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A comprehensive model for measuring real-life cost-effectiveness in eyecare: automation in care and evaluation of system (*aces-rwm*™)

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ABSTRACT. This paper describes a holistic, yet simple and comprehensible, ecosystem model to deal with multiple and complex challenges in eyecare. It aims at producing the best possible wellbeing and eyesight with the available resources. When targeting to improve the real-world cost-effectiveness, what gets done in everyday practice needs be measured routinely, efficiently and unselectively. Collection of all real-world data of all patients will enable evaluation and comparison of eyecare systems and departments between themselves nationally and internationally. The concept advocates a strategy to optimize real-life effectiveness, sustainability and outcomes of the service delivery in ophthalmology. The model consists of three components: (1) resource-governing principles (i.e., to deal with increasing demand and limited resources), (2) real-world monitoring (i.e., to collect structured real-world data utilizing automation and visualization of clinical parameters, health-related quality of life and costs), and (3) digital innovation strategy (i.e., to evaluate and benchmark real-world outcomes and cost-effectiveness). The core value and strength of the model lies in the consensus and collaboration of all Finnish university eye clinics to collect and evaluate the uniformly structured real-world outcomes data. In addition to ophthalmology, the approach is adaptable to any medical discipline to efficiently generate real-world insights and resilience in health systems.

Key words: age-related macular degeneration – cataract – diabetic retinopathy – ecosystem – glaucoma – real-world cost-effectiveness – real-world data

The development of the digital tailor-made *aces-rwm*™ digital tool package received support as Public Procurement for Innovation from Business Finland (directed by Finnish Ministry of Employment and Economy). Innovative Public Procurement refers to new and/or significantly improved goods or services that can help to enhance the productivity, quality, sustainability and/or effectiveness of public services. Business Finland does not influence the contents of the procurement process nor the medical contents of the presented ecosystem.

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Introduction

Medical practices, including ophthalmology, are filled with uncertainties despite the scientific roots of medicine. The same research findings continue to be interpreted in many ways depending on the decision-making processes and environments (Muir Gray 2001). As a result, vast variations in practices across and within countries continue to be reported, also in ophthalmology (Tuulonen et al. 2009; Corallo et al. 2014; MacEven et al. 2019). The key question is whether all parties implementing the variable policies can be 'right'.

The citizens in the developed countries are currently offered more health care services than ever before, are healthier and live longer than ever before. These countries also spend more money on health care than ever before. Paradoxically, simultaneously the demand and costs of services escalate exponentially driving the western health care systems into the verge of financial crises (Tuulonen 2005). Still, most people believe that simply producing and spending even more medical care is the solution (Tuulonen 2004). However, continuing to do more of what is currently done has also counterintuitive effects. Although acknowledged long ago, such side effects have been mostly ignored (Fisher & Welch 1999). However, the recently founded the Cochrane Sustainable Health care Group specifically focuses on a medical excess which threatens the health of individuals and the sustainability of health systems (Johansson et al. 2019, https://sustainablehealthcare.cochrane.org). The group pushes for (1) a broad consideration of resource use, (2) promoting a more sensible prioritization of financial and human resources, and (3) considering the treatment burden for individual patients.

Particularly in health systems with universal coverage, decision-makers at all levels need to consider the finite resources and opportunity costs (Muir Gray 2001). This highlights the need for well-constructed national and regional strategies for improved decision-making also within ophthalmology (Taylor et al. 2006; Tuulonen et al. 2009). This paper presents a comprehensive ecosystem model developed in Finland with the aim to optimize the effectiveness, sustainability and outcomes of eyecare services. As the model includes also cost-effective implementation of digitalization, it is called '***a***utomation of ***c***are and ***e***valuation in ***s***ystem with ***r***eal-***w***orld ***m***onitoring' *(aces-rwm™)*. The model was initiated and is now coordinated by Tays Eye Centre in collaboration with all five university eye clinics in Finland. Although developed within ophthalmology, the principles of the model are adaptable to any health care setting and medical discipline, including primary care.

