

COCIR Contribution to Public Consultation
Disruptive Innovation: Considerations for health and health care in Europe
Report issued by the Expert Panel on Effective Ways of Investing in Health

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Section Title	COCIR Comments
COCIR General Statement	<p>COCIR welcomes the preliminary opinion of the Expert Panel on Effective Ways of Investing in Health regarding “Disruptive Innovation” – considerations for health and health care in Europe. We are happy to share with you our in-depth analysis of this report, which includes detailed comments suggesting possible improvements, as we represent MedTech industry at large and have impressive track records of innovations whether disruptive or not.</p> <p>With regards to business/financial models, COCIR considers such report approaches this matter as an adjunct element, requiring of decision makers to take ‘account’ of when considering the adoption and diffusion of disruptive innovation, rather than recognising that new business/financial models in <i>themselves</i> can be examples of ‘disruptive innovation’. COCIR suggests that limiting reference to business/financial models as only playing a ‘supportive role’ in relation to disruptive innovation rather detracts from the significant disruptive impact such models can have in their own right.</p> <p>COCIR finds that the radical vs. disruptive innovation dichotomy presented by EXPH has limited accuracy and utility, particularly as pertains to the categorization of radiotherapy.</p>



1. EXECUTIVE SUMMARY

The draft report conservatively reflects the approach where agreeing that implementation of disruptive innovations is dependent on new models of commissioning and financing “since what is not paid for can usually not be done...” (*line 317*), yet also conservatively appearing to treat the issue of business/financing models as an aspect which “decision makers should take into account...” (*line 298*), an element upon which the implementation of disruptive innovations will greatly depend; rather than considering new business/financial models in themselves an area of ‘disruptive innovation’ every bit, if not more necessary to recognise, and promote, as those four currently listed (*lines 281-296*).

The EXPH view the question of financing as a framework condition for the implementation of other ‘disruptive innovations’ (*lines 460-462*), yet COCIR believes that any financial innovations occurring within the funding arena that fundamentally enabled increased access to new innovative technologies, furthered health professional education, and by so doing addressed issues of equity, quality and cost effectiveness, should in themselves qualify as ‘disruptive innovations’ under the Expert Panel’s own concept of ‘disruptive innovations’ (*lines 629-631 and 636-638*).

‘Managed Services’ is one such disruptive new business and financing model that is addressing the challenges faced by healthcare systems accentuated by the economic crisis. ‘Managed Services’, offers an adaptable way for hospitals to acquire and use technology – it is effectively a technology partnership between one or more healthcare facilities and one or more technology providers for a fixed period of time. Over this period a technology infrastructure and a broad range of related services, including maintenance, updating and/or renewal and/or substitution of equipment, continuous professional training, and timely exchange of advances in technology are made available against a predictable operational fee. Within this context risk is shared. The provider of the equipment takes responsibility for the availability, quality, maintenance and upgrading over the lifetime of the technology as well as flexibility in the types of technology to fulfil local needs in time, thereby ensuring the facility is assured to benefit from the future improvements and innovations as well as modified technological infrastructure in line with the hospital’s environmental changes.



	<p>Adopting this model, a facility shifts current Capital expenditure to Operational expenditure, allowing the same budget to be spread over a much longer period of time, providing the financial flexibility required in a quickly changing environment, also the operational processes will be continuously optimised in order to make best use of the available technological infrastructure.</p> <p>COCIR also agrees with the EXPH when commenting; "...appropriate Policy actions need to be based on evidence, and not hopes," (<i>lines 1598-99</i>) which is why over the last two years COCIR has worked in close cooperation with DG SANCO and the former Commissioners for Health to formulate and validate 17 Key Performance Indicators that offer a standardised template to measure the efficiency of Managed Services versus the traditional business models in healthcare delivery. The finalised COCIR report is scheduled for publication in 1Q16.</p>
2. BACKGROUND	<p>Currently Medical Technologies represents less than 5% of healthcare budget spending, and have among many other benefits majorly contributed to a 13% reduction in the average length of hospital stay; measure between 2000 -2008, resulting in dramatic savings.</p> <p>The Medical technology industry is focused on ensuring highly innovative medical technology and digital solutions benefit as a many patients as possible, as quickly as possible. There is a general understanding that delivering the services in the way we do today often results in quality and access inequalities, the disparities in care afforded patients seen both within and between healthcare systems both fuel the political aspirations of the EU, and concern the populations they are intended to serve, in equal measure.</p> <p>Member States are painfully aware that that short-term funding freezes or real-term cuts in administrative costs and/or coupled with structural reorganisations, can only get you so far, and rarely do such actions create a change in the status quo. Chasing cost efficiencies alone cannot provide the long-term solution; innovative measures, both technological and, COCIR argues, financial, are necessary for healthcare systems to not just better cope with</p>



