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ORIGINAL ARTICLE

A prototype protocol for evaluating the real-world data set using a structured electronic health record in glaucoma

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Abstract

Purpose: As the first step in monitoring and evaluating day-to-day glaucoma care, this study reports all real-world data recorded during the first full year after the implementation of a prototype for glaucoma-specific structured electronic healthcare record (EHR).

Methods: In 2019, 4618 patients visited Tays Medical Glaucoma Clinic at Tays Eye Centre, Tampere University Hospital, Finland, that serves a population of 0.53 M. Patient data were entered into a glaucoma-specific EHR by trained nurses to be checked by glaucoma specialists. Tays Eye Centre follows the Finnish Current Care Guideline for glaucoma in which glaucoma is defined using a '2 out of 3' rule, that is, ≥2 findings evaluated as glaucomatous in optic nerve head (ONH), retinal nerve fibre layer (RNFL) and visual field (VF).

Results: The clinical evaluations of ONH, RNFL and VF were recorded in 95%–100% of all eyes. ONH was evaluated as glaucomatous more often (44%) than RNFL (33%) and VF tests (30%). Progressive changes in any of the three tests were recorded in 35% of the '≥2/3 glaucoma group' compared to 2%–9% in the other groups. The mean IOP at visit was 15 mmHg. The mean target IOP was 17 mmHg, and it was recorded in 94% of eyes.

Conclusion: The developed structured data presentation enables comparisons between different population-based real-world glaucoma data sets and glaucoma clinics. Compared to a data set from the UK, the proportion of glaucoma suspicion-related visits was smaller in Tays Eye Centre and test intervals were longer.

KEYWORDS
electronic health record, glaucoma, real-world data, reporting protocol

1 | INTRODUCTION

While randomized controlled trials (RCTs) evaluate interventions in one eye of selected patients in optimal conditions (efficacy), the evaluation of interventions and care practices in real-world conditions (effectiveness) requires different data sets and evaluation tools (Franklin et al., 2021; Porzsolt et al., 2015; Thompson, 2021). For example, patients in everyday practices have two eyes with variable comorbidities and may be cared by practitioners with unwarranted variations in the delivery of eye care (MacEven et al., 2019).

When targeting to improve the real-world cost-effectiveness, what is done clinically in everyday practices needs to be measured and evaluated routinely, efficiently and non-selectively (WHO, 2023). Therefore, the Finnish University Eye Clinics have developed a holistic, yet simple and comprehensible *aces-rwm*™ ecosystem model (*automation in care and evaluation of system with real-world monitoring*) to deal with complex challenges in everyday eye care (Tuulonen et al., 2022). The overall aim of the ecosystem is to produce the best possible well-being and eyesight with the available resources.

The *aces-rwm*™ ecosystem advocates a strategy to optimize real-life cost-effectiveness, sustainability and outcomes of the service delivery in ophthalmology. The ecosystem consists of three components: (1) resource governing principles to deal with increasing demand and limited resources, (2) real-world monitoring to collect structured real-world data (RWD) using structured electronic health records (EHRs) as well as measuring health-related quality of life and costs and (3) digital innovation strategy to evaluate and benchmark real-world outcomes and cost-effectiveness between eye care units nationally and internationally. The core value and strength of the ecosystem lie in the consensus and collaboration of all Finnish University Eye Clinics to collect and evaluate the uniformly structured outcome data using EHR (Tuulonen et al., 2022).

RWD collection represents the first step in the development of a framework for routine monitoring and evaluation of what gets done in everyday glaucoma care with respect to the defined strategies. The 4-year Finnish University Eye Clinics' project to develop tailor-made digital tool package for real-world monitoring in glaucoma, age-related macular degeneration, diabetic retinopathy and cataract was completed on 31 March 2023 and is ready to put to use. The experiences of Tays Eye Centre's prototype for structured EHR in glaucoma, implemented in 2018, were utilized during the development project.

In accordance with the CODE-EHR best-practice framework preferring a published protocol for each item on the checklist (Kotecha et al., 2022), the purpose of this study was to report all real-world data recorded during the first full year (2019) after introducing a prototype of glaucoma-specific structured electronic healthcare record.

2 | MATERIALS AND METHODS

2.1 | Background

Tays Eye Centre, Tampere University Hospital, Finland, is the only public unit providing eye care services for the population of 0.53 million in Pirkanmaa Wellbeing Services County. Due to the continuously increasing demand for glaucoma services, the first structured paper data collection tool was implemented in Tays Eye Centre in 2012. The collected data were typed out by secretaries into the hospital's general unstructured digital patient record. Simultaneously, nurses in the Medical Glaucoma Clinic were trained to fill in all examination data, pre-evaluate the fundus photographs and visual field (VF) tests and suggest a treatment and follow-up plan to be checked by a glaucoma specialist, either face-to-face or virtually (Tuulonen et al., 2016). The first prototype of glaucoma-specific EHR was tailor-made for Tays Eye Centre and implemented in autumn 2018 after a 2-year development process. The first full-year EHR data are available for 2019.

The use of structured EHR offers a unique opportunity to develop a learning healthcare system by providing a new evidence generation for large-scale clinical research, including cost-effectiveness (Kotecha et al., 2022). Therefore, a global multistakeholder group developed a 5-item CODE-EHR best-practice framework and checklist for researchers when designing and reporting big data. In addition, CODE-EHR can be used by journal editors and reviewers by requesting the authors to fill in the checklist when submitting structured healthcare data, thus embracing values of transparency, reciprocity, inclusivity and service for the common good. Consequently, we decided to follow the CODE-EHR best-practice framework (including the underneath headings) and fill in the checklist when reporting our RWD (Kotecha et al., 2022).

2.2 | Data set construction and data fitting the purpose

The glaucoma prototype EHR was used in all 4618 patients visiting Tays Medical Glaucoma Clinic in 2019. The standardized care process in Tays follows the Finnish Current Care Guidelines, which have been available for 20 years (Tuulonen et al., 2003), with the latest update in 2023 (The Finnish Medical Society Duodecim, 2023). These guidelines also form the basis for national access to care criteria (Ministry of Social Affairs and Health, 2019a). Collected EHR data are presented in Tables 1–3. Diagnostic codes for glaucoma follow the International Classification of Diseases (Tenth Revision, ICD-10). As laser and surgical procedures were not included in the prototype, we only report their rates for 2019.

