1. **Our first question concerns Surgical Outreach Centers, where local doctors are performing surgeries. How does your organization check the quality of their surgeries?**

   Our partner surgeons upload every case, with pre- and post-operation reports and photos to specially-designed web-based databases. They are systematically reviewed for quality assurance and to find areas for improvement. When we first started our Surgical Outreach Center cleft program, we reviewed 100 percent of them. Our cleft outreach program is currently in its tenth year and the quality is very good. We now review 25 percent for continued quality assurance; funds are not sent to the partner surgeon until that careful review has been done. For burn outreach, we review 100 percent of cases. Next year, as the burn outreach program will be in its sixth year and well established, we will begin a 75 percent review of cases.

2. **Are there times that you recall when the quality review process led to stopping support of a particular outreach center because the surgical quality wasn't up to par?**

   If the quality was not up to par, we would be willing to do that, as safety and high-quality care are crucial; however, we've never had to because we've been conservative and careful about selecting our outreach partners. We never have selected an outreach partner until we've worked with them enough to trust them and their work. In addition, visiting educators or I will go to the surgical outreach centers to provide advanced training and to review their work personally periodically.

3. **Do you have written reports from the trips educators make?**

   Yes, we get post-visit reports from our visiting educators, verbally and/or in writing. We ask how many patients did you see, how many were operated on by local surgeons, etc., and that information is helpful. We are currently working on how to enumerate the long-term impact of a visiting educator's workshop. We often hear that our partner surgeons are using a newly learned technique with success, but we have not been able to capture such information in a systematic way yet.

4. **And who are the educators – are they surgeons affiliated with Interplast?**

   They are Interplast volunteer surgeons, generally with strong credentials, such as the chief surgeon at a major university.

5. **Do these educator trips happen for every single outreach center on a regular basis, or more on an ad hoc basis?**

   Every Surgical Outreach Center director has the opportunity to make a request for training every year, and we try to accommodate his/her needs. However, not every SOC director makes a request and sometimes we are limited by funding and cannot fulfill the request in the year he/she makes it. In addition, visiting educator trips take place at many other Interplast sites, where SOCs have not yet been established. The trainings help to build medical capacity and self-sufficiency at those sites, and empower them to hopefully become a SOC in the future. Moreover, I think some of our best VEs are when a SOC director from one site goes to another SOC site to cross-train. For example, last year, our SOC director in Sri Lanka went with her physical therapist to the SOC in Nicaragua. The Sri Lankan surgeon taught the Nicaraguans new surgical techniques, while the physical therapists in Nicaragua taught the Sri Lankans advanced therapies.

6. **Do you have a sense for how often there are complications from a surgery and how severe the complications are?**

To ensure that our patients receive the safest and highest quality medical care---even in the compromised conditions developing countries often face--- Interplast has developed rigorous quality assurance policies and protocols. Over the last decade, Interplast has made a successful concerted effort to systematically review cases and improve safety and

quality of care. The morbidity and mortality (M&M) report for last fiscal year shows that there are complications, usually minor, in 1-2 percent of our cases, but only one (out of nearly 4,000 cases) resulted in permanent sequelae (a hand injury) and that one can probably be resolved with further surgery. More information is available in our M&M report.

7. **Might you be able to share the reports from team trips?**

   I will provide you a copy of our M&M report, which will have this information from our team trips and outreach centers.

8. **Might you be able to send statistics and records from outreach centers?**

   See above.

9. **Do you ever worry that outreach centers are withholding information about surgeries that go poorly? How do you know you're getting the full story?**

   We trust them. The Outreach directors with whom we work have proven themselves to be honest humanitarians and ethical surgeons long before we have established our relationships with them. If they were more interested in their egos or money, working with Interplast would not be their chosen career path, as there is not much glory or financial gain. They also have shown themselves to want to improve how they do things, not simply continue a status quo. Also and very important, we have geared our programs and relationships toward education and improvement rather than punitive policies, so there has never been any reason not to be forthcoming.

10. **How does that work – the process of becoming an Outreach Center?**

    Most Outreach Center personnel are people we've worked with on team trips for several years – team trips, maybe a couple visiting educator programs – enough interaction with enough different people and enough interaction with the office to where we were comfortable with them.

11. **How many total Outreach Centers are there?**

    There are 11 Surgical Outreach Centers. Cleft work is performed at eight of them and burn work at all of them.

12. **Do you keep the same records for the Outreach Centers that you keep for the trips?**

    We do have all their medical records, the pre- and post-operation reports and photos I mentioned before. Any complications at the SOCs are in those records and reviewed. The statistics are in the M&M report.

