	Supply chain side (manufacturing, selection/forecasting, procurement, distribution and delivery)	Health system side (legislation, coordination, communication, financing)
Multilateral organization	- Supply is not the role of WHO, but when there is nobody else - the Ministry doesn't do something or does not procure those medicines and there is no any other partner. Without countries' request though, the HQ cannot do much. - The role of WHO is actually to make the programmes in the countries to speak to each other and coordinate their needs. - There is a gap between policy and reality, which can be frustrated to all sides - "My opinion is that the word 'integrated' does not have a room here. Because what we need to do is to stop the neglect of those diseases. See, a national medicine system in a country, is the national essential medicine list, right? So this by itself is to cover the essential needs of that given country. So, integrated, well it's the national system, but my point is why do those countries have deliberately excluded NTDs from that service? So who decided to exclude our medicines, the leishmaniasis medicines, from the list? Because if it's not in the national medicine list, then everything gets impossible or difficult, because it's not that we should integrate. We should be in the place where we must be, so the abnormal thing is to have it excluded. Because then it's in a corner, nobody orders, nobody follows and so on."	- WHO depends on external funding, while trying not to duplicate or compete with others. Fund use is not very flexible and WHO ready to chip in the supply chain when neither MoH nor other agencies can take over. - There are some people in WHO who are field-oriented, there should be more trust to WHO - Country should step up and not neglect their VL patients - Capacity in-country should be strengthened as much as possible so dependence on external people can be reduced - Partnership is crucial amongs all the involved stakeholders - The higher level politicians need to commit, just like in Asia - Not all the countries have funding for VL because it's not a priority disease, and affect neglected population so no provisions to give as such. - Level of commitment of people is important, and this is not the case for NTDs - There are only very limited resources and this is linked yo the neglect, the focal geography plays a role as well
Donor	- There have been stock outs of all drugs, over time PM and SSG and also some rapid diagnostic test. In Ethiopia in 2017, there had been a problem with a manufacturer of rK39. - Stock out problem can be due to manufacturing problems, or other bottlenecks such as forecasting the needs, which obviously a problem with supply. - There are stock outs due to unexpected emergencies, but also due to the issue of the one-source suppliers. Either that they could not finish and get the batch in time, the production batch was later than promised and anticipated or that quality issues with a batch. That is the whole problem with the single supplier issue. -	- Lack of transparency and logic behind funder (eg UK-Aid) decisions, eg how to utilize the pot of money for VL or NTD in general, operating in Sudan, etc. - Various donors involved in supply chain strengthening (eg Ethiopia) and requires streamlining and consolidation, clear strategy going forwards - Vertical approached by NGOs like MSF may be best for patients, but it means their presence is needed forever, there is a need for more country level capacity building - "WHO is not natural leader everywhere' – country office can hire many staff but inefficient and there has been some disappointment over specific activities performance. - Stock out can be due to communication problem where the drugs were actually in the country already, but the Ministry of Health had not released them or no communications - A regional programme for leishmaniasis with regional strategy at a ministerial level, like the Asian agreement on elimination. - Sometimes things depend very much on the people involved - There are sometimes in-country dynamics between institutions and/or between people which can complicate ths smooth functioning of supply chain of VL medicines and diagnostics

NGOs	- Timely reports are crucial, because procurement is done at the beginning of the project and updated regularly, estimate is based on, for example, the number of people tested last year and the year before. There was a shortage once (in Turkana), due to the lack of communication at the beginning - When there is shortage, the buffer stock was not quick enough to cover that, but also due to the rainy season it was impossible to land planes in the targeted areas - "Yes. So those are the stock outs due to unexpected emergencies, but we've also had real problems with the issue of the one-source suppliers that have problems. Either that they could not finish and get the batch in time, the production batch was later than promised and anticipated or that quality issues with a batch. That is the whole problem with the single supplier issue." - Who will take the risk of keeping a stock when no one wants to order? The problem also is about the bill, who is going to pay the bill? - "Now what we see is that WHO has to do their own procurement, they cannot rely on IDA, they have to go directly to the manufactures because they have the rule apparently internally that will not allow them to go to a distributer. So this is already removing a major stakeholder in the procurement, but if we could maybe better plan our orders that should not be so much of an issue. Both manufactures should be able to see what has been the order of WHO for the last couple of years. Then you have IDA, IDA was or is doing the procurement for DNDi. At some point these two were supposed to join and again the exact reasons why we didn't join at the time I'm not sure about. I know that we are a little bit like WHO, we like to procure directly from the manufacturer. We don't have to rely on IDA as such. Even though I think that we're now ready to get back to the table, because clearly with a decision we took in 2014 or 2015 was not the best one, because we lost a lot of money and we lost a lot of stock that we couldn't use. " (MSF) - Agreement with manufacturers and also in regards to donation needs to be more correct, with condition to guarantee access in the long term, for example by engaging in registration… the agreement should not be shortsighted. - It's 1 thing to have the donation, but we often see that the donation is not enough or that the donation needs to pave the way for the future. I don't know if this donation, I mean at the end of the day the NTD department is funded by Gilead at the moment. I don't think that they have that their hands are so tight. I'm not saying that, but I just … I'm not saying it's that easy, I'm just saying to the contrary, but as we are more and more asked to sign this kind of agreements with manufactures, if we are not more careful, they are going to put a lot of constraints on us and it would really shrink our activities.	