	<p>the demands of today, but to also withstand the challenges of tomorrow.</p> <p>To achieve the EU goal of healthcare sustainability; the overwhelming imperative to transform our healthcare systems requires Europe to embrace innovative technology as part of the solution; to understand the vital role such advances in technology have in achieving necessary efficiency gains, increased productivity, and in clinical decision support to further better outcomes. It is also evident that obtaining this technology-driven 'value-dividend' is a difficult proposition as it requires finding the financial means to invest in the implementation of advanced technology over a sustained period, at a time when budgets, particularly capital budgets, are continually under pressure.</p>
<p>3. OPINION 3.1. CONCEPT OF DISRUPTIVE INNOVATION</p>	<p>Knowledge-based treatment planning is a key example of a disruptive innovation that has created new networks and organizational changes based on a new set of values and involving new players. Knowledge-based approaches further lead to improvements in value and health outcomes, as well as developing capacities and enhancing efficiency.</p> <p>In the field of radiation oncology, knowledge-based planning software may provide clinicians with models to use as a baseline for developing plans for virtually every time of external beam radiotherapy.</p> <p><i>The problem:</i> Creating a comprehensive treatment plan can be complicated and time consuming, and requires a high level of expertise. Furthermore, quality inconsistencies between plans can arise when clinicians manually create versions of different treatment types.</p> <p><i>The solution:</i> By creating a network between sites across the globe, knowledge-based planning software can use international expertise to create pre-configured plan models to serve as references for clinics and practitioners at all levels.</p> <p><i>The outcome:</i> For experienced users, knowledge-based software primarily serves to increase efficiency by streamlining the planning process through using shared clinical knowledge embedding in the supplied plan models. For new users, this software empowers clinicians to overcome a lack of experience by importing knowledge from international</p>



	<p>experts, thereby increasing accessibility and reducing the need for a highly experienced workforce that may be costly and time-consuming to develop. Finally, clinics at all levels may benefit from the homogenizing effect of utilization; knowledge based planning software can allow clinics to reduce variability in treatment planning to achieve greater consistency, efficiency and quality while providing truly individualized patient care.</p> <p>Furthermore, COCIR asks for clarification whether the line 656 refers to the_market for Healthcare as the one limited by each member state or to the market where the cross-border Directive (DIRECTIVE 2011/24/EU) applies, providing all European Union citizens with access to a disruptive innovation. In case where the reference is done to the cross-border directive, the healthcare procurement should also be considered in the sense where the process of dissemination of new disruptive innovation already assessed through HTA in one MS could be available to the other MS within the EU.</p>
3.3. STRATEGIC AREAS FOR DISRUPTIVE INNOVATION	<p>COCIR supports appropriate investment levels for disruptive, radical, and incremental innovations, echoing the EXPH statement: "While disruptive innovation can be an important concept for policy analysis, it does not mean that other types of innovation are less desirable. Incremental innovation can be very important, as well as more radical innovations that may not be classified as disruptive" (Lines 603-606).</p> <p>However, COCIR disagrees with some of the descriptors used by EXPH for half way technologies, which are considered to be radical innovations. For example, COCIR disagrees with the statement that, "[half way] technologies are often expensive and not particularly effective" (Lines 890-891), particularly given the fact that EXPH considers radiotherapy to be a clear example of half way technology. There is ample evidence of the clinical benefits of radiotherapy, including: (1) evidence-based guidelines documenting the appropriate use of radiotherapy within patient pathways, adapted as needed depending on disease site and stage, among other factors,ⁱ and (2) meta-analyses that examine the overall clinical need and optimal utilization rate for radiotherapy on a global level.ⁱⁱ A second sub-set of the literature documents the cost effectiveness of radiotherapy in terms of: (1) comparison with other treatment modalities,ⁱⁱⁱ and (2) estimated economic benefit to society as a whole.^{iv} Taken together, this robust compilation of clinical literature demonstrates that radiotherapy is an extremely effective form of treatment from both</p>



clinical and cost perspectives.

In addition, COCIR disagrees with the implied dichotomy drawn between “half way” and “high” technologies ([Lines 874-883](#)), in which high technology alone is considered to be “based on a true understanding of the disease” ([Line 879](#)). Radiotherapy technology, purportedly an ideal example of “half way technology”, is capable of treating cancer based on an understanding of the cancerous tumor *at the cellular level*. For example, researchers have discovered that hypoxic tumor cells (tumor cells that lack oxygen) are resistant to radiotherapy. Innovative radiotherapy techniques like simultaneous-integrated boost intensity-modulated radiation therapy (SIB-IMRT) enable higher doses of radiation to be delivered to hypoxic tumors or tumor areas in order to optimize treatment efficacy and patient outcomes. Thus, the assertion that half way technologies are not based on a true understanding of disease is incorrect.

