

# Robotic Assisted Surgery: A solution to European healthcare challenges





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### **Executive Summary**

European healthcare systems are under unprecedented pressure from critical demographic changes, including the ageing of the population, workforce shortages and increasing health inequalities. With nearly 30% of Europeans expected to be aged 65 or older<sup>1</sup> by 2050, coupled with a projected shortage of 1.2 million healthcare workers in the EU<sup>2</sup> and increasing patient waiting times to receive treatment, the demand for healthcare services is likely to rise putting a strain on already limited public budgets<sup>3-7</sup>.

In this context, Robotic-Assisted Surgery (RAS) emerges as a solution to address these challenges, offering to improve patient outcomes with the potential to reduce healthcare costs, and ease the burden on healthcare systems. Literature has shown RAS's ability to enhance surgery precision, reduce complications, and shorten patient recovery times. Median hospitalisation with RAS is found to be shorter than manual surgery, with post-operative wound infections also being lower. Additionally, RAS can help alleviate the physical strain on surgeons, streamline workflows, and enable advanced training through virtual simulations and AI, which can accelerate surgeon proficiency by 30-50%<sup>4</sup>. RAS is becoming an increasingly important tool to support clinical decision-making. The number of surgeries performed using robotic technology is increasing and has the potential to continue growing in the future.

Despite its potential, the widespread adoption of RAS in clinical practice faces barriers, including fragmented reimbursement and funding models and limited awareness of its long-term value. The tendency to adopt a narrow perspective when considering implementing robotic technology creates a risk that the broader clinical and financial benefits of RAS are overlooked, thus creating a focus on mainly the upfront purchasing costs. Lack of coverage recommendations from health technology assessment bodies, absence of dedicated RAS DRG codes, and insufficient financial reimbursement to cover the costs of robotic technology limit the utilization of RAS in clinical practice. Coordinated policy actions are required to (i) raise awareness for RAS's benefits and its value, (ii) establish adequate reimbursement conditions to remove financial barriers for healthcare providers to use RAS, and (iii) enable a wide-spread adoption of RAS in healthcare facilities. This will help ensure European healthcare systems remain equitable, sustainable, and prepared to meet the evolving needs of all citizens.

This position paper is the contribution of the MedTech Europe Robotic-Assisted Surgery Sector Committee to emphasise the value of RAS to help meet the unmet healthcare needs of European citizens and develop strategic policy initiatives to address healthcare system challenges. Developed with insights from leading experts and stakeholder organizations, this paper underscores the urgency of integrating RAS into healthcare systems across the EU.

<sup>&</sup>lt;sup>1</sup> Organisation for Economic Co-operation and Development (OECD). *Health at a Glance: Europe 2024*. Paris: OECD Publishing, 2024. Accessed December 11, 2024. https://doi.org/10.1787/b3704e14-en.

<sup>&</sup>lt;sup>2</sup> Ibid. <sup>3</sup> Ibid.

<sup>&</sup>lt;sup>4</sup> Brian, R., Murillo, A., Gomes, C. *et al.* Artificial intelligence and robotic surgical education. *Global Surg Educ* **3**, 60 (2024). https://doi.org/10.1007/s44186-024-00262-5



# **Challenges disrupting the EU healthcare systems**

In recent years, health systems across the European Union have encountered unprecedented challenges. Firstly, demographic changes, including ageing of the population, with nearly 30% of Europeans predicted to be 65 or older by 2050,<sup>5</sup> will create a larger pool of people who will further stress public budgets<sup>6</sup> and exert growing pressure on health systems to support a rising number of individuals with conditions such as non-communicable diseases (NCDs).<sup>7</sup> At the same time, workforce shortages compound the problem, in an environment where the demand for a qualified health workforce is increasing. Estimates today point to an EU shortage of 1.2 million health workers,<sup>8</sup> with a scary perspective of this number increasing steeply soon. In addition, the average working hours of doctors has decreased in most countries, as many aim to achieve a better work-life balance.<sup>9</sup> Also, the backlog of patients waiting to receive their treatment is increasing. Disparities in access to medicine and variability in clinical outcomes remain critical barriers to equitable healthcare. Finding a solution is paramount to not only address these challenges but also to ensure that European healthcare systems remain equitable, sustainable, and prepared to meet evolving needs for all citizens.

