

2002:
**Development of clinical standards in FDI World Dental
Federation and relationship with the International Organisation
for Standardization (ISO)**

Prepared for the FDI council

The Science Commission Chairman, Professor Elmar Reich presented at Council meeting B in Kuala Lumpur September 2001 a recommendation from the Science Commission that *“the FDI should be involved in the development of clinical standards. It was also felt that a Special Committee for Standardization was required, which would have minor budgetary implications.*

*“The Council **agreed** that more research on the topic was required and that a detailed strategic proposal and budget be presented at its next meeting.”*

This report attempts to summarize and present the options that are available for FDI with advantages and disadvantages. The FDI Science Manager, Professor Asbjorn Jokstad, presented a description of standard developments in dentistry to the Council in KL. The notes distributed here as well as his submitted report should be consulted for further information on the topic.

What are standards and standardization?

The terms standard and standardization may have different meanings and interpretations depending on language and cultural background. This is reflected in the many minutes and exchange of emails in FDI concerning this issue. It is important to reflect and agree on which interpretation on “clinical standards” that is under discussion. There are at least three interpretations related to the presently ongoing discussion on how FDI should be involved in this work:

1. Standardization interpreted as defining or agreeing on minimum requirements of clinical performance, and the actual standard is a description of these requirements. (These can be physical/mechanical or clinical requirements)
2. Standardization interpreted as developing “new yardsticks” to describe and reflect clinical performance of a product, and the actual standard is a description of this “yardstick”. (This is equivalent to the descriptions of the benchmark tests in full detail in today’s ISO standards)
3. Standardization interpreted as developing guidelines for how to carry out clinical trials with adequate internal and external validity, and the actual standard is a description of details in such protocols, e.g. number of participants, outcome measures, time span, etc. In this context, it is explicit that any clinical trial needs to have a valid research purpose.

ISO describe standards as:” *documented agreements containing technical specifications or other precise criteria to be used consistently as rules,*

guidelines, or definitions of characteristics, to ensure that materials, products, processes and services are fit for their purpose.”

The term standard can also in other context signify a “norm”, or “typical” or “average”, but this is irrelevant to the present discussion. However, one needs to pay attention to the fact that the term “norm” is used in German literature for a standard, (while the term “specification” is often applied in USA).

ISO standards and why standardization?

ISO is the largest organization in the world that develops standards. There are some 250 technical committees, of which one, TC106, focus on medical devices in dentistry, i.e. materials, instruments, equipment, implants and oral hygiene products.

The development of standards follows a meticulous and well-structured plan with work through workgroups, then subcommittees, then as a draft standard and finally as an international standard. Voting is being done in all stages by country members with voting rights (P-members). Other countries may choose to limit participation to an observation status (O-members). The members of ISO are invariably national and often also governmental standardisation bodies and each country have only one vote when deciding on acceptance of new standards. If a certain majority are in favour of a new standard it is carried.

The main reason given by ISO for why standardisation is needed is to help rationalize the international trading process. (<http://www.iso.ch/iso/en/aboutiso/introduction/whynEEDED.html>). It is important to emphasise that many countries that adopt ISO standards rely on third party institutions, which are independent of the manufacturer and the standardization organization, to verify that products, which may include a particular product, material, or process, meet such standards. Implementing standards necessarily involves a mechanism for enforcing that standards are being applied by the industry.

TC 106 activities

ISO TC106 consists presently of 22 P-members and 24 O-members. All, with the exception of 2, are regular or associate members of FDI. Ninety-five of the 152 FDI's associate or regular members are not engaged in standardisation work within TC106. These countries have probably various reasons for choosing not to participate in this work. Many of the member country standardisation bodies rely on expertise from dental associations, testing institutions, academia and by the dental industry. Cost issues are of course important, and there has been a marked decline of people from academia during the last years.

ISO Livelink

Since the last council meeting in Kuala Lumpur, the central secretariat of ISO has introduced a site on Internet titled the ISO-livelink. The intention of this site is that all information related to standardization developments within the organisation is to be exchanged here. Little activity has appeared on the TC106 segment of the

site so far, probably due to the novelty of the concept. Presently, only a few sporadic messages from the ISO central secretariat in addition to the minutes from the TC106 meeting in Lillehammer last September. It is assumed that the traffic will increase during this year.

Other international standardisation activities

Dentally related standardisation work is performed also by other organizations. Examples are ANSI/ADA in USA, CEN TC55 in Europe and others in some countries in other regions. Moreover, other technical committees in ISO also develop standards that have a direct influence on dental practice, e.g. TC194 (Biological evaluation of medical devices) and TC210 (Quality management and corresponding general aspects for medical devices). One may argue that the ISO standard 14155 developed in TC194 and titled "Clinical investigation of medical devices in humans", have a more significant bearing on standards in clinical dentistry than any of those defined by TC106. Finally, other international activities such as the development of the Global Medical Device Nomenclature and the Global Harmonization Task Force have direct relevance to the dental profession.