Why measuring real-life effectiveness is important

Randomized controlled trials (RCTs) are crucial in investigating the *efficacy* of interventions in *optimal* settings. Compared to RCTs, pragmatic controlled trials reporting *effectiveness* have different goals, use different tools, and generate different messages (Porzsolt et al., 2015). *Efficacy* (the outcome in ideal RCT setting) differs from the outcomes of interventions in *real-world* settings (Rodrigues et al. 2016; Franklin et al. 2021; Thompson 2021). Patients in everyday practices, presenting with extensive comorbidities, are more diverse than the tight and selected RCT samples. Usual patients may also be cared for non-expert practitioners implementing varied practice patterns (Hagman 2013; MacEven et al. 2019). In addition to under care, over care needs to be considered, such as treating risk instead of manifest disease (e.g., due to low specificities of diagnostic tests and/or financial incentives) (Tuulonen 2004). It is also possible that when care is driven by the worst eye, some elderly patients with good vision in the fellow eye, may be treated too rigorously without positive impact on their quality of life, or visual function. Geographic availability of services may influence the care processes as well.

Based on the above, economic simulation models utilizing RCT data tend to lead to over-optimistic outcomes compared to real life. Moreover, many other biases are related to RCTs (Higgins et al. 2017) which in ophthalmology, by their very nature, present statistical challenges as well (Murdoch et al. 1998). For example, when only one eye per patient included in RCTs (without always reporting whether the better or worse eye), there is 'waste' of information in the analysis. In addition, the quality of life may be driven by the better eye and costs by the worse eye. When an observation by its nature involves two eyes, as for blindness, statistical analyses should be conducted on individuals rather than eyes (Murdoch et al. 1998).

However, everyday eyecare is unselective including all kinds of patients with two eyes. Therefore, the collection of *all* available data of both eyes is vital, i.e., data of diagnostic, treatment, and follow-up interventions as well as quality of life and costs. These data enable evaluation of both individual patient care and benchmarking of real-world outcomes nationally and internationally. Novel concepts have recently been developed for evaluating variable real-life practice patterns, for example, benchmarking controlled trials (BCT) and system impact research (SIR) (Malmivaara 2015; Malmivaara 2016).

Background for the increasing demand in eyecare and limited resources

Although ophthalmology is often regarded as a small speciality, the volumes of eyecare are enormous. For example, in 2019, ophthalmology was the highest volume outpatient speciality in England (MacEven et al. 2019). Within UK National Health Services, ophthalmology provided 7.5 million outpatient visits and more than a half million operations, including cataract surgery as the most performed operation in UK (MacEven et al. 2019), and worldwide. This UK 2019 investigation, reporting substantial unwarranted variations in care, was based on *survey* data and *visits* to 120 health service trusts due to lack of sufficient national data sets available for analysis (MacEven et al. 2019). This clearly highlights the need for systematic and automated real-world data collection, especially regarding the prevalence of sight loss and its related high societal costs (Pezzullo et al. 2018).

Within ophthalmology in Finland, the 'Big Four' eye diseases account two thirds of patients, visits, and costs in public ophthalmic care (Tuulonen et al. 2016). Only the first three of them cause permanent visual loss (Ojamo 2018): (1) age-related macular degeneration (AMD) causes 58% of blindness in the elderly, (2) glaucoma 9%, and (3) diabetic eye disease (4% of blindness all ages included) while (4) cataract causes no permanent visual loss. Yet, the access to cataract surgery remains the only eye disease recognized, and thus highly prioritized, ahead of the three big chronic eye diseases both in political circles and media in the country.

The population of the serving areas of the five Finnish university eye clinics is 3.3 million inhabitants, i.e., 60% of Finnish population. Based on this, the yearly number of services of the 'Big Four' eye diseases in the five university clinics is considerable, i.e., more than 80 000 AMD injections, over 60 000 patients treated for glaucoma and 180 000 diabetics. In addition, the number of cataract operations is over 35 000 yearly. As of 2022, the *aces-rwm™* digital tools will be available also for Finnish central hospitals and international eye clinics.

Within eyecare, the challenge of resource allocation is clearly demonstrated by the mean 16-fold increase in treatments for AMD between 2008 and 2020 in Tays Eye Centre (Fig. 1). In the absence of commensurate increases in overall resources, such a massive

