3. IFCC C-STFT Questionnaire to IFCC Member Societies

Q1. What measures does the laboratory community generally take to mitigate risks due to changes in numerical values/reference intervals/decision limits after standardization: A: Measures upfront (on a long enough timeline before implementing the standardized assays)? B: Do you immediately report the changed numerical values or do you report the relationship of the new values to the values before standardization?
Q2. Which channels do you use to communicate with the clinicians your laboratory is working for?
Q3. For how long and how often do you take these measures?
Q4. Are you aware of recommendations/requirements to act properly by accreditation bodies in your country?
Q5. Suppose a clinician did not capture the change in numerical values, can you figure out what can go wrong and/or what you still can do to prevent risk/misinterpretation?
Q6. Others?

Summary of responses from IFCC member societies and individuals from IFCC member society countries*

Country	Q1a. Measures to mitigate risk upon standardization or changes of RIs: upfront?	Q1b. Do you immediately report the changed values or in relationship to the old ones?	Q2. Channels used to communicate on changes to your clinicians?	Q3. For how long/ how often do you take these measures?	Q4. Are there recommendations or requirements with regard to measures to take in case of changes by national accreditation bodies?	Q5. Suppose a clinician did not capture the change in numerical values, can you figure out what can go wrong and/or what you still can do to prevent risk/ misinterpretation?
Belgium	Differences are internally tested in advance (several weeks)	Old & new values (and conversion factor) shown in parallel (a few months)	In the report: result and comment Specific mail: if differences is iimportant and only few doctors concerned. Interdisciplinary symposium: seminars, intranet messages for all clinicians.	Several months	Belgian accreditation body (BLAC): No	Unlikely, due to the report structure (first RI, second result). Potential misinterpretation of results "prior" to the change.

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The Netherlands	Response: changes should be introduced in compliance with ISO 15189. Validation of new methods is required	It is therefore advisable to report the standardized results on a separate row in the report section to distinguish it more explicitly from the previous and, if decided necessary, concurrent results measured by the (former) non-standardized method.	Response: Laboratories communicate to the clinicians by oral-, electronic and hard-copy channels. Changes can be discussed in meetings laboratory specialist have with the clinicians and communicated by a informative letter.	The time span during which the method transition is marked in the result report, is as long as is considered clinically relevant (consider frequency of monitoring thyroid status for all patient populations).	Medical laboratories which have or pursue NEN – EN ISO15189 + C11: 2015 accreditation are aware of the respective requirements.	A misinterpretation of the FT4 and / or TSH result by a clinician can result in under- or overtreatment of the patient. This can be avoided by assuring all new standardized results are reported with explicit notification of the changes in method.
France	National organization (Coffrac) requires validation by IVD manufacturer	Relationship old-new during 6 months	Specific clinical committee inside the hospital, Publications and presentation at congresses organized by specific French societies and their working groups	1 year	See Q1a validation by “sociétés savantes” and/or sanitary institution. Note: laboratories have to respect this validation and translate the change into new RIs	Mitigate: clear information accompanying result, info by endocrinologist and by sanitary institution as HAS (Haute Autorité de Santé)
Hungary	Yes, inform clinicians with whom contact is very good	Temporarily, old values/RI and new values/RI.	Circular letter issued by laboratory to anyone concerned; Publications and discussion of potential problems with interpretation after standard			Unlikely, because very good laboratory-clinician interface; -Board members of the Hungarian Society for Endocrinology and Metabolism publish/discuss potential interpretation problems after standardization at the level of leading national endocrinologists
Italy	Compare experience enzymatic creatinine, HbA1c, high-sensitive C-reactive protein, and Troponins I/T. Both (upfront and after standardization) measures needed at the level of the individual laboratory staff. Better: shared protocol for clinicians	Once shared protocol used: only report new values, but lab staff should be at the disposal of clinicians to explain, if needed.	Weeks/months before: explain reason of differenced and benefit in meetings, seminars, workshops at the lab-clinician interface; prepare clinicians for shared protocol; release/distribute to all clinical wards, via institutional intranet network	Joint committee including laboratory personnel and clinicians evaluate every six months the impact of differences and new results on clinical practice, as well (e.g. good experience with the high-sensitive troponin assay.	There is no national accreditation body (highest regional), thus also no formal regulations on this topic.	Task of the Joint Committee to evaluate. Misinterpretation unlikely, provided good information as well continuous communication at the lab-clinician interface.

