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## Can the appropriateness of eyecare be measured through retrospective patient record review in eyecare practices? The iCareTrack feasibility study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-024298
Article Type:	Research
Date Submitted by the Author:	01-Jun-2018
Complete List of Authors:	Ho, Kam; University of New South Wales Faculty of Science, School of Optometry and Vision Science Rahardjo, Dian; The University of New South Wales, School of Optometry and Vision Science Stapleton, Fiona; The University of New South Wales, School of Optometry and Vision Science Wiles, Louise; Macquarie University Faculty of Medicine and Health Sciences; University of South Australia Division of Health Sciences, Centre for Population Health Research Hibbert, Peter; Macquarie University Faculty of Medicine and Health Sciences; University of South Australia Division of Health Sciences, Centre for Population Health Research White, Andrew; Cambridge University Teaching Hospitals NHS Foundation Trust, Cambridge, ; Centre for Vision Research, Westmead Millennium Institute, Hayen, Andrew; University of Technology Sydney Faculty of Health Jalbert, Isabelle; The University of New South Wales, School of Optometry and Vision Science
Keywords:	appropriateness of care, record audit, record review, preventative eyecare, Glaucoma < OPHTHALMOLOGY, Diabetic retinopathy < DIABETES & ENDOCRINOLOGY

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**Title page**

**Title:** Can the appropriateness of eyecare be measured through retrospective patient record review in eyecare practices? The iCareTrack feasibility study

**Authors:** Kam Chun Ho<sup>1</sup> ([kam.ho@unsw.edu.au](mailto:kam.ho@unsw.edu.au)),  
Dian Rahardjo<sup>1</sup> ([d.rahardjo@unsw.edu.au](mailto:d.rahardjo@unsw.edu.au)),  
Fiona Stapleton PhD<sup>1</sup> ([f.stapleton@unsw.edu.au](mailto:f.stapleton@unsw.edu.au)),  
Louise Wiles PhD<sup>2,3</sup> ([louise.wiles@mq.edu.au](mailto:louise.wiles@mq.edu.au)),  
Peter Hibbert<sup>2,3</sup> ([peter.hibbert@mq.edu.au](mailto:peter.hibbert@mq.edu.au)),  
Andrew White PhD<sup>1,4,5</sup> ([andrew.white@sydney.edu.au](mailto:andrew.white@sydney.edu.au)),  
Andrew Hayen PhD<sup>6</sup> ([Andrew.Hayen@uts.edu.au](mailto:Andrew.Hayen@uts.edu.au)),  
and Isabelle Jalbert PhD<sup>1</sup> ([i.jalbert@unsw.edu.au](mailto:i.jalbert@unsw.edu.au))

<sup>1</sup>School of Optometry and Vision Science, UNSW Sydney, Australia

<sup>2</sup>Faculty of Medicine and Health Sciences, Australian Institute of Health Innovation, Macquarie University, Sydney, Australia

<sup>3</sup>Centre for Population Health Research, School of Health Sciences, University of South Australia, Adelaide, Australia

<sup>4</sup>Save Sight Institute, University of Sydney, Westmead Hospital, Sydney, Australia

<sup>5</sup>Centre for Vision Research, Westmead Institute for Medical Research, University of Sydney, Westmead Hospital, Sydney, Australia

<sup>6</sup>Faculty of Health, University of Technology Sydney, Australia

**Corresponding Author:** A/Prof Isabelle Jalbert

1  
2  
3  
4 [i.jalbert@unsw.edu.au](mailto:i.jalbert@unsw.edu.au)

5  
6 +61 2 9385 9816

7  
8 School of Optometry and Vision Science, UNSW Sydney, Sydney

9  
10 NSW 2052, Australia

11  
12 **Word count:** 3398

13  
14 **Keywords:** appropriateness of care, record audit, record review, preventative  
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16 eyecare, glaucoma, diabetic retinopathy  
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## Abstract

**Objectives:** The CareTrack study found that a wide range of appropriateness of care (i.e. care in line with evidence-based or consensus-based guidelines) was delivered across many health conditions in Australia. This study therefore aimed to demonstrate the feasibility of using the CareTrack method (a retrospective onsite record review) to measure the appropriateness of eyecare delivery.

**Design:** Cross-sectional feasibility study.

**Setting and Participants:** Two hundred and thirteen patient records randomly selected from eight optometry and ophthalmology practices in Australia, selected through a combination of convenience and maximum variation sampling.

**Methods:** Retrospective record review designed to assess the alignment between eyecare delivered and 93 clinical indicators (Delphi method involving 11 experts) extracted from evidence-based clinical practice guidelines.

**Primary Outcome Measure:** Number of eligible patient records, sampling rates, and data collection time. This feasibility study also tested the ability of 93 clinical indicators to measure percentage appropriate eyecare for preventative, glaucoma, and diabetic eyecare. The outcome for the main trial will be the percentage of encounters at which the appropriate eyecare is received.

**Results:** A median of 20 records (range 9 to 63) per practice were reviewed. Data collection time ranged from 3 to 5.5 hours (median 3.5). The most effective sampling strategy involved random letter generation followed by sequential sampling. The appropriateness of care was 69% (95%CI, 67%-70%) for preventative eyecare, 60% (95%CI, 56%-58%) for glaucoma and 63% (95%CI, 57%-69%) for diabetic eyecare.