Finally, COCIR finds the delineation between “radical” and “disruptive” innovations to be ambiguous. For example, “minimally invasive surgery” is considered to be a “disruptive innovation” because it enables new patients to be included in the “market”, decreases the burden of treatment, and contributes to shorter lengths of hospitalization ([Line 1496](#)). By this same logic, Stereotactic Body Radiation Therapy (SBRT) should be considered to be a disruptive innovation. SBRT is a noninvasive cancer treatment in which numerous small, highly focused, and accurate radiation beams are used to deliver potent doses in 1 to 5 treatments to tumor targets in extra-cranial sites. SBRT has enabled new patients to be treated, decreased the burden of treatment, and contributed to decreased hospitalization rates. For example, SBRT may be used to treat early stage lung cancer patients who cannot tolerate surgery due to comorbidities, and were previously observed without specific cancer therapy. The use of SBRT not only creates new patient pools for treatment, but also has been shown to dramatically increase local tumor control, survival rates, and treatment-related morbidity for non-small cell lung cancer. Similarly, the use of SBRT for Hepatocellular carcinoma (HCC), which is the third leading cause of cancer mortality, has enabled a new group of patients to be treated. Previously, less than 30% of HCC patients were eligible for surgical treatment (resection and transplantation) due to tumor size, location within the liver, vascular invasion, poor liver function, and other factors. The use



	<p>of SBRT as a primary treatment or as a bridge to transplant thus means that a large group of HCC patients who were previously considered ineligible for treatment can receive care. Furthermore, as a noninvasive form of treatment, SBRT decreases the burden of treatment on a patient, as evidenced by the very fact that it can be used on patients deemed ineligible for surgery, and contributes to shorter lengths of hospitalization as radiotherapy is traditionally performed in an outpatient setting. There is thus significant overlap in the benefits from SBRT (considered a “radical innovation” by EXPH) and minimally invasive surgery (considered a “disruptive innovation”) in the very areas that qualify the latter as a disruptive innovation, which calls into question the utility of the radical vs. disruptive innovation dichotomy.</p> <p>It is thus the opinion of COCIR that, as stated by EXPH, it is important to achieve “optimal balance between the investments in half way technology and high technology” (Lines 893-894 and 1442-1445). To this end, the ambiguity of the difference between radical and disruptive innovations, the proven benefits of radical innovations like radiotherapy, and the fact that, as stated by EXPH, “little is known about the practical application of disruptive innovations in healthcare” (Lines 439-400) are all key points to consider when determining this optimal balance.</p>
3.5. CASE STUDIES	<p>Line 1496: Under the heading ‘The innovation’ it would be remiss not to recognise the advances in engineering and design of imaging equipment as a key enabler of minimally invasive surgery; without such imaging-guidance many such procedures would not be possible.”</p>
3.6. CONCLUSIONS AND POLICY RECOMMENDATIONS	<p>COCIR believes that new business models affording hospitals and healthcare providers the financial flexibility to manage, or enter partnerships, to secure long-term access to advanced technologies and/or broader healthcare solutions, are an essential element in the move towards financial sustainability of healthcare systems. Such new business models facilitate predictable operational budgeting, and include an element of risk-sharing, arguably offering the financial platform upon which innovative solutions can benefit a broader number of European patients. And, COCIR suggests, such business models themselves are deserving of the label ‘disruptive innovation’, rather than the label of ‘elements’ to be considered for the adoption and diffusion of ‘other’ disruptive innovation.</p>



Such dynamic innovative business models that have the propensity to further the development and implementation of technology solutions deserve as much, if not more, political support as any other innovation...why? Because the most obvious necessary step to ensure patients benefit from technology is to promote business/financial models capable of maximising implementation of those technologies. Today's marked delay in the implementation of innovative technology, leaves many technological innovations stranded in warehouses or on shelves (no matter their offering of long-term 'value', or their enabling contribution to achieving broader 'socio-economic value,').

Often these can be the very same technologies which are required to facilitate the considerable benefits anticipated by the adoption and diffusion of those disruptive innovations listed on page 9 ([lines 281-296](#)). This delay is evidence of an illogical disconnect resulting from both short-term and silo-budgeting policy constraints. It is evidence too of a flawed assessment of the 'value' process that appears only to perceive or acknowledge 'value' solely within the parameters of such arbitrary timeframes and delineations.

These observations are not a plea for payors to write a blank cheque in relation to technology innovations, but more to solicit discussions regarding incentivising new 'disruptive business innovation models' capable of financing an increased implementation of technological innovations. COCIR agree with the EXPH when commenting; "If there are no incentives for adoption and diffusion of a disruptive innovation, this will not happen" ([lines 1454-1455 & 303-304](#)).

