Monitoring of stable glaucoma patients

institute of Health Policy & Management

Evaluation of the effectiveness and efficiency of a Glaucoma follow-up unit, staffed by nonphysician Health Care Professionals, as an intermediate step towards glaucoma monitoring in primary care

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1 Introduction

A high workload for ophthalmologists and long waiting lists for patients challenge the organization of ophthalmic care. Tasks that require less specialized skills, like the monitoring of stable (well controlled) glaucoma patients could be substituted from ophthalmologists to other professionals (substitution in person). In addition, care could perhaps be provided in an ambulatory setting (substitution in location of care). To date, little is known about substituting care in ophthalmology, the organizational and professional dynamics involved and any consequences for both the quality of care and cost effectiveness.

Glaucoma is the name given to a group of eye diseases characterized by damage to the optic nerve yielding gradual, irreversible loss of visual field. Glaucoma is often related to too high an intraocular pressure (IOP) and is age related. The usual care for glaucoma patients consists of diagnosis, lifelong monitoring, and treatment and is provided by ophthalmologists. However, monitoring stable glaucoma patients will presumably not require the specialist expertise of an ophthalmologist and may be carried out by less specialized professionals. Therefore, the quality of care given to stable glaucoma patients was evaluated when provided by ophthalmic technicians or optometrists based on pre-set protocols and under supervision of ophthalmologists in a Glaucoma follow-up unit (GFU) within The Rotterdam Eye Hospital (REH).

The objective of this study is to evaluate an organizational intervention, a GFU for monitoring stable glaucoma patients in a hospital setting, staffed by non-physician Health Care Professionals instead of ophthalmologists. Furthermore, conditions will be formulated that need to be fulfilled to successfully substitute the monitoring care for stable glaucoma patients to a primary care optometrist (substitution in person as well as in location). The conditions will be based on the experiences with the GFU (substitution in person only).

Research questions to be answered are:
1. What are the effects of the GFU on the quality of care, on patient satisfaction and on the satisfaction of health care providers (HCPs) involved, compared to usual care? Is the care delivered in the GFU at least equivalent to the care provided by ophthalmologists?

2. What are the costs of the ophthalmologists' usual care, versus those of the care provided by the GFU, for the patient, the hospital, the health care system and the society?
3. Which conditions need to be fulfilled (about both quality and costs) to eventually succeed in implementing glaucoma monitoring care for stable patients by optometrists in a primary care setting?

1.1 Realisation study aim and research questions

During this study, the GFU was compared with usual care based on the quality of care, the satisfaction of patients, the satisfaction of the HCPs and costs. Additionally, interviews with stakeholders gave us information about the conditions that need to be fulfilled in order to successfully implement glaucoma monitoring for stable patients by optometrists in the primary care setting.
All objectives have been achieved and all research questions could be answered.

2 Methods

To answer the respective research questions, we undertook the following studies:

1. Randomised Controlled Trial (RCT) and a process evaluation
2. Cost-effectiveness analysis
3. Feasibility study

2.1 The RCT

2.1.1. Main outcome measures

The main outcome measures of the RCT were (1) Quality of care: compliance of the GFU employees to the standard working protocol; frequency and results of examinations performed; treatment changes; (2) Patient experiences: the overall mark given for the care delivered; information about the visit; visit expectations; knowledge of the HCP; opinion about the waiting area.

2.1.2. Details of study population

1) Patients were those with stable glaucoma as assessed by a glaucoma specialist (follow-up visit scheduled for 6 months or more) and patients who are at risk for developing glaucoma.
2) HCPs were ophthalmologists specialised in glaucoma, ophthalmic technicians, hospital optometrists.

2.1.3. Patient selection and Randomisation

Patients who visited a glaucoma specialist or who visited the GFU between September 2005 and April 2006 were considered eligible for inclusion. The manner of patient selection differed depending on whether the patient visited the glaucoma specialist or the GFU before inclusion.
(1) Glaucoma specialist: Once the glaucoma specialist decided during a visit that the patient was suitable for the GFU, he explained the RCT to the patient. After the visit, the medical record of the patient was sent to a member of the study team, who first assessed whether the patient met the inclusion criteria. If this was the case, the patient was randomly allocated to a treatment group using a randomisation table. After randomisation an appointment was made. The patient received the time and

date of the appointment together with written information about the trial by regular mail.
(2) GFU: The GFU started late 2004. Because the clinics of the GFU were fully occupied by patients by September 2005, we decided to include these patients. Before every GFU clinic, scheduled between September 2005 and April 2006, a member of the study team collected the medical records and assessed which patients were eligible for inclusion. The eligible patients were randomly allocated to a treatment group using the same randomisation table as with the glaucoma specialist's patients. The medical records were then given back to the HCP of the GFU. During the visit, the HCP explained the RCT to the patient and gave the patient written information. Patients assigned to the glaucoma specialist treatment group were given a new appointment with the referring glaucoma specialist. Patients assigned to the GFU treatment group and willing to participate were given a patient questionnaire and their medical records were sent to the member of the study team who collected the relevant data.
The two treatment groups were balanced for 2 predetermined stratification variables: the referring glaucoma specialist, and the time to the next scheduled visit, being either ≤ 6 months or > 6 months.

2.1.4. Inclusion criteria
To be eligible for the study, patients had to meet the following criteria:
(1) the patient was referred to the GFU by a glaucoma specialist of the REH;
(2) the patient had a diagnosis of glaucoma in one or both eyes or had a risk factor for glaucoma, i.e. high IOP and / or a positive family history;
(3) the optic disc, macula, and the fundus periphery were examined;
(4) the next scheduled visit of the patient was in ≥ 6 months;
(5) the target pressure (TP) of the glaucoma patients was noted in the medical record. The TP of patients with a risk factor for glaucoma was, by default, ≤ 30 mmHg, unless other risk factors called for an explicitly lower TP;
(6) the actual ophthalmic medication was written in the medical record;
(7) the patient's Snellen visual acuity in each eye equalled ≥ 20/100 and/or the patient had no loss in the central visual field, as measured by a Humphrey Field Analyser, standard 24-2 test algorithm (HFA 24-2; Carl Zeiss Meditec, Dublin, CA, USA)
(8) the patient had no other significant ocular disease;
(9) the patient had not undergone laser therapy for diabetic retinopathy;

(10) the patient had a refractive error between + 5 and – 8 dioptres (spherical equivalent).

2.1.5. Patient Visits

The care provided in the GFU, the back referral criteria to the glaucoma specialist, and the 'care as usual' (glaucoma specialist group) are described in Table 1.

