Introduction of structured record keeping in age-related macular degeneration: a before and after study

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**Abstract**

**Clinical relevance:** Structured record keeping improves documentation in age-related macular degeneration; however, it may have a more limited effect on the management decisions of a group of already highly trained clinicians, especially in the context of other well-embedded clinical decision support tools.

**Background:** Structured record keeping has been associated with a range of advantages including improved history taking and communication, reduced number of unnecessary referrals, and enhanced diagnostic accuracy. The aim of this study was to examine the impact of a structured record keeping, quality improvement tool on recording, reporting and management congruency.

**Methods:** A before and after retrospective record review study was performed in a single academic, intermediate-tier care institute in New South Wales, Australia. The structured record keeping tool intervention captured 31 items in addition to the prior pre-existing medical record: six items relating to historical risk factors, two items relating to patient activation, 13 items signifying core clinical signs, five items for change analysis and five items regarding the ongoing patient management plan.

**Results:** Two hundred medical records from 151 patients with age-related macular degeneration were analysed. There was a statistically significant improvement in the number of reports that explicitly specified the number of clinical structural risk factors (from 24 to 75%; Fisher’s exact p < 0.001) and risk of progression to advanced disease (from 71 to 84%; p = 0.041); however, this documentation had no statistically significant effect on the report-recommended management plan and/or the final report-recommended review period.

**Conclusion:** Disease-specific, structured record keeping improves the outgoing documentation of key clinical signs and is effective in prompting the transposition of these signs into a quantified risk progression score. It has limited value in improving management consistency among a group of highly trained eye care staff.

**Introduction**

Primary eye care has an important role in ensuring that patients either with or at significant risk of vision loss receive high-quality care in a timely manner. Age-related macular degeneration (AMD) is the leading cause of vision loss in developed nations. Patients suspected of neovascular, late disease should be referred to an ophthalmologist within 2 weeks of the identification of a treatable lesion. At-risk patients with intermediate AMD should be reviewed every six to 12 months. Yet, recent studies have shown a discordance between the evidence base and clinical practice.

Clinicians providing routine care display clinically significant variation in their management recommendations across a range of disciplines and professional groups. Various factors influencing care have also been described and may be categorised as either barriers or enablers; patient-centred, practitioner-centred, or structural factors. Consequently, there is growing interest worldwide in clinical decision support (CDS) tools aimed at improving the standard of health care delivery by enhancing medical decisions via the provision of targeted clinical knowledge, patient information, and other health information.

CDS systems are typically designed to present relevant, evidence-based information to the clinician during key moments of clinical decision making. Systems should ideally be transparent, inter-operable and deployed at relevant time points during the regular clinical workflow. They include web-based as well as electronic health record integrated platforms and may be specifically programmed using if-then rules according to an external knowledge base. The aim of this study was to describe the implementation of a novel, structured record keeping CDS tool, also known as tailor-made proforma, in AMD, and to examine the effect of this newly implemented tool on recording, reporting and management congruency among a group of highly trained optometrists practising in an academic, intermediate-tier care setting.

**Methods**

This study was a retrospective audit of a total of 200 clinical records from 151 patients with AMD seen before and after implementation of a new structured record keeping, quality improvement tool reported in accordance with the SQUIRE 2.0 guidelines. The tool (Figure 1A) was implemented on 5 November 2018 at the Centre for Eye Health, UNSW Sydney Australia. The operations of this clinic have been described
previously. In brief, the clinic represents a joint initiative of Guide Dogs NSW/ACT (philanthropy) and UNSW Sydney (academia), with regular input from the local public ophthalmology service. It operates as an intermediate-tier care service, whereby all patient attendances are initiated by referral only, from an optometrist, ophthalmologist, or general practitioner.

Patients are subsequently examined according to a pre-determined clinical examination protocol by a staff optometrist (one of 17 at the time of writing; a full listing of their professional experience, demographic and other characteristics is available on the organisation website: [https://www.centreforeyeclinics.com.au/clinical-services/cfeh-clinicians/](https://www.centreforeyeclinics.com.au/clinical-services/cfeh-clinicians/)). Per standard professional practice, medical notes are recorded at the time of the examination. Approximately, 1 week after examination of the patient, an outgoing report was sent to the referrer. The report summarised the key findings including management recommendations and had undergone internal peer-review.