Discussion and contributors to discussion in FDI

The discussions on standardisation carried out within the organisation during the last twelve months have actually revolved around two main issues.

- Issue 1 concerns the need and willingness by the FDI to complement and actively engage in standardization work within the confines of ISO. The origination of this discussion stems from a letter sent by Professor Dennis Smith who represented ISO for the first time at the Science Commission meeting in Paris. There had been no representation or report from ISO prior to this since Dr John Stanford attended the Commission's midyear meeting in Vancouver in March 1999.
- Issue 2 concerns the need and willingness by the FDI to develop "clinical standards" in context of what the profession, should expect from materials in terms of minimum or optimal clinical requirements.

Two more issues related to clinical standards are also relevant to discuss in the future, but further clarification on resource allocation is needed first.

- Is there a need and willingness by the FDI to decide on or even develop "clinical yardsticks" to reflect clinical performance of a product? E.g. should FDI advice that characteristics of a dental restoration that are observable after e.g. 6 months be included/not included as criteria for clinical performance?
- Although FDI has a history of developing guidelines on how to carry out clinical trials, is there a need and willingness by the FDI to undertake such tasks today, which need to be applicable to new materials, products and techniques?

Finally, it is important to point out that a major change of standardisation and certification has been implemented in Europe by a EU directive for medical devices. This requires that manufacturers need to obtain a "CE" mark in order to sell a product within the European market. This system supersedes all previous certification programs used in Europe before the directive. What is not common knowledge is that manufacturers no longer are required to submit their products

for testing according to standards specific for the product before being certified for sale. Exceptions are products classified as class 3 products, of which there are few in dentistry. It is optional for the manufacturer to instead choose to obtain this by adhering to a management system standard, of which ISO 9000 is the most well known. Such standards describe requirements for what an organization must do to manage processes influencing quality, but do not include specific requirements to quality of the end product. This is analogous to the “good manufacturing practice” term used by the Food and Drug Administration (FDA) in USA. Moreover, the third party experts dedicated to inspect whether the manufacturers comply with ISO 9000 may not need expert knowledge on dental products, but may in spite of the fact thereby allow a manufacturer to CE -mark the product.

It can be debated whether or not FDI as a health organisation should be concerned how this situation apparently has passed unnoticed by most European dentists and apparently been accepted by the community of professionals in Europe involved in standardisation work without alarm.

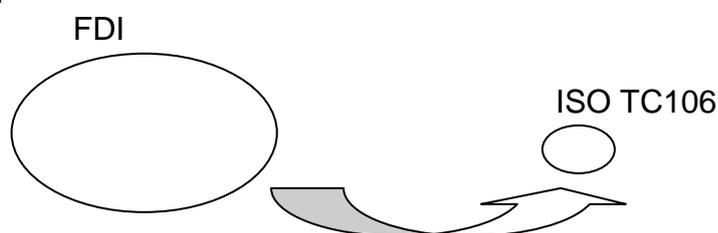
At present, one of the very few countries in the world where clinical testing on a voluntary basis is being carried out is in USA thanks to ADA’s seal of acceptance. There are not requirements to undergo clinical trials before marketing products in USA, but many manufacturers regard the value of obtaining the ADA seal attractive enough to carry out such trials. There should be little doubt that clinical testing of materials and products, mandatory or voluntary, is to the benefit of patients. However, it is not difficult to imagine that the moment the dental industry no longer sees the ADA seal as a promotional advantage there will no basis for its continuance.

Suggestions

Issue 1 - standardization work within the confines if ISO.

Various models for cooperation are possible:

Model 1:



Appointed experts participate within ISO confines

- Will have budgetary implications
- Selection and administration of experts require administrative support from head office

- Experts will not represent “official FDI” views, as there are no mechanisms within the organisation at present to identify such views

Model 2:

The ISO-livelink site is open for active members of ISO, of which FDI is at present. The site present FDI the opportunity to be engaged in standardisation developments by monitoring the activities of ISO, relay information on progress and to answer requests from NDAs, or NDAs appointed individuals, interested in specific topics. It will also allow FDI to rapidly access all information concerning standardization developments in dentistry and to distribute relevant information to selected recipients with little administrative efforts in a very cost-effective way, i.e. create a communication network within FDI structure.

Model 3:

Such service can be rendered even more valuable by approaching experts who would be willing to serve as “expert” advisors to FDI on the documents. Some incentives would need to be formulated to make this possible. If one or more of NDAs, or any appointed experts have a concern with issues related to the drafting of some wording for a standard, this could be signalled in this FDI network. As it is now, FDI is allowed a single voice to comment on draft international standards, i.e. at a near final stage, which does not make much impact on decision making and FDI is not even allow to vote on any stages. In practice, FDI has not put this into effect on a regular basis. If called for, a much more powerful impact on decision making in ISO can be made by advising all NDAs to contact their national representatives in TC106, where such is in existence, and explain viewpoints and concerns directly to them.