Activity	Glaucoma specialist	GFU	Criteria for back referral
1. short history	every visit	every visit	
2. IOP*	every visit	every visit	IOP > Target Pressure
3. Snellen visual acuity	as required, minimally once yearly	every visit	decline in visual acuity of ≥ 2 lines
4. optic disc assessment	every visit	never	
5. GDx ECC**	at doctor's request (approx. once yearly)	every visit	- suspicion of progression - in case of 1st GDxECC; NFI > 35 and/or left/right asymmetry and/or local defect
6. HFA 24-2***	at doctor's request (approx. once yearly)	- once a year in moderate to advanced visual field damage**** - at doctor's request	suspicion of progression
7. overall judgement	every visit	every visit	
8. timing of the next appointment	every visit	every visit	
9. medical prescriptions	every visit	every visit	

* Intraocular pressure by applanation tonometry

** GDx ECC (Carl Zeiss Meditec, Dublin, CA, USA) scanning laser polaritmetric images

*** Humphrey Field Analyser, standard 24-2 test algorithm (HFA 24-2; Carl Zeiss Meditec, Dublin, CA, USA)

**** Criteria moderate/severe visual field damage: the mean deviation (MD) of the last performed visual field was ≤ - 5dB

2.1.6. Data collection

To obtain quantitative data to investigate the quality of care, a member of the study team filled in a Case Report Form (CRF) after each patient visit using the relevant information form the medical record. A different member of the study team checked the CRF before entering it into the computerized system.

A patient questionnaire was designed to score the patients' experiences with the care they received. It addressed the following issues: general/overall satisfaction, courteousness of professionals, HCP/patient communication, professionalism, ease

and time to get an appointment, and some basic questions related to costs (i.e. travelling time, travelling costs).
This was an existing questionnaire, which was previously tested for validity and reliability[1], supplemented with relevant patient cost questions. It was given to the patients after each visit.
The accuracy of the data was monitored regularly by selecting random samples of CRFs and patient questionnaires and then comparing the data entered into the computerized system with the original forms.

2.1.7. Statistical Analysis

To investigate whether there were differences between the treatment groups at baseline and during the study period, we used independent T-tests. When there was no normal distribution we used a chi-square test and Mann-Whitney for independent groups and the Wilcoxon signed rank test for dependent groups. All statistical tests were two sided and were performed at the 5% significance level

2.2 Process evaluation

During the study period, the working processes and implementation of the GFU were carefully monitored. We focused on organizational changes and on changes in the functioning of the GFU after implementation
The process evaluation consisted of a content analysis of relevant documents, 15 semi-structured interviews with the involved employees (i.e. glaucoma specialists, and employees of the GFU), and a logbook with observations was kept by the primary researcher.

2.3 Economic Evaluation

We performed a cost-effectiveness analysis from four perspectives to answer the second research question. In patients with glaucoma, a difference in health outcomes between the GFU and the ophthalmologist group was not expected in the current study, because of the slowly progressive nature of this disease. Therefore, the costs will not be related to health outcomes, but costs and quality of care outcomes will be linked in the overall results. In case the quality of care is equal for the usual

ophthalmologist care and that of the GFU, the economic evaluation becomes a cost minimization analysis.
The perspectives used were those of the patient, the eye hospital, the health care system and the societal perspective.
In any economic evaluation three steps are necessary to estimate the costs:
1. identification of the relevant cost items;
2. measurement of the utilization per item: the estimated amount of consumption (or time);
3. valuation of the cost items: determining the costs per unit (e.g. a visit to an optometrist)

2.3.1. Identification
The following relevant cost items were identified by interviews:
• health care cost of visits to the ophthalmologist;
• health care cost of visits to the GFU;
• health care cost of referral visits to ophthalmologists;
• health care cost of visits to the perimetry department for the GDx and HFA;
• health care cost of medication;
• health care cost of surgery related to glaucoma (including laser therapy);
• cost of patient time related to all types of visits;
• travelling costs related to the visits;
• implementation costs of the GFU.

2.3.2. Measurement
During the trial, the number of visits and the medical procedures performed during each visit were recorded for each patient in a CRF. The durations of these visits were measured in a sample of these visits. If the GFU HCPs needed more (or longer) consultations to establish the same effectiveness, this would then be observed.
Every visit, glaucoma patients were given a questionnaire that we developed to report their travelling distance, mode of transport, travelling time, waiting time and working status, in order to calculate the travelling and time costs for patients in case of hospital care.
The proposed substitution of care to the GFU required organizational changes and hence implementation costs within the hospital. The most important changes were the initial and structural training of the employees of the GFU, writing the standard treatment protocol, additional supervision and monitoring by ophthalmologists. To collect this information, HCPs at the GFU, as well as the ophthalmologists were

interviewed. These costs were added to the costs of a GFU visit as implementation costs for the GFU.

2.3.3. Valuation

All costs were calculated for 2007. The total costs for each type of eye care visit were calculated, including personnel costs, administrative costs, cost of equipment and overhead costs, using our cost estimates based on data provided by the financial administration of the REH. The calculations were done according to the CVZ (The Health Care Insurance Board) costing guidelines and previous research in the REH[2,3]. We used information on costs per unit as produced for the internal budget allocation of the REH. Location costs, interest and costs of medical specialists are included in this information. Only for the costs of non-laser operations, another method was used. The DBC price (a fixed reimbursement rate for a specific diagnosis related therapy) in 2007 was used as a proxy of the real costs, because of the probable transfer of the reimbursements of glaucoma care from the so-called A-segment to the B-segment in 2009. Details of this transfer are outside the scope of the current project.

Relevant items from the CVZ costing guidelines[4], were updated and used for the calculation of patient time costs per hour and travelling costs per kilometre. As the implementation costs were dominated by personnel input, personnel costs per hour was the relevant valuation component.

If appropriate, missing values were replaced by values known from other visits of the same patient. In all other cases, the data from a comparable group of patients were imputed to the missing values.

2.3.4. Cost results

For both treatment options, the total number of visits (per type) was aggregated for all patients and combined with the costs per unit to derive the total health care costs of all visits. We calculated the patient costs using the information of the patient questionnaires combined with the updated time and travelling costs per unit of time and per kilometre.

The implementation costs were calculated as a combination of the additional time investments of all types of personnel as described above multiplied with their respective personnel costs.

The initial implementation costs that were only made before starting the GFU, were spread over 5 years. The structural costs per year were added to the initial

implementation costs per year. The implementation costs per visit were based on the number of visits in 2007 (1598).
The costs have been expressed as average costs per patient per study year and average costs per patient.

2.3.5. Statistical analysis
We used SPSS 15.0 to analyse the data. Since all cost variables were not distributed normally, we performed the parametric Mann-Whitney U-test to compare the two treatment groups.

2.4 Feasibility study

As mentioned previously, the GFU was considered as an intermediate step towards transferring the monitoring of stable glaucoma patients out of the REH. The ultimate aim was to refer stable glaucoma patients and patients at risk for developing glaucoma to primary care optometrists (i.e., a twofold substitution, both in person and in location). There were two motives for this twofold substitution. First, key stakeholders assumed that substitution would decrease the workload of the physicians and waiting lists for patients. Secondly, it would enforce the relationship between primary care optometrists and the REH, which might consolidate or even expand the number of patients consulting the REH in the future.
During the RCT and costing study it became clear that transferring the monitoring of stable glaucoma patients towards ophthalmic technicians (i.e., substitution in person) is probably as safe and effective as the normal monitoring by ophthalmologists. This preliminary outcome supported the idea of exploring the feasibility of transferring the care for this group of patients out to primary care optometrists (i.e., substitution in person and in location).