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4 **Conclusions:** Appropriateness of eyecare can be measured effectively using retrospective record  
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6 review of eyecare practices and consensus-based care indicators.  
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## 9 **ARTICLE SUMMARY**

### 10 **Strengths and Limitations of this Study**

- 15 • The feasibility of a systematic approach (based on CareTrack method) to measure  
16 appropriateness of eyecare on site in eyecare practices was demonstrated.
- 17 • Appropriateness of eyecare was in line with previously measured healthcare but this may  
18 represent a slight overestimation of true appropriateness of eyecare.
- 19 • Measurement of appropriateness of eyecare was limited to those aspects for which clinical  
20 indicators could be derived.
- 21 • The small convenience sample used in this study may introduce selection biases.
- 22 • The study findings support the conduct of a larger trial to determine the percentage of  
23 eyecare encounters at which appropriate care is received.  
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## INTRODUCTION

Globally, 285 million people of all ages suffer from visual impairment with the major causes from both chronic eye conditions, including ocular diseases (e.g. glaucoma, diabetic retinopathy, age-related macular degeneration, cataract) and uncorrected refractive errors such as myopia and presbyopia.<sup>1,2</sup> The prevalence of vision problems is strongly associated with ageing,<sup>3</sup> hence the burden of ocular health problems will increase with an ageing population. Due to the growing demand for eyecare and in the context of resource scarcity worldwide, interest in measuring and enhancing the quality of eyecare delivery is growing.<sup>4,5</sup> Translation of best available evidence into clinical practice can improve the efficacy and cost-effectiveness of patient management.<sup>6</sup> In theory, evidence-based clinical practice guidelines aim to translate research findings into easy to apply care recommendations that are intended to guide practitioners to improve their professional practice and optimise patient care.<sup>7</sup> However, there is mounting evidence that such evidence-based clinical practice guidelines are not always adhered to or fully implemented in the clinical setting.<sup>8</sup>

The measurement of care quality is complex and multidimensional. In Australia, quality is considered as the guiding principle for assessing the health system's performance and this includes nine-dimensions: appropriate, effective, responsive, continuous, sustainable, accessible, capable, efficient and safe.<sup>9</sup> In this study, we focused on appropriateness of care defined as "care/intervention/action that is relevant to the client's needs and based on established standards" (see Box 1).<sup>10</sup> Assessment of the appropriateness of eyecare delivery requires that recommendations from evidence-based clinical practice guidelines or expert-based consensus be transformed into measurable clinical indicators which are designed to assess, compare and determine the potential to improve care.<sup>11</sup>

<b>Box 1. Definitions used.</b>
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**Condition** means clinical ocular conditions (e.g. glaucoma and diabetes) or preventative care.

**Evidence-based care** involves clinical decision making based on the existing best evidence for the care (including eyecare) of individual patients.<sup>12</sup> The practice of evidence-based care means the integration of the clinical expertise of the practitioners with the best available clinical evidence.<sup>13</sup>

**Appropriateness of eyecare** is care/intervention/action provided is relevant to the client's needs and based on established standards.<sup>10</sup> In this study, appropriate eyecare is clinical care for a condition considered to be evidence-based or consensus-based by a panel of clinical experts in Australia in the context in which it was delivered in the years 2013 and 2014.

**Clinical practice guidelines** are evidence-based statements that include recommendations intended to optimise patient care and assist health care practitioners to make decisions about appropriate health care for specific clinical circumstances. Clinical practice guidelines should assist clinicians and patients in shared decision making.<sup>14</sup>

**Clinical indicator** is a measurable component of a standard or guideline, with explicit criteria for inclusion, exclusion, time frame and setting.<sup>15</sup> It is a condition-specific process measurement of healthcare management, appropriate for Australian eyecare practice in 2013-2014.<sup>16</sup>

**Record review** is a method using pre-recorded, patient-focused data as the primary data source to assess quality of care.<sup>17</sup>

**Eyecare practice** refers to practice or clinic (e.g. optometry and ophthalmology practice) where a service related to the eyes or vision is provided.

**Eyecare provider** is an individual who provide a service related to the eyes or vision.

**Surveyor** is a person with appropriate clinical and review experience to review patient records against clinical indicators.

There are indications that the appropriateness of care is at times suboptimal. For example, the RAND study conducted in 2000 in the United States evaluated performance on 439 clinical indicators for 30



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4 acute and chronic health conditions and preventative care. American adults received recommended  
5 health care only 55% of the time.<sup>18</sup> More recently, the CareTrack study showed similar results with  
6 57% of Australian adults receiving appropriate care across 22 health conditions.<sup>15</sup> Very little  
7 information can be found on the quality of delivery of eyecare specifically, as ocular conditions were  
8 not included in the CareTrack study<sup>15</sup> and only small components of eyecare such as senile cataract  
9 were evaluated in the RAND study. According to the National Eye Health Survey (NEHS)<sup>19</sup>, more than  
10 50% of Australians with visual impairment are undiagnosed. To meet the eyecare needs of the  
11 ageing population and maximise the health care spending in this area, it is important to ensure that  
12 eyecare is delivered appropriately. To do this requires a deep understanding of who is getting what  
13 eyecare from whom and why in Australia.