Issue 2 - developing minimum adequate clinical standards

As indicated above, if standards are to be of any value there must be a mechanism to verify that products or processes conform to these standards. This is regulated either on a legislative basis, where governmental institutions carry out controls, or on a voluntary basis, where third parties carry out controls or verify that the manufacturers have documented that criteria for acceptance have been fulfilled.

It is unrealistic to believe that FDI at present will be able to construct a division within the organisation that can carry out clinical tests to verify if they comply with standards, or on behalf of manufacturers.

What perhaps can be achieved is to approach various segments of the dental industry to solicit support for a FDI “recognition of excellence” or “quality stamp” or whatever one wishes to call this. Segments of the dental industry that could be approached are within dental hygiene, dental materials, infection control segment, high technology, etc. The concept should be simple: if the manufacturer can produce published documentation that their product fulfils certain minimum clinical criteria a “stamp” can be used. Examples of criteria are:

- A disinfectant should be able to kill 99.5% of all microorganisms and not cause adverse effects on users, etc.

- Tooth coloured dental restorative remain un-discoloured for more than 12 months in more than 90% of the patients, etc
- Diagnostic tests needs to achieve more than 90% sensitivity and specificity in a specific population with defined disease incidence, etc
- Toothpastes should reduced primary caries incidence xx%, in a specified population with defined disease incidence, etc

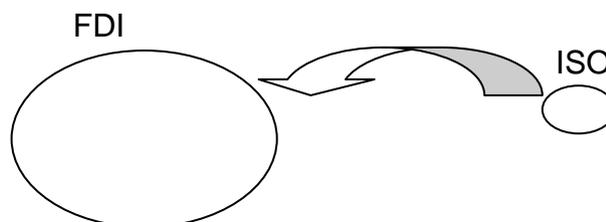
The minimum clinical requirements will need to be defined and described. This can be done by a special committee on standardisation within FDI, or by joint members of the science/practice commission. In addition, some of the minimum clinical requirements can be adopted from the clinical evaluation parts of the acceptance programs of the ADA, as well as on input from NDAs that may want to be engaged.

The prospect of such voluntary system will rely on whether the dental industry will adopt the idea. I.e. will the industry see a clear benefit for sales if they obtain such “stamp”? One may turn the questions around; do FDI and the NDAs within FDI have enough persuasive influence on their members to make these “customers” ask for products with such stamp? Apparently, in USA the dentists have a preference for products with the ADA seal. An analogue situation may be possible for the rest of the world, but it will rely on dentists making demands on the industry. Naturally, this means that eventual clinical minimum criteria for performance as defined by FDI must be realistic, reasonable and relevant.

Development of clinical standards in cooperation with ISO

Developing standards is a meticulous and therefore time consuming process. Years are often used from initiation to agreement of a final international standard, and effective exchange of information is essential. It is therefore crucial that such work can rely on secretarial support. In TC106, many of the subcommittee secretariats are financed by the dental industry, which may be a possibility for FDI, but needs to be clarified. What is important, however, is to emphasise that unless a good administrative support can be provided, there are small chances for meaningful standardisation activities within FDI. The competency of ISO and individuals involved in the work in TC106 may also be constructive in a starting phase. Possible models for cooperation can be:

Model 1

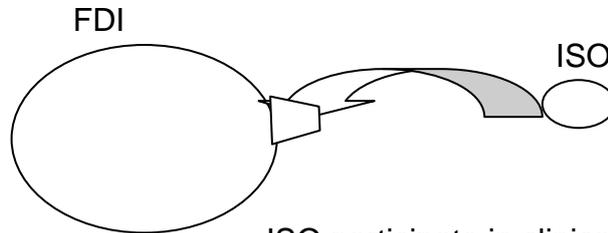


ISO participate in clinical standards development within existing FDI structure, e.g. science and practice commission, or ad-hoc joint officers

- Rely on willingness of ISO to contribute with experts

- If FDI undertakes the administrative function, at least one full time staff is required at head office due to workload

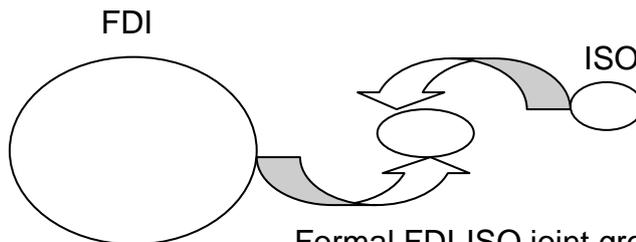
Model 2



ISO participate in clinical standards development with a new “special committee on standards development” in FDI