We conducted a qualitative study to explore the feasibility of the substitution of care to primary care optometrists, organizationally unified in the so-called Optometristen Collectief Rijnmond (OCR). The OCR already collaborates with the REH. The study consisted of a content analysis of relevant documents (e.g., annual reports, policy briefs) and of 27 semi-structured interviews with a purposeful sample of all stakeholders involved: ophthalmologists, optometrists, hospital managers, healthcare insurers, the Dutch Healthcare Authority and patients (see Table 2). The data gathered was analysed against a theoretical framework using theories on

professionalism, hospital management, quality systems and applied political analysis [5,6]. If the results of the feasibility study show that substitution of care to primary care optometrists is possible the willingness to accept by the primary care optometrist will be explored.

Table 2. Stakeholders interviewed

Stakeholder	Number	Clarification
Management of the Rotterdam Eye Hospital (REH)	4	CFO, CEO, Manager of the Eye Care Network, Advisor concerned with optometry relations
Ophthalmologists	4	All 4 glaucoma specialists of the REH
Primary care optometrists	6	4 were self-employed, 2 worked in an optic store chain, 5 participated in the Optometristen Collectief Rijnmond
HCPs of the GFU	5	1 optometrist and 4 ophthalmic technicians
Patients	5	1 representative of the Dutch Glaucoma Patient Association, 4 participated in the RCT: 1 in the arm of the specialist and 3 in the GFU arm
Healthcare insurers	2	Two representatives of the major health insurers in the Rotterdam region
The Dutch Healthcare Authority (Nza)	1	Senior policy advisor

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3 Results

3.1 The RCT

The enrolment of patients began in September 2005 and ran through March 2006. A total of 866 patients were included. There were no significant demographic or clinical imbalances between the treatment groups (Table 3). 51 patients (6%) did not visit the REH in the study period. Of these, 30 patients were no shows, 14 moved their appointment to a date after the data collection ended, 2 underwent cataract surgery and had no glaucoma related appointment in the study period. The exclusion of these patients did not lead to any significant differences between the treatment groups. The only difference between the excluded and included patients was their follow-up time. The follow-up time is the time the glaucoma specialists write in the medical records for a next appointment. The excluded patients (10.9 months, SD ± 2.3), had a significantly longer follow-up time compared to the included patients (9.6 months, SD ± 2.9, sig. 0.001).

We collected information from 2100 visits brought by 815 patients. The average time between visits was 8.8 months, SD ± 4.0. There were no differences between the treatment groups.

Table 3 Characteristics of Included Patients, by Treatment Group

	Glaucoma Follow-up Unit (n = 405)		Glaucoma Specialist (n = 410)	
	n (%)		n (%)	
Age (years)				
Mean ± SD	63.0 ± 12.1		63.1 ± 11.9	
Gender				
Women	218 (54)		214 (52)	
Follow-up time (months)				
Mean ± SD	9.8 ± 2.9		9.5 ± 2.9	
Intraocular pressure (mmHg)				
	Right eye	Left eye	Right eye	Left eye
Mean ± SD	18.68 ± 4.1	18.47 ± 4.1	18.76 ± 4.2	18.76 ± 4.1
Target intraocular pressure (mmHg)				
	Right eye	Left eye	Right eye	Left eye
Mean ± SD	25.1 ± 5.2	25.2 ± 5.2	25.2 ± 5.4	25.1 ± 5.4
HFA				
Mean Deviation ≤ -5 dB	34 (4)		34 (4)	
Medication				
No medication	172 (42)		182 (44)	

3.1.1. Compliance of the GFU employees

In table 1 we described the care GFU employees should provide according to the standard working protocol. A total of 853 visits were brought to the GFU. During those visits, almost every time (> 97.5%) the required tests were performed (table 4. 1 Examinations). The only exception was the HFA. Thirty four patients of the GFU treatment group needed to be monitored with an HFA on a yearly basis, but 20 of these did not perform the test during the study period. In total 43 HFAs were performed in the GFU during the study period. Table 4.2 shows whether patients were referred back to the glaucoma specialist, as the protocol required. In 50% of the required cases they were not referred back to the glaucoma specialist. This mainly happened if the patient had a decline of visual acuity of 2 lines of more.

Table 4 Compliance to the Standard Working Protocol by the Glaucoma Follow-up Unit Employees

1. Examinations (n= 853) (%)		
Intraocular pressure		
	Right eye	850 (99.6)
	Left eye	850 (99.6)
Snellen visual acuity		
	Right Eye	847 (99.3)
	Left Eye	843 (98.8)
Optic Nerve		
	GDx ECC	832 (97.5)
	HFA	43 (5.0)
2. real / protocol required back referrals (%)		
Total		55 / 110 (50)
	Reasons: *Intraocular pressure > Target Intraocular pressure*	16 / 24 (66.7)
	Snellen visual acuity decline of 2 lines or more	27 / 75 (36.0)
	Suspicions of progression GDx ECC	23 / 25 (92.0)
	Suspicion of progression HFA	3 / 4 (75.0)

3.1.2. Care delivered by treatment group

Every third visit of the patients assigned to the GFU treatment group was paid to a glaucoma specialist. We compared the care delivered by treatment group, this means that in the GFU treatment group the visits to the glaucoma specialist have been included. In table 5, the care delivered by treatment group has been compared. We were unable to detect any difference between the treatment groups with regard to the number of times the IOP was measured. In the GFU treatment group, the visual acuity and assessment of the optic disc (by GDx) was performed significantly more often than in the glaucoma specialist treatment group. Obviously, assessments

of the optic disc using the slitlamp occurred significantly more often by the glaucoma specialists than by the GFU HCPs, because these assessments were not required by the GFU protocol. The results of the various tests were not significantly different for the two study arms (Table 5.2).

Table 5 Care delivered by Treatment Group (all visits are included)

		Glaucoma Follow-up Unit (n= 1181)	Glaucoma specialists (n= 919)	P-value
1. Examinations (%)				
Intraocular pressure				
	Right eye	1171 (99.2)	911 (99.1)	0.953
	Left eye	1171 (99.2)	911 (99.1)	0.953
Visual Acuity				
	Right eye	994 (84.2)	626 (68.1)	0.000
	Left eye	992 (84.0)	627 (68.2)	0.000
Assessment of the Optic Nerve		1130 (95.7)	849 (92.4)	0.001
	of which - GDx ECC	897 (76.0)	429 (46.7)	0.000
	- HFA	71 (6.0)	71 (7.7)	0.121
	- Slit lamp	306 (25.9)	774 (84.2)	0.000
2. Results (%)				
Intraocular pressure > Target intraocular pressure				
	Right eye	88 / 1171 (7.5)	65 / 911 (7.1)	0.742
	Left eye	89 / 1171 (7.3)	68 / 911 (7.5)	0.917
Visual Acuity decline of 2 lines or more				
	Right eye	78 / 994 (7.8)	48 / 626 (7.7)	0.896
	Left eye	86 / 992 (8.7)	46 / 627 (7.3)	0.340
Suspicion of progression of the Optic Nerve				
	GDx ECC	41 / 881 (4.7)	27 / 420 (6.4)	0.179
	HFA	11 /70 (15.7)	15 / 67 (22.4)	0.319

3.1.3. Treatment changes

The glaucoma therapy was changed during the study period in approximately 15 % of the patients; this happened approximately equally often in the 2 groups (Table 6).