The recruitment strategy for this study covered 102 patients seen once over the total study window as well as 49 patients with relatively short review periods seen both before and after implementation of the CDS tool. To be eligible for inclusion, each record (referring in this study to both the medical notes and related outgoing report relating to a single patient attendance) had to be related to a case of typical AMD (early, intermediate, or late disease in both eyes according to the Beckman initiative for macular research clinical classification scheme. Follow up records were eligible for inclusion. Atypical cases, or cases featuring multiple ocular co-morbidities e.g. glaucoma or diabetic retinopathy were excluded. Written informed consent was obtained for all subjects (patients) in accordance with the tenets of the Declaration of Helsinki and approved by a Biomedical Human Research Ethics Advisory Panel of UNSW Sydney, Australia.

**Description of the intervention**

Prior to implementation of the structured record keeping tool, a report template, to facilitate the writing of outgoing reports, and macular disease-specific examination protocol were already well embedded in the standard clinical workflow. Report templates are used in all clinical assessments and provide a semi-structured outline of important content to
include in the outgoing correspondence. The content itself is pre-populated using data from medical notes and then edited by the examining optometrist before undergoing peer review.

Standard template features are the organisation’s letter head (logo, clinical staff names and qualifications, practice address and contact details), referent details (name, practice name and address), patient details (name, date of birth), and attendance details (date of correspondence, examining and reviewing staff name and signature). In AMD, the template body comprises five paragraphs addressing: the case history, entering test findings (visual acuity, Amsler grid and Mars contrast sensitivity), imaging notes, case summary (comments on the diagnosis, prognosis, risk factors for progression and incidental findings) and recommended management. The follow-up report template is modelled off the baseline report and includes the same basic information, adapted to include notes about compliance with previous management recommendations and drusen regression for prognostication.

The examination protocol ensures that all patients referred for a macular assessment receive an entering structured medical history questionnaire (unless already performed at baseline) and the following tests: best corrected visual acuity, Amsler grid, Mars contrast sensitivity, optical coherence tomography, fundus photography, fundus autofluorescence and dilated slit-lamp fundoscopy.

The new structured record keeping tool, described herein, was developed with the aim of improving clinical documentation, consistency, and efficiency across all patients with AMD seen in the organisation. A secondary goal was to improve the standardisation of ongoing recommended review periods and to generate closer alignment with key clinical practice guidelines.6,7 Key clinical indicators, historical risk factors, elements of the case history and the ongoing management plan were first identified following a review of the literature (including local and national guidelines6,7) by lead author, AL.

A tailored user-defined form comprising 31 disease-specific items (Supplementary Table 1) was then developed solely again by the lead author and embedded into the core electronic medical record system (VIP.net, Best Practice Software, https://bpssoftware.net/bp-vipnet/) using a mixture of checkbox, textbox, and picklist field options. Two prompts specifying additional prognostic biomarkers and a summary box of overall risk linked to a recommended review period using ‘if-then’ programming rules (Figure 1B) were also included.

Based on the recommendations of the Beckman initiative for macular research clinical classification scheme15 and Age-related Eye Disease Study simplified severity study16 each ticked checkbox for large drusen or pigmented abnormalities in either eye is assigned an independent value of one and the total number summed to calculate the number of age-related eye disease study risk factors for progression. For patients with early AMD and no large drusen in either eye, medium drusen was counted as one risk factor for progression. The total number between zero and four was customised to appear in the bottom bounded box of the CDS tool once the earlier fields were filled.

Similarly, the total number of historical risk factors (ranging from 0 to 6 using family history, age, cardiovascular disease, smoking, poor diet, and obesity appearing at the top of the form) and number of additional structural risk factors (termed biomarkers; zero to four accounting for drusen regression or reticular pseudodrusen across both eyes) are quantified and appear for consideration by the user. Text specifying a recommended review period then pops up automatically adjacent to the label ‘recommended review period’ using the rules shown in Figure 1B. This encourages the clinician to consider manually the summed risk factors for progression, starting with the presented Age-related Eye Disease Study Simplified Severity score and the remembered sequence of 0 factors, 0.5%; 1 factor, 3%; 2 factors, 12%; 3 factors, 25%.16

Because there is no widely accepted clinical risk calculator that adjusts this base percentage using additional historical risk factors or the structural biomarkers described above, the clinician using the tool then needs to consider these additional factors qualitatively against the prepopulated recommended review period and subsequently fills in the final review period manually. Patients with late neovascular AMD are prompted by the CDS tool to refer to an ophthalmologist.

