

# Treatment Outcomes (Quality) Registries

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American Chamber of Commerce in Croatia *Američka gospodarska komora u Hrvatskoj*

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# Introduction

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The quality of patient treatment outcomes is in the focus of the healthcare systems which are striving for quality and cost efficiency. Moreover, the data on treatment outcomes represents the foundation for the informed decisions on investing healthcare budget funds into the most effective and efficient medicines, medical devices and equipment.

In Croatia the purpose of the existing registries maintained by the Croatian Institute for Public Health (HZJZ), e.g. registries for cancer and diabetes, is to collect statistics in order to improve healthcare, establish prevalence and incidence of the disease and record morbidity and mortality on the national level. However, in order to ensure systematic collecting of patient outcomes data, the Quality Registries need to be introduced.

Experiences from Sweden have shown that the benefits of quality registries are far reaching as they represent an invaluable tool in improving clinical practice and quality of patient treatment outcomes – namely, their introduction produces direct benefits to patient health and efficient healthcare spending.<sup>1</sup>

Croatia falls far behind in this area and introduction of Quality Registries is urgently needed to accomplish significant improvements in the treatment quality of the diseases which are largest burden and leading causes of death in the country such as ischemic heart diseases, cerebrovascular diseases, lung and bowel cancer and diabetes<sup>2</sup>.

## Situation in Croatia

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Croatia invests less in healthcare than EU average, its healthcare system has been generating debt for years, while the economy has been suffering from losses of workforce (consequently the taxpayers) due to the decades of long negative fertility rate, wartime casualties and most recent strong emigration trends (including HCPs). The strategies which can lighten the pressures on the healthcare budget, pension system and state budget, increase the quality of life of the population and reduce the disability and mortality rates should be of priority interest to Croatia. AmCham Healthcare Committee would like to draw attention to the concrete opportunity in wider collecting and using of treatment outcomes which the healthcare administration can immediately act on to set solid basis for systematic solutions for many key

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<sup>1</sup> Adami et al. Learning how to improve health care delivery: the Swedish Quality Registers, *J Intern Med.* 2015 January; 277(1): 87–89; published online 2014 Nov 24;doi:10.1111/joim.12315; available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4296318/>

<sup>2</sup> The “*Ranking and proportion of leading death causes in Croatia in 2016*”, published by the HZJZ on 20 February 2018, available at <https://www.hzjz.hr/sluzba-epidemiologija-prevencija-nezaraznih-bolesti/odjel-za-srcano-zilne-bolesti/attachment/tablica1/>

challenges of the healthcare sector while at the same time producing noticeable benefits to the economy and society as a whole.

As the systematic collecting of treatment outcomes data is undeveloped in Croatia, clinicians (HCPs), hospitals (HCOs) and the Croatian Health Insurance Fund (HZZO) do not have enough information on the quality of various procedures and therapies. Consequently, data on HCPs' success in treating specific disease states is unavailable which makes comparison of different HCOs difficult, so the payer (HZZO) does not have a solid basis to implement corrective measures (e.g. to adequately allocate the healthcare funds), where appropriate<sup>3</sup>.

However, certain positive examples in practice, which present exceptions to the generally non-existence of Quality Registries include the use of international registry platforms (e.g. ResQ international stroke registry<sup>4</sup>). Such initiatives are often the result of high level of HCPs'/HCOs' awareness, forward thinking and devotion, rather than coordinated action within the healthcare system, which indicates that support for the introduction of quality registries exists among the part of advanced HCPs / HCOs in the country.

Under the existing legal framework, the Croatian Institute for Public Health (HZJZ) is entrusted to keep state healthcare registries and information of healthcare's interest<sup>5</sup>. While the existing registries may suffice for statistical purposes, those may hardly serve as a basis for a more significant, continuous and overall improvement of the healthcare system.