The Finnish healthcare system covers the whole population, and its services are primarily tax-financed. Glaucoma medications are reimbursed for patients with an ICD-10 code for glaucoma and in accordance with the '2 out of 3' rule (defined underneath in Disease and outcome definitions), as well as for patients with IOP ≥30 mmHg. The data for reimbursements of glaucoma medication expenses including number of recipients as well as prescriptions and cost data were received from the Social Insurance Institution of Finland, which also include the number of patients followed solely in private practice, including their number of VF and imaging tests but without clinical data (Kela, 2023).

A flow diagram of different data sets is presented in Figure 1, including missing data and their proportion for each variable, and specifications for linked data sets. Regarding the data fitting the purpose and to ensure transparency, the data include all structured clinical data, which were recorded in EHR of all patients visiting the Medical Glaucoma Clinic at Tays Eye Centre in 2019.

2.3 | Disease and outcome definitions

The glaucoma care process in Tays Eye Centre follows the 20-year-old Finnish Current Care Guideline for glaucoma in which glaucoma is defined using the '2 out of 3' rule, that is, when at least two concomitant findings are evaluated as glaucomatous in optic nerve head (ONH), retinal nerve fibre layer (RNFL) images and VF tests

TABLE 1 Distributions according to the diagnosis as recorded in the electronic health record (patient-specific data for right eyes).

Distributions of different diagnoses recorded in the electronic health record	All eyes	Primary open angle	Normal tension	Exfoliative	Angle closure	Related to other disease	Pigmentary	Suspicion	Other	No diagnosis
Number of patients, *n*	4618	1512	561	403	145	94	63	1086	334	420
Percentage	100%	33%	12%	9%	3%	2%	1%	24%	7%	9%
Number of eyes, *n*	9236	3027	1132	801	299	180	129	2173	683	811
Percentage	100%	33%	12%	9%	3%	2%	1%	27%	5%	9%
Age of the patient in years, mean ± SD	71 ± 14	74 ± 11	75 ± 9	80 ± 8	72 ± 11	61 ± 16	57 ± 14	65 ± 15	72 ± 13	68 ± 16
Females, *n*	2835	892	383	270	59	44	25	815	134	213
Percentage	62%	59%	68%	67%	59%	47%	40%	66%	64%	54%
History (hx) of laser treatment for glaucoma, *n*	1972	786	228	312	267	26	49	185	67	52
Percentage	21%	26%	20%	39%	89%	14%	38%	8%	16%	7%
Pseudophakia, *n*	3735	1369	552	557	161	113	35	396	267	286
Percentage	40%	45%	49%	70%	54%	63%	27%	18%	39%	35%
Hx of glaucoma surgery, *n*	456	157	87	93	17	66	10	0	17	9
Percentage	5%	5%	8%	12%	6%	37%	8%	0%	4%	1%
Hx of other than glaucoma or cataract surgery, *n*	417	126	49	48	9	68	9	52	11	45
Percentage	5%	4%	4%	6%	3%	38%	7%	2%	3%	6%
Other eye diseases, *n*	1194	393	127	121	17	105	5	230	49	147
Percentage	13%	13%	11%	15%	6%	58%	4%	9%	11%	19%
Number of medications recorded, *n*	9236	3027	1132	801	299	180	129	2173	683	810
Number of eyes without medication, *n*	3507	282	242	100	53	38	8	1932	242	610
Percentage	38%	9%	21%	13%	18%	21%	6%	89%	35%	75%
Number of eyes on medication, *n*	5726	2744	890	701	246	142	121	241	441	200
Percentage	62%	91%	79%	88%	82%	79%	94%	11%	65%	25%
Number of medications, mean ± SD	1.1 ± 1	2.0 ± 0.9	1.9 ± 0.9	2.0 ± 0.9	2.0 ± 0.9	2.5 ± 1.1	2.0 ± 0.8	1.5 ± 0.6	1.7 ± 0.8	1.8 ± 0.8
Glaucoma test set										
1 year, %	44%	45%	64%	52%	42%	53%	50%	26%	49%	42%
2 years, %	44%	53%	34%	44%	54%	43%	50%	35%	47%	39%
3 years, %	0%	0%	0%	0%	0%	0%	0%	1%	0%	1%
No control, %	2%	2%	1%	3%	3%	0%	0%	1%	2%	1%
Missing, %	11%	0%	1%	1%	1%	3%	0%	37%	2%	17%

TABLE 2 Findings in groups classified according to the Finnish Glaucoma Guideline's '2 out of 3' definition.

