

The Trouble With Labeling a Health Problem a Disease

By AARON E. CARROLL

As any parent knows, babies spit up. It's gastroesophageal reflux, a pediatrician will explain — milk leaking backward from the stomach. When I was a pediatrics resident, my hospital constructed foam wedges for infants to sleep on. The thinking was that infants who were sleeping at an angle would be less likely to have milk come back up.

The wedges cost about \$150. They didn't work.

Wedges aren't the only fix doctors have tried. We've tried to construct special infant seats to prevent reflux. We've tried thickening foods. We've tried changing to special formulas. None of these things really work. An incredible amount of time and money has been wasted.

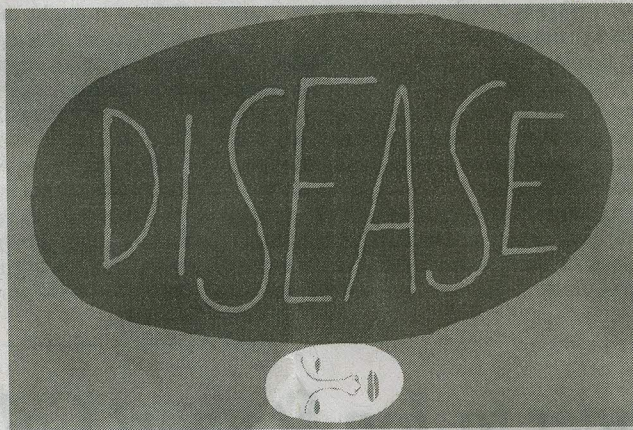
The bigger problem, though, is that most of these infants weren't "sick." We just gave them an official diagnosis. This labeling of patients with a "disease" can have significant consequences, for both people's health and the nation's health care budget.

About 50 percent of healthy infants will spit up more than twice a day. About 95 percent of them completely stop doing that without treatment. When a majority of infants have (and have always had) a set of symptoms that go away on their own, it isn't a disease — it's a variation of normal.

Infants vomit more often because they have an all-liquid diet. They have an immature esophageal sphincter, which doesn't quite close off the stomach from the esophagus. They eat every few hours, and they have small

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stomachs. Countless infants will have symptoms of gastroesophageal reflux.

Gastroesophageal reflux disease (GERD) is different. Children with GERD have symptoms so severe that it degrades their life. It's rare. But over time, more and more babies with reflux were labeled as having a "disease." The incidence of a diagnosis of GERD in infants tripled from 2000 to 2005.

We often treat diseases with drugs. Today, we commonly treat infants with a group of drugs called proton pump inhibitors (P.P.I.s). Between 1999 and 2004, the use of one child-friendly liquid form of P.P.I. increased more than 16-fold. This was in spite of the fact that P.P.I.s have never been approved by the Food and Drug Administration for the treatment of GERD in infants.

In 2009, a randomized, placebo-controlled trial examining how well a P.P.I. worked for infants with symptoms of GERD was published. It found that the drug had no more of an effect than a placebo. It also found that children who received the P.P.I. had

significantly more serious adverse events, including respiratory tract infections.

There's plenty of blame to go around for this mess. But broadening our definition of disease probably made all of this possible.

My friend and colleague Dr. Beth Tarini, a health services researcher at the University of Michigan, published a study last year that examined how parents react when given a diagnosis of GERD for their infants.

Dr. Tarini and her colleagues randomly chose certain parents to be told that an infant with symptoms of reflux had GERD or, instead, "a problem." Half of each of these groups were also told that medications were ineffective.

Parents who were told that their infant had GERD were significantly more interested in having their child put on medication, even when they were told that medication was ineffective. Parents of infants who were not labeled with GERD were not interested in medication once they were told it didn't work.

Words matter. Studies have shown that once people with high blood pressure are labeled "hypertensive," they are significantly more likely to be absent from work, regardless of whether treatment was begun. Many diseases have become so much broader in definition that they now encompass huge swaths of the public.

When statins were first approved, they were used to treat people with very high levels of cholesterol. Their benefit was thought to be clear in that population.

Last year, however, the release of new guidelines meant that more than 87 percent of all men age 60 to 75 would be recommended to be on statins, and the same for more than 53 percent of women in the same age group. Nearly every single African-American man over 65 would be counseled to be on the drug.

The American Academy of Pediatrics released guidelines a number of years ago recommending that children as young as 8 be treated with medication for an LDL cholesterol level above 190. Many think this is going too far. No one knows the long-term consequences of being on such drugs for decades.

Allowing the medicalization of normal variations in physiology to be transformed into "treatable conditions" is leading to unintended consequences. We're spending billions of dollars on treatments that might not, or don't, work. We're making people worry when they don't have to. And we may be causing actual health problems in the process.

As Dr. Tarini puts it, "Our job as doctors is to make sick patients healthy, not to make healthy patients sick."