The final layout and wording were modified slightly following pilot testing and feedback from a subset of end users (four clinicians, and one post-doctoral researcher working in an academic environment with a self-identified interest in macular disease). The pre-existing outgoing report template was then updated to pre-populate using data entered directly into the newly developed structured record keeping tool. All staff practising in the clinic (17 locally trained, registered optometrists with varying levels of practise experience and qualifications) were notified by email of the new tool, including instructions for use, and invited to comment and provide unstructured feedback. Uptake and use of the new tool were then monitored for 1 month.

The tool was embedded within the core medical record and its adoption was not mandatory; however, all optometrists performing examinations within the organisation elected voluntarily to use the tool. Following an informal group discussion by the same self-identified group of five staff members above, all feedback received in this phase was deemed positive and no further modifications to the intervention were made.

Data extraction

The case summary, recommended management plan, date of examination, examining and reviewing clinicians, and AMD severity per eye were extracted by a single, unmasked research assistant, supervised and trained by the lead author, from the patient-associated medical notes and outgoing report to the referer. Report data were subsequently coded into five fields: 1) number of reported Age-related Eye Disease Study risk factors, 2) reported Age-related Eye Disease Study simplified severity percentage risk of progression, determined by the examining clinician in accordance with the simplified severity scale16 3) review/referral plan, 4) nutritional supplement-related recommendation, and 5) Amsler grid self-monitoring recommendation. Coded data from 100 records in each group, pre- and post-implementation of the new structured record keeping tool were then compared.

Statistical analysis

All statistical analyses were performed using SPSS (Version 26; IBM corporation, Chicago, USA) and figures were generated using GraphPad Prism (Version 7; GraphPad software, California, USA). Coded data were analysed using frequencies
of occurrence. Chi-square and Fisher’s exact tests were used to determine statistical significance. P-values less than 0.05 were considered significant.

The documentation rate was defined as the number of records where the key clinical parameter was reported in the outgoing correspondence divided by the total number of reports analysed. Contingency tables were used to analyse the relationship between Age-related Eye Disease Study risk factors and the report-recommended review plan.

Results

A total of 221 records, describing cases of AMD, were reviewed. Twelve cases were excluded due to the presence of co-morbidities: diabetic or other retinopathy (six cases), other maculopathy (e.g., vitreomacular traction syndrome; four cases) or glaucoma (including a suspect with primary angle closure; two cases); nine other cases were excluded due to an atypical presentation of AMD, identified by the examining optometrist or reviewing clinician (age of onset earlier than 50 years or an unusual distribution of clinical signs with or without change analysis).

Using the final dataset of 200 eligible records, all related patient examinations were conducted between the 18 April 2018 and 13 January 2020 by one of 17 staff optometrists. Each optometrist contributed an average of 12 records (range 1–37, varying based on their rostered time in the clinic). The severity of AMD was specified (described explicitly as early, intermediate or late) in 158/200 (79%) of all outgoing reports and 200/200 (100%) medical notes. Across the total sample, the severity of disease was most commonly intermediate (166, 72%), followed by early (13, 7%), late neovascular (12, 6%), and late geographic atrophy (nine, 5%). There was no statistically significant difference in the distribution of case severity (Chi-square test: \( P = 0.66 \); Table 1) or the non-specification rate in the outgoing report (21/100 in each group; Chi-square test: \( P = 0.28 \)) with or without use of the structural record keeping tool.

Structured record keeping significantly improved the outgoing reporting of the total number of reported Age-related Eye Disease Study risk factors (from 24% to 75%; 51% improved documentation rate, Fisher’s exact test: \( P < 0.001 \); Figure 2), as well as the reported simplified severity scale level of progression risk over a five-year period (71% versus 84%; 13% improved documentation rate, Fisher’s exact test: \( P = 0.041 \)). There was no statistically significant difference in the report-recommended management plan, nutritional supplementation or Amsler grid self-monitoring with or without the structured record keeping tool.

Table 2 shows the relationship between the outgoing reported Age-related Eye Disease Study simplified severity scale value and the recommended review period in cases with intermediate AMD seen without the structured record keeping tool.