13. **Can you tell us about the severity of some of the conditions that are treated other than clefts, such as burn scars and hand deformities?**

    Burns afflict more than 6 million people in developing countries each year. In some parts of the globe, burns affect more children than HIV/AIDS, malaria or tuberculosis.

    Burn victims are frequently disfigured, disabled, stigmatized and shunned. Their injuries often limit mobility and function, as well as disfigure them in ways unimaginable in the United States, where such injuries are never allowed to progress to such a devastating degree. Without adequate acute burn care, for example, a burned foot may attach to the shin as the wound "heals" and the skin contracts, consequently eliminating the ability to walk.

Reconstructive plastic surgery can make a lifetime of difference to the person's quality of life. Cases vary from repairing the foot/shin injury described above so a little girl can walk to separating a neck, chin, and lower lip that have permanently fused to the neck so a person can move their head again to restoring someone's contracted hand so that they can work. Hand problems can be terribly debilitating. If you've got immobile fingers because of a burn contracture, then your economic output often is worthless, and all it takes is releasing those figures to restore your productivity.

14. **It seems like hand deformities could vary a lot in terms of how debilitating they are. Some might render a person's hands unusable whereas other deformities might affect only a couple of fingers.**

Definitely. If you look at the original World Health Organization's Global Burden of Disease study, they didn't even try to assign disability weights to hand injuries because it's too wildly varied. We're generally going to try to treat people who have major and largely correctable disabilities or deformities. If we can give someone the ability to feed themselves or to hold a pencil, we will do whatever we can to help.

15. **If someone has only a minor/cosmetic deformity, do they get turned away?**

It depends on how minor and what the impact will be for the patient. For example, an 8-year-old child might have a contracted little finger – not totally debilitating, but a big potential impact over the course of his life for a relatively minor operation. So we'd generally do that operation.

Overall, we prioritize returning functionality and productivity. Some might say repairing a cleft lip is a cosmetic surgery, but we know that without that repair, the child's chances for a productive life are greatly diminished. With burns, we repair injuries that are correctable and will have the biggest impact to a person's ability to be a productive citizen---repairing a hand so she can feed herself or a leg so he can walk again.

16. **Can you give us your educated guess on what the frequency distribution looks like, i.e., out of 100 burn scars treated – about how many are totally debilitating, vs. significantly debilitating, vs. minor/cosmetic?**

Approximately 10-15 percent are totally debilitating, around 85-90 percent are significantly debilitating and about 2 percent are minor.

17. **Do you ever get mistakes – operations that are reviewed after the fact and that wouldn't have been approved?**

Not often.

18. **So if someone comes in with a minor deformity, something that isn't highly debilitating, do they get turned away?**

Yes. If someone has a scar on their arm that's not affecting them, that's too much cost for not enough benefit. On the other hand, a scar on the face that can be corrected is a big deal.

19. **Do you guys have written guidelines for these kinds of judgment calls?**

Part of being a good surgeon is knowing on whom you should and shouldn't operate. Our surgeons are experienced, screened and need extensive credentials. That being said, our surgery committee is now examining this issue more thoroughly---not because we need written guidelines on the basic judgment calls, but because we want to explore more thoroughly our choices in burn case selection so that we can make the biggest impact in the time available.

20. **Do you have written materials laying out the potential complications for different sorts of operations?**

There is a huge amount of literature – surgical texts, the Burn Journal, Cleft Palate Journal, Annals of Plastic Surgery, the Plastic Surgery journal, etc.

21. **Do you know of a good overview of the basics – what the big potential complications are for different kinds of surgeries?**

    Go to the American Cleft Palate Association's website; they have some nice brochures for parents.

22. **I think I looked at those brochures. For me the difficulty in understanding them is that they'll say to parents that follow-up surgeries, speech therapy, etc. is needed, without being specific about how severe the problems could be if follow-up surgeries, speech therapy, etc. don't end up happening.**

    For a cleft palate patient, ideally, if you can do it, every patient should be evaluated by a speech therapist. In the US, a speech therapist sees every patient with a cleft palate. Some of them require speech therapy in childhood, and some of them require further palate repair.

23. **Another way to possibly get at this question would be to see all the reports we can from the Nepal center, and take a look at how many people end up needing follow-up care.**

    Reports from the speech camps in Nepal have been sent.

