for the simple reason that it was the only variable on the spreadsheet that was under their control. And still there is no scrutiny of the claims. Furthermore, the authors make no effort to clarify in the public mind that the figures are nothing but planning estimates.

No proof

Supporters of vaccination might argue that this does not prove vaccines are of no use. And again, I agree. In fact, let me say it first: *none of this provides any evidence whatsoever of the value of vaccination.* That is the crux of the matter. The media stories have trumpeted the success of the plan, and given us all a pat on the back for making it happen. But the stories are fabrications. The only aspect of them that is factual is that which tells us vaccination rates have increased.

In essence, we have seen a modern-day triumph, portrayed in similar fashion to the earlier claim that vaccines were the magic bullet that saved us from our past. Perhaps this will also become enmeshed in the fabric of our beliefs. Perhaps it already has.

THE BELIEF

Vaccines have reduced measles deaths in Africa by 91%

THE TRUTH

Vaccination rates have increased in Africa

Rubber data

As an example of how poor the data in these areas is, let us look briefly at the seven countries of southern Africa, where an “elimination” program was undertaken by the Measles Initiative in 1996-2000. The team reported triumphantly that measles deaths in the seven countries had been reduced to zero by the end of the program¹¹.

However, nowhere do the authors reveal the source of the “reported measles deaths” data, showing zero. We are left to assume it was their own counting. This is troubling because, despite gross under-reporting of deaths, South Africa alone reported seven measles deaths in the year 2000¹². The other six countries simply didn't report. In addition, the WHO estimated just two years later that there were 6900 measles deaths in the region¹³... not zero! **Someone is seriously wrong!**

A clue as to how the “zero” count may have been conceived is revealed in a

10 Dabbagh et al. Global Measles Mortality, 2000–2008; Morbidity & Mortality Weekly Report. 2009;58(47):1321-1326 <http://www.medscape.com/viewarticle/714345>

11 Biellik et al. First 5 years of measles elimination in southern Africa: 1996–2000; Lancet 2002; 359: 1564–68 [http://www.measlesinitiative.org/mi-files/Reports/Measles%20Mortality%20Reduction/Global/Biellik%20Lancet%202002%20359\(9317\)1564.pdf](http://www.measlesinitiative.org/mi-files/Reports/Measles%20Mortality%20Reduction/Global/Biellik%20Lancet%202002%20359(9317)1564.pdf)

12 We can verify this here <http://apps.who.int/whosis/database/mort/table1.cfm>

13 Estimated total deaths by cause and WHO Member State 2002; Spreadsheet available here <http://www.who.int/entity/healthinfo/statistics/bodgbdeathdalyestimates.xls>

closer study of one of the countries—Zimbabwe¹⁴. After mass vaccination, the *rules* were changed. Measles cases now had to be confirmed through laboratory tests, before they could be recorded. A laboratory was appointed, and the cases were tested. Only 1-2% tested positive for measles virus, so only 1-2% were recorded. In other words, they recorded a 98-99% decrease, through administrative means alone. This appears to have been the *success*.

This concept of changing the *rules* will be discussed at length, as we make our way through the book. By and large, it appears that many of the stories of success we hear, are preceded by a change in the rules. Although the significance of this may elude you at the moment, it will begin to make sense later in the book.

Some 'real' good-news?

Some may think I am simply being negative. In Chapter One we examined the claim that vaccines saved the developed world from the measles, whooping cough and diphtheria scourges of the past, and found it to be flawed. Now we have examined the *good-news* about measles deaths plummeting in poorer countries, and discovered the same.

However, I do have something positive to report. I am quite sure measles deaths are in fact going down. How do I know this? Well, I don't because nobody is counting them. But we do know that mortality rates in general are going down, significantly. That means deaths from *all causes* are reducing. How do we know this? Because an inter-agency group, led by UNICEF and WHO, has been evaluating demographic surveys in countries that do not have adequate death registration data. These surveys have been going on for more than 50 years. One of the reasons they do this is to monitor trends in mortality; particularly infant, and under-five mortality.

Although the health burden in developing countries is inequitably high, there is reason to be positive when we view these trends. Deaths are declining, and according to the best available estimates, they have been steadily doing so for a considerable time; well over 50 years.

One of the most useful indicators of a country's *health transition* is its under-5 mortality rate: that is, the death rate for children below five years old. The best estimates available for Africa show a steady decline in under-5 mortality rate¹⁵, of around 1.8% per year, since 1950¹⁶. Figure 7 shows this decline from 1960 onward¹⁷. It also shows the *infant* mortality rate. Both are plotted as averages of all countries in the WHO region of Africa.