- KalaCORE program will end in March 2019 and there has been progress, but discussions still ongoing on what needs to be done by the national programmes. The fear is that without external funding, control will collapse and go back to how it was. - Very unclear situation once the KalaCORE ends, who will buy the medicines? Sustainability is clearly a major issue, between actors we can coordinate but it is far from ideal - Lack of awareness and varied capacity between counties endemic of VL - NGOs need to coordinate always, like in Kenya, (FIND) has strategy to improve access to diagnosis, through an agreement with the DNDi and with WHO or whoever take the responsibility of making drugs accessible in these counties, whenever they are necessary. - "The main countries where we have activities are Sudan, Ethiopia, Kenya and Uganda and for each of these countries we have partners who are the ones implementing the research, but in order for us to be able to implement the research we have also a component of capacity building and even when we don't have clinical trial going on, we have to maintain minimal structure in this clinical trial site. This means that we are also supporting sides for the routine treatment of viscera leishmaniasis in the region." (DNDi) - Changing regulations are not easy to follow and there is no real interests from the manufacturers to do registration - "For diagnostic tests for leishmaniasis, the total shelf life is 14 months and according to the regulation of FMHACA when they arrive at port of entrance, they should have at least 50% remaining shelf life." (Ethiopia) - "I think that Gilead, did not do it for patients with kala-azar, but more because they see the market opportunities with HIV-patients with Cryptococcus meningitis But still, it could benefit so we need to sell that wave and benefit from as much as we can from that. And then we need to push countries that are affected by kalaazar to join this collaborative registration procedure so that they can also register faster. - It was a great initiative to have ERP mechanism in order to have a quality access to a quality product, but there remains no market incentive behind it, so manufactures will not be inclined to continue to provide information and update their manufacturing standards and also it wasn't really advertised or shared or communicated - Without coordination, money and time are lost - Unclear responsibility in the health facility regarding reporting of cases

Distributor or procurement agency	- It's difficult without forward planning nor predictions and there is stock rupture. Pooled procurement is ideal but sometimes people are not completely open about that. There are issues of trust and communication. -Each drug is challenging and people need strategy to deal with them. "Gilead is difficult, but in the end we will manage but for me, Gland Pharma is much more unclear on what is going to happen. Albert David isn't such a difficult manufacturer " -Definitely, IDA has been busy with these manufacturers from the beginning of the 90s, and there's no other organisation with so much experience with SSG. - "For NTD, it's the same system, only then we do more strategic meetings on what products we keep in our stock. It's an effort we do especially for the regulatory affairs, then I come in and interfere a little bit to get it in the right direction… And of course, we have a policy internal about what kind of focus areas and which type of neglected diseases we would like to give some extra attention" - There is not a better preparedness in case of a large outbreak as in 2014, "When quite quickly all our stock were depleted and msf had to buy large quantities directly from the manufacturer and Gland Pharma, being in that day, a very unreliable partner and made it very difficult." - Costs are increasing, because there are so many regulatory requirements every time so there, or a change like in Kenya, suddenly "Oh, now registration is not needed anymore". But still there is a need of country representative to navigate through different things, and there are regulations that you can only find out when you start a registration. Sometimes they are easy, but sometimes they can be very difficult, and they can get a little bit annoyed if they want all kind of things, leaflets and changes. - If there are contradictions between all these countries for the requirements of one product, then it becomes very difficult. - Harmonization of the regulation is needed. Of course every country differs, but…	-"The problem then and all the time is to try to establish who's going to be doing what … I feel like people always try to do something, but it's not very coordinated. It's not in the open and clear, and that's what I'm still missing a little bit." - All the parties and stakeholders need to do it better than this, even if they have specific purposes like research, because we are there to serve the people and to get better access if everyone put the experience in that. - "Relations between organizations isn't always easy, but there are possible solution. Better to have one party doing whole stock keeping, who has a more global view on the situation. IDA, for years, has been the leading supplier with good contacts with the current manufacturers. For me, again with the experience I have with IDA, they're always willing to negotiate and come to a very good solution. They take action. I think, you should sort this out instead of wanting to do it yourself. But again, our experience with IDA is positive and I can't say that the French or MSF Logistique think that way. So, if you look at the role of WHO, which of course is difficult, because I know that in the past WHO and IDA used to cooperate and now because… As I understood, the administrative system of WHO with regard to procurement has changed and they're not allowed to work in the same way with IDA, so you