24. **And if they're not treated in this way? We're concerned about the possibility – especially with team trips – of a person's coming in for the initial surgery but never receiving follow-up care. What would this person's life be like? Would they talk normally, eat normally, interact normally?**

    We need better long-term data, but what we have learned from 40 years of experience is that even one operation can make a difference, especially with a cleft lip; the difference is dramatic, immediate and can keep a small child from being stigmatized and shunned. That being said, speech therapy, orthodontics and revision surgeries also are needed, but sometimes that is not possible in developing countries. And that is what I consider our biggest shortcoming: that we are not able to provide post-surgical care in all of our sites. Our Nepal SOC is our model, as they provide not just surgical care but long-term orthodontic care, speech therapy, etc. They go out to the hard-to-reach communities and have speech therapy camps every six weeks or so and send us reports of those camps, and in those reports they can tell us how many kids they saw and how many kids needed another operation for any reason. Unfortunately, it isn't possible for every center to operate like the one in Nepal. Ecuador does a great job. But Zambia, for example, is a whole different challenge because the surgeon there is the only plastic surgeon in the whole country.

But back to your question about the specific impact follow-up care makes. That is the same question I asked in my thesis. I looked far and wide in the literature at the time and there was nothing on this question. WHO's Global Burden of Disease doesn't really give us enough information. We know from UNICEF that only 3 percent of disabled children in developing countries go to school, but every culture/community is a little different on what they consider a disability. In some places, there are children with cleft lips going to school and in others, they are systematically abandoned as babies. And what does it mean for quality of life if someone has a beautifully repaired lip but her teeth remain unfixed? There really is nothing on that.

That being said, there is a Ph.D. student at UCSF who is hoping to do ask that exact question in Nepal over the next couple of years. She's going to focus on the sociological rather than the surgical aspect – if you go rural Nepal, and find an unrepaired adult, are they working? What's their social life like? This Ph.D. student at UCSF is going to take at least 2-3 years for her study, which will at least give a start on the question you asked.

There's also a woman who's got a Fulbright scholarship to go to China and tell us exactly what is the rate of persistent speech problems in the kids with cleft palates, are they in school, etc., etc.? She speaks the language and knows something about the culture and I'm hoping she can do that effectively.

In my thesis, I ended up doing economic models using the DALY framework.

25. **Can we get a copy of your thesis?**

Yes.

26. **What would you say the average number of surgeries per patient is, including follow-up surgeries?**

For burns, our average is three. Usually, all these operations would be done on one visit, but often that is not feasible nor desirable; it could be more than that, too.

For a cleft lip/palate from our current database, it is difficult to know which ones are repeats or revisions; my guess would be that there are few revisions and our average would be one operation per lip and/or palate. We do revisions when they are presented, but in the developing world sometimes patients are never able to come back. Getting the first operation was a major disruption on a poor family, it made a difference and they just don't come back to make another improvement, which is unfortunate. In the US, with a cleft palate, there are at least 2-4 operations before you're 16 years old. Unfortunately, we're a long way from that in the developing world.

27. **One deformity type we haven't discussed at all is ptosis. How debilitating is that usually and how many operations does it take?**

Usually one operation. If you've got a significant case of ptosis, you really do not have upper field vision, because your eyelid is half shut; you also look like you're half asleep at all times. As far as operations go, it's usually not that difficult. I've seen a lot of ptosis patients in Vietnam.

28. **Do you do perineal fistula repair at all?**

No. That operation is usually done by gynecologists, not plastic surgeons.

29. **Have we covered all the relevant types of deformities?**

Burn scars, clefts, ptosis and then there's the miscellaneous category, usually involving extremities, particularly hands. We have many hand deformity cases (not just hand injuries from burns and other accidents). Historically plastic surgeons handled congenital/penile problems, but in the last 30 years plastic surgeons have largely taught urologists to do that.

30. **What would you do with more funds? What would your priorities be?**

The first thing I'd probably do is really ramp up burn care in India. It's colossal in terms of the burden of disease, and it is something that can be helped. Many people have horribly debilitating problems that could have been taken care of with a simple skin graft 4-5 years ago, but they can't get to a city and if they could they wouldn't have the money to get surgery anyway. The district hospital system in India lends itself to ramping up burn care. I would aim to increase facility quality, build medical capacity, increase volume, etc.

We would also work to get the Nepal speech camp model everywhere. I also would ramp up educational capabilities at our sites. And I would ramp up our expansion. It would be really nice if we could have somebody on the ground 365 days a year in new parts of India and Nepal, in China, in Tanzania, in Ethiopia, etc.

31. **I just want to make sure that we have the right understanding of the Outreach Centers and how they work and Interplast's role. My picture basically is that there's a doctor or team of doctors in a local country and Interplast will meet up with them on a team trip at first, and eventually Interplast will determine that they**

can be trusted, and so Interplast will fund their work so they can do surgeries on their own – they may already have been doing surgeries on their own, but Interplast will fund them, conditional on their submitting records of their completed surgeries.