# What is Robotic Assisted Surgery (RAS)?

Robotic-Assisted Surgery (RAS) represents innovation, combining machines and computers with human expertise to modernise surgical precision. Originally developed in the 1980s from military technology for remote treatments, RAS quickly transitioned to civilian healthcare. It first gained traction in urology and gynaecology, later expanding in the 2000s to orthopaedic, digestive, thoracic, paediatric, and ENT (ear, nose, and throat) surgeries, becoming a cornerstone of modern surgical advancements<sup>10</sup>. Today, increasingly more surgical procedures are performed using RAS, which is transforming surgery with unmatched precision, faster recovery times, and standardised practices. RAS has shown to deliver measurable improvements in patient outcomes. With AI and digital tools enhancing decision-making, surgeons – who undergo specialised training – remain at the heart of this technology, supported by continuous advancements from manufacturers<sup>11</sup>. Innovations such as advanced robotic instruments, integrated imaging tools, and data-driven surgical planning are set to further improve outcomes and preserve patient health. As RAS expands into new fields like neurosurgery, it is expected to drive healthcare standardisation, enrich research, and elevate surgical efficiency. With its potential to transform patient care, RAS is an enabler of modern medicine<sup>12</sup>.

<sup>&</sup>lt;sup>5</sup> Organisation for Economic Co-operation and Development (OECD). *Health at a Glance: Europe 2024*. Paris: OECD Publishing, 2024. Accessed December 11, 2024. https://doi.org/10.1787/b3704e14-en.

<sup>&</sup>lt;sup>6</sup> European Commission, Joint Research Centre, 2021. Europe's ageing society: More labour mobility could help the EU meet demand in health and long-term care, available here: <u>https://joint-research-centre.ec.europa.eu</u>

 <sup>&</sup>lt;sup>7</sup> World Health Organization, 2023. The global burden of chronic diseases and public health strategies. Available here: <u>https://www.bmj.com/content/384/bmj.q8</u>
 <sup>8</sup> Organisation for Economic Co-operation and Development (OECD). *Health at a Glance: Europe 2024*. Paris: OECD Publishing, 2024.

Accessed December 11, 2024. https://doi.org/10.1787/b3704e14-en.
 Ibid.

<sup>&</sup>lt;sup>10</sup> Le Roy, É., Allard, N., & Grelle, C. (2024). Innovation en Robotique: Progrès dispositifs médicaux. Presse Infos Plus. Maison de la Mécanique, 39 Rue Louis Blanc, CS 30080, 92038 La Défense Cedex.

<sup>&</sup>lt;sup>11</sup> Le Roy, É., Allard, N., & Grelle, C. (2024). Innovation en Robotique: Progrès dispositifs médicaux. Presse Infos Plus. Maison de la Mécanique, 39 Rue Louis Blanc, CS 30080, 92038 La Défense Cedex.
<sup>12</sup> Le Roy, É. Allard, N., & Grelle, C. (2024). Innovation on Robotique: Progrès dispositifs médicaux. Presse Infos Plus. Maison de la Mécanique, 39 Rue Louis Blanc, CS 30080, 92038 La Défense Cedex.

<sup>&</sup>lt;sup>12</sup> Le Roy, É., Allard, N., & Grelle, C. (2024). Innovation en Robotique: Progrès dispositifs médicaux. Presse Infos Plus. Maison de la Mécanique, 39 Rue Louis Blanc, CS 30080, 92038 La Défense Cedex.



# The Value of RAS

As the elderly population is expected to grow rapidly,<sup>13</sup> the burden of NCDs - the leading causes of death globally - and the demand for surgical procedures will increase<sup>14,15</sup>. RAS has the potential to bring value to healthcare systems in multiple ways.