Table 6 Treatment changes by Treatment Group

	Glaucoma Follow-up Unit (n= 405)	**Glaucoma specialists (n= 410)**	**P-value**
At least one treatment change	57 (14.1)	63 (15.4)	0.603
Reasons: *- Intraocular pressure*	44 / 87 (50.6)	45 / 93 (48.3)	0.769
- Optic Nerve (GDx ECC, HFA)	13 / 87 (14.9)	16 / 93 (17.2)	0.680
- Intolerance to current medication	19 / 87 (21.8)	17 / 93 (18.3)	0.551

3.1.4. Patient experiences

We received 1492 questionnaires from the patients (response rate 71%).

The patient experiences will be reported in 2 ways. Patients in the GFU group visited the GFU as well as the glaucoma specialists. We wanted to report per treatment group because it summarizes the experiences of patients per treatment method. In addition, we wanted to know what the experiences of the patients were per kind of HCP.

In table 7, the experiences of the patients have been compared in several dimensions. We asked the patients to give an overall mark for the visit they paid in which a score of 1 was very bad and a score of 10 was very good. When comparing the HCPs, those of the GFU scored slightly higher than did the glaucoma specialists. Compared per treatment group, however, a similar difference did not reach statistical significance. The dimensions, knowledge, information, and waiting area had a scale of 1 (bad) to 4 (good). The GFU HCPs scored significantly lower than the glaucoma specialists on the dimensions knowledge and information. The questions about the courteousness of the HCPs were poorly filled-in by the patients. Patients were asked questions like; did the HCP provide support or did the HCP help you when you felt insecure or anxious? Did the HCP give sufficient information about what was going to happen? Because these questions were so poorly answered in the questionnaires, we have refrained from further analysing them.

Table 7 Patient experiences

	By Treatment group			**By HCP**		
	Glaucoma Follow-up Unit (n)	Glaucoma specialists (n)	P-value	Glaucoma Follow-up Unit (n)	Glaucoma specialists (n)	P-value
Overall mark (1-10) ± *SD*	8.50 (785) *1.05*	8.42 (676) *1.15*	0.147	8.56 (615) *1.02*	8.40 (846) *1.15*	0.006
Knowledge (1-4)* ± *SD*	3.84 (698) *0.42*	3.83 (625) *0.47*	0.588	3.82 (539) *0.44*	3.84 (784) *0.45*	0.044
Information (1-4)** ± *SD*	3.14 (655) *0.76*	3.20 (577) *0.70*	0.232	3.11 (511) *0.75*	3.21 (721) *0.72*	0.030
Waiting area (1-4) ± *SD*	3.20 (621) *0.62*	3.13 (584) *0.67*	0.120	3.20 (486) *0.59*	3.14 (719) *0.67*	0.318

* knowledge: did the HCP know about the patient's disease and which test were needed?

** information: did the patient know what was going to happen during the consultation?

3.2 Process Evaluation

3.2.1. General comments

The monitoring of the working process and the implementation showed that there were minor changes throughout the study period. The glaucoma specialists as well as the ophthalmic technicians said that the GFU was functioning satisfactorily. The GFU started late 2004. Today the GFU is structurally embedded in the REH. The glaucoma specialists are convinced the quality of care delivered at the GFU is guaranteed. The ophthalmic technicians enjoy working in the GFU. They appreciate the contact with the patients and the responsibility that monitoring of stable patients entails. On the other hand, the optometrist got little satisfaction out of the work. The optometrist called the work tedious. In the next section we will discuss the main findings of the process evaluation.

3.2.2. Structure and capacity

The GFU started in September 2004 with 2 clinics a week, which was swiftly expanded to 5 clinics a week. Currently, the GFU runs 7 clinics a week. In table 8, an overview of the number of patient visits is shown by the Glaucoma clinic (staffed by glaucoma specialists) and the GFU.

Table 8. Number of patient visits

Year	Glaucoma clinic	Glaucoma Follow-up Unit	Total
2003	6405	0	6405
2004	6283	14	6297
2005	7716	572	8288
2006	7447	1444	8891
2007	8623	1598	10221
2008 (until September)	6243	1390	7633

The number of patient visits is increasing. According to the glaucoma specialists and the GFU HCPs, there are enough patients to expand the GFU to 10 clinics a week. At present, however, there is not enough manpower available to staff the GFU for more than 7 clinics a week.

During the course of the study, there were a few personnel changes in the GFU. Initially, the 5 GFU clinics were staffed by 4 ophthalmic technicians and 1 optometrist. The optometrist left the REH in October 2005. He was replaced by another optometrist. This optometrist left the GFU in October 2007. Her services

were needed elsewhere in the REH. She was not replaced by another optometrist, but by an ophthalmic technician. One ophthalmic technician left the GFU in December 2006, she was replaced by another ophthalmic technician. All glaucoma specialists working in the REH at the start of the study still worked as glaucoma specialist in the REH at the end of the study. No extra glaucoma specialist was taken on.

Per consultation at the GFU, 20 minutes was scheduled, which also covered the taking of a GDx image. The consultation time has not been changed. If an HFA was required, a separate appointment had to be made. Almost all interviewed GFU employees mentioned that 20 minutes per patient was a bit tight in the beginning. Performing the tests was not a problem but talking with the patients turned out to be time consuming. Through experience, they learned to run the conversation more efficiently.

3.2.3. Distribution of responsibilities

There have been no changes in de distribution of responsibilities during the study period. The glaucoma specialists and GFU employees believed the distribution of the responsibilities was clear and needed no adjustments.

3.2.4. Protocols

The glaucoma specialists and employees of the GFU were all involved in formulating the protocols.

The referral protocol for ophthalmologists to the GFU was not changed during the study period. At the start of the GFU, patients who did not meet the inclusion criteria were sent to the GFU regularly. Ophthalmologists received verbal feedback on their referral behaviour. Currently, almost all patients referred to the GFU meet the inclusion criteria.

The standard working protocol of the GFU was satisfactory in almost every way. The visual acuity turned out to be difficult to capture in the protocol. Loss of visual acuity is usually not a sign of glaucomatous progression. Some issues were not well covered by the protocol, such as what ought to be done with patients with beginning cataract, or those requiring new glasses, or those with a frequently fluctuating visual acuity? According to the protocol, these patients had to be referred back to the referring ophthalmologist. This did not always happen. The interviewed glaucoma specialists were quite satisfied how the GFU employees acted in the spirit of the protocol, rather than to the letter.

An HFA was not always performed as required by the standard protocol. There were several reasons for these protocol violations. Firstly, patients were, mostly due to old age, not always able to perform the HFA any more. An HFA is generally far more exhausting to a patient than a GDx. Secondly, when ophthalmologists referred patients to the GFU with a follow-up time of 1 year, they were not always aware the patient required an HFA according to protocol and did not specifically request one. When the patient showed up at the GFU by appointment, it was not always possible to perform an unscheduled HFA, due to waiting lists.