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26 Record review is commonly used to measure adherence to practice guidelines, the translation of  
27 clinical education into practice, and the effect of interventions intending to improve care delivery.<sup>8 15</sup>  
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20-22 The greatest advantage of a record review is that the data are already collected, making it  
relatively inexpensive and easy to obtain a large amount of data over an extended period.<sup>17</sup> However,  
patient records are not designed for research purposes, so the data can be incomplete, unavailable,  
or difficult to interpret.<sup>23</sup>

This paper describes a cross-sectional feasibility study to test whether retrospective onsite reviewing  
patient records from eyecare practices can be used to assess the appropriateness of eyecare delivery  
in Australia. The feasibility study therefore aims to determine patient record sampling methods for  
the main trial, and explore potential issues associated with recruiting eyecare practices and with  
accessing, extracting, recording and analysing clinical records.

## METHODS

An onsite retrospective record review of eyecare practices was designed to determine the types of  
problems that might be encountered and to inform the future main study; this included testing the

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4 selection of eye conditions, their clinical indicators and the logistical and practical aspects of  
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6 recruiting eyecare practices, assessing patient records and extracting, recording, storing and  
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8 analysing the data. The feasibility study was designed to assess the alignment between eyecare  
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10 delivered and consensus-based care indicators (see below) extracted from evidence-based clinical  
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12 practice guidelines for three representative eye conditions. The representative eye conditions  
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14 glaucoma and diabetic retinopathy were selected based on prevalence (sufficiently high to be  
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16 measured using the proposed methodology), burden of disease, and the availability of Australian  
17  
18 and international evidence-based clinical practical guidelines against which to measure  
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20 appropriateness of eyecare delivery.<sup>24-27</sup> Preventative eyecare was also selected as effective  
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22 prevention is a key policy initiative for all health care delivery.  
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### 25 **Study settings**

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28 A sample of eight optometry and ophthalmology practices located in Sydney, Australia were selected  
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30 by the investigators based on convenience and maximum variation sampling, ensuring  
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32 representation from a variety of eyecare practice settings using different record types (e.g. paper or  
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34 electronic records), electronic document and records management system (EDRMS)<sup>28</sup> and business  
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36 models (e.g. franchisee, corporate and independently owned practices).  
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### 39 **Eligibility**

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42 A random sample of adult patient records (aged over 18 years old) from each of the selected eyecare  
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44 practices who attended for eye examination between 1st January 2013 and 31st December 2014  
45  
46 were reviewed. Visits were included if they were billed as a comprehensive eye examination (i.e.  
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48 Medicare item numbers 10900, 10907, 10912, 10913, 10914 or 10915),<sup>29</sup> representing consultations  
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50 longer than 15 minutes in length of time, or those categorised as comprehensive eye examination by  
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52 the billing eyecare practitioner. Post-operative visits, contact lens fitting or aftercare, unscheduled  
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4 visits due to acute conditions, and subsequent follow-up visits (e.g. visual field test) were excluded  
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6 from the sample.  
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9 To assess the appropriateness of glaucoma eyecare, patients were included if they were diagnosed  
10 with glaucoma, ocular hypertension, were at risk of glaucoma, or were categorised as glaucoma  
11 suspects. To assess the appropriateness of diabetic eyecare, patients were included if they were  
12 diagnosed with diabetes mellitus (both with and without diabetic retinopathy). Pregnant patients  
13 were excluded from all appropriateness assessments and patients with diabetes mellitus type 1  
14 were excluded from the assessment of appropriateness of diabetic eyecare as different sets of  
15 clinical indicators were expected and the prevalence might be too low to measure the  
16 appropriateness of eyecare for these two conditions.  
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### 25 26 **Protocol and Sampling** 27

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29 The study protocol was based on the CareTrack Australia protocol and the RAND methodology.<sup>18 30</sup>  
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31 Eight clinical indicators for preventative eyecare (Appendix 1), 13 for glaucoma eyecare (Appendix 2)  
32 and 17 for diabetic eyecare (Appendix 3) were developed –by the investigators based on  
33 recommendations extracted from relevant published national and international clinical practice  
34 guidelines (Table 1) –using the Delphi method. The purpose of the clinical indicators development  
35 was not to create new sets of clinical practice guidelines or care recommendation, but to facilitate  
36 quantitative measurement of appropriateness of eyecare. This rigorous Delphi review process  
37 involved a panel of three to five nationally recognised clinical experts from the relevant fields who  
38 were invited to review and rate the clinical indicators for feasibility, acceptability and impact.  
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40 Experts were identified as clinical leaders in their field and typically were employed in an eye  
41 department in a large hospital or a large teaching clinic and/or held an adjunct academic  
42 appointment. Experts were invited to comment and score the indicators for their appropriateness, in  
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the context of eyecare delivered in Australia from 2013 to 2014. Experts from both the optometry and ophthalmology field were involved in the Delphi review process for all clinical indicators.