That's right. Interplast supports local surgeons with training opportunities, funding and oversight (quality assurance). These local surgeons operate on their own and always have, but they can't take care of all the poor people for free. We're able to pay enough to put the poor people at the head of the line with the people who can pay for themselves. For example, if you have the capacity to serve 30 people but 100 are lined up, of which 60 can pay, you'd ordinarily treat only people who can pay, but Interplast pays for free surgeries and that puts the people who can't pay on the same basic footing in terms of priority.

32. **That seems to imply that the Outreach Centers do a constant number of surgeries, because of limited capacity, and your expectation is that the Interplast funds reallocate some of those surgeries from wealthier patients to patients who are unable to pay.**

    Right. In India, for example, the public-sector capacity is very limited. People who need treatment mostly seek it from the private sector. I like to think that we're able to take people who would otherwise fall through the cracks and put them on more equal footing with wealthier people. I think that's what happens and that's certainly what I want to happen.

33. **So do you think that by paying for free surgeries, Interplast is reducing the number of surgeries done for people who can pay?**

    I do not think that is true. People who can pay generally get taken care of. Generally, people paying for themselves will pay more than what Interplast can pay.

34. **Do you think Interplast's activities are increasing the surgical capacity in these countries overall? It sounds to me from what you're saying like Interplast isn't increasing capacity – it's more increasing equity of access to surgical care.**

    I think both. By providing surgical care for a large segment of the population who had no other access to care, I think that we are definitely increasing capacity. We also have partner surgeons who do more operations now, caring for more people, because they have funding to care for the poor. For example, there's a surgeon who works until 2 in the morning one day a week (after his government hospital job) to care for the poor, and if not for our program, I don't think he would be able to do that.

35. **Are you worried about doctors charging fees under the table?**

    In our Outreach Centers, no, because of our trusted partnership I spoke about earlier. We are talking about around a dozen SOC directors, a small number to manage, not hundreds. In addition, in this day and age of information, patients have a way of finding us if they need to. We would hear from them if they were being treated unfairly.

36. **Why aren't you concerned about this issue now?**

    We make our expectations perfectly clear in our agreements with Outreach Centers that they are to provide surgeries free of charge, and we've never gotten any evidence that we should not trust these people.

37. **Do team trips go to the same locations where Outreach Centers are located?**

    In very few sites, we do. One example is our Dehradun, India site where the volume of burn case is so great that they request 1-2 teams a year to help with the overwhelming number of cases and to have further educational

opportunities, such as in physical therapy. Another example is Dhaka, where we send teams to do only hand operations, while the SOC does clefts and burns. However, as a general rule, we do not because SOC operations are more cost-effective, efficient and available year-round.

38. **How does the funding literally work? Does Interplast pay by the patient?**

    Yes, there is a grant for each poor patient treated for free.

39. **Do you have a sense of how many patients at a given Outreach Center are paying for themselves vs. covered by Interplast funds?**

    First of all, I think it is important to realize that a surgical outreach center is not a building, but is based on a specific partnership with a developing world plastic surgeon. That plastic surgeon is somewhat of an independent agent who may be required to work part-time for the government hospital or may choose to have a small private practice. I do not know how many paying patients each one has, if they have a private practice at all.

    What Interplast does is help him or her provide life-changing operations also for those who do not have the funds to pay; most do it as an act of charity or as partially-funded volunteer work. Interplast does not really pay enough to make it a profitable vocation---or another way of communicating this is to say that it may be similar to those working in the nonprofit field here because they are motivated to make a difference and are willing to sacrifice some financial gain, although they still need to pay for their basic needs. Some of our surgeons only perform a couple of dozen operations for Interplast each year, while others provide hundreds each year.

40. **Do you know what measures are taken to gauge ability to pay?**

Our surgeons generally don't conduct formal "means testing," but because they are immersed in the culture and community, they can tell who can and can't pay.

41. **Do you think that these Outreach Centers have more patients than they can treat?**

    Cleft outreach centers are pretty much working at capacity; there is no limit to the amount of cases they can upload. Burn outreach centers could do about 42 percent more cases if we had unlimited funding.

42. **How much do you pay per surgery?**

    About $200 for shorter operations, $300 for longer ones. Cleft operations get about $300.

43. **And how long do surgeries take?**

    We don’t have times for cleft cases, but generally a cleft lip will take 45 minutes to an hour; a cleft palate will take about 1.5 hours. Burn cases vary dramatically and go from under an hour to more than two hours, per procedure.

44. **I wonder if doctors prefer to do the quicker operations because that means their return on time will be higher.**

    Certainly that's a dynamic in the U.S. If you're getting the same amount for a cleft lip or palate, why should you do a palate? But I haven't seen that issue in our outreach centers, but I couldn't tell you it doesn't happen. However, given the variety of cases---complicated and not---that we see seems to strongly indicate that this is not happening.