Table 3 shows the same relationship in cases seen using the tool. There was no statistically significant in the total distribution of cases recommended referral, review in 3–6 months, 9–24 months or discharge with or without CDS (Chi-square test: \( P = 0.56 \)).
Discussion

This study specifically investigates the value of structured record keeping on documentation and clinical decision making in AMD. The results indicate an interesting ceiling effect regarding the value of CDS in an academic, intermediate-tier care setting as applied by a group of already highly trained clinicians, supported by pre-existing processes including a report template and examination protocol. All 200 cases included in the study (including 100 unsupported by the structured record keeping tool) had the severity of AMD clearly documented in the medical notes, implying strong pre-existing familiarity with clinical staging schemes, reinforced through weekly ‘clinical update’ sessions, a team-based care culture, and electronic access to the peer-reviewed literature (through a university subscription provided through an affiliation agreement with UNSW Sydney, Australia).

Two of the clinicians working at the Centre were also co-authors on the local clinical practice guideline for optometrists. As a result, it is likely that the impact of the CDS tool described in this work may show a different effect in a more heterogeneous group of practitioners and/or alternative settings, particularly those unaffiliated with teaching or academia.

The value of clinical decision support in AMD

Medical records form an important mechanism for documenting facts about the current health status of the patient and ongoing management plan. They also form an important medicolegal document. For these reasons, structured record keeping tools are generally favoured in the healthcare community and have been associated with a range of advantages including increased speed of history taking, a more systematic history, memory aid, improved communication with other health professionals, reduced number of unnecessary referrals, easier data entry, enhanced diagnostic accuracy, quality in care, especially with regards to drug–drug interactions.

On the other hand, the potential to harm and solutions to mitigate harm have also been previously described. The movement towards structured record keeping (at least with regards to coding of the case history) is ‘far from straightforward’ and lacks consensus. Arguments against the use of structured record keeping also draw attention to the significant and ongoing resources required for maintenance, non-uniformity in implementation and aspects of the clinical encounter that cannot be easily coded, such as the individual accuracy of Amsler grid self-monitoring. Their integration with other tools of proven efficacy, such as self-audit of clinical records with quantitative, automatically generated feedback based on participants’ responses to the audit questions, also requires further study.

Advances in technology, such as machine learning, may further make manual structuring or coding ultimately obsolete. Finally, such systems may be considered overly prescriptive, or worse, predispose to long-term de-skilling and there is a paucity of data regarding their implementation among different professional groups and settings, including primary eye care.

Table 2. Contingency table itemising the relationship between reported risk of progression to advanced disease (over five years) and the recommended management plan for cases with intermediate AMD only, seen without the structured record keeping tool.

| 5-year risk of progression (%) | Refer | Review 3-6 months | Review 9-24 months | Discharge | Total |
|-------------------------------|-------|--------------------|--------------------|-----------|-------|
| 5                              | 3     | 0                  | 1                  | 4         | 0     | 5     |
| 12                             | 0     | 0                  | 16                 | 18        | 0     | 34    |
| 25                             | 0     | 9                  | 4                  | 0         | 13    |
| 50                             | 2     | 10                 | 1                  | 0         | 13    |
| Not specified                  | 0     | 3                  | 12                 | 1         | 16    |
| Total                          | 2     | 39                 | 39                 | 1         | 81    |

Table 3. Contingency table comparable to Table 2 for cases seen using structured record keeping.

| 5-year risk of progression (%) | Refer | Review 3-6 months | Review 9-24 months | Discharge | Total |
|-------------------------------|-------|--------------------|--------------------|-----------|-------|
| 5                              | 3     | 0                  | 3                  | 1         | 0     | 4     |
| 12                             | 1     | 20                 | 24                 | 0         | 45    |
| 25                             | 1     | 6                  | 5                  | 0         | 12    |
| 50                             | 0     | 16                 | 1                  | 0         | 17    |
| Not specified                  | 0     | 3                  | 4                  | 0         | 7     |
| Total                          | 2     | 48                 | 35                 | 0         | 85    |
Implications for practice and research

Clinical decision making is a complex process, and there is foreseeable value in CDS systems generally, especially for education and community practice. In AMD, primary eye care practitioners must make a quick and accurate diagnosis and, more importantly, recognise the need for timely, specialist care. They require cost, time and clinically effective tools, ideally integrated into daily working practices, to help them deliver high-quality, evidence-based care more effectively.18

In keeping with other studies from other fields, a statistically significant improvement has been demonstrated here in the documentation rate of two key clinical parameters (level and total number of Age-related Eye Disease Study risk factors for AMD progression) following the introduction of this AMD-specific, structured record-keeping tool.22–24 Improved documentation in a more structured manner benefits patients, clinicians and the broader medical community.19,25, individuals in the latter may be copied in to receive outgoing reports.