**Table 1. Evidence-based clinical practice guidelines used to develop clinical indicators**

Guideline	Year	Publisher	Country
<b>Preventative eyecare</b>			
NHMRC guidelines for the Screening, Progress, Diagnosis, Management and Prevention of Glaucoma <sup>†27</sup>	2010	National Health and Medical Research Council (NHMRC)	Australia
Guidelines for the Management of Diabetic Retinopathy <sup>†26</sup>	2008	NHMRC	Australia
Canadian Ophthalmological Society evidence-based clinical practice guidelines for the periodic eye examination in adults in Canada <sup>31</sup>	2007	Canadian Ophthalmological Society (COS) guidelines	Canada
Preferred Practice Pattern <sup>®</sup> guidelines. Comprehensive Adult Medical Eye Evaluation <sup>32</sup>	2010	American Academy of Ophthalmology (AAO)	United States of America
<b>Glaucoma eyecare</b>			
NHMRC guidelines for the Screening, Progress, Diagnosis, Management and Prevention of Glaucoma <sup>27</sup>	2010	NHMRC	Australia
Canadian Ophthalmological Society Evidence-based Clinical Practice Guidelines for the Management of Glaucoma in the Patient Eye <sup>33</sup>	2009	COS guidelines	Canada
Diagnosis and Management of Chronic Open Angle Glaucoma and Ocular Hypertension <sup>34</sup>	2009	National Institute for Health and Care Excellence (NICE)	United Kingdom
Preferred Practice Pattern <sup>®</sup> Guidelines. Primary open-angle glaucoma <sup>35</sup>	2010	AAO	United States of America
<b>Diabetic eyecare</b>			
Guidelines for the Management of Diabetic Retinopathy <sup>26</sup>	2008	NHMRC	Australia
Canadian Ophthalmological Society evidence-based clinical practice guidelines for the management of diabetic retinopathy <sup>36</sup>	2012	COS guidelines	Canada
SIGN Management of diabetes A national clinical guideline <sup>37</sup>	2010	Scottish Intercollegiate Guidelines Network	United Kingdom
†Only the recommendations related to preventative eyecare were considered			

It was initially intended that 10 records per condition per practice be reviewed, however in practice the number of records sampled varied based on the time available and the complexity of the on-site record review. When a list of eligible patients or eligible visits could not be automatically generated,

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4 a range of possible sampling methods were used to identify eligible records, as appropriate. These  
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6 methods varied between different eyecare practice settings with the final method determined based  
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8 on how the records were stored. Briefly, this involved the surveyors (KCH, DR) generating either “a  
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10 list of patients” who were examined at the eyecare practice within the study period or “a list of visits”  
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12 conducted within the study period (i.e. multiple visits from the same patient could be included) and  
13  
14 taking a random sample from this generated list. For practices with EDRMS that could not generate  
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16 any of the types of lists mentioned above, “a list of random dates” was generated with eligible visits  
17  
18 on those dates included in the sample pool. For practices without EDRMS where paper records were  
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20 used, ten random letters from the alphabet were generated anew each time and sampling started  
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22 from the patient whose surname starts with the letter selected; sequential records were then  
23  
24 checked until one eligible patient per letter was identified. For one practice, only records from  
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26 patients who visited the practice between September 2016 and March 2017 were available for  
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28 sampling due to the practice having undergone extensive renovation during the mandated sampling  
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30 period and their patient records having been relocated to other premises and not being accessible.  
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32 Sampling for that practice therefore occurred from the pool of patients examined in 2013 or 2014  
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34 who happened to have been re-examined in the period between September 2016 and March 2017.  
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36 In instances where sampling occurred by patients and not by visits, only the first eligible visit was  
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38 included. In one practice, patients with diabetic mellitus could best be identified using the Medicare  
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40 item 10915 (comprehensive consultation of more than 15 minutes duration for a patient with  
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42 diabetes mellitus including dilation<sup>29</sup>) but this was not the case for other practices sampled.  
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46 In order to facilitate the progress of this feasibility study, clinical indicators from different but  
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48 advanced stages of the drafting and Delphi method review process were used for certain conditions.  
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50 For preventative eyecare, clinical indicators drafted based on the clinical practice guidelines but that  
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52 had not undertaken Delphi expert review were used in this feasibility study. For glaucoma and  
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4 diabetic eyecare, streamlined clinical indicators which had been reviewed in the first but not the  
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6 final round of the Delphi process by the panel of experts were used.  
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### 8 9 **Data extraction**

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11 Patient age, gender, ethnicity and date of visit were extracted from each patient record selected.  
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13 Records were also reviewed for appropriateness by one of two trained surveyors (K.C.H. and D.R.),  
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15 recording whether individual indicators and sub-indicators were met with 'yes' (care provided during  
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17 the encounter was consistent with the indicator), 'no' (care provided during the encounter was not  
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19 consistent with the indicator) or 'not applicable' (the indicator was not relevant to the encounter) in  
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21 a secure Microsoft Excel spreadsheet.  
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25 Every effort was made to minimise the occurrence of missing data. For example, for occurrences  
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27 where data for an indicator were consistently missing (e.g. instrument used for intraocular pressure  
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29 measurement), the practice manager or the eyecare practitioner were interviewed and relevant  
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31 information (e.g. only a single tonometer type available in the practice) used to record answers to  
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33 relevant indicators. In other instances, for example where the practices' EDRMS only retained a  
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35 record of the last recommended recall period, information about the recommended review period  
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37 could not be verified retrospectively and therefore any indicators related to recommended review  
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39 period were noted as 'not applicable'.  
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43 The extracted data from two records were cross-checked at each eyecare practice to ensure the  
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45 inter-reliability of the two data surveyors and any differences were resolved by discussion. Percent  
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47 appropriateness of care for each indicator was averaged across all eligible records.  
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### 50 51 **Patient and Public Involvement**

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53 In this study, patients were not involved. All data were collected from the patient records.  
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Ethics approval (Approval no.: HC15336) was obtained from the University of New South Wales (UNSW) Sydney's Human Research Ethics Committee and a waiver of consent to access patient records retrospectively from eyecare practices was granted. Informed consent was obtained from the eyecare practices.