3.2.5. Monitoring / feedback

All medical records of the first 200 patients visiting the GFU were checked by a glaucoma specialist. It turned out that virtually no mistakes had been made. Therefore the glaucoma specialist decided he would thereafter be checking medical records at random, about 1 out of every 10. Two other glaucoma specialists also wanted to check part of the medical records and asked the GFU employees to periodically keep a sample of them apart. One glaucoma specialist did not feel the need to check the work of the GFU. The ones who wanted to see some medical records did this whenever they deemed necessary. There were no formal meetings arranged between the GFU employees and the glaucoma specialists during the study period. Neither of the HCPs felt the need to.

3.2.6. Implementation

Although all glaucoma specialists were involved in formulating the protocols they were not all equally willing to refer patients to the GFU. Two glaucoma specialists started referring patients to the GFU from the start. A third glaucoma specialist was reluctant to refer any patients to the GFU. This glaucoma specialist generally gives the patients a relatively early next appointment to more closely control their follow-up. The GFU was considered a bridge too far, because it did not allow an equally close control of follow-up. Currently, this glaucoma specialist is referring more patients than before to the GFU. Because the experiences with the GFU have been positive over the years and positive interim results of the RCT, this glaucoma specialist has gradually become convinced that the quality of care provided by the GFU is sufficient. Another incentive to start referring ever more patients to the GFU was the increasing number of patients on the glaucoma specialist's own clinic. It was becoming more and more difficult to make additional appointments for patients.
A fourth glaucoma specialist initially refused to refer patients to the GFU. This glaucoma specialist's main concern was not the quality of care delivered at the GFU

but the consequences of referring stable patients to the GFU could have on his own clinic, and the effect the GFU would have on his workload. This glaucoma specialist was afraid the referring of patients to the GFU would change his patient mix. He expected his clinic to become more difficult, more time-consuming. Today this glaucoma specialist refers patients to the GFU but only when the people who make the patient appointments remind him that his own clinics are already overbooked. He then browses through the medical records of many of his patients to determine which of these are suited for the GFU.
Currently all four glaucoma specialists refer patients to the GFU, all at their own discretion.

3.3 Economic Evaluation

3.3.1. Study duration

The randomization procedure per treatment group has been described in the method section. Patients who were randomized to glaucoma specialist treatment group on the day of their visit to the GFU, entered the study at their next visit (to the glaucoma specialist), whereas patients who were randomized to the GFU treatment group, entered the study immediately. Therefore, the mean study duration was longer for the GFU treatment than for the glaucoma specialist group. The mean study duration for the glaucoma specialist group was 1.43 year, ranging from 0.19 to 2.40 (SD= 0.35) and 1.81 year for the GFU group ranging from 0.12 to 2.50 (SD=0,50). This difference was statistically significant ($p<0.001$). Hence, for a better comparison, we will present the costs per patient per year in most tables. The costs per patient have been described in the text only.

3.3.2. Hospital perspective

The hospital costs covered hospital visits, diagnostic procedures and further treatment, but were mainly driven by the costs of the hospital visits. There were different types of hospital visits: a visit to the glaucoma specialist, a visit to a resident, and three types of visits to the GFU, as there were three different types of personnel within the GFU. Per HCP, the duration of 10 study related visits was measured (Table 9). It also shows the composition of these unit costs per type of visit. The costs of a visit included (direct) personnel costs of the HCP, indirect personnel costs (e.g. the receptionist and outpatient administration) and overhead costs (e.g. building maintenance, management of the REH, the financial department and cleaning costs,

etc). Implementation costs of the GFU were added only to the GFU visits. They consisted of internal preparatory meetings, visits to another Dutch hospital, writing the standard working protocol and the training of the employees of the GFU.

Table 9. The composition of the unit costs per type of hospital visit in € (2007)

	Visit glaucoma specialist	**Visit resident**	**Visit GFU MOA***	**Visit GFU TOA****	**Visit GFU Optometrist *****
Costs per visit					
Total direct personnel costs	24.36	14.49	15.05	16.61	19.09
Total indirect personnel costs	5.46	5.46	6.59	6.59	6.59
Total overhead costs	29.76	29.76	35.90	35.90	35.90
Implementation costs GFU	0.00	0.00	3.08	3.08	3.08
Total costs excluding GDx	59.58	49.71	60.62	62.18	64.66
Costs GDx** **(fraction performed)**	25.00 (0.41)	22.25 (0.36)	3.05	3.05	3.05
Total costs including GDx	**84.58**	**71.96**	**63.67**	**65.23**	**67.71**
Mean visit duration in minutes	9.06	11.00	20.40	20.40	20.40

* Visit to a MOA (medical ophthalmic assistant)

** Visit to an ophthalmic technician

*** Visit to an optometrist or senior employee

**** At the start of the GFU, a GDx was purchased by the REH. The costs of the GDx performed during GFU visits, consists only of the GDx imaging device. When performed in the glaucoma specialist group, the GDx was taken separately from the visit. In that situation, the costs of a GDx image included personnel and overhead costs as well and were €61.61 based on a duration of 13.30 minutes.

The direct personnel costs were calculated based on the mean time spent on one visit as mentioned in table 9. However, the indirect personnel and overhead costs were calculated top-down, based on the mean duration of a visit in the hospital as a whole. The REH distinguishes first visits (per year) and follow-up visits. Taking into account the proportion of both types of visits per department, the indirect personnel costs and the overhead costs were based on a 9.03 minutes duration of a visit to the glaucoma specialist and resident and 10.89 minutes for a visit to the GFU.

Patients within one treatment group could have different types of visits. In the glaucoma specialist treatment group, most visits were paid to the glaucoma specialist or resident. Patients in the GFU arm, visited the ophthalmologist at every third visit

and in case the patient was thought to have an unstable glaucoma. Therefore, the hospital visit costs per visit could vary within one patient and between patients within one treatment group. Because of the different types of visits within one treatment group, the mean costs per hospital visit including GDx were 83.77 (SD=30.64) in the glaucoma specialist group and €68.34 (SD=15.66) in the GFU group. This difference in mean costs per visit between the two treatment groups was statistically significant (t-test, p=0.000).

Table 10 describes the hospital care use per patient per year for the two treatment groups. Although the number of visits per patient per year was higher in the GFU group, the difference between the two treatment groups was not statistically significant. In the glaucoma specialist group, significantly more appointments were made in the refractive unit, compared to the GFU group. On the other hand, a statistically higher number of auto-refractions were made in the GFU treatment group. The HCPs involved in the GFU also spent more time on asking advice.