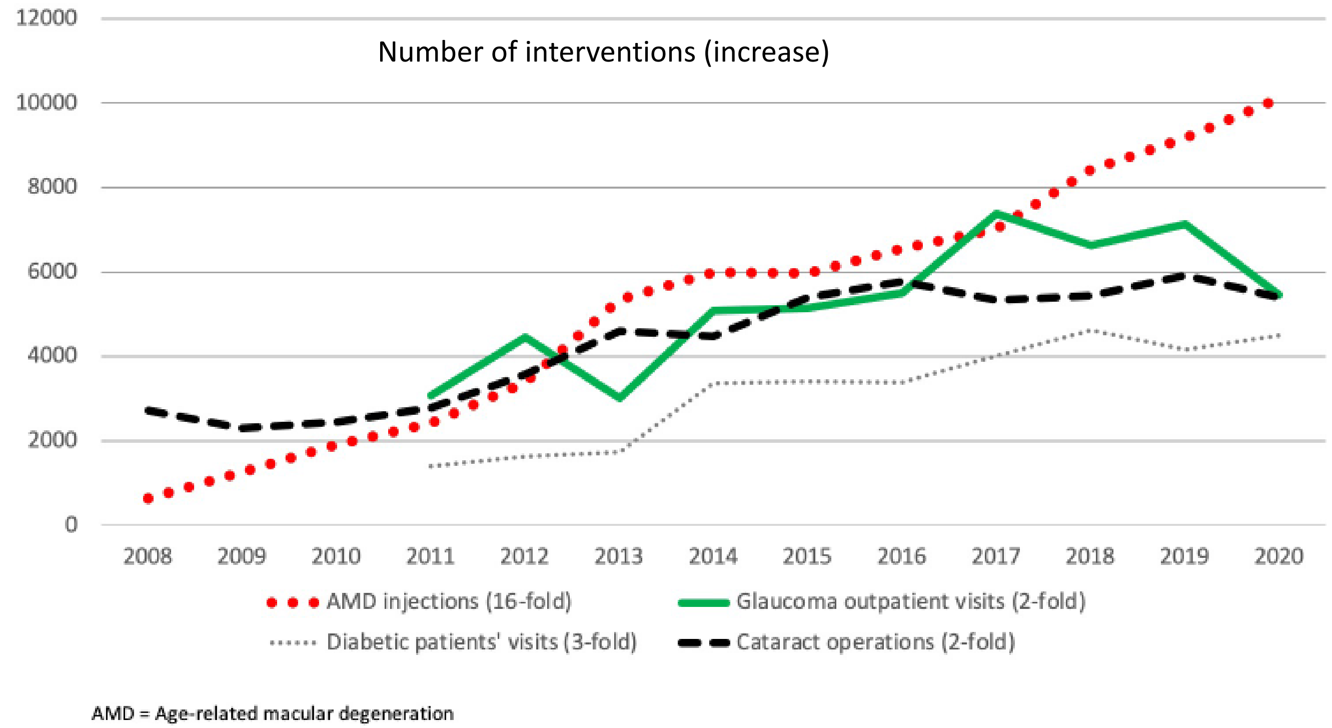

Fig. 1. The graph illustrates the 2- to 16-fold increases of eyecare services in 2008–2020 in Tays Eye Centre, Tampere University Hospital, Finland, with simultaneous population increase of 12%. The labor input grew 41% (from 61 to 86) in 2011-2020, i.e., actualized working hours equaling the number of full-time employees. The declines in 2020 reflect covid pandemic further demonstrating the need for resilience. These real-world data (totaling 195 300 interventions in Tays) have already been collected and are available for (inter)national benchmarking.

surge in demand for one disease threatens to compromise the care for all other eye diseases. The development of completely new approaches to eyecare delivery are obvious (Kokkinen & Lehto 2011; Tuulonen et al. 2016).

Collaboration of university and other eye clinics in Finnish public sector

The goals of health systems typically include quality, efficiency, equity, affordability, and accessibility of health services (e.g., EXPH 2014). Balancing and optimizing among them is a continuous tradeoff process requiring normative judgments from all decision makers, for example, between affordability and quality (EXPH 2019). Finland has a predominantly tax-financed universal health care system. The Constitutional Act instills a responsibility on the public authorities to provide equal and *adequate* health care services (Finlex 1999). Constantly increasing gap between growing demand and limited resources makes it impossible even for trying to produce 'everything for everyone'. Due to missing definition of what is considered 'adequate', the Finnish public eye clinics have taken the initiative for defining principles on how to promote best possible well-being and eyesight in eyecare with allocated resources.