Distributions in different diagnoses according to '2 out of 3' definition	All eyes	≥2/3 glaucoma with glaucoma diagnosis	≤1/3 glaucoma or OHT >30 mmHg with glaucoma diagnosis	≤1/3 glaucoma with suspected glaucoma	Mixed/ undefined diagnosis
Number of eyes, *n*	9236	3219	3033	2173	811
Percentage	100%	35%	33%	24%	9%
Glaucomatous findings (3/3 = ONH, RNFL, VF)					
0	50%	0%	44%	66%	49%
1/3, or OHT >30 mmHg	14%	0%	56%	34%	37%
2–3/3	36%	100%	0%	0%	17%
Mean deviation (MD) recorded, *n*	7011	2895	2065	1485	566
Percentage of recorded MD	76%	90%	68%	68%	70%
MD dB, mean (SD)	−5 ± 7	−9 ± 8	−3 ± 4	−2 ± 4	−3 ± 5
MD dB, median	−3	−6	−2	−1	−2
MD > −6 dB, %	68%	44%	87%	92%	80%
MD −6…−12 dB, %	17%	29%	10%	6%	13%
MD < −12 dB, %	13%	28%	3%	2%	6%
Visual field (VF) evaluation, *n* of eyes	8753	3108	2762	2138	745
Percentage of VF evaluation	95%	97%	91%	98%	92%
Glaucomatous	30%	76%	6%	2%	13%
Normal	50%	13%	66%	81%	61%
Other than glaucomatous abnormality	8%	3%	11%	10%	10%
Poor VF quality	7%	5%	9%	6%	8%
No VF	5%	3%	9%	2%	8%
ONH evaluation recorded, *n* of eyes	9079	3219	2927	2159	774
Percentage of recorded evaluations	98%	100%	97%	99%	95%
Glaucomatous	44%	97%	19%	10%	20%
Normal	51%	3%	73%	87%	71%
Other than glaucomatous abnormality	2%	0%	3%	2%	3%
Poor picture quality	1%	0%	3%	0%	1%
No picture	2%	0%	3%	1%	4%
RNFL evaluation recorded, *n* of eyes	9074	3219	2922	2159	774
Percentage of recorded evaluations	98%	100%	96%	99%	95%
Glaucomatous	33%	85%	5%	3%	15%
Normal	47%	2%	63%	84%	65%
Other than glaucomatous abnormality	2%	0%	2%	2%	4%
Poor picture quality	17%	13%	26%	11%	12%
No picture	2%	0%	3%	1%	4%
Evaluation of progression recorded, *n*	7534	2633	2301	1934	666
Percentage of recorded progression	82%	82%	76%	89%	82%
Progression compared to previous visits	17%	35%	5%	2%	9%
No previous glaucoma tests available	30%	21%	12%	58%	52%
Visual acuity (VA) recorded, *n*	9232	3218	3031	2173	810
Percentage of recorded VA	100%	100%	100%	100%	100%
Snellen VA, median	0.8	0.63	0.8	0.8	0.8
Snellen VA, mean ± SD[a]	0.6 ± 0.3	0.6 ± 0.3	0.5 ± 0.3	0.8 ± 0.3	0.6 ± 0.4
ETDRS VA, median	80	75	80	80	80
ETDRS VA, mean ± SD	74 ± 19	73 ± 17	71 ± 23	79 ± 12	73 ± 23
ETDRS VA, range	100	100	90	100	100
IOP recorded at visit, *n*	9233	3219	3031	2173	810
Percentage of recorded IOP	100%	100%	100%	100%	100%
Mean IOP mmHg, ±SD	15 ± 5	14 ± 5	15 ± 5	17 ± 5	15 ± 5
Median IOP mmHg, ±SD	14	13	14	17	15

TABLE 2 (Continued)

Distributions in different diagnoses according to '2 out of 3' definition	All eyes	≥2/3 glaucoma with glaucoma diagnosis	≤1/3 glaucoma or OHT >30 mmHg with glaucoma diagnosis	≤1/3 glaucoma with suspected glaucoma	Mixed/ undefined diagnosis
Target ideal IOP recorded, *n*	8708	3196	2918	1870	724
Percentage of recorded target ideal IOP	94%	99%	96%	86%	89%
Mean ideal IOP, mmHg, ±SD	17±4	15±3	18±3	20±2	18±3
Median ideal IOP mmHg, ±SD	18	14	18	20	20
Maximum tolerable IOP recorded, *n*	8733	3196	2917	1894	726
Percentage max tolerable IOP recorded	95%	99%	91%	87%	90%
Mean IOP, mmHg, ±SD	20±5	17±4	21±3	26±5	22±5
Median IOP mmHg, ±SD	21	16	21	28	22

[a]Mean VA calculated using ETDRS letters and then converted to Snellen.

(The Finnish Medical Society Duodecim, 2023; Tuulonen et al., 2003) (example in Figures 2a and 2b).

In accordance with the Finnish Guideline, the glaucoma test set in Tays Eye Centre is evaluated clinically and consists of ONH and RNFL digital photographs (Tuulonen et al., 2000) using Canon CX-1 camera (Canon Medical Systems Europe BV) and VF tests using Humphrey 24–2 fast or faster programs (Carl Zeiss Meditec Inc.). The test set is taken in Tays Eye Centre at diagnosis and thereafter every 1–2 years depending on the patients' risk profile. The test set does not include optical coherence tomography (OCT) because the Finnish Current Care Guideline (The Finnish Medical Society Duodecim, 2023) and the European Glaucoma Society Guideline do not recommend glaucoma diagnosis or follow-up using OCT only (European Glaucoma Society, 2021). In accordance with the Finnish guidelines, central corneal thickness measurements are not included in the glaucoma test set in Tays Eye Centre.

Visual acuity (VA) and refraction are measured with an autorefractometer (ARK-1, Nidek Co, Ltd), or when not applicable, with a Snellen chart. Snellen VA was converted to ETDRS letters using the formula 85+50*log (Snellen fraction) (Gregori et al., 2010). The autorefractometer has been integrated to transfer the VA and refraction data automatically to the EHR. Visual acuities <0.05 were converted as follows: counting fingers equals to ETDRS 3, hand motion to ETDRS 2, light perception to ETDRS 1 and no light perception to ETDRS 0 (Mehta et al., 2018). Intraocular pressure (IOP) is measured using a rebound tonometer (Kontiola, 1996–1997) (Icare Finland Oy).

For patients with stable glaucoma, a 1- to 2-year treatment and monitoring plan is created as recommended by the Finnish Glaucoma Guideline. Patients are instructed to have their IOP measured in their local opticians' shops with a rebound tonometer. The frequency of IOP measurements follows each patient's individual monitoring plan, typically every 6 months in stable glaucoma. An 'ideal' target pressure is recorded for all patients, that is, at least 25% reduction from the untreated IOP level taking additionally into account the IOP level at which glaucomatous changes might have progressed. Simultaneously, an estimate for maximum tolerable IOP is defined, that is, an IOP level, which is considered to require a change in treatment. In case patient's IOP reaches the pre-defined maximum tolerable level, the patient knows what to do as their individual monitoring plan includes also the next two interventions on how to proceed. In this case, patients are instructed to call Tays Eye Centre to have the pre-defined treatment changes implemented. The Finnish Glaucoma Guideline has separate directions on how to treat and follow-up patients with high-risk glaucoma (The Finnish Medical Society Duodecim, 2023; Tuulonen et al., 2003).