Table 10. Average hospital care use per patient year for both treatment groups

	GFU	**Glaucoma specialist**	**P-value**	**Costs per unit (in €)**
Hospital visits	1.65	1.57	0.158	See Table 9
GDx ECC	1.28	0.77	0.000	61.61
HFA	0.10	0.11	0.266	158.44
Refractive Unit	0.01	0.05	0.002	32.43
Auto-refraction	0.20	0.08	0.000	4.64 - 6.59*
Pachymetry	0.02	0.04	0.246	23.17
IOP diurnal curve	0.01	0.02	0.109	92.66
Asking advice	0.24	0.10	0.000	8.19 – 15.86**
Laser treatment	0.002	0.007	0.267	78.38
Glaucoma surgery	0.002	0.001	0.558	1251.70
Patients using medication	0.57	0.59	0.614	2.53 – 18.82***

* Depending on HCP

** Depending on HCP and advising HCP

*** Costs per month

The average hospital care utilization as described in Table 10, has been translated into costs per patient year for the two treatment groups in Table 11. The total hospital costs were significantly higher for the glaucoma specialist group than for the GFU group, mainly because of the higher hospital visits costs. The costs of asking advice were modest, but significantly higher for the GFU group than for the glaucoma specialist group, as was to be expected.

Table 11. Mean hospital costs in Euros per patient per year (SD)

	GFU	Glaucoma specialist	P-value
Hospital visits (including GDx ECC)	111.93 (50.93)	133.17 (50.44)	0.000
Other tests (HFA, refraction, pachymetry, etc)	20.66 (47.03)	24.18 (48.72)	0.001
Laser treatment related to glaucoma	0.18 (2.54)	0.57 (5.18)	0.258
Glaucoma surgery	2.84 (40.35)	1.72 (34.90)	0.558
Asking advice	3.24 (5.35)	1.78 (5.13)	0.000
Total hospital costs per patient per year	138.85 (89.30)	161.43 (86.88)	0.000

3.3.3. Patient perspective

The patient costs consisted of time and travelling costs of patients and their accompaniment. Table 12 shows that the patient costs per visit were significantly higher in the glaucoma specialist group, because of higher time costs. This was mainly caused by a longer waiting time in the hospital and the higher number of patients with accompaniment in the glaucoma specialist group. Patients in the GFU group spent, on average, 44.6 minutes in the hospital against 59.4 minutes for the patients in the group of the ophthalmologist (p=0.000). The number of adults accompanying the patients was, on average, 0.25 vs. 0.29 in the GFU group and glaucoma specialist group, respectively (p=0.010).

However, because of a higher number of visits per patient year in the GFU arm, the patient costs per patient year were not statistically significantly higher anymore.

Table 12. Patient costs per visit and per patient year in Euros (SD)

	GFU	Glaucoma specialist	P-value
Patient costs per visit			
Travelling costs of patient and accompaniment	8.26 (11.83)	8.19 (12.10)	0.966
Time costs of patient and accompaniment	40.58 (28.87)	47.51 (34.36)	0.000
Total patient costs per patient per visit	48.83 (33.68)	55.70 (37.88)	0.000
Patient costs per patient year			
Travelling costs of patient and accompaniment	13.04 (17.16)	12.70 (17.87)	0.488
Time costs of patient and accompaniment	66.62 (50.20)	75.17 (61.37)	0.088
Total patient costs per patient per year	79.66 (58.51)	87.87 (68.17)	0.143

3.3.4. Health care perspective

The health care costs consisted of the hospital costs as described above and the medication costs. Table 13 shows the health care costs per patient per year. Despite higher medication costs in the GFU arm, the total health care costs per patient per year were significantly higher for the glaucoma specialist group.

Table 13. Total health care costs per patient per year in Euros (SD)

	GFU	Glaucoma specialist	P-value
Hospital costs	138.85 (89.30)	161.43 (86.88)	0.000
Medication costs	91.54 (101.37)	89.82 (100.53)	0.867
Total health care costs per patient per year	230.39 (154.57)	251.26 (146.02)	0.004

3.3.5. Societal perspective

In the societal perspective all costs were taken into account. Despite the limited difference in costs of less than 10%, the total (societal) costs per patient per year were significantly higher in the glaucoma specialist group (Table 14). The total costs per patient were €568.07 in the GFU group and €494.44 in the glaucoma specialist group (data not presented in Table 14).

Table 14. Total societal costs per patient per year in Euros (SD)

	GFU	Glaucoma specialist	P-value
Hospital costs	138.85 (89.30)	161.43 (86.88)	0.000
Patient costs	79.66 (58.51)	87.87 (68.15)	0.143
Medication costs	91.54 (101.37)	89.82 (100.53)	0.867
Total societal costs per patient per year	310.05 (181.86)	339.13 (180.39)	0.009

The mean difference in the total societal costs per patient year was -29 euro (the GFU treatment group was cheaper). The 95% confidence interval for this difference ranged from -54 to –4 euro.

3.3.6. Sensitivity analysis

We performed a sensitivity analysis to determine the effects of plausible policy changes in the (near) future on the costs per patient year (Table 15). We considered the following scenarios:

1. No optometrists will be involved any longer in the GFU. This actually happened during the study.
2. Because of an uncertainty in the duration of the visits as measured during this study, we varied the duration of the visits. The mean duration of the visit to the glaucoma specialist was 9.06 minutes, to the resident 11 minutes and to the GFU 20.4 minutes. In this analysis we varied the duration of the visits from 7 to 11 minutes for the glaucoma specialist, from 9 to 13 minutes for the resident and from 16 to 24

minutes for the GFU visits. The variation was based on the range of durations measured in this study.

a. all visit durations were shorter (7, 9 and 16 minutes respectively);

b. all visit durations were longer (11, 13 and 24 minutes respectively);

c. visits to the GFU group were shorter and visits to the glaucoma specialist group longer;

d. visits to the glaucoma specialist group were shorter and visits to the GFU group longer.

Table 15. Total average costs per patient year for all scenarios in the sensitivity analysis

		Base case	**Scenario 1**	**Scenario 2a**	**Scenario 2b**	**Scenario 2c**	**Scenario 2d**
Hospital costs	GFU	138.85	135.16	117.79	156.79	117.79	156.79
	Specialist	161.43	159.47	141.80	179.98	179.98	141.80
	P-value	*0.000*	*0.000*	*0.000*	*0.000*	*0.000*	*0.000*
Patient costs	GFU	79.66	79.66	79.66	79.66	79.66	79.66
	Specialist	87.87	87.87	87.87	87.87	87.87	87.87
	P-value	*0.143*	*0.143*	*0.143*	*0.143*	*0.143*	*0.143*
Health care costs	GFU	230.39	226.70	209.33	248.33	209.33	248.33
	Specialist	251.26	249.30	231.62	269.81	269.81	231.62
	P-value	*0.004*	*0.002*	*0.001*	*0.006*	*0.000*	*0.000*
Societal costs	GFU	310.05	306.36	289.00	328.00	383.23	452.3
	Specialist	339.13	337.17	319.49	357.68	434.64	379.99
	P-value	*0.009*	*0.006*	*0.005*	*0.010*	*0.000*	*0.000*

In all but the last sensitivity analysis, the costs per patient per year were significantly lower for the GFU treatment group than for the glaucoma specialist group. Only when the duration of a visit to the glaucoma specialist was relatively short (7 minutes) and the duration of a visit to the GFU was relatively long (24 minutes, scenario 2d), the costs per patient year were significantly higher in the GFU treatment group.