This proactive collaboration of all chief ophthalmologists in the Finnish public sector eye clinics is dated back to 2004. As part of the new Finnish access to care legislation (valid in 2005), they defined the first uniform criteria for access to non-urgent eyecare (Tuulonen et al. 2009). These criteria (updated in 2010 and 2019) are based on national Current Care Guidelines for the 'Big Four' eye diseases (National Access to Care Criteria in Finland 2019, Finnish Current Care Guidelines). In 2015, the chief ophthalmologists made an initiative to the newly founded Council for Choices in Health Care (COHERE, Ministry of Social Affairs and Health, Finland) for including the off-label bevacizumab for the treatment of age-related macular degeneration to be financed by public funds. This COHERE's first ever recommendation, like all its later recommendations, consider both scientific evidence and costs.

Despite uniform criteria for care, the productivity benchmarking between university eye clinics in 2012-15 ended up in recognizing variable practice patterns for all 'Big Four' eye diseases. Instead of continuing to benchmark these already recognized variabilities, in 2016 the university eye clinics decided to aim for measuring the real-life *outcomes* in their service delivery. In 2019, all Finnish chief ophthalmologists in public sector united in acknowledging the finite level of resources and began to advocate that policy choices are needed to integrate clinical priorities in public eyecare, i.e., prioritizing prevention of permanent visual loss. This prioritization principle, ophthalmology being the first specialty in Finland to introduce it in 2015, was published as part of the update of National Access to Care Criteria (2019). The first Choosing Wisely Recommendations for eyecare were published in 2019 as well (Tuuminen et al. 2019).

aces-rwm™ optimizing the effectiveness, sustainability, and outcomes

Particularly in publicly funded health systems, a pressing issue remains on how to allocate the resources equally and cost-effectively. The seeds for the *aces-rwm*™ model have been sown along the years since 2000 when responding to the needs for service modernization in ophthalmology (Tuulonen 2005; Tuulonen et al. 2009; Kokkinen & Lehto 2011; Tuulonen et al. 2016). They evolved into three components: (1) resource-governing principles (i.e., how to deal with increasing demand and limited resources), (2) real-world monitoring (i.e., how to collect structured real-world data utilizing automation and visualization of clinical parameters as well as health-related quality of life and costs), and (3) digital innovation strategy (i.e., how to evaluate and benchmark real-world outcomes and cost-effectiveness) (Fig. 2). The model also enables to evaluate allocative efficiency among the 'Big Four' eye diseases within each department and compare resource allocation among the 'Big Four' eye diseases nationally and internationally rather than only analyzing each patient groups separately.

1 Resource-governing principles: How to deal with increasing demand and limited resources The resources principles (P5SE model, left column in Fig. 2) consist of

−Prioritization (P) of patients with the highest risk for permanent visual impairment[1]
−Stratification (1S), i.e., organizing eyecare to identify the patients with highest risk [1]
−Standardization (2S) of care processes in lower risk ('usual') patients
−Sustainability (3S) of care in the face of resource limitations (annual capping of budgets)
−Shared care (4S) utilizing the skills of different health care professionals and multidisciplinary teams
−Self-care (5S) by patients
−Evaluation (E) of the impact of the above P5S principles at both the patient and system levels.

Implementation of these P5SE principles in eyecare in Tays Eye Centre since 2012 has enabled more than double its production with 41% increase in labour input (Fig. 1) (Tuulonen et al. 2016). Simultaneously, the AMD drugs for 10 152 injections in 2020 cost 23 000 € *less* (−3%) compared to the drug costs of 626 injections in 2008 in Tays. This was based on (1) changing into bevacizumab in 2009, (2) prioritising its use for the treatment of AMD, (3) starting to divide aflibercept into three doses in 2016 without detecting change in the outcomes (Hujanen et al. 2019), 4) developing national guidelines for AMD (Tuuminen et al. 2017), (5) developing national 'Choosing Wisely' recommendations for eyecare (Tuuminen et al. 2019), and 6) re-defining the criteria for changing into and continuing treatment with aflibercept in 2019. The visual outcomes in the already published 2008-13 real-world data set in Tays Eye Centre (11 562 treatments in 1117 patients) were in accordance with other real-life studies (Kataja et al. 2018).