RAS has shown to improve patient outcomes with the potential to reduce healthcare costs and ease the burden on healthcare systems. RAS contributes to improved patient outcomes by offering enhanced surgical precision, reducing complications, minimizing trauma, and shortening hospital stays<sup>16,17</sup>. Its technique leads to less pain and a lower risk of infection<sup>18</sup>, enabling faster recovery times and reducing the overall costs associated with extended hospitalisation. RAS not only improves patient satisfaction but also improves the allocation of healthcare resources, creating potential long-term cost savings. By reducing revision rates, RAS contributes to lessening direct costs linked with complications, while also mitigating indirect costs such as extended recovery times and lost productivity for patients<sup>19</sup>.

#### CASE STUDY<sup>20</sup>

A retrospective analysis conducted in 2024 at Assistance Publique-Hôpitaux de Paris (AP-HP), Europe's largest hospital network, highlights how RAS optimises healthcare resources. Between 2021 and 2022, 9,326 procedures were performed, with RAS used in 41.4% of cases, leading to significant reductions in the length of hospital stay (LOS). Specifically, RAS shortened the median LOS by up to four days compared to open surgery and by one day compared to laparoscopy in urological procedures, such as prostatectomy and nephrectomy. This translates to 5,390 hospital days saved across all procedures, with 86% of these savings attributed to urological surgeries.

This reduction in LOS directly addresses hospital overcrowding and resource constraints. By freeing up hospital beds, RAS enables more efficient patient turnover without additional staffing. Indirectly, shorter hospital stays mitigate risks of complications, such as infections, and reduce the economic burden associated with extended recovery times.

RAS can also address workforce shortages, a critical challenge in Europe. Healthcare systems face a projected shortfall of 10 million health workers by 2030<sup>21</sup>, significantly affecting the quality and availability of care<sup>22</sup>. By easing the pressure on surgical teams and streamlining workflows, RAS helps maintain high standards of patient care, especially in overburdened systems<sup>23</sup>. Furthermore, RAS not only enhances surgeons' health and well-being through ergonomic benefits - such as reducing musculoskeletal pain in areas like the neck, back, and shoulders<sup>24,25</sup> – but also has the potential to elevate surgical capabilities.

vol. 2022, no. 1, Jan. 2022, p. snac003. DOI.org (Crossref), https://doi.org/10.1093/jsprm/snac003. <sup>18</sup> Reddy, Kavyanjali, et al. 'Advancements in Robotic Surgery: A Comprehensive Overview of Current Utilizations and Upcoming Frontiers'.

<sup>20</sup> Blanc, T., et al. (2024). Impact of robotic-assisted surgery on length of hospital stay in Paris public hospitals: a retrospective analysis. Journal of Robotic Surgery, 18, 332–338. https://doi.org/10.1007/s11701-024-02031-4.
 <sup>21</sup> WHO, Health Workforce. https://www.who.int/health-topics/health-workforce. Accessed 23 Oct. 2024.

<sup>&</sup>lt;sup>13</sup> Eurostat, Ageing Europe - statistics on population developments, available here: https://ec.europa.eu/eurostat/statistics-

explained/index.php?title=Ageing\_Europe\_-\_statistics\_on\_population\_developments

<sup>&</sup>lt;sup>14</sup> European Commission, Knowledge for Policy - Competence Centre on Foresight 'Live Forever (Ageing/NCDs/Covid-19)', available here: https://knowledge4policy.ec.europa.eu/foresight/live-forever-ageingncdscovid-19\_en Eurostat, Ageing Europe - statistics on health and disability, available here: https://ec.europa.eu/eurostat/statistics-

explained/index.php?title=Ageing\_Europe\_-\_statistics\_on\_health\_and\_disability 16 Ahmad, Arif, et al. 'Robotic Surgery: Current Perceptions and the Clinical Evidence'. Surgical Endoscopy, vol. 31, no. 1, Jan. 2017, pp. 255-

<sup>63.</sup> Springer Link, https://doi.org/10.1007/s00464-016-4966-y. <sup>π</sup> Goh, Elizabeth Z., and Tariq Ali. 'Robotic Surgery: An Evolution in Practice'. Journal of Surgical Protocols and Research Methodologies,

Cureus, vol. 15, no. 12, Dec. 2023, p. e50415. PubMed, https://doi.org/10.7759/cureus.50415. <sup>19</sup> World Laparoscopy Hospital, 'Cost-Effectiveness of Robotic Surgery in Long-Term Healthcare Planning', 2024, available here: https://www.laparoscopyhospital.com/news/index.php?id=543&p&search

<sup>22</sup> Ibid. 23 Ibid.