To develop the tool, appropriate clinical reference parameters were identified, as in previous work,26 using pre-existing clinical guidelines, an interest group approach and two meeting rounds. Focus groups and surveys of the end-users were not performed; however, group and one-on-one discussions were important for identifying key barriers to adoption, including a lack of familiarity and/or change readiness. Some clinicians also felt that the pro forma style was too ‘authoritarian’, representing an additional process, which restricted their clinical and professional autonomy.18

To minimise the participant burden, the described CDS structured record keeping tool was effortlessly embedded directly into the electronic health record system. By capitalising on traditional form structure (using textboxes, check and pick-list tools), it is relatively intuitive and easy to use, requiring little training. It can also be adapted and applied using other common patient management systems found in different clinics. On the other hand, the logic rules behind the recommended review period ‘calculator’ (based on a simple, non-weighted aggregate of risk factors) could be criticised as rudimentary and imprecise.

Strengths and limitations

Traditional record review studies typically analyse concordance of medical records across several items using pre-determined criteria and a benchmark.23 Rather than itemising the documentation rate of all 31 fields in the new structured record keeping tool, attention was focussed towards the coding protocol of this study on just five fields: the number of reported Age-related Eye Disease Study risk factors, percentage risk of progression, review/referral plan, nutritional supplement and Amsler grid recommendations.

Data captured in each of the individual 31 items in the complete tool, or using other aspects of the standard clinical intake process not included in this specific CDS tool, such as ethnicity and gender, were not specifically analysed but have the potential to yield interesting new insights into routine clinical practice behaviour, e.g. in the post-structured record keeping group, 9/100 records had the historical risk factor for ‘smoking’ checked. Of these nine, only four had the quit smoking recommendation also checked implying that smoking cessation was discussed during the consultation. Five remained unchecked, either because it was the default record state, the patient had quit smoking (two documented instances), or the clinician actively chose not to discuss smoking cessation.

Other diet and lifestyle elements of the management plan, including options to address the historical risk factors of the patient, e.g. obesity, were also considered too variable to capture across the whole group and subject to differ following counselling with the patient.17 The technician involved in data collection was not blinded to whether the intervention or was used or not, thus introducing potential bias. Evaluation of the accuracy of disease staging and diagnosis were beyond the study scope but have been explored elsewhere.1,10

Given that this was a retrospective study, staff were not aware that the study would take place but may have altered their documentation patterns in direct response to the new tool (Hawthorne effect). The total sample size of 200 records was also chosen out of convenience (in line with previous work)18 and inter-grader reliability of each case was also not explored though countered in part by the peer review system of the institute (each outgoing correspondence is reviewed by a senior peer prior to transmission).

This was not a time-motion study so it was not possible to document an improvement in clinical efficiency although it was anticipated that the application of this tool and its integration into the pre-existing document template saves time. Investigating the long-term adherence to the new structured record keeping tool, at different sites, among staff with a wide range of practise experience and qualifications, duplication of data/processes, and the relative contribution of different CDS elements (structured record keeping versus the report templates, self-audit, or clinical examination protocol as described herein or elsewhere21) on documentation accuracy, as well as the exploration of data inaccuracies were also beyond the scope of this pilot study. Finally, cost effectiveness, quality of care provided, clinical improvements, and patient-reported outcome measures represent additional important future considerations.

Conclusion

Clinical decision making is complex and therefore neither easy to develop, nor support. These results show an improved documentation rate regarding risk factors for disease progression among a group of highly trained clinicians in AMD. Further investigation into the benefits or otherwise of this structured record keeping tool over time, in different settings and among different professional groups is required before recommending more widespread implementation of the tool. These results describe an overall positive yet realistic effect of structured record keeping in AMD in a routine clinical setting.

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