Patients with ocular hypertension (OHT)<30 mmHg or glaucoma suspicion without elevated IOP and without glaucomatous damage are not routinely followed in Tays Eye Centre. Despite normal ONH, RNFL and VF findings, some of these patients may be invited to have another glaucoma test set within 1–2 years to rule out progression. The OHT patients with IOP<30 mmHg are instructed to have their IOPs measured typically once a year in opticians' shops. In case the IOP increases, their monitoring plan instructs them to call Tays Eye Centre for a control glaucoma test set. In patients with ≥30 mmHg, treatment is initiated in all patients favouring selective laser trabeculoplasty as primary therapy.

The overall goal of Tays Medical Glaucoma Clinic is to organize the high-volume care for 'usual' glaucoma patients and to be able to detect the progressive cases early enough for glaucoma surgery. Although the glaucoma EHR prototype did not include data collection tools for surgical consultations and procedures, such tools have been built in the next EHR version that will be implemented in 2023 (Tuulonen et al., 2022).

2.4 | Analysis

For the analysis, the distributions are presented in two ways: (1) according to the recorded diagnosis in the EHR (Table 1) and (2) in four groups based on the '2 out of 3' rule (Tables 2 and 3):

- '≥2/3 glaucoma' refers to 2–3 compatible glaucomatous findings in ONH, RNFL and/or VFs and an ICD-10 code for glaucoma.
- '1/3 glaucoma' refers to 0–1 glaucomatous findings and an ICD-10 code for glaucoma.

TABLE 3 Distributions of diagnostic groups according to the Finnish Glaucoma Guideline's '2 out of 3' rule.

Distributions in different diagnoses according to '2 out of 3' definition	All eyes	≥2/3 glaucoma with glaucoma diagnosis	≤1/3 glaucoma or OHT >30 mmHg with glaucoma diagnosis	≤1/3 glaucoma with suspected glaucoma	Mixed/undefined diagnosis
Number of eyes, *n*	9236	3219	3033	2173	811
Percentage	100%	35%	33%	24%	9%
Age of the patient in years, mean ± SD	71 ± 14	72 ± 13	73 ± 12	64 ± 15	69 ± 15
Diagnosis, %					
Primary open angle	33%	45%	52%		
Normal tension	12%	25%	11%		
Exfoliative	9%	12%	14%		
Angle closure	3%	4%	6%		
Related to another disease	2%	2%	4%		
Pigmentary	1%	1%	3%		
Glaucoma suspicion or ocular hypertension	27%			100%	
Other	5%	12%	10%		
Not applicable	9%				100%
Highest untreated IOP recorded, *n*	7258	2475	2113	2024	643
Percentage	79%	77%	70%	93%	79%
Highest untreated IOP, mean, mmHg ±SD	25 ± 8	26 ± 9	28 ± 9	22 ± 6	22 ± 8
Number of medications recorded, *n*	9233	3219	3031	2173	810
Number of eyes without medication, *n*	3507	635	330	1932	610
Percentage	38%	20%	11%	89%	75%
Number of eyes on medication, *n*	5726	2584	2701	241	200
Percentage	62%	80%	89%	11%	25%
Number of medications per treated eye, mean ± SD	1.1 ± 1	2.2 ± 0.9	1.8 ± 0.8	1.5 ± 0.7	1.8 ± 0.8
Any laser treatment for glaucoma, *n*	1972	983	769	159	60
Percentage	21%	31%	25%	7%	7%
Selective laser trabeculoplasty, *n*	927	511	318	73	25
Percentage	10%	16%	10%	3%	3%
Argon laser trabeculoplasty, *n*	420	246	156	15	3
Percentage	4%	8%	5%	1%	0%
Iridotomy, *n*	624	226	295	71	32
Percentage	7%	7%	10%	3%	4%
Pseudophakic eyes	3735	1826	1227	396	286
Percentage	40%	57%	40%	18%	35%
History of glaucoma surgery, *n*	456	328	119	0	9
Percentage	5%	10%	4%	0%	1%
Trabeculectomy, *n*	284	228	51	0	5
Percentage	3%	7%	2%	0%	1%
Tube shunt, *n*	58	38	19	0	1
Percentage	1%	1%	1%	0%	0%
Deep sclerectomy, *n*	31	25	4	0	2
Percentage	0%	1%	0%	0%	0%
Cyclodiode, *n*	83	37	45	0	1
Percentage	1%	1%	1%	0%	0%

TABLE 3 (Continued)

Distributions in different diagnoses according to '2 out of 3' definition	All eyes	≥2/3 glaucoma with glaucoma diagnosis	≤1/3 glaucoma or OHT >30 mmHg with glaucoma diagnosis	≤1/3 glaucoma with suspected glaucoma	Mixed/undefined diagnosis
Glaucoma surgery 2019, *n*	44	33	9	2	0
Percentage	0.5%	1%	0%	0%	0%
Patients invited to next gla0ucoma test set, %					
1 year	44%	68%	31%	26%	43%
2 years	44%	30%	65%	35%	39%
No control	2%	1%	2%	1%	1%
Missing data	11%	1%	1%	37%	17%