Figure 7. Child mortality, Africa

14 Munyoro et al. Impact of Nationwide Measles Vaccination Campaign among Children Aged 9 Months to 14 Years, Zimbabwe, 1998–2001; J Infect Dis. (2003) 187 (Supplement 1): S91-S96

<http://www.journals.uchicago.edu/doi/full/10.1086/368116>

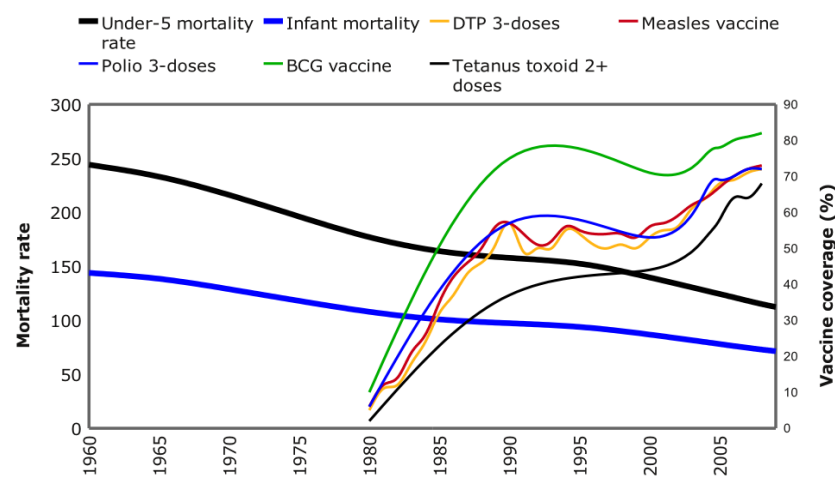
15 Infant mortality rate is “under-1 year of age” mortality rate.

16 Garenne & Gakusi. Health transitions in sub-Saharan Africa: overview of mortality trends in children under five years old (1950-2000); Bull WHO June 2006, 84(6) p472 <http://www.who.int/bulletin/volumes/84/6/470.pdf>

17 If you perform a 'google' search for 'infant mortality rate' or 'under-5 mortality rate' you will locate a google service that provides most of this data. It is downloadable in spreadsheet form by clicking on the 'More info' link. Vaccine coverage data is available from the WHO website

http://www.childinfo.org/files/Immunization_Summary_2008_r6.pdf

AFRICA



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 Sources: Inter-agency Group for Child Mortality Estimation
 (UNICEF, WHO, World Bank, UNPD, universities and research institutions)
 Vaccine coverage data from WHO

This graph may appear complex, but it is not difficult to read. The two thick lines running horizontally through the graph are the *infant* (the lower blue line) and *under-5* (the upper black line) mortality rates per 1000 from 1960 to 2009. The handful of finer lines which commence in 1980, at a low point, and shoot upward over the following decade, represent the introduction of the various vaccines. The vertical scale on the right side of the graph shows the rate at which children were vaccinated with each of these shots.

The primary purpose of this graph (as well as that in Figure 8) is to deliver the real *good-news*. The two thick lines illustrate a slowly, but steadily improving situation. Death rates for infants and young children are declining. I decided to add the extra lines (for vaccines) to illustrate, once again, that they appear to have had no impact on the declining childhood mortality rates; at least, not a positive impact. If they were as useful as we have been led to believe, these vaccines (covering seven illnesses) would surely have resulted in a sharp downward deviation from the established trend. As we can see, this did not occur.

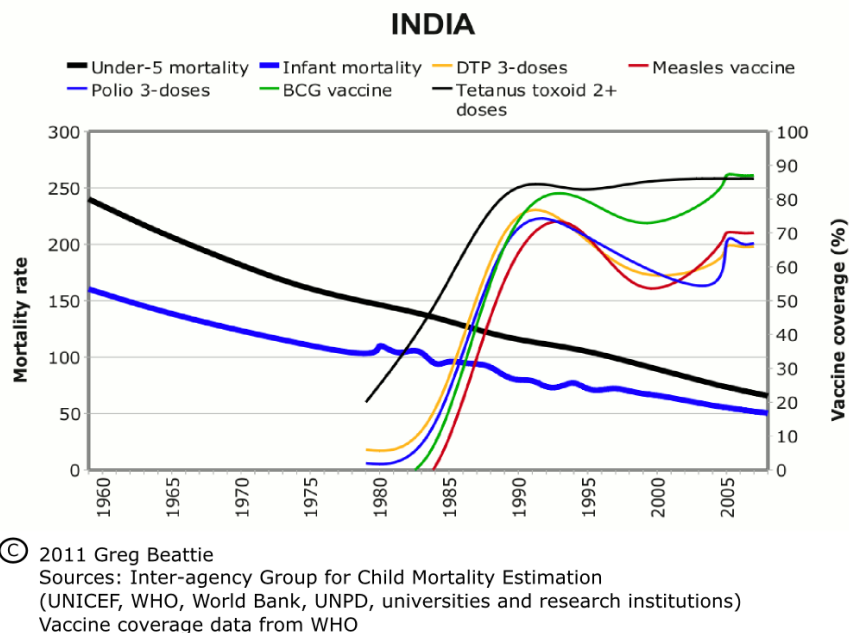
In Africa, the vaccines were introduced at the start of the 1980s and, within a decade, reached more than half the children. The only effect observable in the mortality rates, is a slowing of the downward trend. In other words, if anything were to be drawn from this, it would be that the introduction of the vaccines was counter-productive. One could argue that the later increase in vaccine coverage (after the year 2000) was followed by a return to the same decline observed prior to the vaccines. However, that does not line up. The return to the prior decline predates it, by around five years.