One step towards systematic healthcare data collection, processing and use was made with the **Act on Data and Information in Healthcare**<sup>6</sup>. Among other things, the Act provides for:

- the healthcare registries, stating that data contained therein will be used as a ground for, *i.a.* plans for financing the healthcare system. Unfortunately, the relevant implementation bylaw, under which the Register will be established, has still not been adopted<sup>7</sup>.
- the Catalogue on Healthcare Information Standards in the of Republic of Croatia which shall regulate the interrelations of the information

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<sup>3</sup> Reports such as "Ranking the Hospitals by success (2016-2017)", (Cro. „Rangiranje bolnica prema uspješnosti (2016-2017)“, published by the Croatian Agency for Quality and Accreditation in Health Care and Social Welfare (AAZ) are valuable, but do not provide a full picture and can make a significant contribution to future decision making processes regarding funding.

<sup>4</sup> <https://www.qualityregistry.eu/>

<sup>5</sup> See the Act on Healthcare Protection (Cro. *Zakon o zdravstvenoj zaštiti*; Official Gazette No 100/18), Article 130.

<sup>6</sup> Official Gazette No 14/19; entered into force on 7 February 2019

<sup>7</sup> According to the Act, the implementing bylaws should be passed within six months following Act's entrance into force (i.e., 7 August 2019). Hence, there is already a delay in its adoption.

systems within the healthcare information structure as well as processes of managing healthcare registries and other records in the area of healthcare.

Thus, there are grounds upon which the Quality Registries may be initiated, but these have still not been developed and the formal obligation to establish and keep Quality Registers does not exist.

Introduction of Quality Registries would also be in line and supplementary to the provisions of other acts in the healthcare sector, *e.g.* :

- **Act on the Quality of Healthcare Services**<sup>8</sup> provides that measures to ensure quality of healthcare services shall be based on principles of efficiency and effectiveness, which include optimizing (balancing) the costs and relevant outcomes.
  - ✓ Those aims may directly be achieved by implementation of Quality Registries that will enable comparison of different therapeutic treatments and optimizing costs by funding only those most efficient.
- **Act on Mandatory Healthcare Insurance**<sup>9</sup> provides that, generally, the Management Board of the HZZO annually decides on, *i.a.*, standards and norms of healthcare insurance, types and numbers of therapeutic and diagnostic procedures, as well as of the amount of funds required, subject to the prior opinion of the relevant chambers.
  - ✓ Given the wide scope of health insurance benefits, Quality Registries would provide for a better picture, consequently leading to a more accurate and better planning and achieving not only the overall savings but also the higher quality of healthcare services in general.
- **Act on the Protection of Patients' Rights**<sup>10</sup> sets out quality healthcare services as one of the main principles and patients' entitlement.
  - ✓ Quality Registries may support this principle and its implementation in practice. Moreover, Quality Registries may also affect some other patients' rights – *e.g.* the right to be informed about advantages and risks of recommended procedures (such information would be more accurate if based on outcomes of systematic monitoring through the Quality Registries).

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<sup>8</sup> Cro. *Zakon o kvaliteti zdravstvene zaštite*, Official Gazette No. 118/18.

<sup>9</sup> Cro. *Zakon o obveznom zdravstveno osiguranju*, Official Gazette No. 80/13, as further amended.

<sup>10</sup> Cro. *Zakon o zaštiti prava pacijenata*, Official Gazette 169/04, as further amended.

# Benefits of the Quality Registries

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Introduction of quality registries would benefit not only stakeholders included in the Croatian healthcare system, but the very processes as well. Some of the benefits of the Quality registries are as follows:

- Introduction of the national outcomes data would serve as a valid argument for measurement and decisions in the Croatian healthcare sector („local data for local decisions“).
- Providing the possibility to compare outcomes of conservative treatment and different innovative technologies for future funding and investment decisions. The payer (HZZO) will be able to validate engagement of HCPs' time, healthcare resources and funds in the therapies and procedures which are providing optimal results and abandon those that do not justify the investment.
- Overseeing the key disease states and related spending from the perspective of effectiveness of medical technologies to treat them.
- Health technology assessments (HTAs).
- Wider and more elaborate application of most economically advantageous tender (MEAT) concept in public procurement of medicines, medical devices and equipment ensuring efficient spending of healthcare budget.
- Obtainment of data crucial for planning national strategies for fighting key diseases.
- Accelerating the improvement of clinical practice and promotion of excellence of the HCPs, closing the gap of treatment variances (which are present in many countries<sup>11</sup>).
- Development and improvement of treatment guidelines.
- Accelerating the access of more patients to appropriate innovative, effective and safe medicines and therapies which will positively impact recovery rates, decelerate progression of disease, improve quality of life, reduce disability and mortality rates and improve life expectancy.
- Regarding the HCPs, introduction of Quality registries means an additional platform that would enable faster development of medical profession and further improvement of expertise, results and utilization of HCPs' time and usage of resources and infrastructure at their disposal in the most effective way. Outcomes data will serve as the basis for research, scientific work, publication and international scientific co-operation which will contribute to international validation of experts in the field along with their institutions. Improved conditions for professional development and scientific work will provide valid argument for the young professionals to remain living and working in Croatia. The HCPs who maintain the high level of outcomes will in

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<sup>11</sup> For more, see: <https://www.bcg.com/industries/health-care-payers-providers/addressing-practice-variation-worldwide.aspx>

fact create preconditions for steady patient referrals and potential additional financing from the payer (HZZO) in the future.

- On the overall basis, introducing the Quality Registries means increased transparency for all healthcare stakeholders - from patients, payer, administration and industry to taxpayers and the Government. Increased transparency will provide the authorities with the better insight and more control over the healthcare system. The ability to compare information on the most successful HCPs/HCOs will enable criteria for potential additional funding to those among with the highest quality, reliability and effectiveness so that the superior medical treatment is provided to a wider number of patients.

## Barriers to further development of Quality Registries in Croatia

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There are three main points that could be seen as obstacles to a further development of Quality Registries in Croatia:

- **Lack of awareness** and stakeholders' failure to recognize the benefits of maintaining the Quality Registries. Moreover, the maintenance of Quality Registries may be considered as an additional administrative burden imposed to HCPs / HCOs.
- **Absence of legal obligations** to maintain Quality Registries creates a general environment of the absence of Quality Registries altogether, while the more advanced HCPs / HCOs are often left without clear guidelines and management instructions.
- **Lack of funds** on national and institutional level.

In drafting the future regulations authorities are therefore encouraged to provide appropriate solutions in order to overcome any legal and institutional barriers and to promote the obligatory and easy establishing and implementation of the Quality Registers for the disease states that carry the highest burden on Croatian patients and healthcare system.

## Good Practice Examples in EU

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Sweden is one of the most advanced countries with the total of over 100 quality registries.<sup>12</sup> In Sweden national competence centers have been established for National Quality Registries. Several registries in a single competence center share costs for staff and systems but registries are decentralized and governed by professional collaboration.<sup>13</sup> Some well-known Swedish registries are:

- **Swedeheart** – umbrella for several cardiac registries (e.g. SEPHIA, the national quality registry for secondary prevention after cardiac infarct)<sup>14</sup>
- **Swedish Hip Arthroplasty Register**<sup>15</sup> - since its founding in 1979, “Sweden has reduced its revision burden ... to 10 percent - one of the lowest national rates in the world. Thirty years of data have helped Swedish hip surgeons identify not only the best clinical practices but also the highest-performing implants (in sharp contrast with other countries, the number of implants used in Sweden is small, with six different types accounting for more than 90 percent of all total hip replacements). ... Sweden avoided some 7,500 revisions in the decade 2000–09 that would have taken place if Sweden’s revision burden had been as high as that of the United States in that decade. That represents approximately \$140 million, or \$14 million per year, in avoided costs. The amount is equivalent to about 8 percent of the cost of total hip arthroplasty overall in Sweden during this period.”<sup>12</sup>
- **Swedish Knee Arthroplasty Register**<sup>16</sup>
- **Spine Registry**<sup>17</sup>
- **Riksstroke – the Stroke Registry**<sup>18</sup>
- **Swedish National Diabetes Register (NDR)**<sup>19</sup>

