Obvious benefits to the system would be that information and feedback from clinicians and patients to innovators could be collected more systematically and would allow for accommodating the learning curve inherent to any procedure. Relevant and updated information could be given to patients and adaptive processes would prevent overuse of technologies before evidence is good enough.

On the other hand, adaptive approaches are demanding for all parties involved and it is anticipated that the coordination and management of such pathways might require more resources than the current processes. Remaining questions regarding who will fund the processes are still open and political aspects cannot be avoided, however having a clear process, with a set of criteria preliminarily agreed upon by the stakeholders should continue to increase the transparency and minimize issues.

One key aspect is the definition of criteria in cases of unmet need, when "high value" is expected and there is no good existing gold standard. In these cases, the criteria might be linked to the disease (type and severity), the targeted patient population(s), and the harm/benefit balance.

Given the diversity of medical devices, there is also a need to define for which type of medical devices an adaptive approach could be applied. Depending on the situation, the goal could be either to maximize the benefit of a new technology or to minimize the risks.

A key challenge is the differences in processes between legislations / countries. Having adaptive coverage in place would be a departure from the TAVI example where patient access greatly differs from one country to the other. It would mean having a coordinated system allowing patient access with data collection along the way to broaden/refine the target population. With time the technology itself would be expected to change (i.e., modifications to the device) as well as the procedural aspects such as expanding to trans-apical and femoral access.

Finally, TAVIs illustrate the need to address the clear disconnect between regulatory/reimbursement pathways and purchasing processes for in-hospital medical devices. Adaptive processes would require better coordination, and ideally upstream of technology introduction.

## CONCLUSIONS

The process of adaptive pathways, whether to facilitate licensing or coverage, needs to be transparent, flexible, and predictable. One key benefit would be to bring to industry more clarity on the requirements linked to market access in general and as a consequence better predictability for research and development decisions. An adaptive approach will also have an impact on organizational, economic, social, and ethical aspects.

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# HTAI POLICY FORUM: KEEPING HTA ON TRACK

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The most recent discussions of the HTAi Policy Forum are being showcased in this issue of our Journal. The topic of adaptive approaches to technology management has been a policy area of continuing importance and relevance to health technology assessment agencies and policy makers as well as industry. The latest Policy Forum publication (Husereau et al., in this issue) demonstrates that the discussions at the meeting about this complex topic were very wide indeed.

Our HTAi Policy Forum is unique in providing the opportunity for senior people from organizations in the public and private sector to discuss HTA topics of strategic importance in a safe and nurturing environment. Discussions during Policy Forum meetings usually reveal a wide range of views. Indeed a key attribute of the Forum is that it manages to make participants feel sufficiently safe that they air their genuine perspectives, having been informed by excellent briefing papers and expert commentaries. In this way, the Forum manages to identify fundamental issues associated with the topic, highlight where viewpoints align and differ and provide commentary on key actions needed to make progress.

From its inception, the Policy Forum has not shied away from tackling difficult topics. The publications developed from Policy Forum discussions (1–8) are well worth reading and freely accessible on the HTAi website. Looking back at this output since 2007 gives an indication that "technology management" has been, in some shape or form, an area of interest for most meetings. Policy Forum discussions about coverage with evidence development, managed entry arrangements, optimal use of technologies and interaction between HTA bodies and regulators are, of course, interrelated to each other and closely linked to the current topic. Whilst this might suggest a rather narrow scope of interests for Policy Forum members, it is quite the opposite. We cannot overestimate the importance of constructing an interdependent, mutually beneficial ecosystem between life science R+D and healthcare systems, to deliver on behalf of the public at large. This, coupled with the complexity involved in contemplating how current systems need to develop, means that it is necessary to spend time exploring the issues from many angles and with a variety of viewpoints.

You might view the latest Policy Forum topic – "Adaptive Approaches to Licensing, HTA and the Use of Technology" – as the culmination, pinnacle or perhaps even the finale to the discussions on technology management. But I don't think it is. We have not identified the optimum solution to the question of how to achieve efficient and sustainable introduction of innovative technologies into healthcare systems. So we certainly will need the work of the Policy Forum to continue. It is a delight to affirm that HTAi will continue to excel at delivering this exceptional and irreplaceable initiative.

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