

COVID-19 HUB

Ethics and Community engagement working group

E&CE Leaders meeting

Date: 20/08/2020

Location: Zoom

1) Discuss the position paper: COVID-19 and Vulnerable populations

Farah: New vulnerabilities in the context of COVID-19; it is hard to have an exhaustive list of all vulnerabilities so we could suggest in the objectives/scope of the paper that we are examining the changing vulnerabilities/those which have emerged or evolved in the era of COVID-19. This would be a good place to start; better than categorising them as old and new

Julio: For me 'new vulnerabilities' wasn't clear enough; we would need to include arguments about why they were new not the same but in a new context; It's not enough to mention that COVID-19 affects the same group – If we want to keep the argument of old and new we would need to expand the argument defending the 'new' vulnerable populations.

Sadia: Thanks Farah and Julio for your comments; the concept at the start was the effect of COVID-19 on vulnerable groups. In the paper I wrote all of the vulnerable groups and recommendations for them; In our big call we had members mention that we are all vulnerable, and new entities are becoming vulnerable. I then incorporated these groups in the paper and incorporated them into the paper; So this discussion paper was brought about by the idea of how COVID-19 is affecting previously vulnerable groups but also identifying new groups who are vulnerable. I have mentioned all of these new things, eg children in lockdown threatened by mental and physical abuse; also females who were working but are now at home – high tensions have led to increased incidence of domestic abuse. This paper is therefore based on the above 3 points. All physically disabled people are already vulnerable, yes, but how are they especially vulnerable to COVID-19 and what can we do to relieve these stresses. Same with migrants etc.

Roxana: I think the merit is precisely that – the fact that we are not adding to the groups, we are just highlighting how these groups have been made more vulnerable; this should probably be highlighted in the introduction; not a discussion of vulnerability per se, but heightened vulnerability. Impact of COVID-19 on these groups should be represented by hard data – from WHO? In Pakistan do you have hard facts about abuse etc? Eg in Peru 1,000 people have gone missing – noone could search for them due to lockdown; to fill the gap that Julio identifies maybe we could highlight the fact that COVID-19-related aggravated vulnerability is the basis of the paper. We also need hard data, numbers, stats. If we listen to Julio's observation the paper will probably be more vulnerable.

Nicole: Due to the number of members in the WG we could try and represent all of the eg Global South with numbers from all countries represented by the members.

Roxana: Too many numbers could diffuse the point of the paper; could do use regional papers instead, eg Africa/South Asia/South America

Nicole: Regarding the idea of the new vulnerabilities: Yes, we have those with heightened vulnerability but we also have people who may have become vulnerable due to socioeconomic status for example which could predispose to vulnerability with the implementation of PHIs.

Farah: I would agree to almost all the comments and that, as Sadia said, this paper has evolved. I would say that we need to carefully state that – to ensure that there is no ambiguity. In the introduction it should be clear what the paper is about – set the rules and scope of the paper.

Julio: I agree with Farah's comments; determine the scope of the paper and clarify it in the introduction

Sadia: If there is something missing in the introduction, I will add it. We need to ensure the reader needs to see the importance of this paper. I can take the data from the WHO and we can make it one brief paper about all the stats already mentioned. This would be more valuable for the reader. If I can add this part to the paper it will definitely be worth reading

Nicole: Ok Sadia if you work on it then we can continue moving forwards when it is ready

****It was agreed that Sadia: will incorporate comments and suggestions within a week and by Friday share it**

2) Ethic Preparedness:

Nicole: The other topic to discuss is the survey results; 58 responses, 3 biggest topics:

1: 8) IRB member training needs; understanding the standard of care for novel diseases and risk benefits assessment in the absence of sufficient safety and efficacy data remain difficult questions for IRB members

2: 4) Constitution of an Emergency Response Ethics Panel: do we need these, drawing on specialist members when new or niche expertise is required

3: 7) IRBs in LMICs where ethics and regulatory systems are not fully developed and lack national comprehensive guidance; national level dialogue to identify the gaps and make recommendations for comprehensive guidance; how experienced bodies support this

Trying to figure out the scope was mainly trials and observational studies; 1 open answer about child and maternal health. It would be useful to discuss the scope of the workshop. I also had a call with? and she agreed with the idea to use the survey; she also agreed that through the workshops we continue to explore and examine the topics within these topics – hopefully we can find specific resources through these etc. If we have specific things the member groups would need she can also help to find us resources/hold another workshop on a specific topic. Farah, have you thought through ideas for the initial workshop?