With both interpretations we are splitting hairs. Since we are discussing an intervention that has been marketed as a modern miracle, we should see a marked effect on the trend. We don't.

The WHO region of Africa (also referred to as sub-Saharan Africa) is where a substantial portion of the world's poor-health burden is thought to exist. The country that is believed to share the majority of worldwide child mortality burden with sub-

Saharan Africa is India, in the WHO south-east Asia region. Together, the African and South-east Asian regions were thought in 1999 to bear 85% of the world's measles deaths¹⁸. Figure 8 shows India's declining infant and under-5 mortality rates, over the past 50 years. Again, the introduction of various vaccines is also shown.

Figure 8. Child mortality, India



And again, vaccines do not appear to have contributed. Mortality rates simply continued their steady decline. We commenced mass vaccination (for seven illnesses) from the late 1980s but there was no visible impact on the child mortality trends.

In each case (Africa and India), we see a consistent decline from the outset. In a nutshell, what happened in the developed world is still happening in the *yet-to-finish-developing* world, only it started later, and is taking longer. The processes of providing clean water, good nourishment, adequate housing, education and employment, freedom from poverty, as well as proper care of the sick, have been on-going in poor countries.

Enter the Millennium Development Goals (MDGs)

In the year 2000, a UN summit was held at which 189 world leaders made a commitment to end poverty by 2015. To achieve this, a set of eight goals were developed, as follows:

1. Eradicate extreme poverty and hunger
2. Achieve universal primary education
3. Promote gender equality and empower women
4. Reduce child mortality
5. Improve maternal health
6. Combat HIV/AIDS, malaria and other diseases
7. Ensure environmental sustainability

18 MMWR: 1999 / 48(49);1124-1130 <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4849a3.htm>

8. Develop a Global Partnership for Development

These are known collectively as the Millennium Development Goals (MDGs). They represent probably the most ambitious, as well as the most supported, international cooperative effort to combat disadvantage, and promote equity among the world's impoverished. You will notice vaccination does not figure visibly on the agenda. It is there, however. Goal No. 4 has one target, namely:

Reduce by two thirds the mortality rate among children under five.

This target is to be monitored by three indicators:

- Under-five mortality rate (of course)
- Infant mortality rate
- Proportion of 1 year-old children immunised against measles

So, the measles vaccination rate of 1-year-old children was mentioned as an indicator of achievement for the MDG4 target. I guess we can draw a long bow, and forgive the team at the Measles Initiative for extrapolating this to a worldwide declaration that measles deaths have plummeted. Then again, it would be a very long bow.

As can be seen, the MDGs are quite interdependent. For example, removing poverty indirectly leads to improvements in nutrition, greater access to education and clean water, reduced childhood mortality, and progress toward other goals. Reducing poverty is the primary goal, as well as the key theme, of the MDGs.

"Ill-health pushes people into the poverty trap. Poverty is a major factor determining ill-health, as well as being both a cause and an outcome of ill-health."¹⁹

MDG1 has three targets:

- Reduce by half the proportion of people living on less than a dollar a day
- Achieve full and productive employment and decent work for all, including women and young people
- Reduce by half the proportion of people who suffer from hunger

The latest UN reports suggest considerable progress has been made as indicated in the following charts²⁰ (Figure 9 and Figure 10).

