The Moral of the Story
Perri Klass, M.D.

I came home the other night clutching a scrap of paper towel with a mother's cell-phone number scribbled on it. I had been precepting in the residents' pediatric primary care clinic, and an intern had presented a patient: a 20-month-old boy who had been brought in by his mother because he was vomiting. He'd thrown up seven times since 2 that morning. No diarrhea, but he wasn't eating or drinking much. Still, he didn't look dehydrated, his mother said; he'd had several wet diapers, and when the intern examined him, she found his diaper wet again.

The intern said he had a temperature of 100.8°F, and his ears looked infected. “Oh, great,” I said, “so we know what's going on.” She nodded but looked puzzled. “Why would an ear infection make him throw up?” she asked hesitantly.

When I answered honestly — some kids have touchy stomachs, and when they get sick with anything, they throw up — she looked disappointed; she was expecting pathophysiology. I drew myself up. Perhaps, I suggested, the ear infection was the sequela of a preexisting upper respiratory infection, and the child was producing a lot of mucus, which was dripping into the stomach and provoking the emesis. That went over a little better.

We went in to see the child. He was a sweet, clingy toddler, warily sheltering on his mother's shoulder, and he didn't look happy to see me. In fact, he started crying, which allowed me to verify that indeed he was not dehydrated, since his face was soon wet with tears. I examined him and agreed that his ears looked infected, the eardrums red on both sides and one of them bulging, not moving, hinting at infected fluid behind it. Yes, I said, good job, I agree, not dangerously dehydrated, I agree, ear infection. And let's remind the mother to encourage him to drink liquids and watch him carefully to make sure he doesn't get dehydrated. I smiled at the mother reassuringly and was relieved to see that she looked mature and competent, as she comforted and soothed her child with efficient, fond caresses.

But she looked anxious. She had something else she wanted to bring up, something she hadn't told the intern or mentioned to me when I was questioning her. “Doctor, let me ask you one more thing,” she said. “It couldn't be that this was from falling down, could it? From falling down the stairs?”

And out came the story: the night before last, the child's brother had come up the stairs from the basement, and when he opened the door, the baby was right there, reaching for something, and he fell forward down the stairs. “I didn't see it,” she said, “but I heard the thump-thump-thump when he fell. And his brother said he got hurt all over his head. But that couldn't be doing this, right?”

So we had a problem. One of the danger signs after head trauma...
is vomiting. Here was a child who had fallen down a flight of stairs about a day and a half ago and a little more than 24 hours later had begun throwing up repeatedly. And I was about to send him home with a diagnosis of acute otitis media.

I could see that I was disappointing the mother when I didn't just wave it away: don't be silly, what could one thing have to do with the other? She had offered up the falling-down-the-stairs story as a “doorknob moment” — the doctor essentially done, her hand (or the patient's) literally or figuratively on the doorknob, and the patient brings up a deliberately by-the-way question that turns the whole thing inside out. So I put her through the story in more detail, and it sounded pretty benign: just a few wooden steps, the whole flight maybe 3 feet high. The child hadn't been knocked out — a sign that the head trauma was relatively minor. The mother hadn't noticed any changes in how he was walking — though actually, he wasn't walking much; he was too clingy because he was feeling sick. Of course, he didn't have the language to say whether he felt pain. And even if he'd had language, he could have pointed at his head and told us it hurt and left us completely unsure whether it was his head or his ear.

Head trauma shouldn't give you — words deliberately chosen, in part, because they don't sound medical alarms. Clingy and cranky, not playful or active; in fact, he was unwilling to walk. I asked his mother to put him down for a minute, but when she tried, he began to wail. He pulled up his legs into the fetal position, and good-bye to any hope of assessing his gait to confirm that he looked neurologically normal. It's like that with toddlers. His mother smiled at me apologetically as she gathered him up again. “He's been like this,” she said. “Not running around. Not playing so much.”

We examined his head for bumps or bruises. We went over the story again. Finally, I sent the mother home with prescriptions for amoxicillin and acetaminophen and gave her some of the what-to-watch-for signs off the standard head-trauma information sheet: if he starts vomiting again, if he seems less alert than usual, come to the emergency room. I wrote her phone number on a piece of paper towel, saying I'd call her later to see how he was doing.

And I worried. It would be silly to send him to the emergency room or radiology when the overwhelming odds were that he just had an ear infection. The timing didn't really make sense for a head bleed, I told myself, and he looked like a kid with a viral syndrome.

Later that night, when I called, the mother was as reassuring as could be: “Oh, Doctor, he's doing great, he's playing, he's running around, he's really acting like himself. He even ate a little bit.” No more emesis, no mental-status changes, normal energy level restored.

But I’ve been thinking ever since about why I was so worried. It’s not such an unusual story, after all, a toddler who took a fall. I’ve probably examined dozens of children who were brought in with that as the chief complaint: fell off the bed, tumbled out of the stroller, climbed up on the back of the couch and dived right over. I’ve felt their heads and looked in their eyes. Some I’ve sent to radiology, but not most. Some I’ve worried about for obvious reasons — concerns about child abuse and inflicted injury — and I’ve looked them over for bruises and unexplained marks. Some I’ve sent home with their parents holding head-trauma instruction sheets. And so far, nothing terrible has transpired with any of them.