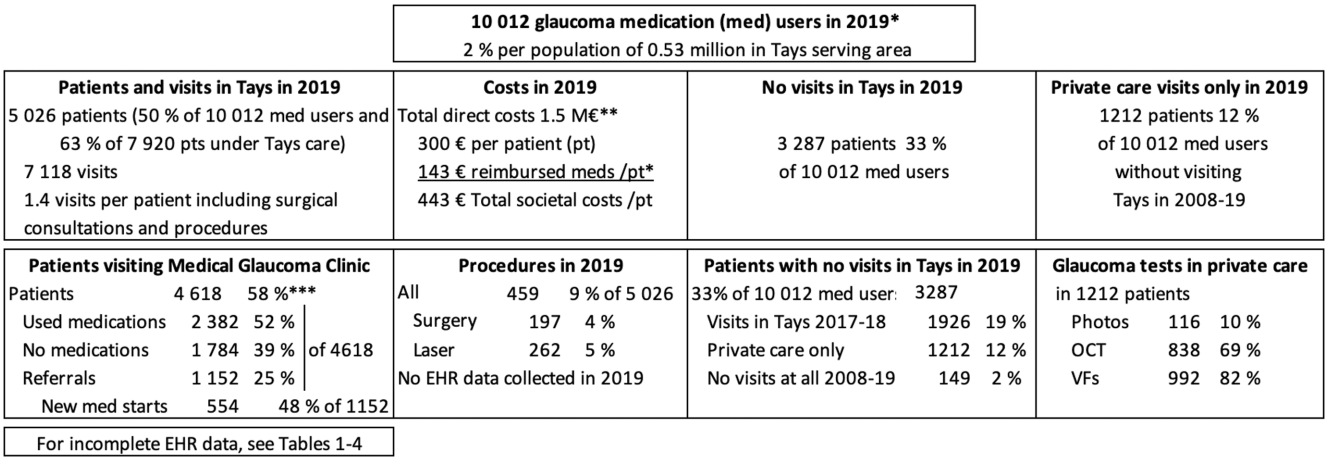

FIGURE 1 The flow diagram positions our real-world data set, collected using the electronic health record (RWD-EHR), of 4618 patients visiting Medical Glaucoma Clinic in Tays Eye Centre in 2019, and presents its representativeness among different background data sets in Pirkanmaa Wellbeing Services County, including missing data and their proportion for each variable and specifications for linked data sets.

- '≤ 1/3 suspected glaucoma' refers to 0–1 glaucomatous findings in either eye and no ICD-10 for glaucoma.
- Mixed group: All remaining eyes not included in the above groups, that is, mixed diagnosis between eyes indicating either nonmatching diagnoses in the left and right eyes, and/or the two eyes belonged to different subgroups based on the '2 out of 3' rule.

Progression is evaluated clinically by comparing the most recent ONH and RNFL images and VFs to the first ever taken images and VFs as well as all tests taken during the follow-up (Figures 2a and 2b). If the tests are only compared to those taken 1–2 years earlier, the progressive changes may be hard to detect unless they are significant. Progressive changes in any of the three tests (ONH, RNFL and VFs) are marked as 'progression' in the EHR. Progression leads to increase in medication, laser therapy and/or surgery, taking simultaneously into account the severity of the damage, the progression rate and patient's age, as recommended in the Finnish Guidelines (The Finnish Medical Society Duodecim, 2023).

Although reimbursement of medication requires the 2 out of 3 criteria for glaucoma, they may not have always been strictly followed, which may lead to over-diagnostics and over-treatment. For example, patients may be referred to Tays by private practitioners who may have already started the treatment and given a glaucoma diagnosis to the patient, sometimes even years before visiting Tays.

2.5 | Ethics and governance

This study was approved by the Tays Research Services (number R21519/2021) and was conducted in accordance with the Declaration of Helsinki. The Ethics Committee of Pirkanmaa Wellbeing Services County does not require ethics approval for this study as it evaluates aggregated unidentified real-world data of glaucoma patients.

The use of EHR data in this study complies with the Finnish legislation, data security regulations of Tampere University Hospital and the Finnish recommendations on research ethics. In Finland, a separate law has been decreed on the Act on the Secondary Use of Health and Social Data (552/2019) (Ministry of Social Affairs and Health, 2019b). The purpose of the Act is to facilitate effective and safe processing and access to the personal social and health data for steering, supervision, research, statistics and development in the health and social sector. A second objective is to guarantee an individual's legitimate expectations as well as their rights and freedoms when processing personal data. According to the Act on Secondary Use of Health and Social Data, patients' personal data can