Compared to Tays, other Finnish university eye clinics have drawn different conclusions from the same

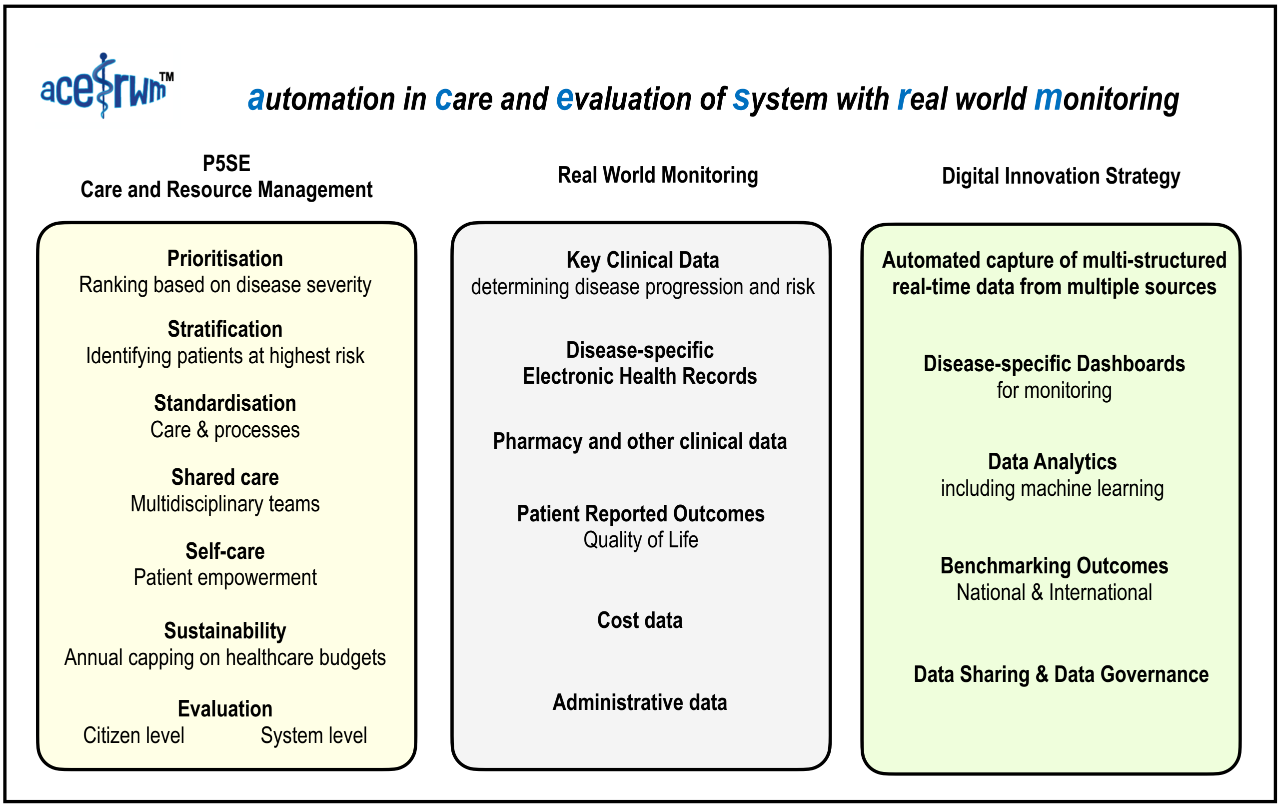

Fig. 2. The overview the *aces-rwm*™ concept consists of three components: (1) resource-governing principles (P5SE model, left column), (2) automated and structured real-world data monitoring (middle column), and (3) digital Innovation Strategy (right column). Tays Eye Centre was awarded a one-star Reference Site for the P5SE model in 2016-18 and a three-star Reference Site for the *aces-rwm*™ model in 2019-21 by EI PAHA (European Innovation Partnership on Active and Healthy Ageing) of the European Commission within B3 Action Group (Bousquet et al 2019).

national guidelines leading, e.g., into over 6-fold higher AMD drug costs per population than Tays in 2016 (Fimea 2017) as well as 10- to 25-fold increases of injections over time between units. Internationally, in 2017 the number of AMD injections in Finland and Sweden was about the same despite Swedish population being double compared to Finland (Tuuminen et al. 2019). The question remains which departments and countries are under- and/or over-treating as well as under- and/or over-spending. These examples of unwarranted national and international variabilities demonstrate the urgent need of 'Evaluation' component of the P5SE model (Fig. 2), i.e., analysing and benchmarking real-world cost-effectiveness nationally and internationally.

2.Real-world monitoring: How to collect structured real-world data utilizing automation and visualization

The tailor-made digital tool package for real-world monitoring in *aces-rwm*^{TM} (middle column in Fig. 2) consists of five modules of which first three deal with identifiable patient data and last two with disease-level aggregated data. This real-world data collection model follows the data protection requirements and legal basis of the recent Finnish Act on Secondary Use of Health and Social Data (552/2019). The legislation aims to narrow gaps in wellbeing and health between patient groups, as well as maintaining and improving well-being.

