

## How can national health authorities promote quality and safety when considering new and expensive medical devices?

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## The National strategy for quality improvement :

The strategy, which has been developed for the period 2005-2015, use the following definition of the concept of "quality".

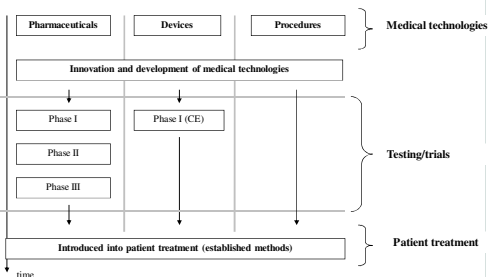
"For the health services, high quality means that the services:

- Are effective
- Are safe and secure
- Involve users and give them influence
- Are coordinated and continuous
- Utilize resources efficiently
- Are available and evenly distributed.

## The Norwegian Council for Quality Improvement:

- The Ministry of Health (MoH) established the Norwegian Council (NC) for Quality Improvement in 2007.
- The aim of the council:
  - Clarify the roles and responsibilities of agents responsible for the work on quality improvement.
  - Improve interaction between actors on different "levels"
  - Produce more comprehensiveness and transparency around the work on and quality development in the health service.
- The NC – 25 members (heads of health services and patient organizations).

## How may new technologies create concerns about quality and safety?



## Aim and methods:

- To analyse how a recently established national body can be instrumental in promoting quality and safety issues when assessing whether or not to introduce new (and often expensive) medical devices in hospitals.
- A case study of the decision-making process of whether to introduce left ventricular assist devices (LVAD), and transcatheter aortic valve implantation (TAVI) in Norway was performed.
- Particularly attention was paid to the quality and safety issues considered by the NC, and how these considerations were transformed into explicit recommendations.

## The story prior to the discussion in the NC:

- The two medical devices under consideration were both, at the time of assessment in the NC, at an early stage of development.

### National experiences:

- TAVI - 10 patients had been operated at a private clinic (2 died under/immediately after the operation). No efforts at systematic documentation of treatment made.
- LVAD – 13 patients operated at the National hospital (11 as a part of the CE-study – sponsored by the producer). 6 of the patients had undergone heart transplantation after LVAD, 5 still used the LVAD, and 2 patients had died (to ill).

## Results:

- HTA-documents presented to the NC revealed documentation on safety as well as efficacy to be scarce for both devices.
- After extensive discussions, the Council recommended to limit the use of LVAD to patients needing a “bridge” to heart-transplantation. It should not replace transplantation altogether.
- Moreover, the LVAD-procedure should be restricted to one hospital (The National hospital).

## Results - “further evidence need”:

- For TAVI the NC recommended that the procedure should, at the present time, only be offered within the framework of a clinical trial.
- For both LVAD and TAVI the importance of securing systematic documentation of results to be used in subsequent quality improvement was stressed by the NC.

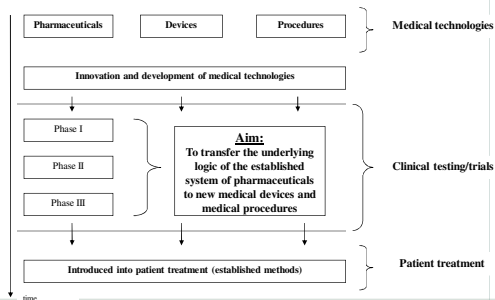
## Conclusion:

- The two cases both illustrates that aspects of quality and safety ought to be an integrated part of any discussion on the introduction of new (and expensive) medical devices, and that good documentation on both issues are needed.
- It also shows the importance of broad discussion among all relevant stakeholders to secure that the necessary, but sometimes difficult, decisions are taken prior to general use.
- One way of promoting quality in the long run could be to formulate explicit requirements, for instance related to the systematic documentation of clinical effects and safety.

## Towards a system for introducing new technologies in health care:

- An additional effect has been a renewed governmental focus upon how to provide a system of safe and effective services (e.g. devices) in hospitals.
- This renewed focus lead to discussions about how to create a system for introducing new technologies. Key features of the new system will be to provide:
  - *Safe, and*
  - *Well documented (effective) services, which also show*
  - *A reasonable cost-effectiveness-ratio*
- A draft version of such a system is currently being discussed within the MoH.

## One ambition of the new system:



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