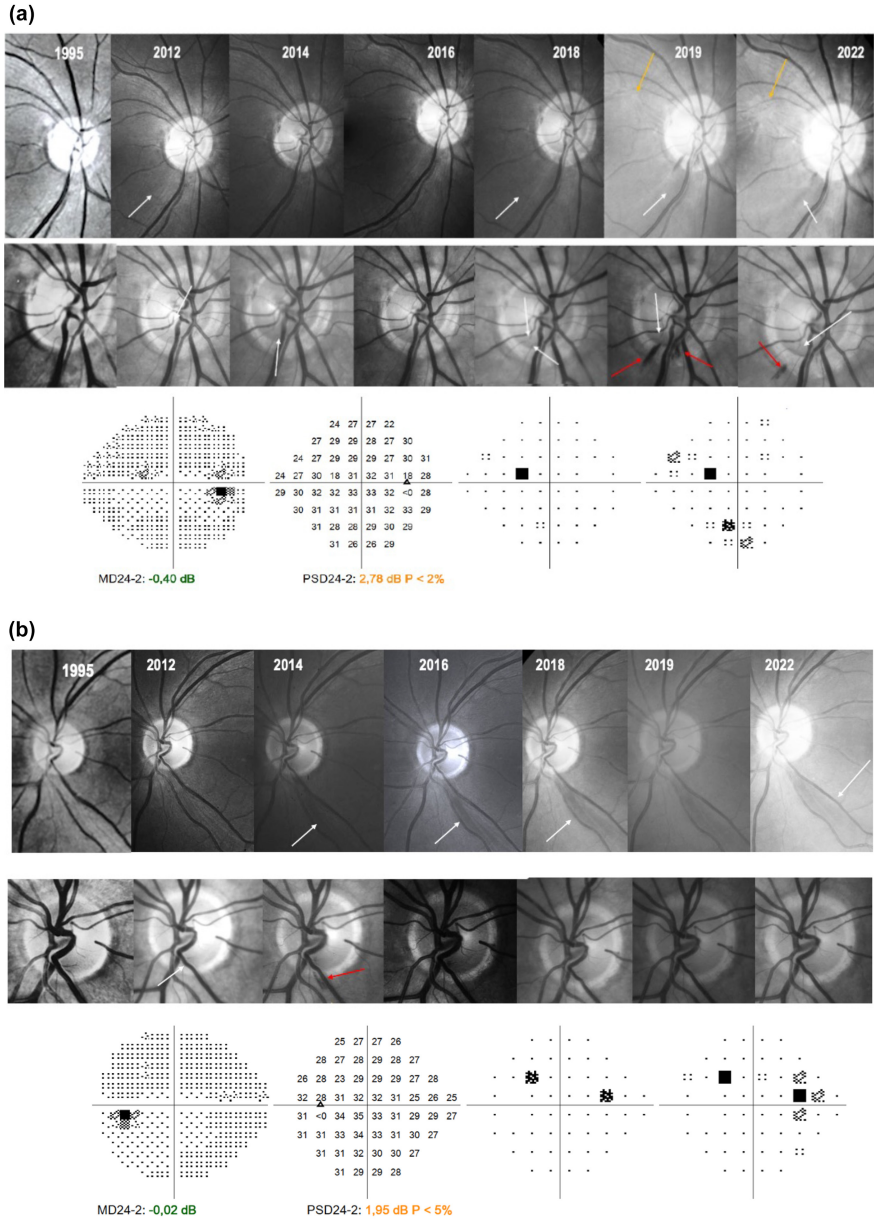

FIGURE 2 2a (right eye, above) and 2b (left eye, below). A 27-year follow-up of ONH and RNFL pictures and the latest visual field taken in 2022. The patient was examined in Tays Eye Centre for the first time in 2012 and brought a picture taken in 1995. Treatment had been started in 2006. The white arrows in the ONH and RNFL pictures indicate the areas of progressive changes, the red arrows optic disc hemorrhages and the yellow arrows epiretinal membrane. Glaucoma Hemifield Test of the visual field indicated abnormality in 2022 in the right eye and since 2015 in the left eye. The glaucoma risk regression model G-RISK of the ONH (Hemelings et al., 2023) yielded a positive trend of about 0.01 risk increase per year which matches with the clinically detected progression.

be managed without informed consent in officially audited and secured environments under the permission granted by the organization responsible for patient care, in our case by Tays, Tampere University Hospital. The audit of Tays secured environment was carried out in April 2022 by auditing companies approved by the National Supervisory Authority of Welfare and Health. The secured environment was added to the Toini database (the National Supervisory Authority of Welfare and Health, 2023).

The EHR data have been transferred and are stored in a secured environment based on Azure cloud technology in Tays Research Workspace. The research group has been provided a virtual server in its own sandbox with no direct internet connections. The authentication of each member of the research group is verified with unique username and password. Remote access to the sandbox is done using secure, encrypted virtual private network (VPN) connection. The service provider loads both source data and needed software programs into the sandbox, allowing also transferred learning for the artificial intelligence (AI) algorithms. All data and AI programs used in the Workspace will be audited/inspected before entered or taken out.

3 | RESULTS

Table 1 presents the patient data and distributions in different diagnostic groups as recorded in EHR, history of procedures prior to 2019, other eye diseases, medications and the interval for the patients' next visit to Tays Eye Centre.

The mean ages were higher for the patients with primary open-angle, normal-tension and exfoliative glaucoma (74–80 years) compared to glaucoma suspects (65 years) (Table 1). The patients with a glaucoma secondary to another eye disease were the youngest (mean ages 57–61 years). Female gender dominated in all groups (59%–68%) except for patients with secondary glaucoma due to another eye disease (40%–47%). 44% of the follow-up glaucoma test sets were appointed within 1 year and another 44% within 2 years. The data entry for the next control visit was missing in 11% of all eyes, most commonly (37%) in suspected glaucoma (Table 1).

Table 2 presents the different subgroups according to the 2 out of 3 rule: '≥2/3 glaucoma' (35%), '≤1/3 glaucoma' (33%), '≤1/3 suspected glaucoma' (24%) and mixed glaucoma (9%) groups. VFs, ONH and RNFL images were clinically evaluated in 95%–98% of all eyes. VFs were recorded normal in 50% and glaucomatous in 30% of all eyes. In the '≥2/3 glaucoma group', 76% of eyes had glaucomatous VF defects compared to 2%–13% of eyes in the other subgroups. The mean deviation (MD) was recorded in 76% of cases with the lowest median of −6 dB in the '≥2/3 glaucoma group' compared to the median of −1 to −2 dB in the other groups. Among all eyes, the MD was better than −6 dB in 68%, between −6 dB and −12 dB in 17%, and worse than −12 dB in 13% of eyes (Table 2).

RNFL was recorded normal in 47% of all eyes and glaucomatous in 33%. ONH images were recorded to be glaucomatous more often (44%) than VFs (30%) and RNFL images (33%) (Table 2). No cases were excluded from the data of patients visiting the Medical Glaucoma Clinic. Other than a glaucomatous abnormality was recorded in 8% of VFs and in 2% of both ONH and RNFL images. Poor quality or no VF was recorded in 12% of all eyes, and poor picture quality or no picture was recorded in 3% for ONH and 19% for RNFL, respectively (Table 2).

The mean number of medications in the '≥2/3 glaucoma group' was 2.2, with the highest mean of 2.5 medications in eyes with secondary glaucoma due to another eye disease. In the '≥2/3 glaucoma group', 31% of eyes had received laser treatment and 10% glaucoma surgery (Table 3). The evaluation of progressive changes in any of the tests (ONH and/or RNFL and/or visual tests) over time was recorded in 82% of all eyes. The highest progression rate was reported in the '≥2/3 glaucoma group' (35%) compared to 2%–9% in the other groups (Table 2). The mean IOP was 14–15 mmHg (median 13–15 mmHg) in all groups except for suspected glaucoma with the mean and median of 17 mmHg. Target and maximum tolerable IOPs were recorded for 94%–95% of eyes (Table 2).

In glaucoma suspects, the IOP distributions of the untreated IOP were ≥27 mmHg in 21% of eyes, between 22 and 26 mmHg in 31% of eyes and <22 mmHg in 43% of eyes. In these eyes with glaucoma suspicion, 86% were evaluated as ≤1/3 abnormal findings in ONH, RNFL and VFs and 2% were recorded to have progressed compared to previous visits. Similar to eyes with a glaucoma diagnosis, ONH was evaluated to be glaucomatous more often (10%) compared to VF tests (2%) or RNFL (3%) in glaucoma suspects.

4 | DISCUSSION

The European Expert Panel on Effective Ways of Investing in Health has published recommendations for digital transformation of health services (ExPH, 2018): 1. develop a strategy for the digital transformation and evidence-informed policy measures to support decision-making, 2. develop and invest in coherent framework for monitoring and evaluation methodology, 3. create an environment that can adopt innovations and 4. be progressive with caution. As a follow-up for the published decision-making and monitoring strategies in Tays Eye Centre (Tuulonen et al., 2009, 2016), the current article describes the first step in the development of a framework for continuous monitoring and evaluation of what gets done in everyday glaucoma care with respect to the defined strategies, which was further developed into the *aces-rwm*™ ecosystem by all five Finnish University Eye Clinics (Tuulonen et al., 2022).