<sup>&</sup>lt;sup>24</sup> Jim McCartney, 'Robotic Surgery Is Here to Stay— and So Are Surgeons', American College of Surgeons Bulletin, May 2023, available here: https://www.facs.org/for-medical-professionals/news-publications/news-and-articles/bulletin/2023/may-2023-volume-108-issue-5/robotic-surgery-is-here-to-stay-and-so-are-surgeons/

<sup>&</sup>lt;sup>25</sup>Knudsen ML, Ludewig PM, Braman JP. Musculoskeletal pain in resident orthopaedic surgeons: results of a novel survey. Iowa Orthop J. 2014:34:190-6. PMID: 25328481: PMCID: PMC4127715



To meet rising patient demands and keep pace with technological advancements<sup>26</sup>, healthcare systems must prioritise the urgent need of upskilling and modernisation. Investing in RAS supports these goals by standardising procedures, enhancing training, reducing manual labour, and fostering digital skills. RAS uniquely introduces structured and advanced learning pathways, such as virtual simulations and modular training, which facilitate precision-based learning<sup>27</sup>. This approach helps trainees consistently achieve a high level of competence, reducing variability among surgeons and leading to improved patient outcomes and standardised quality of care across institutions<sup>28</sup>. By integrating technologies like augmented dexterity and digital overlays, RAS can support benchmarking and greater transparency around surgical skills, fostering opportunities for continuous improvement. This is particularly relevant in areas where precision is critical, and variations in skill can impact patient outcomes<sup>29</sup>.

#### CASE STUDY BOX<sup>30</sup>

A multi-country 2024 study, on the Robotic Surgery Training Curriculum (RoSTraC) demonstrates how structured learning pathways enhance precision-based RAS training. Through three phases—virtual simulations, laboratory exercises on synthetic organ models, and supervised clinical practice—residents develop advanced RAS skills. Cloud-based video feedback further refines their techniques. For instance, trainees' GEARS scores improved significantly, from 17.1 to 23.1, after completing the laboratory phase. RoSTraC ensures surgical residents are equipped to safely integrate RAS into clinical practice while maintaining high precision and efficiency. This structured pathway ensures that participants not only acquire advanced RAS skills but also demonstrate significant improvement in their technical abilities.

RAS also improves and facilitates training curricula by offering a progressive learning pathway that enables trainees to move from basic skills to complex, real-world procedures. Through the standardisation of cohesive training processes, all surgeons, regardless of their background or geographic location, can develop a similar level of expertise and confidence in performing complex procedures. Additionally, telesurgery and remote mentorship can fundamentally address disparities in access to high-quality training<sup>31</sup>, enhance cost efficiency<sup>32</sup>, and retain highly trained professionals to mitigate future shortages and associated training costs<sup>33</sup>.

By integrating RAS into surgical training programmes, healthcare systems can reduce reliance on manual labour, alleviating the physical demands on surgeons. Hospitals implementing RAS training programmes experienced a significant rise in robotic procedures for all general surgery procedures, from 1.8% in 2012 to 15.1% in 2018<sup>34</sup>, indicating a substantial increase in surgical volume and a decrease in physical labour, by efficiently allocating surgeons' skills.

<sup>&</sup>lt;sup>26</sup> WHO EURO, 'Health and Care Workforce in Europe: time to act', 2022, available here: https://www.who.int/europe/publications/i/item/9789289058339

<sup>&</sup>lt;sup>27</sup> Sinha, Ankit, et al. 'Current Practises and the Future of Robotic Surgical Training'. The Surgeon: Journal of the Royal Colleges of Surgeons of Edinburgh and Ireland, vol. 21, no. 5, Oct. 2023, pp. 314–22. PubMed, https://doi.org/10.1016/j.surge.2023.02.006.