Figure 9. Proportion of people living on less than \$1.25 a day 1990 and 2005 (Percentage)

¹⁹ African Regional Health Report 2006; World Health Organisation, p xiv

²⁰ http://en.wikipedia.org/wiki/Millennium_Development_Goals

Proportion of people living on less than \$1.25 a day, 1990 and 2005 (Percentage)

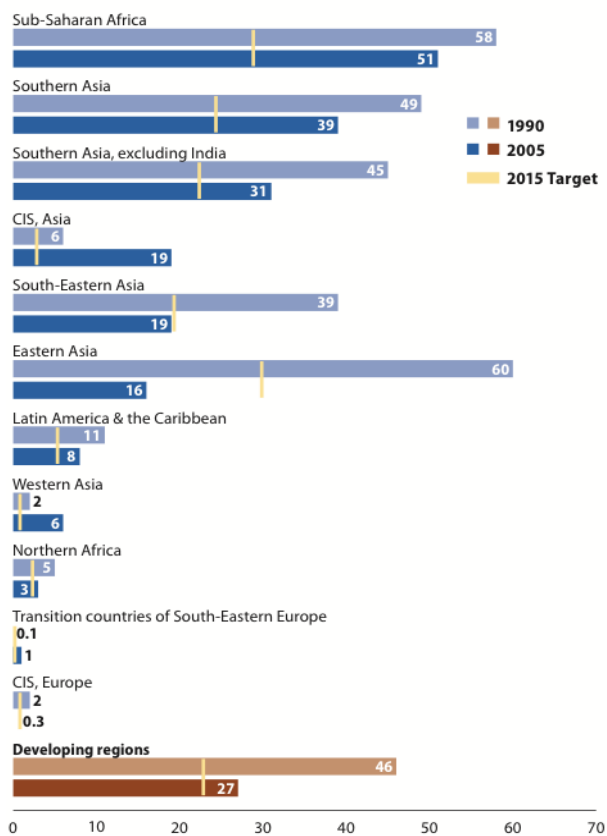
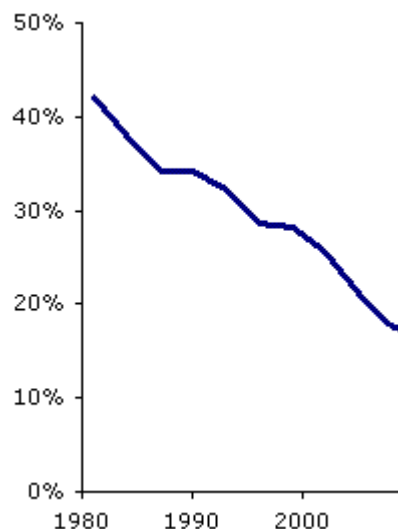


Figure 10. Percentage of the world's population living in extreme poverty 1981—2010



The *good-news* is that progress is being made toward the achievement of these goals. This means we can expect improvements in health prospects. Despite the negative impact of the recent global financial crisis, most developing countries have enjoyed improvement in poverty-related and other goals. As these represent the major determinants of health, we are seeing corresponding improvements in each country's *health transition*.

I would have loved to go back further in time with the preceding graphs (Figures 7 and 8) but unfortunately I was not able to locate the data. I did uncover one graph in an issue of the Bulletin of the WHO, showing the under-5 mortality rate in sub-Saharan Africa to be an estimated 350 in 1950²¹. It subsequently dropped to around 175 by 1980, before vaccines figured. It continued dropping, though slower, to 129 by 2008²².

Do you see something familiar? Just like the graphs presented in the previous chapter, we see a death rate declining consistently over a long period of time. As our graphs here commence in 1960, and the trend was downward right from the outset, it is reasonable to conclude that the decline was already in place. That is, if we go back further in time, the deaths were probably higher, just as in our Chapter One graphs from the developed world.

Like before, we are probably looking at a substantial and constant decline in deaths, over many years. Once more, vaccines have arrived in the final moments, and are preparing to take credit.

The decline represents a substantial *health transition*, and a lot of lives saved. When cause-of-death data improves, or at least some genuine effort is made to establish credible estimates of measles deaths, it will undoubtedly be found they are

21 Garenne & Gakusi. Health transitions in sub-Saharan Africa: overview of mortality trends in children under five years old (1950-2000); Bull WHO June 2006, 84(6) p472 <http://www.who.int/bulletin/volumes/84/6/470.pdf>

22 UNICEF; <http://www.childinfo.org/mortality.html>

dropping as well. Why wouldn't they? This is good news, and all praise needs to be directed at the architects and supporters of the international activities that are helping to achieve improvements in the real determinants of health. In the midst of all the hype, I trust we will not swallow attempts to give the credit to vaccines... again.

I am not confident, however. I feel this is simply history repeating itself. Deaths from infectious disease will reach an acceptable "low" in developing countries, at some point in time. And although this will probably be due to a range of improvements in poverty, sanitation, nutrition and education, I feel vaccines will be given the credit. To support the claim, numerous pieces of evidence will be paraded, such as:

Measles Deaths In Africa Plunge By 91%

We need to purge these pieces of "evidence" if we are to have rational discussion. The public have a right to know that these reports are based on fabricated figures. Otherwise, the relative importance of vaccines in future health policy will be further exaggerated. Once more, an error needs to be corrected, regardless of how much the concrete has already set around it. This time it needs to be corrected in such a way that everyone hears about it.