[1]Prioritizing prevention of permanent visual disability in the *aces-rwm*^{TM} does, of course, not refer to posteriorizing cataract patients to be operated only after *all* patients with the other three chronic eye diseases have been treated. First, the Finnish access to criteria legislation decrees the time frame for all non-urgent care, including cataract surgery (Tuulonen et al. 2009; Falck et al. 2012). And obviously, if cataract patient's visual acuities in both eyes were poor and patient would benefit from rapid intervention, also such cataract patients would be prioritized according to Stratification principle of P5SE in *aces-rwm*^{TM} model.

Module 1: Automated transfer of key measures to the structured electronic patient record (EPR)

As the primary goal of eyecare is to minimize visual impairment, the key outcomes are based on the clinical measures defining impairment: (1) central visual acuity (best correction estimated by autorefractometer, and/or manual assessment) (Stoor et al. 2018) and (2) visual field indexes (mean defect/deviation). The instruments providing these electronically quantified key measures (as well as intraocular pressure measured by rebound tonometer) (Stoor et al. 2020) have been integrated to transfer these data automatically to the structured disease-specific electronic patient records (Module 2) for the 'Big Four' eye diseases.

Module 2: Structured disease specific electronic patient records

Use of the jointly designed, uniform, tailor-made *aces-rwm*^{TM} digital tools for the 'Big Four' eye diseases creates the basis for benchmarking of outcomes between the five collaborating university eye clinics. The structured 'Big Four' disease-specific EPRs can be used in front of any general unstructured EPRs nationally and internationally, with the Finnish university hospitals currently using three different general EPRs. The structured data for every patient are then transferred automatically also in text format into the general unstructured EPRs and from there to the national Kanta archive where all patients have access to their health data.

To facilitate feasibility, the main prerequisites for all tailor-made digital tools are user-friendly data input minimising clicks and clear cut, easy to read visual outlines to ensure safe and efficient increases in lead times as well as conversion flexibility to stand the test of time. In addition, data need to be entered into structured EPR only once compared to e.g., many disease registries suffering from incomplete data sets due to, e.g., requirements of multiple entries (Rodrigues et al. 2016). As the digital tools should facilitate care processes, not slow them down, also their cost-effectiveness will be evaluated as part of streamlining the eyecare processes.

Module 3: Visual tools to improve patient-level decision-making

Successful management of individual patients having potentially blinding chronic life-long eye diseases requires longitudinal data collection even over decades. In *aces-rwm*^{TM}, the automated visualization of uniformly structured longitudinal key data generates an immediate general overview of the patient history side by side to the structured data in Module 2 (Fig. 3). The visualization aids recognizing the high-risk cases. In addition, such automated tools bypass many of the most time-consuming processes which doctors and nurses now must go through to assemble and evaluate test results.

Module 4: Evaluation of group-level aggregated data

Aggregating automatically the longitudinal and structured data of individual patients allows evaluation of vision outcomes at the group level for each of the 'Big Four' eye diseases. These group evaluation tools are designed to work similarly to making, e.g., an online hotel reservation enabling to select parameters of interest (age, treatment, vision, better or worse eye, *etc*.). This enables getting an immediate result, e.g., before and after changing the practice pattern (Hujanen et al. 2019). In addition, the transfer of the yearly (or any other selected period) real-world data for statistical analysis requires only one keystroke.

Module 5: National and international benchmarking

At system level, the health care organizations need to compare their consolidated aggregated outcomes data of their practice patterns and performance nationally and internationally between each for the 'Big Four' eye diseases as well as resource allocation among them. Participating organizations can then collaboratively aim to define optimum, good-enough, and equal national and international levels of services for the 'Big Four', considering both under and over care. The outcomes of the benchmarking efforts may lead into reduction of resources in some departments and increase in others.