<sup>&</sup>lt;sup>28</sup> Thomaschewski, Michael, et al. 'Conception and Prospective Multicentric Validation of a Robotic Surgery Training Curriculum (RoSTraC) for Surgical Residents: From Simulation via Laboratory Training to Integration into the Operation Room'. Journal of Robotic Surgery, vol. 18, no. 1, 2024, p. 53. PubMed Central, https://doi.org/10.1007/s11701-023-01813-6.

 <sup>&</sup>lt;sup>29</sup> Robots Could Help Close Surgeons' Skill Gaps and Improve Patient Outcomes | CDSS at UC Berkeley. https://cdss.berkeley.edu/news/robots-could-help-close-surgeons-skill-gaps-and-improve-patient-outcomes. Accessed 8 Jan. 2025.
 <sup>30</sup> Thomaschewski, M., et al. (2024). Conception and prospective multicentric validation of a Robotic Surgery Training Curriculum (RoSTraC) for surgical residents: from simulation via laboratory training to integration into the operation room. Journal of Robotic Surgery, 18, 53–67. https://doi.org/10.1007/s11701-023-01813-6.

<sup>&</sup>lt;sup>3</sup> Lawrie, Louisa, et al. 'Barriers and Enablers to the Effective Implementation of Robotic Assisted Surgery'. *PLoS ONE*, vol. 17, no. 8, Aug. 2022, p. e0273696. *pmc.ncbi.nlm.nih.gov*, https://doi.org/10.1371/journal.pone.0273696

 <sup>&</sup>lt;sup>32</sup> Robots Could Help Close Surgeons' Skill Gaps and Improve Patient Outcomes | CDSS at UC Berkeley. https://cdss.berkeley.edu/news/robots-could-help-close-surgeons-skill-gaps-and-improve-patient-outcomes. Accessed 8 Jan. 2025.
 <sup>33</sup> Robots Could Help Close Surgeons' Skill Gaps and Improve Patient Outcomes | CDSS at UC Berkeley. https://cdss.berkeley.edu/news/robots-could-help-close-surgeons-skill-gaps-and-improve-patient-outcomes. Accessed 8 Jan. 2025.
 <sup>34</sup> Sheetz KH, Claflin J, Dimick JB, 'Trends in the Adoption of Robotic Surgery for Common Surgical Procedures'. *JAMA Netw Open*. 2020; doi:10.1001/jamanetworkopen.2019.18911



Finally, investing in RAS fosters a digitally skilled healthcare workforce by combining advanced virtual training and Al-driven feedback<sup>35</sup>. Virtual simulation training reduces the time needed to achieve proficiency by 30-50% compared to traditional methods, allowing surgeons to reach competency faster and more consistently<sup>36</sup>. Additionally, AI integration enables personalised feedback, which has been shown to improve skill retention rates by up to 20%, ensuring that surgical teams maintain a high level of readiness.<sup>37</sup> Furthermore, AI enhances RAS by improving preoperative planning, intraoperative guidance, and postoperative analysis. In preoperative planning, AI processes medical imaging to create detailed 3D models of patient anatomy, ensuring precise surgical strategies<sup>38</sup>. During surgery, AI provides real-time guidance, enhancing precision and reducing risks. Postoperatively, AI analyses surgical videos to assess performance and refine techniques. These advancements ultimately lead to increased surgical efficiency, improved precision, and better patient outcomes<sup>39</sup>.

In short, RAS has the potential to bring value to healthcare systems in multiple ways. RAS has shown to improve patient outcomes with the potential to reduce healthcare costs and ease the burden on healthcare systems. RAS is becoming an increasingly important tool used to help support clinical decision making. The number of surgeries performed using robotic technology is increasing and has the potential to continue growing in the future. However, barriers for effective implementation of RAS would need to be removed first to ensure its widespread adoption.