The importance of collecting outcomes has been internationally recognized by organizations such as:

- **European Federation of Pharmaceutical Industries and Associations (EFPIA)** representing the pharmaceutical industry operating in Europe.<sup>20</sup>
- **MedTech Europe**, the European trade association representing diagnostics and medical devices manufacturers operating in Europe, published the

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<sup>12</sup> List of all Swedish Quality Registries is available at:

<http://www.kvalitetsregister.se/englishpages/findaregistry/allswedishqualityregistries.2028.htmlRwegistry>

<sup>13</sup> For more, see: <http://www.kvalitetsregister.se/englishpages/aboutqualityregisters.2422.html>

<sup>14</sup> <https://www.ucr.uu.se/swedeheart/dokument-sh/arsrapporter-sh>

<sup>15</sup> <https://shpr.registercentrum.se/shar-in-english/the-swedish-hip-arthroplasty-register/p/ryouZwaoo>

<sup>16</sup> <http://www.myknee.se/en/>

<sup>17</sup> [http://4s.nu/4s\\_eng/index.htm](http://4s.nu/4s_eng/index.htm)

<sup>18</sup> <http://www.riksstroke.org/eng/>

<sup>19</sup> <https://www.ndr.nu/#/english>

<sup>20</sup> For more, see: <https://www.efpia.eu/about-medicines/use-of-medicines/outcomes-focused-sustainable-healthcare/>

Position paper for health authorities titled *"Medical Technology Registries: Six Key Principles"* in which it "supports principles of evidence-based healthcare, health economics and social science. The future growth and well-being in Europe critically depend on the adoption of effective, qualified and sustainable methods to increase the quality and efficiency of decision making in healthcare and to have the right measures in place to assess the value of the investments made."<sup>21</sup>

- **International Society for Pharmacoeconomics and Outcomes Research (ISPOR)**<sup>22</sup>, the "leading professional society for health economics and outcomes research (HEOR) globally" and "actively working to improve standards and practice for the collection and analysis of real-world data."<sup>23 24</sup>
- **International Consortium for Health Outcomes Measurement (ICHOM)**<sup>25</sup>, the organization that publishes global Standard Sets of outcome measures for the most relevant medical conditions and drives adoption and reporting of the measures internationally.

## Recommendations

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The patient outcomes are an area of interest to all stakeholders in the healthcare system, and **benefits from their introduction would spill over to the Croatian state budget and society in general**. Therefore, urgent action is recommended to the healthcare administration to facilitate fast introduction of the Quality Registries in Croatia.

Since registries are not homogenous in their focus and levels of coverage, even in the most advanced healthcare systems such as Sweden's<sup>26</sup> there are no out-of-the-box solutions that could be instantly applied in any settings and for any disease state.

Therefore, administration should explicitly open door for collaboration in the exchange of technical know-how in outcomes collecting between the healthcare providers, international organizations, patient associations and industry.

In this way, the registries can be created on case by case basis and established in the fastest and most efficient manner.

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<sup>21</sup> Available at: <https://www.medtecheurope.org/wp-content/uploads/2017/07/Medical-Technology-Registries-Six-Key-Principles-170509.pdf>

<sup>22</sup> For more, see: <https://www.ispor.org>

<sup>23</sup> <http://www.ispor.org/strategic-initiatives/real-world-evidence>

<sup>24</sup> <https://www.ispor.org/publications/books/ispor-taxonomy-of-patient-registries-classification-characteristics-and-terms>

<sup>25</sup> For more, see: <https://www.ichom.org/>

<sup>26</sup> For more, see: <http://www.kvalitetsregister.se/englishpages/userregistrydatainyourresearch.2251.html>

Taking into consideration a wider perspective, it is very important that all publicly financed health data collected and generated by the health service providers, insurance companies and health administration are quickly and easily publicly accessible to the third interested parties from the health sector applying the highest degree of the personal data protection in accordance with the GDPR.