When using EHR systems, the rate of recorded complete examination findings has been reported to be significantly higher than in paper records (Sanders et al., 2013). Systematic collection and comparison of EHR-RWD between different providers and countries also create a potentially efficient platform for future innovations, for instance, using AI for predicting the

TABLE 4 Comparison between Tays and UK data, which are partly differently reported.

	Tays Eye Centre 2019	UK 2016 (Fu et al., 2023)
Population	0.53 mill.	Not reported
Patients	4618	21 719
Mean age, years	71	72
Female	62%	52%
White ethnicity	100%	91%
Dg recorded (eyes)	86%	82%
POAG	33%	36%
Other and mixed	39%	20%
Suspect/OHT	28%	41%
IOP, mean	All eyes 15 mmHg	Lower 17 mmHg
MD recorded	76%	66%
Eyes	All eyes −3 dB	Better eye −2.7 dB
POAG	All eyes −6 db	Worse eyes −5.4 dB
> −6 dB	All eyes 68%	All eyes 70%
−6…−12 dB	17%	16%
< −12 dB	13%	14%
VA recorded	100%	57%
ETDRS letters	74	80
No medications	38%	45%
Procedures	9%	7%
Laser trabeculoplasty	14%	1%
Cost per patient	443 €	405 £
Visits per patient, mean	1[a]	2

[a]1.4 visits per patient when also 2500 visits related to surgical consultations and procedures are included for which no clinical data were available in 2019.

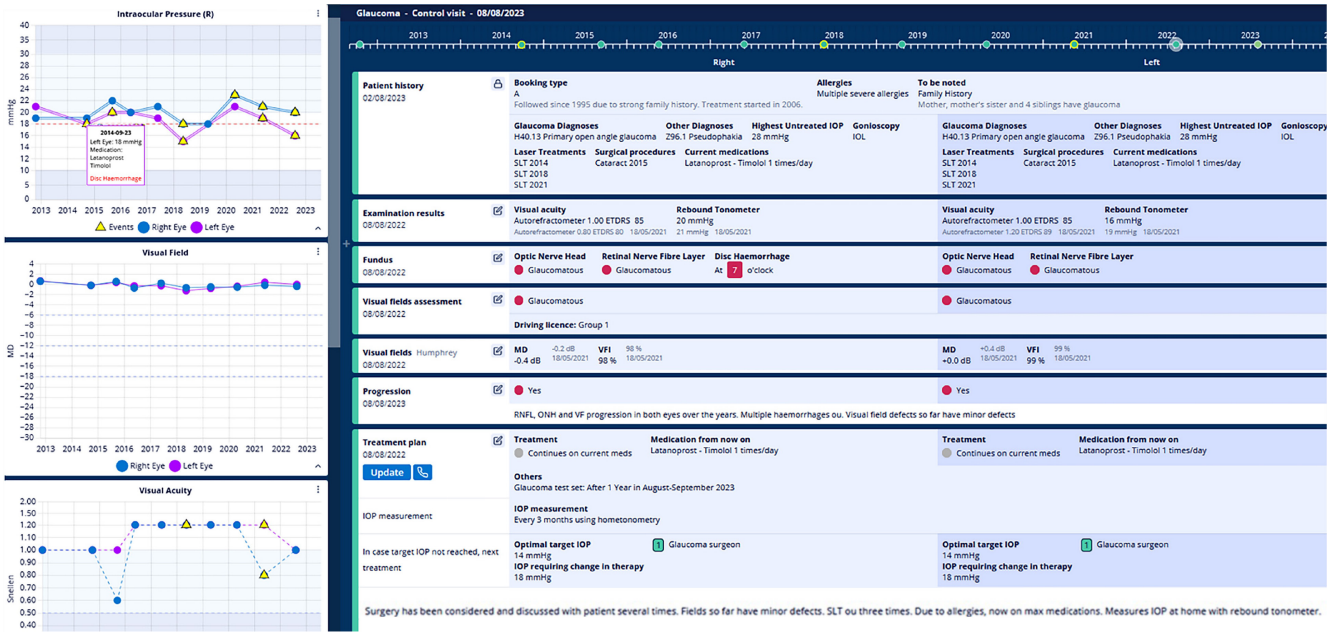

FIGURE 3 The clinical data in 2012–22 of the patient presented in Figures 2a and 2b were entered into the structured glaucoma-specific EHR, which has been developed using the prototype described in this study (Tuulonen et al., 2022) (Avenue Flow, Optomed Plc, Finland). On the IOP graph on the left, the number of lines refers to the number of medications, which can be read by clicking the visit. The triangle refers to events (e.g., laser trabeculoplasty, disc haemorrhage or progression). On the right, the clinical data are presented in the last visit in 2022. In each visit, previous entries are available enabling to change only required parameters. The swim lane on the top presents the previous visits and the planned next visit with the yellow circle indicating a procedure. The patient responded to health-related quality of life 15D (Sintonen, 2001) questionnaire in 2020. Both total and vision scores were normal (1.0).

progression of glaucoma (Ting et al., 2019, Figures 2a and 2b) and for genetic association studies (Restrepo et al., 2015). So far, there has been limited evidence of incorporating EHR-RWD in AI algorithms and no prospective studies, for example, to demonstrate how well AI algorithms could predict the development of glaucoma (Ting et al., 2019). Most studies have collected EHR data from surgical cases of glaucoma only (e.g., Sun et al., 2022; Wang et al., 2022). The updated version of the structured glaucoma EHR (Figure 3) will be implemented into routine use in 2023 and will also enable prospective RWD study designs.