# **Barriers for effective implementation of RAS**

Limited awareness and understanding of RAS and its potential short- and long-term benefits for patients, healthcare providers, and healthcare systems impact its perceived value among general population and healthcare decision-makers thus hampering its adoption in clinical practice at a larger scale. Despite existing evidence supporting its benefits over traditional manual methods<sup>40</sup>, scepticism often heard is that patients may feel less comfortable with RAS than surgeons assume,<sup>41,42</sup> healthcare decision-makers may find it challenging to fully assess the cost-effectiveness of RAS due to the current limitations in long-term data and randomised controlled trials (RCTs), and concerns may be there about being overly-reliant on robotic systems potentially diminishing foundational manual skills in new surgeons. This often makes RAS appear as a costly enhancement rather than a transformative tool. There is a need to demystify RAS for citizens, patients, healthcare providers, and policymakers by conducting evidence based, data-driven dialogue and position RAS as a valuable solution to address challenges faced by our healthcare systems.

The integration of RAS relies on reimbursement systems that accurately balance both costs and the technology's value. Due to lack of adequate RAS reimbursement and funding models that account for its initial investments and ongoing costs, scaling RAS technology remains difficult. Currently, the lack of coverage recommendations from health technology assessment (HTA) bodies, absence of dedicated DRG codes to be used by healthcare providers for RAS, and insufficient financial reimbursement to cover the costs of robotic technology limit the utilisation of RAS in clinical practice. Coverage recommendations from HTA bodies play an important role in decision-making around the introduction of (new) technologies for routine use in clinical practice. HTA bodies have recently initiated value assessments for RAS to inform its

- 40 Ibid.
- <sup>41</sup> Ibid.

<sup>&</sup>lt;sup>35</sup> Chen, IH.A., Ghazi, A., Sridhar, A. et al. Evolving robotic surgery training and improving patient safety, with the integration of novel technologies. World J Urol 39, 2883–2893 (2021). https://doi.org/10.1007/s00345-020-03467-7

<sup>&</sup>lt;sup>36</sup> Brian, R., Murillo, A., Gomes, C. et al. Artificial intelligence and robotic surgical education. Global Surg Educ 3, 60 (2024). https://doi.org/10.1007/s44186-024-00262-5
<sup>37</sup> Ibid.

<sup>&</sup>lt;sup>38</sup> The State of AI in Surgical Robotics. https://encord.com/blog/state-ai-in-surgical-robotics/. Accessed 19 Dec. 2024.

<sup>&</sup>lt;sup>39</sup> Ibid.

<sup>&</sup>lt;sup>42</sup> Reddy, Kavyanjali, et al. 'Advancements in Robotic Surgery: A Comprehensive Overview of Current Utilizations and Upcoming Frontiers'. Cureus, vol. 15, no. 12, Dec. 2023, p. e50415. pmc.ncbi.nlm.nih.gov, https://doi.org/10.7759/cureus.50415.



adoption in healthcare systems, like NICE in the UK. It's critical to adopt a broader, societal perspective in these assessments and include all relevant evidence available on RAS (i.e. both RCTs and Real-world Evidence) to ensure both direct and indirect costs and benefits associated with RAS are considered to reflect its true value. Hospitals and other healthcare facilities generally use a DRG code to claim reimbursement for surgical procedures performed. Currently, there are no RAS dedicated DRG codes in most EU member countries. Healthcare providers use DRG codes associated with traditional (manual) methods instead. The initial investments and ongoing costs associated with RAS such as the purchase price, maintenance, consumables, specialised training, and regular software upgrades can therefore pose a financial challenge for healthcare facilities. Often there is a tendency to adopt a narrow perspective thus focusing mainly on these upfront costs with the risk of broader clinical and financial benefits RAS being overlooked. There is a need to adopt a broader perspective when considering implementing robotic technology to shift the emphasis from cost containment to rewarding the (long-term) value and enhancing the understanding of RAS' overall value to the healthcare system and wider society.