## RESULTS

Eight eyecare practices were invited and agreed to participate in the feasibility study. This diverse convenience sample included two franchises, one corporate, one teaching clinic, one referral clinic, two independent optometry clinics and one private ophthalmology clinic (Table 2). Although all eight practices used some form of EDRMS, four of the practices predominantly used paper records.

**Table 2. Characteristics of the sample eyecare practices**

<b>No. of Optometry practices : No. of Ophthalmology practices</b>	7 : 1
<b>Electronic document and record management system (EDRMS):</b>	
• <b>Commercially available (e.g. Optomate, Sunix)</b>	3
• <b>Bespoke</b>	5
<b>Record types:</b>	
• <b>Electronic record only</b>	4
• <b>Structured paper record</b>	2
• <b>Semi-structured paper record</b>	1
• <b>Unstructured paper record only</b>	1
<b>Sampling method:</b>	
• <b>By patients</b>	5+
• <b>By visits</b>	1
• <b>By dates</b>	2
<b>No. of records sampled per practice§:</b>	
• <b>Preventative eyecare, median (range)</b>	23 (21 to 50)
• <b>Glaucoma eyecare, median (range)</b>	10 (8 to 20)
• <b>Diabetic eyecare, median (range)</b>	4 (1 to 10)
<b>No. of practitioners sampled per practice, median (range)</b>	3 (1 to 14)
<b>Time taken (hours per practice), median (range)</b>	3.5 (3 to 5.5)

†One practice was able to provide a list of all eligible patients (i.e. patients with glaucoma, glaucoma suspects and diabetic patients).

§Appropriateness of preventative eyecare was assessed in 3 of 8 practices; appropriateness of glaucoma and diabetic eyecare was assessed in 7 of 8 practices.

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4 Patient records for glaucoma and diabetic eyecare were randomly sampled using different methods  
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6 among the practices to determine the best feasible sampling strategy to use in the main trial as a  
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8 diversity of EDRMS and record types were used in the eyecare practices sampled. One practice  
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10 categorised patients based on diagnosis (e.g. glaucoma and diabetes) and visit types (e.g. initial and  
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12 follow-up visits) and a list of eligible patients was therefore provided by the practice and could be  
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14 used for random sampling. Another practice categorised patients by diagnosis and a list of eligible  
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16 patients could be generated from the EDMRS for random sampling. For the other five settings, the  
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18 eligibility had to be checked consecutively for each randomly sampled individual patient record, until  
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20 the required number of records was found; this process proved to be much more time consuming  
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22 but was necessary in a majority of sampled practices.

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25 For preventative eyecare, ten record review was completed within 1 hour for all methods, but more  
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27 time was required to identify eligible records for glaucoma and diabetic eyecare. If a list of patients  
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29 eligible for random sampling could not be generated, sampling by patients was the most feasible (for  
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31 both paper and electronic records) and least time-consuming method of identifying the eligible  
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33 records for glaucoma and diabetic eyecare. Ten eligible records related to glaucoma eyecare could  
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35 be identified and reviewed within 1 to 1.5 hours for most methods. For diabetic eyecare, up to 4  
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37 eligible records could be identified and reviewed within 1.5 to 2 hours whereas only 1 or 2 eligible  
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39 records could be identified if sampling occurred by visits or dates. Sampling of diabetic patients by  
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41 Medicare Item 10915 was therefore suggested as a potentially more feasible option. This was  
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43 attempted in the last practice where diabetic eyecare was measured for the feasibility study. The  
44  
45 overall time spent to review the records per practice ranged from 3 to 5.5 hours.

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48 Two hundred and thirteen records were reviewed in the feasibility study, and the characteristics of  
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50 the randomly selected records (patients) are shown in Table 3. Appropriateness of preventative  
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52 eyecare was assessed in 3 practices; appropriateness of glaucoma and diabetic eyecare was assessed  
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in 7 practices. The glaucoma and diabetic patients randomly sampled were older and a majority of the visits reviewed for these patients occurred in 2013. Three quarters of glaucoma patients were glaucoma suspects, followed by 17% with moderate glaucoma, 7% with severe glaucoma and 1% with early glaucoma. Nearly 80% of diabetic patients did not have diabetic retinopathy, followed by 7% with moderate diabetic retinopathy and 4% mild diabetic retinopathy.

**Table 3. Characteristics of the record review's random sample**

	Preventative eyecare	Glaucoma	Diabetic eyecare
<b>No of practices sampled</b>	3	7	7
<b>No of records sampled</b>	94	82	37
<b>Patient age (mean ± SD, years)</b>	43.1 ± 17.6	56.2 ± 15.2	61.6 ± 10.6
<b>Patient gender:</b>			
• <b>Male</b>	39 (41%)†	44 (54%)	22 (59%)
• <b>Female</b>	53 (56%)†	38 (46%)	15 (41%)
<b>Year of the sampled visit:</b>			
• <b>2013</b>	39 (41%)	53 (65%)	30 (81%)
• <b>2014</b>	55 (59%)	29 (35%)	7 (19%)
<b>Eyecare provider:</b>			
• <b>Optometrist</b>	94 (100%)	72 (88%)	36 (97%)
• <b>Ophthalmologist</b>	0 (0%)	10 (12%)	1 (3%)

†Gender was missing from 2 records.

