Principles for technical evaluation of new methods

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The specifications for instrumentation used during the development of new clinical methods for perinatal monitoring differ considerably. Part of the instrumentation is home made by the research teams and part is added on to commercial equipment or is slightly moderated commercial equipment. Before a multicenter evaluation of the methods is initiated it is thus important to compare the specifications for the equipment and to agree on common features. Such action may lead to a decrease in cost of the use of biomedical methods and to an increase in safety for the patients.

Cost of the methods

In the research phase the cost of new methods is low. Cost start to increase when industry plan to produce the equipment (Fig. 1) and increases considerably when the method is adopted for general clinical use.

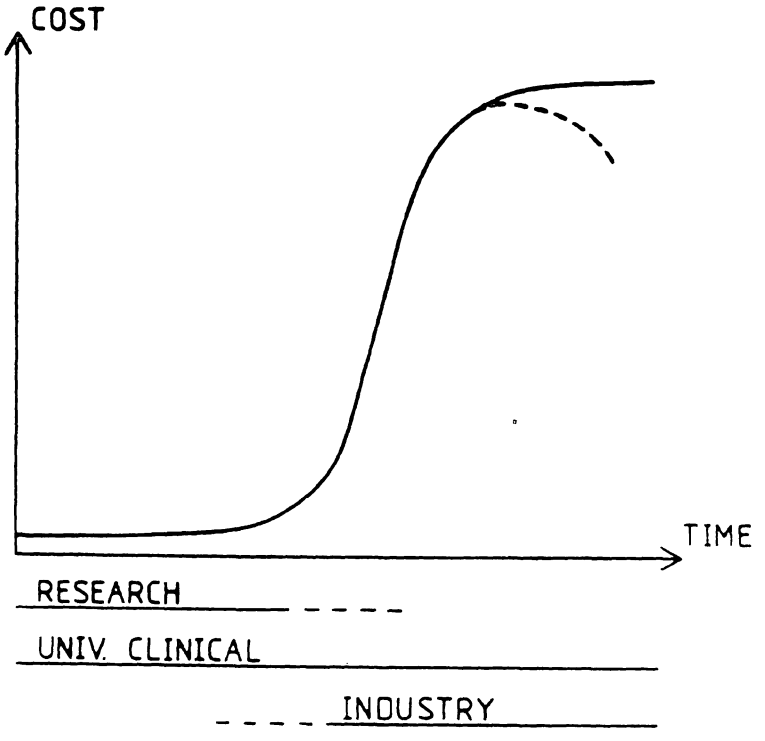

Figure 1

Cost of biomedical methods, scales in arbitrary units.

The channels for transfer of information between research teams, industry and clinicians need to be improved. Research teams are always well aware of the accuracy, repeatability and stability of their methods, but they tend to forget to publish their experience on errors and pit-falls encountered while the methods were developed. If this knowledge is not transferred to industry and clinicians it may increase cost and invalidate the methods.

J.Perinat.Med. 12(1984)

Patient-safety

The safety of the patient depends on i) validity of the method, ii) minimal risk to the fetus and mother (e.g. from bioeffects of ultrasound) and iii) electrical safety.

ad. i) as previously mentioned the validity of the methods need to be evaluated in multicenter tests. Such evaluations should use standardized equipment (e.g. for ultrasound tests with respect to high pass filter level, doppler frequency, spectrum analyser, wave form analysis and several other features).

ad. ii) The risk of bioeffects from ultrasound equipment to the fetus and the mother has previously been considered negligible. However, at the Consensus Conference initiated by the National Institute of Health (Feb. 6-8, 1984) it was pointed out that new methods use equipment with higher ultrasound intensities than previously used in imaging equipment (1). It was stressed that new methods should not be used unless the output intensity of the equipment was measured. The EEC group could participate in setting up guidelines for the measurement of output intensities and probably rules on limits for intensities.

ad. iii) The electrical safety was early considered important and rules have been worked out by the International Electrotechnical Commission (2, 3). These rules are followed in the EEC countries.

References

1) The use of diagnostic ultrasound imaging in pregnacy, National Institute of Health, Consensus development Conference (Feb. 6-8, 1984) Consensus statement.
2) International Electrotechnical Commission: Safety of Medical Electrical Equipment. - Part 1: General Requirements. IEC Publication 601-1, Genève 1977.
3) International Electrotechnical Commission: Requirements for Electrical Installations in Medical Establishments. IEC 62A (Secretariat) 55. 3rd draft, July 1982.