have all kinds of matters influencing the solution of what, again in my eyes, is a very simple …. I mean, we're talking only about a few drugs. We're talking about a disease that is being well-monitored so you could react quite quickly if you had a centralised approach. And the moment you chose not to do that, that's the core issue. You fragment the demand and you fragment the supply and that makes it very difficult, and again, it's something we cause ourselves. If for some reason we're not wise enough to step out of whatever problem we have and look for a solution. Again, I'm not naive, but in this case I find it very difficult to accept that you cannot find a supply solution here." - "For registration, somebody has to be the owner of the dossier, add the stability data and pay for new updates stabilising and continue the stability. Then you can out contract it to any manufacturer, that is not the problem. The formula of the contract, that's possible of course, but then you should have somebody who owns the intellectual property of the manufacturing process and update a dossier everytime and do the registration, the submissions … And that's also still quite costly, these kinds of things. IDA very often has people telling them: "Oh do the registration". And then they don't realise that there's quite some effort and capacity needed for that." -

Manufacturer	- Availability and accessibility is criticial, especially the capacity of the different partners to provide the forecasts. - « Now the major problem they have, talking about the WHO, PAHO, and others, is that they provide this to governments. Governments… The Ministry of Health its intentions to buy is in terms of volumes, but those who give the forecasts of intentions to buy in terms of volumes, are not the financial guys. A lot of intentions to buy do not materialise, because they don't have the money when they go back to double check. So whenever we have a tentative forecast, we know it's not going to be correct and the production takes a lot of time and is costly so it's hard to keep a big amount and it expires gradually because the orders are not coming. So, that is our main challenge at our level. » - SSG has a dedicated facility, so it will be there as long as needed - For PM the amount is 65-70,000 ampoules per batch, and the company is not making any profit to that, this is cost to produce, with very negligible margin, that has been fixed since 10 years.. and since then everything has gone up and they take it as CSR (Corporate Social Responsibility) initiative - Production will continue as long as there is order, and capacity can even be increased - It is simple: 60,000 ampoules, 1,5 $ each so total is 100,000 so not that much. So anyone can do this and buy supply for one batch and then distribute to whoever will buy from them. Irregularity of the order is a problem. The low margin also an issue as it means keeping stock is like blocking money, resources. - Sustained demand is the key issue - Price is agreed before, and Knight has policy of different prices when it is a full batch or more than a full batch. What happens when we do a full batch, because of the regulation we have to do regular analysis on the quality of the product. You rate the time and date of expiry. Those analyses are very expensive. It increases the cost of the product if we sell a batch over a long period of time. Now, if we sell this batch immediately, we only have to do the regulatory control of the quality for the time that we have it. If we sell it within 6 months, then … Because we don't have it anymore, we can't do this testing. It's already in usage, so that way we can offer a different price when the batch is sold full. Those prices are already been communicated to WHO, DNDi. - "That agreement says also that the price has to be covering the costs plus a margin. That agreement was signed, I don't know how many years ago, but before 2000. And since then there has been an increase in costs everywhere. That particular agreement never took that specifically in consideration. Now, we were not the signatories of this agreement, but it has come to us with the acquisition of the product and what we look at is how much it cost us to make and you very well know, regulations on pharmaceutical drugs have not reduced the number of controls and checks and quality this and quality that and reporting this and reporting that. All the opposites, everything is increasing everyday, you know. So considering that the price that was valid 20 years ago is today is counter intuitive"	- "Pre-qualifications process is sometimes seen as looking into destination in the European market nowadays. For SSG, they asked a lot, a lot of data, on identification of all kind of product, because there is perception it is not a very well characterized product and you have to investigate further, and the whole thing is just process, I don't see AD as culpability but I don't know if they'd do it if they know the product is good." - "Registration of the drugs in the different countries may have lapsed, because the last owners really pursue this, as they never get orders from the private sector and when the orders are coming from the public sector there's always an agreement from the government to get it in. So, a registration process, for example in Brazil, for a normal drug takes 5 years. In many countries it takes 3 years. It's costly in terms of work, because you have to follow up on it permanently, you have to add new documents and you have to do this and then the other. So even us at this point in time, because we never have all private orders, we are not even looking into re-establishing the registration. " - Regular meeting between Gilead and WHO - For this kind of disease with no private market, there definitely a need for collaboration - The price is about quality, with assumption that lower price is lower quality, an analogy made: " there is already generic manufacturers in India, its like 18K gold versus 24 K gold. If you don't have money for 24K gold you should be happy with 22 K gold." - Technology transfer is done but nobody is able to make the medicines

	- Expanding indication is not easy and reqires all the trials - Donation as a policy is not universally possible for all manufacturers as it is not seen as economically sound. - "Consistently right now, with the trends we have, the trends are more for producing the orders than increasing them. We're caught into this particular situation."	