#### **CASE STUDY BOX**

In Germany, when a hospital or healthcare provider seeks to implement an innovative medical technology, reimbursement occurs through mechanisms such as Diagnosis Related Groups (DRG), a global budget, or product categories. If the technology can be incorporated into the current reimbursement framework, funding decisions can typically be made quickly and with minimal obstacles. However, for truly groundbreaking medical technologies, modifications to existing reimbursement models or the establishment of new financing routes may be necessary (e.g., creating a new DRG code, adding it to the reimbursement list, introducing specific innovation schemes). This model is flawed particularly for innovative technologies<sup>43</sup>. For example, DRGs are calculated based on average actual costs of traditional treatment methods two years past and therefore do not take into account any additional value innovations might bring. Studies in Germany have shown that DRGs related to colorectal cancer treatment disincentivize the use of RAS, despite its clinical benefits<sup>44</sup>. These frameworks need to be reformed to reflect the long-term cost savings and benefits that RAS can provide.

In short, despite its potential, the widespread adoption of RAS in clinical practice faces barriers, including the lack of coverage recommendations from health technology assessment bodies, absence of dedicated RAS DRG codes, and insufficient financial reimbursement to cover the costs of robotic technology limit the utilisation of RAS in clinical practice. There's a need to address and overcome these barriers to unlock the full potential of RAS, transforming it into an essential, accessible component of modern healthcare.

# **Proposed Policy Actions**

To realize a wide-spread adoption of RAS in clinical practice, decision-makers must engage with targeted policies and strategies that can drive meaningful change. Therefore, coordinated policy actions are required to (i) raise awareness for RAS's benefits and its value, (ii) establish adequate reimbursement conditions to remove financial barriers for healthcare providers to use RAS, and (iii) enable a wide-spread adoption of RAS in healthcare facilities. Here are the proposed policy actions:

• Raise Awareness of RAS Benefits and its Value: Launch EU and Member States wide campaigns and stakeholder engagement efforts to educate decision-makers, professionals, and the public about the clinical and economic value of RAS, addressing any potential misconceptions and fostering broader acceptance and adoption. Demystify RAS for citizens, patients, healthcare

<sup>&</sup>lt;sup>43</sup> Lieven Annemans. Feb 2021. Access to Medical Technology Innovations: A Proposal for a Value of Innovation and Partnership ModelLieven Annemans. Feb 2021. Access to Medical Technology Innovations: A Proposal for a Value of Innovation and Partnership Model <sup>44</sup> Manuel Heurich. Positiver Gesundheitsökonomischer Einflussfaktor Medizintechnischer-Infrastruktur Am Beispiel Der Roboter-Assistierten Chirurgie Bei Der Sigmaresektion

providers, and policymakers by conducting evidence based, data-driven dialogue and position RAS as a valuable solution to address challenges faced by our healthcare systems. The European Union and its Member States should launch coordinated campaigns and stakeholder engagement efforts to educate decision-makers, healthcare professionals, and the public on the clinical and economic value of RAS. Adopting this strategy across the EU can enable equitable access to RAS, drive broader adoption, and enhance healthcare outcomes continent-wide.