3.Digital innovation strategy – How to evaluate and benchmark the overall outcomes

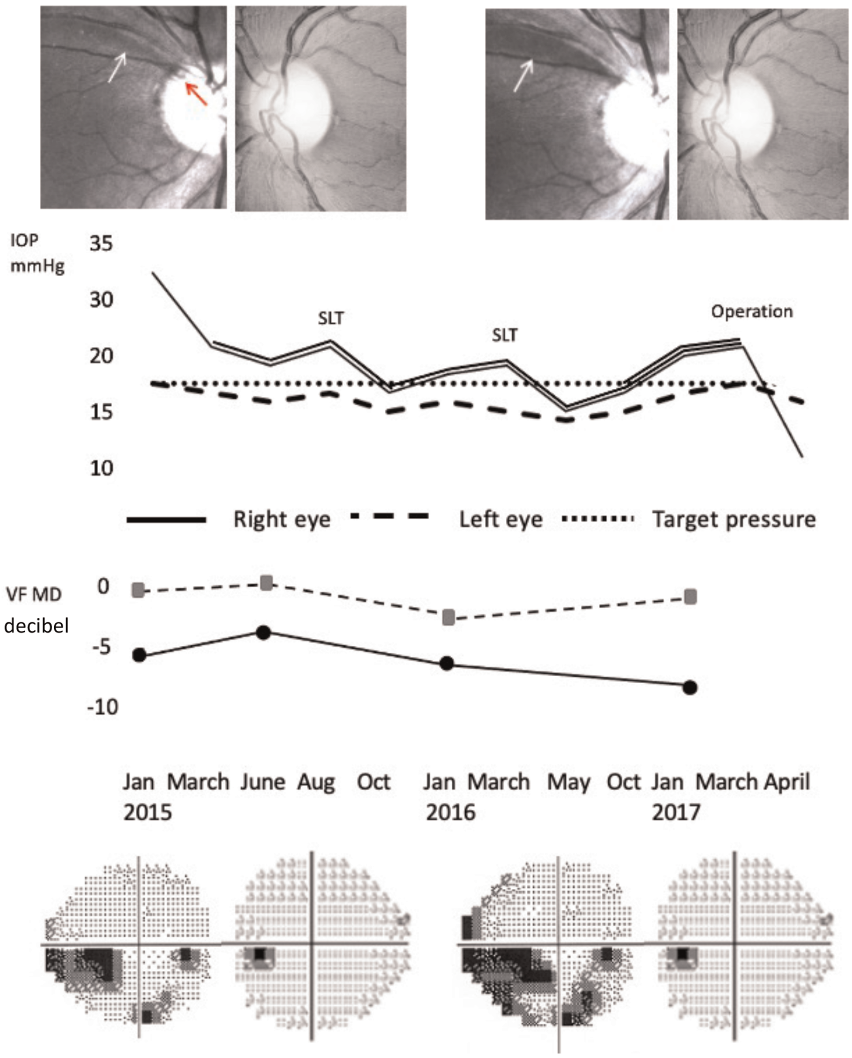

Fig. 3. The automated visualization of uniformly structured longitudinal key data (Module 3) generates an immediate overview of the patient history, i.e., in glaucoma intraocular pressure (IOP), mean defect of visual field (VF MD) and treatments. In addition, demonstrative thumbnail pictures indicating abnormalities (arrows indicating optic disc haemorrhage with progressive nerve fiber layer defect) and corresponding visual fields can be chosen to be posted to Module 3. The number of lines refers to number of glaucoma medications which can be read by clicking the date in the IOP curve. This overview can also be presented side by side to the structured data of Module 2.

The overall goal of the *aces-rwm*™ evaluation (right column in Fig. 2) aims to (1) to explore the drivers of value in eyecare systems, (2) to operationalize value as defined in value-based health care, and (3) to employ and test the value measurements empirically (e.g., Riippa et al. 2014). Figure 4 presents an overview of the comprehensive real-world data entities collected with the 5-module *aces-rwm*™ digital tools and the evaluation framework for analyzing these data. The already collected Tays data in 2008-20 (195 300 interventions) are offered for national and international benchmarking (Fig. 1).

Evaluating real-world cost-effectiveness requires combining clinical outcomes with cost and quality of life data. Due to variability in the accountancy policies between Finnish university hospitals, the payers' perspective has been chosen for the Finnish model, i.e., the yearly total invoicing for each 'Big Four' paid by the public health care sector.

