## 5. Collection of information from laboratory scientists, physicians, and patient organization

*Responses received from ARUP, Mayo Clinic, LabCorp, Academic Hospital Ghent*

| Question | Respondent* | Reply | Details |
|---|---|---|---|
| Q1. Are you satisfied with manufacturers' information policies when they restandardize assays/introduce new reference intervals. | 1 | Yes and No | My understanding is that when vendors do make this type of change, they may provide a product bulletin directly to our laboratory supervisors and purchasing team. Alternatively, they may simply update their package insert and indicate the update with a small line in the margin indicating a change was made. This is obviously my least favorite form of communication, because I cannot guarantee that my staff notices these changes with each and every package insert that comes in the door. If they provide a product bulletin, we are usually made aware of the change well in advance of its institution.<br>Regarding whether they give us "adequate" information…that varies by vendor, and there is so little I can do about it…we just have to adapt to the change and determine how much it differs from our existing results/calibration/etc. |
| | 2 | Yes | |
| | 3 | Yes and No | Reply mostly related to the quality of the RIs: Yes, for the many MFs who are conducting nice population-based RI studies and provide us with good data. No, for some MFs who do rely on old literature or transfer RIs from other sources, which we do not like.<br>Note: our choice of methods that we offer for our clients in large part is influenced by robust RI studies. |
| | 4 | No | We are not satisfied with the documentation that companies provide us, in case of restandardization or new reference intervals. In most cases, we get a short descriptive text, as well as the request to download the new application. In most cases we do ask the company explicitly to provide us more information and details about the rationale and validation of the restandarisation, but this is only provided upon request. Each restandardized method is validated internally in our lab before it is implemented in our daily routine. |
| Q2. Have you ever done a risk-benefit analysis when switching from an immunoassay to a mass spectrometric method? For example, for FT4 by ED ID-LC/tandem MS, this was also associated with new reference intervals and decisions limits? | 1 | Yes negative | We have generally operated on the underlying assumption that mass spectrometry is usually more analytically specific, and that this would imply a benefit |
| | 2 | Yes negative | No I have never done since we were subjectively in favor of mass spec assays. |
| | 3 | yes | In our daily practice, we have a number of tests that we offer by two (or sometimes more than two) difference methodologies and are typically using different sets of reference intervals that are method-dependent. We really do not have to cope with the risk analysis in this situation as it is quite well accepted by our clients and if some questions arise, our explanation is that the difference in RIs is simply because of the difference in sensitivity/specificity/ recovery/calibration of the methods. Clients seems to understand it quite well. In our opinion, there should be no or minimal risk to patients outweighed by a significant benefit, if all free T4 assays independently of methodology will be standardized that will allow for universal RIs. |
| | 4 | Yes | We do not have a real separate procedure fort this. |

** Responses anonymized*