- Establish Adequate Funding and Reimbursement Conditions: Support equitable investment opportunities across Europe and advocate for RAS dedicated DRG codes to remove financial barriers for healthcare providers to use RAS. It's critical to adopt a broader, societal perspective in HTA assessments and include all relevant evidence available on RAS (i.e. both RCTs and Real-world Evidence) to ensure both direct and indirect costs and benefits associated with RAS are considered to reflect its true value. The EU should advocate for adequate reimbursement conditions for RAS to ensure that advanced surgical technologies like RAS are accessible across all healthcare facilities, including smaller and underfunded hospitals. The integration of RAS relies on reimbursement systems that accurately balance both costs and the technology's value. Therefore, reimbursement assessments should fully capture the benefits of RAS. The Dutch HTA model<sup>45</sup> could serve as an example, integrating clinical outcomes with patient-reported experiences to assess both the technical success and patient-centred value of new technologies.
- Invest in Training and Development: Promote initiatives at Member State level to integrate RAS into surgical training programmes to build a digitally skilled and modern healthcare workforce capable of meeting future challenges. The EU should promote initiatives at Member State level to integrate RAS into surgical training programmes through the implementation of standardised curricula, such as the Robotic Surgery Training Curriculum (RoSTraC). This structured training pathway<sup>46</sup>, validated for effectiveness and feasibility, includes simulation-based learning, laboratory exercises, and supervised integration into the operating room. By adopting proven frameworks like RoSTraC, Member States can ensure that surgical residents acquire the necessary skills and competences to build a digitally skilled and modern healthcare workforce capable of meeting future challenges.
- Integrate Real World Evidence (RWE) in Decision-making: Encourage EU policymakers to
  integrate RWE into regulatory frameworks and reimbursement decision-making processes,
  supporting the establishment of best practices, especially in areas with limited clinical trial
  evidence. EU policymakers should prioritise the development of secure, standardised methods
  for the collection, analysis, and sharing of RWE generated by RAS. These efforts should align
  with key EU initiatives, such as the European Health Data Space (EHDS) and the European plan
  on the cybersecurity of hospitals and healthcare providers, to foster a robust framework for
  evidence-based policymaking and innovation in healthcare. Specifically, the integration of RWE
  into regulatory frameworks and reimbursement decision-making processes will enhance the
  establishment of best practices for leveraging RWE in areas where clinical trial data is limited. By
  creating a harmonized approach to data use and security, the EU can ensure the advancement
  of innovative healthcare solutions while maintaining trust and resilience across its healthcare
  systems.

<sup>&</sup>lt;sup>45</sup> Erskine J, et al. Best practice considerations on the assessment of robotic assisted surgical systems: results from an international consensus expert panel. International Journal of Technology Assessment in Health Care. 2023;39(1):e39. doi:10.1017/S0266462323000314
<sup>46</sup> Thomaschewski M, et al. Conception and prospective multicentric validation of a Robotic Surgery Training Curriculum (RoSTraC) for surgical residents: from simulation via laboratory training to integration into the operation room. J Robot Surg. 2024 Jan 27;18(1):53. doi: 10.1007/s11701-023-01813-6. PMID: 38280113; PMCID: PMCI0821832.



These proposed policy actions will enable the wide-spread adoption of RAS in healthcare facilities and help ensure European healthcare systems remain equitable, sustainable, and prepared to meet the evolving needs of all citizens.

## Conclusions

European healthcare systems are under unprecedented pressure from critical demographic changes. With an ageing population, workforce shortages, patient backlogs and increasing treatment waiting times, and health inequalities, the demand for healthcare services is likely to rise, putting a strain on already limited public budgets. Robotic-Assisted Surgery (RAS) emerges as a solution to address these challenges, offering to improve patient outcomes with the potential to reduce healthcare costs, and ease the burden on healthcare systems. RAS is becoming an increasingly important tool used to help support clinical decision making. The number of surgeries performed using robotic technology is increasing and has the potential to continue growing in the future. Despite its potential, the widespread adoption of RAS in clinical practice faces barriers, including fragmented funding and reimbursement models and limited awareness of its long-term value. Lack of coverage recommendations from health technology assessment bodies, absence of dedicated RAS DRG codes, and insufficient financial reimbursement to cover the costs of robotic technology limit the utilisation of RAS in clinical practice. Coordinated policy actions are required to (i) raise awareness for RAS's benefits and its value, (ii) establish adequate reimbursement conditions to remove financial barriers for healthcare providers to use RAS, and (iii) enable a wide-spread adoption of RAS in healthcare facilities. This will help ensure European healthcare systems remain equitable, sustainable, and prepared to meet the evolving needs of all citizens. This position paper is the contribution of the MedTech Europe Robotic-Assisted Surgery Sector Committee to emphasise the value of RAS to help meet the unmet healthcare needs of European citizens and develop strategic policy initiatives to address healthcare system challenges. Developed with insights from leading experts and stakeholder organizations, this paper underscores the urgency of integrating RAS into healthcare systems across the EU.

# **#Robotic-Assisted Surgery - We're all in!**

#### About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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