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Poland	2 weeks upfront implementation; information sent to all hospital units via intranet (=SOP); addressees: heads of clinics; info: descry. Of stand test + new RIs + relationship old-new values (statistically established)	-Immediate report of new values with reliance only on the flagging system from an LIS to show the changes in the reported values	-Reporting in urgent cases: direct communication to clinicians; -written reports by using e-hospital information system		Actions in accordance with accreditation standards established by the Government	Misinterpretation unlikely, because the lab is very alert to potential misinterpretation by clinicians. If there is an indication, phone contact and information about new method/RI is re-sent in written or electronic form.
Japan	Upfront, convince clinicians that without standardization, different tests give different results; conversion equations should be presented.	-Some report immediately new values; not a real problem because the reported values are color coded i.e. red when above ULs and blue when below LLs; -others report old-new in parallel with conversion equations, because it takes time until clinicians are accustomed to new values.	Clinicians' societies should be involved in announcing the differences	How long should be decided before the information campaign; the latter should prepare for the differences	Yes, accredited labs obey the national standards. Nation-wide surveillance is performed (e.g., Japan Medical Association and Japanese Association of Medical Technologists).	Potential misinterpretation due to new results which cannot be compared to old one's on a time scale; therefore: conversion equations needed. Clinicians are concerned about standardization of thyroid function testing if not all aspects are considered: pediatricians (what about neonatal screening and age-adjusted RIs); obstetricians/physicians: RIs during pregnancies; physicians: subclinical hyperthyroidism/hypothyroidism.
Paraguay	-Before: the Paraguayan Society of Endocrinology will organize meetings to reach a consensus related to change.. -Before, we conduct a review of the clinical impact of new RIs or analytical changes, especially in critical areas; obj: communicate and alert.		-Internal communication/ alert via e.g. SIH Integrated Hospital System. Coordination: Medical Director who is liable on Patient Safety. Alerts drastic: even upon accessing e-lab request for FT4 and TSH. - Paraguayan Association involved to alert laboratories if general change.. - Alert via continuing educa.			Misinterpretation, very unlikely, simply because the very effective Paraguayan Security Social Institute continuously alerts doctors (via Comp system). Also lab personnel is instructed to route them when they fail to capture.

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Norway	When possible, yes. IS done by newsletters and webpages. In Norway, there is the tradition of direct contact between lab and endocrinologists; when there is an important change in an assay, besides direct contact between lab and clinician there is also contact with clinicians through the respective Norwegian societies	Yes, with a note describing the relationship between new and old values. If there is a change in units, the numerical values in both old and new units are reported for a period of e.g. 3 months.	Website; newsletters; information on lab report; direct contact with the major stakeholders (Head of department & staff members	Appr. 3 months, but depends on the analysis	We send a note of change to Norwegian Accreditation. Will include validation reports in which we have tested the new vs the old assay. The validation reports will be included among our accreditation documents for revision by Norwegian Accreditation upon the next audit	In general, risk is unlikely since results are interpreted against RIs, and results outside the RI will be marked to come to the attention of the physician. Risk will be most imminent: -when there is no RI -when the RI is not properly validated (children, pregnancy) -when results are compared with more loosely defined treatment target values. For THs, greatest risk of misinterpretation will be in special conditions: in which TSH is not reliable such as pituitary or hypothalamic disease and when TSH has been suppressed for a long period of thyrotoxicosis. In Norway, there is the tradition of direct contact between lab and endocrinologists; also through the respective Norwegian endocrine society when there is an important change in a hormone assay.
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Tunis	about a month before the implementation of standardized assays are carried out bilateral meetings with the medical services teams that we consider the most relevant. Also a courier will be sent following these meetings mentioning new RIs with an explanation of the benefit of standardization; meetings also with the lab to decide on the manner to proceed ; meeting also with LIS people		Meetings with medical services/couriers	after the implementation of standardized assays, meetings with medical teams is necessary to judge and appreciate the impact of standardization on the clinical management of their patients and take note of their main remarks.	a trial period of one month to appreciate the impact of standardization on the old values and to judge whether it will be necessary to establish conversions. The results of this trial period will communicate to the unity of biology laboratories of the Public Health Ministry to discuss a common strategy on the way to communicate our results to different laboratories in the public and private sector, an information day organized jointly informing the various stakeholders.	

**Responses were obtained from representatives or individuals from IFCC member societies and may not reflect the official position or opinion of the organization or country*