



10 June 2019

Dr. Michael Baker

Dear Michael

This morning around 7 am, I dropped off to Maureen documents related to your Inquiry into patient care at UHN. These include:

1. In 41 patients who from 2009 to 2015 had been switched by Drs. Ward, Yeo, Kuo, *et al* from licensed therapies to then-unlicensed deferiprone, summaries of their relevant medical histories and laboratory tests. For the data of the first 29 patients the histories and data are organized into separate binders. The data of patients #30 to #41 are organized separately, but collated together in a large white binder.
2. A separate folder titled "Liver Enzyme Changes on Deferiprone" (outlining these in colour, for additional clarity)
3. Another binder containing the files: "CBC monitoring during deferiprone"; "Non-liver complications during deferiprone" and "Transfusion alterations during deferiprone"
4. A 18" x 24" glossy sheet providing all the data contained in the PLoS paper to which you can refer.

As for patient names I will be providing these to Dr. Gallie, who will drop this list to you at your convenience in person. We do not wish to have this information transferred electronically in the interests of patient confidentiality.

As we have emphasized in many communications, Dr. Gallie and I have an ethical obligation (indeed a heightened obligation, because even now intervention could mitigate the risk/damage to patients) to disclose to the research participants the harms suffered during exposure to deferiprone, medical treatment that came to light during our study, and that they were exposed to unlicensed treatment in favour of not one, but two drugs which are licensed as first line agents.

Our duty to inform patients whose harms were exposed as a result of our research, and UHN's ethical obligation to allow us to do, is reflected in Canada's [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#) (TCPS2); the Canadian Medical Protective Association [guidelines](#) and [policy](#); the Canadian Patient Safety Institute [guidelines](#); the Canadian Medical Association's [Code of Ethics](#), and

the [guidelines](#) of the Professional Standards Authority. The long-term harms arising from the exposure to unlicensed deferiprone that have already been sustained, are unknown. We believe that patients are at ongoing risk.

This is why your Inquiry as outlined previously will need to consider the data I have provided this morning.

To date, we have been received no reply despite several approaches to Drs. Smith, Hodges and Oza to help our efforts to contact these patients directly. We are the only individuals who must disclose specific harms sustained by individual patients, because no one else acted as a collaborator in the research which exposed these findings and, should others purport to disclose harms, we believe that information provided -- by the same individuals who exposed the patients to harms and/or enabled that exposure -- would be misleading and incomplete. Therefore providing the data to you is, **at this time**, the only way we are able to fulfill our obligation as above. The risk of non-disclosure of the harms/risks to the patients is greater than the risk of disclosure of the fact of research participation to you, in confidence

In advance of providing these names to you we ask if you could you please provide us with assurances that that information will not be given to anyone else except your colleague who is assisting you in this Inquiry. We ask that these names not be provided to Drs Ward, Yeo and Kuo *et al* because (as MRP but not research PI) Drs Ward, Yeo and Kuo *et al* have no right (see Tri Council Statement cited above) to the information that the patients participated in any research study on which the above are not co-investigators, including ours.

I will also be providing you with names of additional patients who were not consented under my study, but who, as I have been informed by others, were switched to deferiprone from licensed therapies from 2009 to 2015.

Sincerely

Nancy

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cc. Dr Brenda Gallie