The general health-related quality of life of patients is measured using general health related quality of life instrument (15D with 15 health dimensions including vision) (Sintonen 2001). 15D is sensitive to detect changes in eyecare, e.g., in cataract and even early glaucoma patients (Kuoppala et al. 2012; Hagman 2013). In the pilot test of 200 'usual' patients in Tays Eye Centre, both the 15D instrument's total and visual scores separated general population and populations with glaucoma, age-related macular degeneration and visual disability from each other (data on file). Tampere University Hospital has adopted 15D instrument to be used in all specialties thus facilitating each other's data collection and without exhausting patients with multiple questionnaires. Patients fill in the questionnaire in the 'Own Tays' website. By now, 15D data are available for 2300 ophthalmic patients.

Conclusions

Health care systems can be made more cost-effective, e.g., making the existing system work better or changing the system (Williams 1993). Regardless of

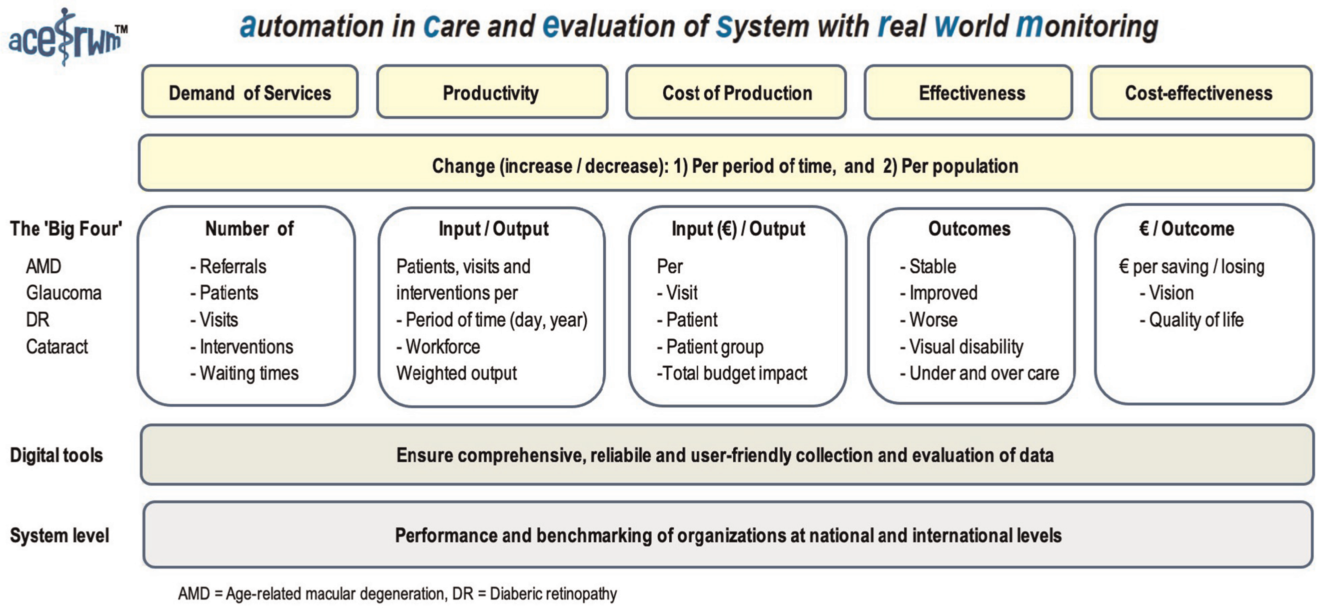

Fig. 4. FrameworkA for the overall evaluation of real-world data in *aces-rwm*™ ecosystem.

the means of change, what gets done in every-day practices now and after any modification, needs to be measured by collecting all data of all patients comprehensively and efficiently. We have presented a framework which is realistic (understanding and accepting public budget constraints), fair (allocating resources depending on the disease severity), and responsive (evaluating continuously how to adjust the policies over time). The five modules of *aces-rwm™* model represent a digital tool package to collect, visualize and evaluate real-world outcomes data to aid seeing both the forest (the big picture: the health system) and the trees (the details: data of individual patients).

The core value and strength of the *aces-rwm™* model lies in the consensus and collaboration of all university eye clinics to collect and benchmark the uniformly structured real-world data of outcomes. All impacts health care (both good and bad), including costs, arise from the decisions of eyecare professionals. As part of our society, we carry responsibility for delivering equal and adequate health services. The only way to know whether the selected strategies and policies serve the defined purposes is to systematically and continuously measure what gets done on individual and system levels. If – despite sincere intentions – the chosen tactics would appear to lead to unexpected unfavourable directions, the strategies and policies need to be redesigned and continue measuring real-world outcomes.

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