So why did this boy get me so worried? Maybe precisely because the head trauma wasn’t the reason for the visit. He was brought in for vomiting, and we didn’t even think to ask about head trauma, because the vomiting seemed to be part of some viral syndrome, and we heard about it only in the elaborately casual doorknob question. Somehow that made it seem much more likely that the injury was severe, the story not what it appeared to be. I hadn’t asked the right question, I had been pursuing the wrong story. I had almost missed the story altogether — didn’t that make it more likely that I’d missed something serious? Wouldn’t that turn out to be the “teaching point” if you were telling this story to medical students? Listen properly, and don’t overtake...
Howard drove home from the hospital. He took the wet, dark streets very fast, then caught himself and slowed down. Until now, his life had gone smoothly and to his satisfaction — college, marriage, another year of college for the advanced degree in business, a junior partnership in an investment firm. Fatherhood. He was happy and, so far, lucky — he knew that. . . . So far, he had kept away from any real harm, from those forces he knew existed and that could cripple or bring down a man if the luck went bad, if things suddenly turned.

There it is, I thought, rereading the story. The understanding of how close we all are to being unlucky. The child who steps off a curb without looking. The story in the exam room that you don't listen to properly. The superficially well patient who is sicker than anyone thinks. So I had this story stuck in my mind, and the message I remembered best is one Carver probably never intended, one better suited to an ER instructor sheet: Even minor head trauma can be serious.

At the same time, I had a true story nagging at me, one that my own preceptor in primary care told when I was a pediatric resident. We had been talking about head injuries, and the preceptor had offered up a grim story: an adolescent who had hit his head in some freak accident but seemed fine and then died from an unsuspected bleed. The story had made a tremendous impression on me — because what sounded like a minor injury had killed someone, because it had happened in the practice of a very good doctor whom I regarded as my mentor, because he knew the family well and had been the one they called when their son died.

But I had heard that story at least 20 years earlier, when it was already many years old, and I wondered how much of it I was inventing. So I tracked down my preceptor and called him and said, rather hesitantly, “I think there was a story you told, back in 1986 or 1987, and it’s stayed with me — I must have been full of sadness when I discussed it with the group. But over the course of my 30-plus years, this little boy who died is the only one.”

“So what is the real moral?” I asked.

“Medicine is knowledge, judgment, experience, and luck,” he said. “It still grieves me — I must have been full of sadness when I discussed it with the group. But over the course of my 30-plus years, this little boy who died is the only one.”

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So I have been thinking about the voices that echo in your head when you make a clinical decision — even a relatively low-acuity deci-
Exploiting a Research Underclass in Phase 1 Clinical Trials

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In November 1996, the Wall Street Journal reported that Eli Lilly was paying homeless alcoholics from a local shelter to participate in safety testing of new drugs at its trial site in Indianapolis.1 “These individuals want to help society,” asserted Lilly’s director of clinical pharmacology. The subjects, however, said they took part for easy money and free room and board. Although Lilly reportedly offered the lowest per diem in the business, it managed to attract poor subjects from all over the country.1 The medical director of the local Homeless Initiative Program said Lilly had created a “shadow economy” of paid human subjects.

Today, the Lilly episode seems like an early warning about an emerging set of ethical problems. Over the past decade, clinical trials have moved from universities to private testing sites, the pressure to recruit subjects quickly has intensified, and ethical oversight has been outsourced to for-profit institutional review boards (IRBs). Payment to subjects has escalated, creating “shadow economies” in cities throughout North America and elsewhere. In 2005, Bloomberg Markets reported that SFBC International, a contract research organization, was paying immigrants to participate in drug trials under ethically questionable conditions in a dilapidated Miami motel. A few months later, nine apparently previously healthy subjects at an SFBC subsidiary in Montreal contracted latent tuberculosis during a trial of an immunosuppressant. In 2006, six healthy subjects required intensive care in a phase 1 trial of a monoclonal antibody at a London facility run by the contract research organization Parexel. For all the ethical debate over these cases, however, few commentators have addressed the most troubling question: Is it ethically problematic to pay poor people to test the safety of new drugs?

Paying study subjects is not a new practice, but neither is it uncontroversial. According to regulators, payment should not be so high as to become an “undue inducement,” lest subjects enroll in risky, unpleasant, or degrading trials against their better judgment. But this standard gives IRBs little practical guidance: a sum of money that the wealthy can easily resist may be very tempting for poorer people. Keeping payments low, however, seems unfair to the poor, who submit to trials precisely because they need the money. And whether or not such people are being unduly induced, the larger question is whether they are being exploited.

To exploit people is to take unfair advantage of them, but there is no consensus that current trial arrangements are unfair. Defenders of the status quo argue that people who enroll in trials have agreed to their conditions, that they get paid enough to make it worth their while, and that they are made better off by the arrangement. Nevertheless, there are good reasons to believe that poor subjects are being exploited.

First, poor people are less likely than wealthier ones to get access