Records review in eyecare practices often required that 'judgment calls' be made by trained surveyors. For example, non-standard ocular acronyms were also often encountered, which required specialist knowledge in the area to decipher. A review manual was drafted and continuously updated, to devise a consistent and explicit set of rules that can be employed by trained surveyors to conduct a full record review in the future.

In this feasibility study, the overall appropriateness of preventative, glaucoma and diabetic eyecare was 69% (95%CI 67%, 70%), 58% (95%CI 56%, 60%), and 61% (95%CI 55%, 66%), respectively (Figure 1). Overall, preventative eyecare showed the highest appropriateness, most particularly for the indicator related to history taking. Only seven of 82 glaucoma patients reviewed met the inclusion criteria for clinical indicators related to glaucoma management (Appendix 2, indicators 4 and 5). It

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4 was notable that none of the records reviewed in this feasibility study recorded ethnicity, a common  
5 risk factor for many eye conditions including glaucoma<sup>38 39</sup> and diabetic retinopathy<sup>40</sup>.  
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## 10 11 **DISCUSSION**

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14 Using a small, diverse sample of eyecare practices (i.e. different business models, practice size,  
15 EDRMS systems, record format, professions and specialties) located in Sydney, this study  
16 demonstrated the feasibility of reviewing optometry and ophthalmology records to measure  
17 appropriateness of eyecare delivery. Based on these findings, a larger, more comprehensive review  
18 of appropriateness of eyecare in Australia is feasible and indicated. Whilst indicators were  
19 developed, and appropriateness of eyecare assessed for three conditions only (preventative,  
20 glaucoma and diabetic eyecare), there were no indications from this study that feasibility was  
21 condition specific.  
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31 Given that most of the EDRMS were not designed for record review and diagnostic coding was not  
32 commonly used, identification of eligible records was challenging. Different sampling strategies were  
33 used based on how the records were stored and the EDRMS design. The most feasible and efficient  
34 sampling method that could be used in a majority of practices was to sample randomly by patient.  
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40  
41 A very low proportion of diabetic patients were found in the eyecare practices that were selected for  
42 this feasibility study. This may be partially attributed to their location as the prevalence of diabetes is  
43 very low in many eastern suburbs of Sydney, <http://www.diabetesmap.com.au/#/>, to the patients'  
44 profile in the sampled practices and to the speciality of the practitioners in these practices. Some  
45 practitioners also may have only recorded the presence of disease (e.g. the patient having diabetes  
46 mellitus) rather than documenting both absence and presence of all relevant diseases covered  
47 during the history taking. Patients with an established diagnosis of diabetes mellitus may also be  
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4 more likely to consult a secondary care specialist in diabetic eye diseases such as a medical retina  
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6 ophthalmologist. Some of these patients might also have had other health conditions which required  
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8 hospital care and prevented them from attending primary eyecare practices.  
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11 The appropriateness of preventative, glaucoma and diabetic eyecare found in this feasibility pilot  
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13 study was in line with the overall appropriateness of other health care previously measured in the  
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15 CareTrack Study.<sup>15</sup> Regular diabetic eye checks were recommended 89% of the time in this study, a  
16  
17 slightly higher frequency than that of 78% found by the NEHS.<sup>19</sup>  
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19  
20 Despite evidence showing ethnicity as a risk factor for a multitude of ocular disease<sup>41-43</sup>, none of the  
21  
22 eight settings audited in this feasibility study systematically recorded ethnicity. Although further  
23  
24 investigations are needed to determine whether ethnicity might factor in care decisions without  
25  
26 being recorded, it should be noted that criticisms exist regarding the use of ethnicity as a risk  
27  
28 factor.<sup>44-46</sup>  
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30  
31 The process of conducting a record review and the reporting of findings to individual practices  
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33 following the study completion appeared to at times induce some beneficial changes. These  
34  
35 anecdotal findings originated from a single practice where the following changes were reported post  
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37 study: 1) modification of record form plus staff training to reinforce the importance of addressing  
38  
39 the chief complaint and history taking of driving status; and 2) add diagnostic coding for new  
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41 patients with diabetes to improve patient management and promote a strong care evaluation  
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43 culture.  
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#### 45 46 47 **Strengths and Limitations** 48

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50 Important questions were answered with this feasibility study such as the sufficiency of the number  
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52 of eligible patients, data collection time and preferred sampling strategy. Since the purpose of this  
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54 study was to test the feasibility of reviewing patient records from Australian eyecare practices to  
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4 assess the appropriateness of eyecare delivery, eyecare practices with diverse settings were audited  
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6 using convenience sampling, but this may have limited the generalisability of the results. In addition,  
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8 all sampled practices were located in Sydney for convenience purposes; the appropriateness of  
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10 eyecare measured may thus not be representative of the rest of Australia. The majority of the  
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12 patients sampled in this feasibility study were glaucoma suspect or diabetics without diabetic  
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14 retinopathy and the appropriateness of eyecare measured for these two conditions may therefore  
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16 not reflect that of more severe presentations of disease. The unequal number of records obtained  
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18 from each practice may skew the results towards the performance of the practice or practices with  
19  
20 the most records reviewed. Finally, the indicators used were still in development and it is therefore  
21  
22 possible that any significant changes to the indicators that occurred in the final round of review may  
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24 affect the validity of these results.  
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## 26 27 28 **CONCLUSION**