3.4 Feasibility study

The substitution of care to primary care optometrists does not seem feasible in the near future. Seven main findings support this conclusion.

1. Glaucoma specialists did not adhere to the substitution in location. They approved the substitution of care to the GFU within the hospital, which reduced their workload. Furthermore, they welcomed the possibility to check the quality of care delivered by

the ophthalmic technicians. The physicians feared to lose control over their patients if they were to be referred to optometrists outside the hospital.
2. Without the active support of physicians, most patients are unlikely to visit primary care optometrists for glaucoma monitoring. With more advanced visual field loss, they were probably more reluctant to visit primary care optometrists. They nevertheless admitted several advantages of the substitution of location, such as faster and more flexible appointments, a shorter travelling distance to the HCP, and the poor accessibility of the REH.
3. Optometry is a fairly new and relatively unknown profession in the Netherlands. In addition, the degree of organisation of the OCR optometrists is still quite rudimentary. The OCR optometrists usually are self-employed. The OCR is therefore not as well organized as for example large optician chains. This weakens their position in discussing the substitution of care. Their role is therefore relatively passive.
4. The health care insurers are reluctant to initiate discussions between optometrists and the REH about shared care. They are currently little driven to start discussing reimbursement of substituted care. If however, the REH can guarantee the quality of care, they will seriously consider reimbursements.
5. Since the GFU was primarily run by ophthalmic technicians, not by optometrists who also worked in optic dispensaries, the bonds between the ophthalmic technicians and ophthalmologists tightened, strengthening mutual confidence, at the expense of and confidence in optometrists.
6. Many GFU employees also took part in another project with optometrists. This collaboration gave the GFU employees insufficient confidence in the optometrists' level of expertise.
7. The REH has recently embarked on other collaborative projects with optometrists, thereby reducing the need to pursue shared glaucoma care, as an indirect means to consolidating, or even increasing, the inflow of patients.

In table 16 a summary of the positions (support/opposition) and the power-positions of the stakeholders is shown.

Table 16 Summary of the stakeholders positions

Stakeholders	**Support/opposition**	**Power-position**
Primary care optometrists	Strong support	Low
Glaucoma specialists	Strong opposition	High
Patients	Moderate support	Medium
Health Insurers	Moderate support	High
REH management	Moderate support	Medium
GFU employees	Strong opposition	Low

On the other hand, some factors are in favour of the feasibility of the substitution of location. The primary care optometrists support the idea of substituting the monitoring of glaucoma patients to their stores. They were confident they could completely monitor stable glaucoma patients. The only skill they thought required extra training was the interpretation of GDx images. Those primary care optometrists that were already involved in another shared care project, i.e., into glaucoma screening with the GDx, did not think they required additional training, though. In that glaucoma screening project, a well functioning ICT platform had already been established, which could equally be used for the transfer of any medical information between the hospital and the optometrists' stores. In our design of shared care, the GDx played an important role. It would have to be available in any such shared care project. In the screening project described earlier, all participating optometrists already had access to the GDx.

Substituting the monitoring of stable glaucoma patients to optometrists' stores would improve their image of professionalism, thereby strengthening their position in the commercial competition with others, notably the larger optic dispensary chains. To the optometrists' dismay, there are currently no reimbursements for optometric examinations or care. In their shops, they are faced with a dilemma: they were trained to carry out optometric examinations, which are not reimbursed, whereas they have to make a living by selling glasses, which requires relatively few optometric skills. Without any appropriate reimbursements, monitoring (stable) glaucoma patients would be highly unprofitable.

Since the substitution of location is improbable, we will not report about the Willingness to Accept (WTA) the substitution of care by the primary care optometrist.

4 Conclusions

4.1 RCT and process evaluation

The results of the RCT and process evaluation showed that the quality of care delivered by the GFU employees was comparable to the care delivered by the glaucoma specialists. Patients and HCPs were satisfied with the functioning of the GFU. The GFU standard working protocol worked well in most respects; for the visual acuity, however, it was too tight, which led to protocol violations that were deemed acceptable by GFU employees and ophthalmologists alike. For simplicity, the protocol was left unchanged.

4.2 Economic Evaluation

The costs of the GFU treatment group compared to glaucoma specialist group were significantly lower for three of the four perspectives used. Only the patient costs did not differ between the two treatment arms. Therefore, we can conclude that the substitution in person is cost-effective. The sensitivity analysis did confirm this cost effectiveness when varying the duration of the visits and when replacing the monitoring by optometrists with monitoring by other GFU employees. Only when reducing the duration of the visits in the glaucoma specialist group, while increasing the duration of the GFU treatment group, the total costs for the GFU treatment group were significantly higher compared to the glaucoma specialist group.

4.3 Feasibility study

The substitution of care to primary care optometrists (i.e., in person and location) did not seem feasible in the near future. In short, the GFU functioned to the satisfaction of the glaucoma specialists and other HCPs. They consequently did not feel the need to involve a third party, the primary care optometrist. Why change a winning team?

5 Discussion

A main reason for establishing the GFU was the expected increase in the demand for glaucoma care in general, resulting from an aging population. The overall increase that we found in patients seeking glaucoma care in the REH further substantiated the need for shared care projects such as ours.
A report by The Dutch College of Ophthalmologists (NOG, 2003)[1], based on questionnaires amongst ophthalmologists, states that the policy of the college should be focused on allocating supporting personnel like optometrists and ophthalmic technicians.
Little is known about the substitution of care in ophthalmology, the organizational and professional dynamics involved and its consequences for the quality of care and cost effectiveness. Substituting tasks within hospitals is currently taking place, but there has not been an extensive evaluation on the effects of this substitution. In the UK, there has been a long running study, including an RCT, on substituting care for stable glaucoma patients to primary care optometrists[2-6] showing a similar quality of care provided by optometrists and glaucoma specialists.

Although not all GFU employees were optometrists, we expected to find a similar quality of care in the two treatment groups. This turned out to be correct. The substitution of care to the GFU was succesfully implemented.
1. The quality of care provided in the GFU was comparable with the care provided by the glaucoma specialists, for a subset of glaucoma patients, i.e., those that were deemed stable;
2. The patients, GFU employees and the glaucoma specialists were pleased with the functioning of the GFU;
3. The costs per patient per year were significantly lower for the patients visiting the GFU than for those visiting the glaucoma specialist;
4. Since the start of the GFU, we have seen a yearly increase of glaucoma patients visiting the REH.
The costs per visit in the GFU appeared to be lower than per visit to the glaucoma specialist. We expected this because of lower personnel costs of the GFU employees compared to glaucoma specialists. Based on the study of Druss[7], we did not expect to save costs. Since substitution of care often results in a more annual visits because of a shorter follow-up time and extra (unnecessary) referrals to the specialist, the savings in personnel costs are often reduced. However, in our study the annual number of visits was not much larger compared to the usual care and the percentage

of referrals was just 6%. The total costs per patient per year turned out to be lower in the GFU group than in glaucoma specialist group.