Farah: All of the areas highlighted are very close to the challenges of my primary job – so these are areas close to my heart therefore I'm very keen to work on these areas. IRB training needs came close to the top, and we have already recognised the need for this. In Pakistan Ethical Review works in a decentralised way – there has been no effort to train/communicate with/support IRBs and so we weren't ready to approve the influx of COVID-19 related research proposals. There is no national dialogue involving local IRBs; we now have a quantified response in terms of expression of interest in making this. Identifying the areas which are prioritised by extended groups and their members is what we should do to find topics to focus on. The survey informs our next steps – I am keen to hear thoughts from all of you. A series of national level conferences; If we have something specific to go to Suzie (?) with that would be great.

Nicole: Thanks Farah, we need to decide the topics. From the 8 we had, 3 or 4 stand out. For number 4, Roxana your Peru case study would be great. Last time we spoke to someone in Italy which would be another good one. For point number 7 the Pakistan case study could also work; We could do a couple of case studies for each workshop then let all members speak; The last topic would be good to have a conversation then an analysis on what was said; As we progress we could have (regional?) break out groups discussing specific needs.

Julio: The Peru example is a great example for point 4; we have already had a great discussion with Roxana, and we have something similar in the DR. 2 bioethicists were called to the national response

lobby. It could be good to understand whether we have other countries with a similar experience. We can examine how good plans led to good outcomes. I don't think we are losing anything from examining all off the topics, but I agree that it may be useful to pick 2-4 topics. Number 7 is also a good one, as well as number 8 – very important, most voted; definitely needs further discussion

Roxana: I'd like to say that I like the format we are taking; On Tuesday I attended a 1 day seminar from ?; they had simultaneous panels on specific topics but it was very frustrating – lots of good things to hear and learn but you could only attend one at a time... For large topics we could do 2 mornings in 2 consecutive months; a couple of keynote discussions followed by wider discussion with all participants. 2 or 3 consecutive 45 min sessions in one day, then maybe the next week we hold another one after people have digested the information

Nicole: I agree; shorter and spread out so people don't have to block a whole day in their schedule. As this is a global event we would need to find a good time in the middle or do it 2 times; When we did all of the different COVID WG calls at the start 1-2 or 2-3 worked well; If we did end up doing a whole day we would need breaks etc as looking at a screen all day without interaction is not feasible. Have a 1/1.5-hour call to ask members for their specific needs and ideas etc.

Roxana: We'll come up with different needs from different groups; eg in Peru our IRBs are very strong ethically and scientifically – will need very different training to those in countries who don't have very advanced IRBs.

Nicole: You made a comment about different training needs; perhaps after doing a first call we could have different workshops for eg less/more advanced IRBs.

Farah: I completely agree and believe that this is a very important insight – knowing ourselves there are very basic concepts that we need to hear; working in a decentralised ethics review system we end up in a lot of uncertainty and there are many gaps in national level guidance; The ones that will need basic training have v different needs; In our part of the world we never knew how to inform IRB members how to do a risk-benefit assessment for treatment.

The concern is that it is always hard to draw lines between eg basic and advanced level IRB's; maybe 1 session discussing basic training needs and in a later session move on to more advanced concepts. I agree that the right time and duration of a meeting is something we need to think about.

Nicole: regarding the case studies, should we include case studies for other members of this WG?

Farah: Good idea. Maybe we can do expression of interest? I can write 4- questions to be replied and from there we choose?

Nicole: good idea this will ensure representation across regions, areas research etc.

****It was decided that Farah will write the questions for the expression of interest**