MoH	- WHO emergency stock is in Geneva, for all the world. "Few years ago, 2014 we had shortage for long period for PM, even this time we have problem with PM.. that is internal logistic in WHO, people who received is not the one responsible, one month nobody knows where it is… they say IDA sent it, the logistic received it and keep them in the stock not knowing that people are waiting.. e are asking for the drug and we don't get them, there was an outcry and somebody remembers oh I received that some time ago can you check..and that was three months later.. - "Before KalaCORE, there was sometimes no drugs in the country, a national shortage" (Sudan) - "The health centre may saw only 10 people because after 2 weeks rupture in drugs so nobody came, but the next month they only ordered the same .. that ability to have a constant supply also limits their knowledge on the number of cases, because they don't record the case that they weren't able to treat" (South Sudan) - Microplaning at the health facility level - There might be infrastructure and connectivity issues with the platform (DHIS2)	- Complexity of the disease, with treatment regimens vary for both visceral and cutaneous leishmaniasis and at country level, we lack of capacity to manage them, these compounds being also neglected, unlike malaria - Elimination target brings donor attention, but for country in Africa this is still very far thus less attractive for funding - "Regional approach I think indeed it can be easier and the drug can be closer, we do this with WHO emergency stock the drugs go to Somalia, South Sudan, where forecast is difficult. So perhaps regional approach makes sense. However agreement between countries are needed, a kind of MoU similar like what they did in the elimination in India, at least in the region." - Training and supervision of the staff is important - There is not enough budget to cover leishmaniasis as one, not separating VL and CL. So there is not enough budget because of the CL challenge.
Implementing actors (local NGOs)	- Transporting sample can be a problem, for example for DAT samples, adding delays of 3 weeks, 1 month. Other places they told the patients to wait after checking for malaria, but unclar if or whether they were coming back - Geographical access to the areas can be difficult, borrowing from MSF until the consignement arrives - "Whenever there is a stock amount below the threshold, we run and try to avoid any rapture. There are sometimes issue with the expiry or customs, but total rapture is rare" - "In 2016, we had that very shortage, especially SSG was out of stock. WHO supply was not available; so we tried to get from Nairobi, but it was very costly and cant be sustained by us' (local NGO in Somalia) - "Yes there were several stock outs perhaps every 2 or 3 months. Main reason again, because it's not integrated in the system, if it was integrated it was only PFSA who distribute it to the health facilities, and would have been better… but the problem was it's kind of orphan drug, it goes through the programme, due to lack of integration, the estimation or quantification is done separately at national task force, we did quantification for three years, we made distribution lists based on treatment sites, or needs that we thought per site based on case load, and after for every	- Capacity of the health facility varies (cold chain, drug administration) - Procurement always by external agent, eg AmBisome is just with WHO. - Referrals very difficult. - "Pool procurement, including to align the ordering schedule is something that needs to be done, but it's not simple because everybody needs to agree … I do think that what happened a couple of years ago is that MSF needed urgently some products and could not wait for this pool procurement to be set up and that's the reason why they decided to go ahead: they had a big need and they just went." - Training is difficult because people changing all the time; the poor functioning of the healt system definitely is a barrier - "Having the integrated system I do think that was the way forward but then you just need to get the people that buy in and get the training and actually do it. You need to have a health centre, a health post who has a champion. If you have one strong person who is willing to drive it, willing to push these processes through then I think you can have success, but often that's what missing. You have people who don't show up to work,

	compound, antimonial, PM, the tests and this was distributed by the ministry every three months. In collaboration with the Regional Health Bureau. So it means it is not fully integrated in the PFSA so sometimes you have the drugs in the Regional Health Bureau, but at the health facilities there are no communication and the stock of PFSA at regional level was not properly communicated to the program." (Ethiopia) - Especially like, considered the diagnosis tests for leishmaniasis. This data in total shelf life is 14 months and according to the regulation of FMHACA when they arrive at port of entrance, they should have at least 50% remaining shelf life. -	there's a super high turnover, they're always being shifted to different locations, so there's very little consistency." -