In particular, the existing mechanism for recording and billing procedures involving all primary care physicians (PHC) could be extended by recording specific treatment outcomes.

#### PRIMARY FOCUS SHOULD BE PLACED ON:

- Existing data collecting efforts ("low hanging fruit") – map, provide with legitimacy and support.
- Introducing mandatory Quality Registries for diseases with heaviest burden: ischemic heart diseases, stroke, cancer (lung and bowel) and diabetes.
- Introducing mandatory Quality Registries for implants and medical devices that remain permanently in the human body and with an average market price of over 1,850 HRK.

To ensure that long and complex processes of informatization of the healthcare sector do not slow down or postpone development of the Quality Registries, it is recommended that in all cases where special interest (e.g. certain disease states, procedures, medicines or medical devices) or initial structure for outcome collection exists, the decentralized registries on national, local or HCPs / HCOs level should be established via the shortest route. It is necessary to introduce simple, clear and actionable rules so that the data collecting can start as soon as possible. Important condition would be scalable and flexible software architecture (compatible to the structure of CEZIH) for complete flexibility in future edits, expansion and integration. Following this approach, data collection would start sooner in various formats, and in the next stages the databases/registries would be upgraded to national level registries and integrated into the healthcare IT structure, that is CEZIH.

For the purpose of introduction of quality registries, AmCham hereby makes the following recommendations:

- 1. Raising awareness** among **all the key stakeholders** (HCPs, HCOs, relevant authorities [Ministry of Health, HZZO, HZJZ] and patient organizations) **and including** them in the relevant discussions.
- 2. Fully leverage provisions of the Act on Mandatory Healthcare Insurance**<sup>27</sup> which empowers Management Board of the HZZO to decide on the types and numbers of therapeutic and diagnostic procedures (e.g. based on their proven clinical effectiveness) and subject to the prior

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<sup>27</sup> Cro. *Zakon o obveznom zdravstveno osiguranju*, Official Gazette No. 80/13.

- opinion of the relevant chambers (e.g. by adopting Guidelines of the Professional Societies of the Croatian Medical Association (HLZ)).
3. Making populating of **Quality Registries database a mandatory** and regular activity by passing necessary regulations (e.g., laws and decisions) that would also define an access to analysts and scientists with the highest security standards and protection especially of sensitive personal data in accordance with the GDPR.
  4. **Conditioning** that the payments by the payer (HZZO) for the delivered health services are made **only after** the relevant **data** pertaining to case of medical treatment have been **entered into the Quality Registries**.

Taking into consideration the new EU financial perspective 2021-2027, there is a possibility of financing the Quality Registries (meaning development of the Quality Registries for the key diseases and implementation of the Quality Registries into the healthcare system and existing IT and e-Health infrastructure) by EU funds. In order to do that, it is recommended to **undertake the necessary preparations and set ground for their financing through EU funds**, such as placing registries prominently in the national strategic documents.

## Conclusion

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Introduction of the Quality Registries can significantly contribute to the improvement of the key parameters of the Croatian healthcare system - primarily to the quality and costs (by financial consolidation through generated savings). In addition to being precondition to rational functioning of the area of healthcare system within their scope, the Quality Registries represent at the same time an exceptional opportunity for rapid development certain areas of Croatian medicine. The Quality Registries can demonstrate relatively fast that the best Croatian HCPs / HCOs are not only capable of providing exceptional quality treatment outcomes for patients in Croatia, but also, through improved clinical practice and results, they can turn out to be at the level of comparable European counterparts. It is therefore of utmost importance that the healthcare administration implements measures which will enable the examples of best practice Quality Registries to start emerging as soon as possible. These will provide invaluable guidance and momentum for further and wider introduction of registries in key disease areas with all the mentioned synergy and cumulative effects on outcomes quality, healthcare budget efficiency and, equally important, reputation of Croatian medicine and HCPs / HCOs in the country and internationally.

AmCham Healthcare Committee invites the healthcare administration to urgently take measures which will enable Quality Registries to start producing the benefits for the Croatian patients and healthcare.

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