A limitation of our study is that we were not able to use glaucomatous progression as an outcome measure, for several reasons; (1) glaucoma typically runs a very slow course. We did not expect to be able to detect any glaucomatous progression in the 30 months of our study period. To detect any glaucomatous progression over time, clinical trials typically run between 5 to 8 years. When the diagnosis of primary open angle glaucoma (POAG) is made, the average life expectancy is 13 to 16 years[8]; (2) moreover there is no general agreement on the best way to detect any glaucomatous progression of glaucomatous visual field loss.[9]

In the unit costs of a visit in the REH used for the internal budget allocation, the overhead and general personnel costs were calculated per minute of monitoring. These were based on the total number of patient visits per year in the REH and the mean duration per visit. We were able to adjust the visit duration to the real duration for this specific group of patients. Most of the sensitivity analyses did not affect the cost-effectiveness of monitoring patients in the GFU.

Although the substitution of care to the GFU was a success, our feasibility study showed that referring patients from the REH to primary care optometrists is currently not a realistic option. The success of the GFU was a reason for the REH to start other follow up units as well, such as a cornea follow-up unit staffed by optometrists. In addition, plans are under way to further expand shared care projects in the REH, involving other areas of (chronic) eye diseases.

Currently, several hospitals participating in the Eye Care Network are interested in the concept of a GFU. These, as well as other hospitals outside the Eye Care Network, could benefit from our results when starting a GFU and use our referral criteria and standard working protocol. We used a GDx to judge the optic nerve, but it is also possible to use visual fields or other imaging devices. The standard working protocol should then of course be adjusted accordingly.

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6 Recommendations

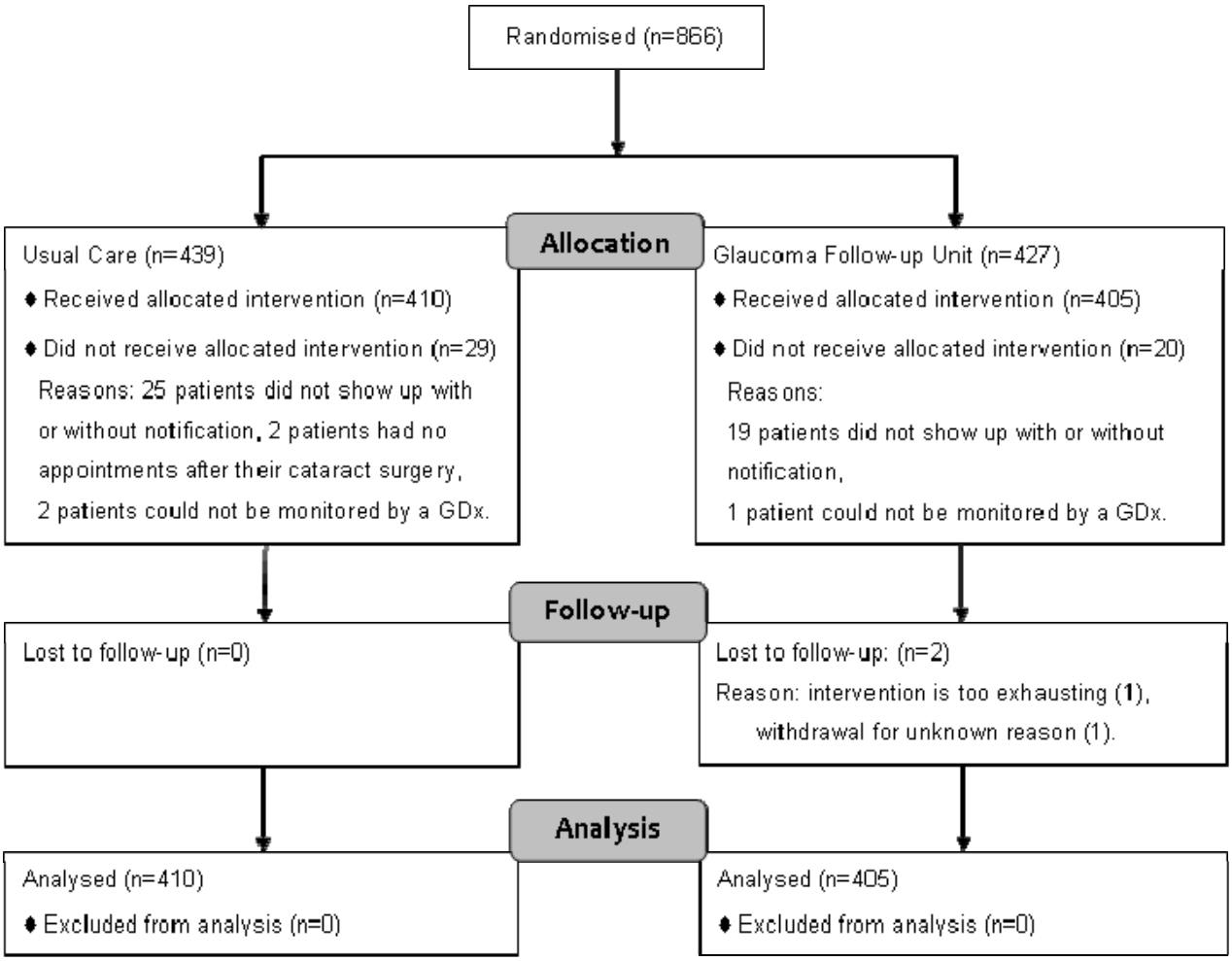
6.1 Generic policy recommendation

One has to decide who is to staff the GFU. In the REH, the ophthalmic technicians proved to be perfectly capable of monitoring stable glaucoma patients. They already were highly experienced with the GDx. The GFU was not staffed with primary care optometrists. If a hospital wants to expand the monitoring of stable glaucoma patients to optician stores, it is probably helpful to staff the GFU with primary care optometrists from the beginning.

6.2 Practical recommendations

1. An ophthalmologist should be made project manager of the GFU. The GFU in the REH would probably not have been a success without the close ties between the glaucoma specialist and the GFU.
2. All ophthalmologists monitoring glaucoma patients should be involved in the formulation of the referral criteria and the standard working protocol. The criteria and protocol of the GFU in the REH could be used as guideline.
3. GDx images are used in the GFU to judge the optic nerve. Not all hospitals own a GDx device. The ophthalmologists should decide which device they would like to use.
4. Arrange extra training for the GFU employees as required.
5. Check the medical records of patients monitored by the GFU. Start by checking all medical records and provide immediate feedback if required; when things run smoothly and accurately, downsize the checks to approximately 1 out of 10 medical records. A smaller proportion may perhaps function well enough to safeguard the quality of care.
6. Plan the GFU clinics when ophthalmologists may answer any questions.
7. Evaluate the referral criteria and the standard working protocol. In the beginning, it is sensible to do this more frequently, for example after 6 months. When the GFU runs satisfactorily, you could do this at greater time intervals of, for example, 3 years.
8. Plan once yearly meetings with all involved ophthalmologists and GFU employees.

7 Appendix 1. Patient flow chart



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