In England, EHR data of 45 309 patients from five different regions showed that less than one-fifth of OHT patients converted to glaucoma over a 5-year period, suggesting that many patients may require less intensive follow-up (Kelly et al., 2020). In 2023, Fu et al. published another UK study with at least 1-year EHR data in 2013–18 in five clinics in the National Health Service, including 43 742 patients. They also suggested that glaucoma care within the NHS Hospital Eye Service seems to be disproportionately directed towards patients with mild, low-risk glaucoma, who may be more appropriately managed using alternative models of care. Fu et al. (2023) proposed measures to reduce demand in hospital glaucoma clinics such as virtual clinics to remove the need for face-to-face clinician consultations, longer intervals between follow-up visits when appropriate and discharge of low-risk patients and ocular hypertensive patients, that is, all measures already implemented in Tays Eye Centre. Interestingly, the UK 2016 EHR data (Fu et al., 2023), including cost level, were very similar to our 2019 data (Table 4), except for the proportion of suspicions being smaller in Tays. In another UK study (Kelly et al., 2020), the interval between VF tests was 10–11 months for glaucoma suspects, OHT and glaucoma patients, that is, shorter compared to the test intervals of 1 year (44%) and 2 years (44%) in Tays Eye Centre (Table 1).

In spite of the differences, the yearly reports between Tays and the UK seem however surprisingly similar to each other in many aspects (Table 4), as well as between different years during the UK study (Fu et al., 2023). This raises an incentive to search for ways to further improve the long-term reporting and analysis protocols on how to compare and improve cost-effectiveness on everyday clinical outcomes. Although the resource allocation (e.g., longer test intervals, smaller proportion of suspicions and implementation of virtual clinics) in Tays Eye Centre seems different compared to the UK data set, obviously our data as presented in this article cannot be used to assess whether the glaucoma care protocol in accordance with the Finnish Guidelines would lead to same or different long-term outcomes in respect of preventing glaucoma-induced visual disability.

Similar to efficacy trials, it is also extremely important to create minimum standard framework for big data sets to be used by researchers and clinicians to improve the design of RWD studies and enhance transparency of study methods (Kotecha et al., 2022). The CODE-EHR best-practice framework prefers a pre-published protocol for each of its 5 items in the checklist (Kotecha et al., 2022). Publishing our first version of the EHR reporting protocol according to the CODE-EHR checklist, to the best of our knowledge for the first time in eye care, offers an opportunity for current and future collaborators to evaluate and compare RWD sets and to suggest how the reporting and benchmarking protocols could be further improved.

The first year also clearly revealed opportunities to improve the data recording in Tays. For instance, although VFs evaluations were recorded for 95% of eyes, MD values were recorded only for 76%. To ensure complete recording, similar to VA measured using an autorefractometer, the automated transfer of MD data to EHR was implemented in 2020. Obviously, evaluation protocols for follow-up RWD need to be developed next. Because Tays Eye Centre is the first one in Finland to use a structured glaucoma-specific EHR, our study is also the first one to report glaucoma care using the '2 out of 3' rule, as recommended in the Finnish Glaucoma Guideline.

A single-centre RWD report may be considered a limitation. Baxter et al. (2021) predicted the need for glaucoma surgery using EHR data. They reported that national data achieved superior performance compared to single-centre data. However, a combination of RWD sets from many units may simultaneously unintentionally hide substantial unwarranted variabilities between centres (Tuulonen et al., 2022) and thus prevent identification and reduction of variability. Single-centre RWD sets analysed in the perspective of their population and service area, as in our study, may also promote a better understanding of both under care and over care as well as cost-effectiveness.

During the next steps, our 2019 data will be compared to the manually collected RWD in 2012–17 in Tays Eye Centre – especially by trying to identify factors predicting the progressive changes detected in the 2019 data set – as well as to serve RWD benchmarking purposes in Finland and internationally. More than 200 000 digital ONH and RNFL images have been transferred to Tays Research Cloud to be analysed by AI algorithms (Figures 2a and 2b). In addition, the use of different medications, including their costs and reimbursement data from pharmacies will be analysed and reported separately, enabling also evaluation of treatment compliance. In addition to clinical and cost data, evaluation of cost-effectiveness also requires utility measures. Both Tampere, since 2019, and Helsinki, since 2022, University Hospitals have been measuring health-related quality using a 15-dimensional (15D) instrument (Sintonen, 2001) (Figure 3). 15D has been reported to be sensitive also in evaluating glaucoma care (Hagman, 2013). The first 5-year 15D data of glaucoma patients in Tays Eye Centre will be analysed separately.

Finally, the experiences derived from this first prototype glaucoma EHR have been extremely valuable when the five Finnish University Eye Clinics invited tenders in 2019 for the development of next-generation tailor-made data collection and analysis tool package for the 'big four' eye diseases, that is, not only for glaucoma, but also for age-related macular degeneration, diabetic retinopathy and cataract (Tuulonen et al., 2022) (Figure 3). The new Avenue Flow tool package (Optomed Plc, Finland) for glaucoma that will be implemented into routine use in 2023, will include also records for surgical consultations and procedures. Special attention has been paid to the single-entry user-friendliness and evaluation of long-term trends to deallocate the professionals' time on clinical decision-making (Figure 3). The aim of the glaucoma-specific EHR is to aid continuous routine monitoring and evaluating our everyday glaucoma care. With easy access to structured individual and aggregated patient data, we will have better opportunities to target our efforts for improved care.

AUTHOR CONTRIBUTIONS

Concept and design: AT. Analysis, interpretation and writing: SS, SL, EL, PH, HU-J and AT. AI-analysis: RH and IS. Data collection: SS, EL, SL, US and AV. Overall responsibility: HU-J.

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CONFLICT OF INTEREST STATEMENT

SS, SL and EL have nothing to declare. PH and AV received Santen lecture and congress fees. AT Business Finland has supported Tays Eye Centre to bid development of tailor-made *aces-rwm*™ data collection and analysis tool package, and the project led by AT. HU-J was the advisory board member for Abbvie, Bayer, Novartis and Roche and received lecture fees from Santen. IS received grants from Santen and Théa Pharma; consultancy fees from Aerie, Alcon, Allergan-Abbvie, Eye-D Pharma, Horus Pharma, Santen and Théa Pharma, and co-founder, shareholder and consultant of Mona.health, a KU Leuven/VITO spin-off to which the G-Risk model was transferred. RH received consultancy fees from Mona.health, to which G-RISK has been transferred. Under the terms of employment at KU Leuven, RH is entitled to stock options in Mona.health.

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