Conclusion:

Recognise 'new business/financial models' alongside the other four areas currently listed as 'disruptive innovations.' Such a move will, importantly, shift the emphasis of political action related to the financing of innovative technologies in healthcare; it will require political action aimed at 'incentivising adoption and diffusion' of new disruptive business/financial innovations, and reinforce the recognition that a continuation of incremental tinkering of



traditional funding models is an area most requiring of a more 'disruptive' approach.

Recommendations:

1. EC and Members States should direct/target investments and resource allocation to innovative, results-oriented and sustainable long-term operational models like Managed Services.
2. The European Commission should develop a technical and financial guide to help Member States use new business models like Managed Services in the implementation of Cohesion Policy.
3. Models like Managed Services should be considered in all Member States as part of the solutions for providing and maintaining high quality health services

Managed Services as an example of Disruptive Innovation

The Problem: To overcome the huge delays and inequalities in implementation of new technologies to make the benefits afforded by advanced technologies available to as many patients as possible. Technology solutions ranging from cutting edge molecular diagnostics to low-cost imaging technology and new healthcare software already exist. However, there is considerably more effort needed to design smarter and more flexible business/financial options to maintain the necessary flexibility for both doctors and patients to fully benefit from the implementation of these technological solutions.

The innovation: A business/financial model that shifts the onus from Capital Expenditure driven product purchase, to a shared risk partnership involving the technology provider delivering a managed service and or healthcare solutions as part of a long-term agreement. Managed Services can be standalone agreements or form part of larger public private partnership contracts, either way the deliverable involves more than mere purchase and maintenance of equipment, but rather the provision of a technology infrastructure, involving risk-sharing, over a period of between 10-15 years, affording the flexibility in the types of technology to fulfil local needs.



The disruption: Removal of the uncertainties related to the Capital expenditure model. Replaced with the delivery of a technology infrastructure and a broad range of related services, including *maintenance, updating and/or renewal and/or substitution* of equipment, continuous professional *training*, and timely exchange of advances in technology are made available against a predictable operational fee. Securing technologies that supports the medical profession in making more rational value-based decisions regarding workflows and care pathways and in parallel provide higher quality clinical decisions. Within this context risk is shared. The provider of the equipment takes responsibility for the availability, quality, maintenance and upgrading over the lifetime of the technology as well as flexibility in the types of technology to fulfil local needs in time, thereby ensuring the facility is assured to benefit from the future improvements and innovations as well as modified technological infrastructure in line with the hospital's environmental changes.

The benefit: Adapting the way hospitals are acquiring and using technology to the way they deliver healthcare to the public, provides opportunities to structurally improve high quality healthcare, and long-term sustainability, coupled with easier and quicker access to suitable and diversified technology over time. Additionally, employment, life-long learning and healthy aging are aspects that can be improved by this change.

Triggers: Drivers –To sustainably manage the uncertainties of Capital Expenditure that can directly lead to delays in implementation of innovative technologies. Enablers – new business/financial models that recognise the need to share risk and present healthcare providers with services and solutions at a more predictable operational expense to replace the traditional CapEx purchasing of products. Incentives – broader implementation of innovative technologies for a predictable outlay coupled with a security that more patients will benefit from today's and tomorrow's innovations; shifting from short-term purchasing decisions toward a more sustainable longer-term solutions-driven partnership.

Adverse- effects The lack of political support in part perhaps due to the perceived challenges from those few pioneering partnerships from which the concept has now been much improved.



Costs: This approach, when developed correctly for each partnership (one-size does not fit all) can increase access and quality of care through broader implementation of innovative technologies, and offers opportunities for cost savings both in terms of direct healthcare and indirect societal benefits

ⁱ *NCCN Guidelines for Treatment of Cancer by Site, National Comprehensive Cancer Network; http://www.nccn.org/professionals/physician_gls/f_guidelines.asp
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ⁱⁱ *Delaney G, Jacob S, Featherstone C, Barton M. The role of radiotherapy in cancer treatment: estimating optimal utilization from a review of evidence-based clinical guidelines. *Cancer* 2005; 104: 1129-37.
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Atun et al., *Expanding global access to radiotherapy, The Lancet, no. 16 (2015).**

ⁱⁱⁱ *Barton MB, Frommer M, Shafiq J. The role of radiotherapy in cancer control in low-income and middle-income countries. *Lancet Oncol* 2006;7:584-595.*

^{iv} *Dr. Gilberto Lopes, "Investing in Cancer Prevention and Control to Reduce Global Economic Burden," American Society of Clinical Oncology Daily News, <https://am.asco.org/investing-cancer-prevention-and-control-reduce-global-economic-burden>.
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