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30 This study demonstrated that appropriateness of eyecare can be measured using record review of  
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32 eyecare practices. Variations from best eyecare practices were identified in this feasibility study  
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34 however this was in line with care previously measured for other health conditions. Different  
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36 sampling strategies were tested to cater for the diverse nature of eyecare practices, EDRMS and  
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38 record types and random sampling proved to be at times challenging and time consuming. It is  
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40 recommended that the personnel involved in extracting data from the clinical records should have  
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42 eyecare backgrounds to be able to make 'judgement calls' during the review process.  
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## 46 47 **ACKNOWLEDGEMENT**

48 We thank the expert reviewers for their contribution towards the Delphi rounds of review of the  
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50 clinical indicators.  
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## 52 53 **FUNDING**

This work was supported by a UNSW Sydney Tuition Fee Scholarship [to KCH]; a UNSW Sydney Faculty of Science June Griffith Fellowship [to IJ]; and a UNSW Sydney Faculty of Science Research Program Grant.

#### CONFLICT OF INTERESTS

The authors declare no conflict of interest.

#### AUTHOR STATEMENT

Substantial contributions to the conception or design of the work [KCH, IJ, FS, LW, PH]; acquisition, analysis, or interpretation of data for the work and drafting the work [KCH, DR]; developing clinical indicators through the Delphi method [KCH, IJ, FS, LW, PH, AW]; revising it critically for important intellectual content and final approval of the version to be published [KCH, IJ, FS, DR].

#### DATA STATEMENT

Technical appendix, statistical code, and dataset available from the Zenodo repository, DOI: [10.5281/zenodo.1196760].

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### 53 **FIGURE LEGENDS**

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4 **Figure 1. The percentage of appropriate eyecare delivery measured by domains of care. 95%**

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6 confidence interval around the mean is displayed. Preventative eyecare: 94 records from 3 practices  
7  
8 were reviewed; glaucoma eyecare: 82 records from 7 practices reviewed; diabetic eyecare: 37  
9  
10 records from 7 practices reviewed. None of the records reviewed met the inclusion criteria for the  
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12 domain of care “referral”, hence this was not plotted.  
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For peer review only

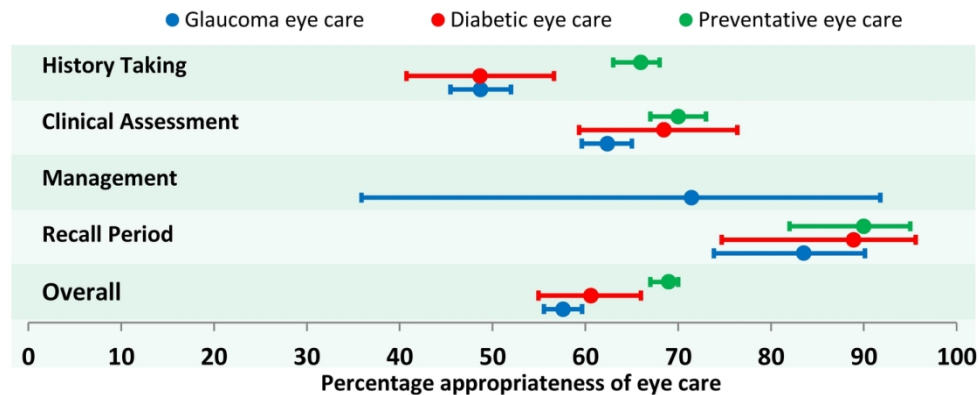


Figure 1. The percentage of appropriate eyecare delivery measured by domains of care. 95% confidence interval around the mean is displayed. Preventative eyecare: 94 records from 3 practices were reviewed; glaucoma eyecare: 82 records from 7 practices reviewed; diabetic eyecare: 37 records from 7 practices reviewed. None of the records reviewed met the inclusion criteria for the domain of care "referral", hence this was not plotted.

64x26mm (600 x 600 DPI)

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**Appendix 1. Preventative eye care clinical indicators**

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**History Taking**

1 Patients presenting for initial comprehensive eye exam should have the following documented:

- name, AND
- age, AND
- ethnicity, AND
- gender, AND
- driving status, AND
- chief complaint, AND
- current medication and allergies, AND
- ocular history, AND
- medical history, AND
- Presence of diabetes mellitus, AND
- ocular family history, AND
- medical family history.

**Clinical Assessment**

2 Patients presenting for comprehensive eye exam should have the following assessments performed and documented:

- habitual visual acuity (VA) at distance, AND
- habitual VA at near, AND
- best corrected monocular VA with refraction at distance, AND
- best corrected binocular VA with refraction at distance, AND
- best corrected binocular VA with refraction at near, AND
- anterior eye examination, AND
- intraocular pressure (IOP) taken more than once, AND
- IOP instrument recorded, AND
- IOP time recorded, AND
- optic nerve head examination, AND
- fovea examination.

