

Impacta Team Issues

1) Laboratory

- Sr. Technologist that was trained in the US changed the calibrators of the HSV-2 test
- Another lab tech found the paperwork documenting this change
- Issue almost shut us down as an NIH site
- 4 months of no enrollments; just follow-up
- All testing for HSV-2 re-run at UW
- 99% concordance between UW and Impacta lab testing for HSV-2
- The lab tech was under a lot of pressure to go home early by her husband (she was pregnant)

2) Community Issues

- Community felt that gay men should be married
- Difficult to provide health care within the MOH in Peru
- Finally came out with a successful joint venture with the NGOs and political activists- being gay should not cause discrimination- health, policies, and human rights

3) Clinical Research

- Managing 5 clinics in 3 cities is difficult
- Keeping track of GCP is difficult in detail level
- A foreign visitor to Pucallpa who was on a grant fell into a misleading trap from former disgruntled participants (care was not adequate for participants, reimbursement was too high, acyclovir caused blood in the urine, etc.). These claims were sent to FHI and DAIDS. DAIDS visited and had a complete investigation with the IRB, site, and participants. In the end it turned out that foreign visitor wanted to do another grant and was looking for funds from NIH

4) Data Management

- Challenge to keep up with 5 sites with low turnaround time and low volume of queries
- System today is much better than first iteration