Dragon, Karen E. (CDC/NIOSH/EID)

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To: NIOSH Docket Office (CDC)
Subject: 105 - HazDrug Update Comments

Some thoughts on the proposed list(s) of Hazardous Drugs 2006:

- Sirolimus is on both lists.
- Trastuzumab is indicated to be organ toxic, and **not fitting** the NIOSH criteria, however, rituximab is also indicated to be organ toxic, but is on the list **fitting** the NIOSH criteria...

other thoughts:

The appendix to the NIOSH Alert that contains the list of Hazardous drugs was set up differently than the lists of 'New FDA drugs and warnings not fitting and fitting NIOSH criteria for Hazardous Drugs 2006'. The way the appendix A list of Hazardous drugs is presented in the NIOSH Alert (2004) the drug names are followed by a grouping of numbers indicating 'Source(s)'. (the sources are referenced in the footnotes at the end of the sample list). Nowhere in the 'sample list-2004' does it say which of the NIOSH criteria apply to the drug - causing it to be a hazardous drug and on the HD list.

The 'New FDA drugs and warnings not fitting and fitting NIOSH criteria for Hazardous Drugs 2006' has a very easy to follow table indicating the NIOSH criteria that applies to each of the drugs...making it much clearer to the reader why the drug is considered hazardous- according to the previously stated NIOSH criteria (2004).

The difficulty we are having here in BC, is with a drug, such as Alemtuzumab. The NIOSH Alert list has it listed as hazardous according to the sources 1,3,4,5. I can not find any information to assist me in finding out which of the 6 NIOSH 'criteria' cause it to be considered a HD. I can't access the four sources' HD list(s), to see why they have considered it a HD. In Canada, the manufacturers of prescription drugs do not supply us with MSDS information. We are reliant on the manufacturer's monograph, which in this case just states that no long term studies have been done with respect to Carcinogenicity, Teratogenicity, Reproductive Toxicity, etc.

We are currently treating this drug as a HD. However, there are patients who will be treated with it subcutaneously and wish to take the drug ampoules to their homes for in-home SC treatment. If the drug is considered a HD, then we must have the patient have the treatment prepared and administered in a facility. Interested parties are asking for proof to show them why this drug has to be considered a HD.

There are other examples of drugs that some facilities within Canada are considering as HD's while others are not. So one encounters the problem that in one province a drug may be considered a HD, but in the province next door, it is not. Most of these drugs are either monoclonal antibodies, vaccines, or some other targeted therapy..and most are relatively 'new' drugs where long term studies have not been performed. Evidence of the 6 NIOSH criteria for a HD may or may not be stated in the drug monograph or manufacturer's information.

Rituximab is another drug that facilities in British Columbia are asking for clarity on. This drug can be used as a treatment for non-cancer diseases. Therefore facilities that do not handle cancer HD are preparing and administering rituximab and may not have the proper set up to handle Hazardous Drugs.ieClass II BSC, in a separate mixing room etc or the nurses may be preparing the infusions on the wards, or in clinics... If we (BCCA) come out and say that it is a HD, then it will restrict these facilities handling of the rituximab, and have a huge operational effect on their delivery of services. If the drug is a HD, then by all means the workers handling it should be protected properly (according to NIOSH and ASHP guideline), however if the drug is not HD, then we should not call it one.

The question is; should we be placing a drug on the HD list because it is new and we are not really sure if it is hazardous or not with long term frequent handling?(i.e. targeted therapies - what are the long term effects?) And

we do not want it to be handled without proper HD precautions?(i.e. 'bare hands' on a nursing ward, or in a laminar flow hood) Should we err on the side of caution? Should we place all the targeted therapies on the HD list, until proven otherwise?

What I would like to see is a published update (a re-publication) of the HD sample list from NIOSH Alert 2004 appendix A, showing which criteria that applies to each drug(s) that make them a HD. i.e. are they carcinogenic, teratogenic etc. similar to the 'New FDA drugs and warnings not fitting and fitting NIOSH criteria for Hazardous Drugs 2006' lists (tables) show. There should be consistent handling of these drugs between facilities.

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