- Will have budgetary implications
- If FDI undertakes the administrative function, at least one full time staff is required at head office due to workload
- Rely on willingness of ISO to contribute with experts

Model 3



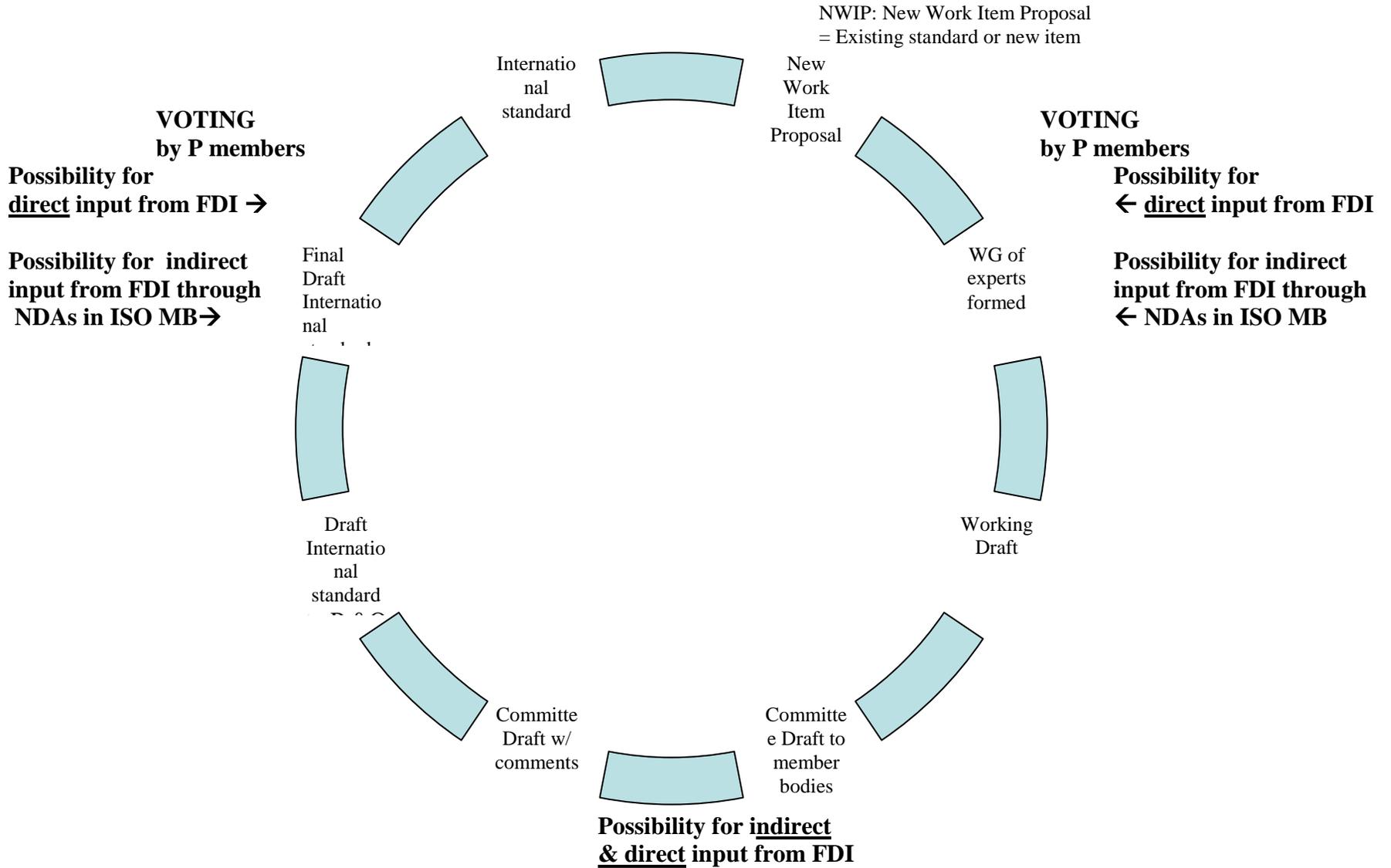
Formal FDI-ISO joint groups develop clinical standards

- Will have budgetary implications
- Rely on willingness of ISO to contribute with experts
- The previous model of the FDI-ISO cooperation, which didn't function very effectively mostly due to poor contribution from the FDI representatives
- Needs to be clarified whether FDI or ISO should monitor progress and offer administrative support
- If FDI undertakes the administrative function, at least one full time staff is required at head office due to workload

Ferney-Voltaire, 20 April 2002

TC106, 8 SCs and 47 WGs, 300 experts, 24 participating countries and 21 observer countries.

All SCs work according to a structured procedure:



FLOW CHART FOR MANAGEMENT OF ISO DOCUMENTS

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