**Recall Period**

- 3 Patients aged  $\geq 19$  and  $\leq 39$  with no identified risk are advised to undertake comprehensive eye examination checks at least every 5 years.
  - 4 Patients aged  $\geq 40$  and  $\leq 64$  are advised to undertake comprehensive eye examination at least every 2 years.
  - 5 Patients aged  $\geq 65$  are advised to undertake comprehensive eye examination at least 1 year.
  - 6 Patients with diabetes should be advised to undertake comprehensive eye examination at least every 2 years.
  - 7 Caucasians, aged  $>50$  are advised to undertake regular comprehensive eye examination.
  - 8 Africans, aged  $>40$  are advised to undertake regular comprehensive eye examination.
-

## Appendix 2. Glaucoma clinical indicators

### History Taking

- 1 Patients assessed for OR with glaucoma should have the following documented during the initial visit:
  - age, AND
  - ethnicity, AND
  - personal ocular history, AND
  - general health history, AND
  - history of migraine, AND
  - smoking status, AND
  - current ocular medication, AND
  - current systemic medication, AND
  - current and past steroid use, AND
  - family ocular history, AND
  - diabetic status, AND
  - high blood pressure, AND
  - low blood pressure, AND
  - Raynaud's syndrome.
- 2 Patients assessed for OR with glaucoma should have the following documented during the glaucoma follow-up examination:
  - interval ocular history, AND
  - interval systemic medical history, AND
  - side effects of ocular medications, AND
  - frequency and dosage of medication use, AND
  - time of last IOP-lowering medications, AND
  - review of use of medications.

### Clinical Assessment

- 3 Patients assessed for glaucoma OR with ocular hypertension (OHT) OR newly diagnosed glaucoma should have a glaucoma examination performed and documented or referral for the following procedures is organised:
  - habitual VA, at both distance, AND
  - pupil reaction, AND
  - intraocular pressure (IOP), AND
  - the time of IOP measurement, AND
  - type of IOP measurement (applanation/Goldmann/non-contact tonometer), AND
  - central corneal thickness at regular intervals, AND
  - anterior ocular health by slit lamp, AND
  - peripheral anterior chamber configuration by gonioscopy OR van Herick's peripheral anterior chamber depth assessment, AND
  - size of optic disc, AND
  - cup/disc ratio, AND
  - pattern of the neuroretinal rim, AND
  - presence of disc rim haemorrhage, AND
  - presence of thinning of the nerve fibre layer, AND
  - imaging of optic disc AND/OR optic nerve fibre AND/OR fundus photography, AND
  - visual field examination.

### Management

- 4 Patients with glaucoma AND asthma should NOT be treated with non-selective beta-blockers

(Timolol OR Tenopt OR Timoptol OR Ganfort OR Combigan OR Azarga OR Cosopt OR Xalacom OR Latanocom OR Duotrav).

- 5 Patients with newly diagnosed glaucoma should be treated with topical prostaglandin analogue (Bimatoprost/Latanoprost/Tafluprost/Travoprost), unless contraindicated, OR selective laser trabeculoplasty

#### Recall Period

- 6 Patients with suspected glaucoma should be advised to have a glaucoma follow-up examination within 6 to 18 months.
- 7 Patients with suspected glaucoma (low risk) should be advised to have a glaucoma follow-up examination within 6-24 months.
- 8 Patients with suspected glaucoma (high risk) AND are treated AND archiving target should be advised to have a glaucoma follow-up examination within 3-6 months.
- 9 Patients with suspected glaucoma (high risk) AND are treated AND without archiving target IOP should be advised to have a glaucoma follow-up examination within 4 months.
- 10 Patients with early glaucoma should be advised to have a glaucoma follow-up examination within 12 months.
- 11 Patients with moderate glaucoma should be advised to have a glaucoma follow-up examination within 6 months.
- 12 Patients with advanced glaucoma should be advised to have a glaucoma follow-up examination within 4 months.

#### Referral

- 13 Patients (assessed for glaucoma OR with OHT) AND are treated AND NOT achieving target IOP should be referred to ophthalmologist.

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**Appendix 3. Diabetic eye care clinical indicators**

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**History Taking**

- 1 Patients with diabetes should have the following documented:  
duration of diabetes, AND  
most recent HbA1c result OR self-reported level of blood glucose control, AND  
presence of history of high blood pressure (hypertension), AND  
presence of history of dyslipidaemia (high cholesterol).

**Clinical Assessment**

- 2 Patients with diabetes should have the following assessments performed and documented:  
visual Acuity, AND  
examination of iris, AND  
a dilated fundus exam OR retinal photography with grading.

**Referral**

- 3 Patients with diabetes with a suspicion of macular ischemia AND clinically significant macular oedema (CSME) should have or be referred for fluorescein angiography.
- 4 Patients with diabetes presenting with any reduction in best corrected visual acuity that is suspected to be due to diabetic retinopathy (DR) should be referred to an ophthalmologist within 4 weeks.
- 5 Patients with diabetes presenting with suspected diabetic macular oedema (possible/suspected thickening, hard exudate, oedema) should be referred to an ophthalmologist within 4 weeks.
- 6 Patients with diabetes presenting with proliferative diabetic retinopathy (PDR) should be referred to an ophthalmologist within 4 weeks.
- 7 Patients with type 1 diabetes presenting with persistent vitreous haemorrhage should be referred to an ophthalmologist.

**Management**

- 8 Patients with diabetes AND cataract presenting with diabetic macular oedema should have macular laser before cataract surgery if possible OR intravitreal anti-vascular endothelial growth factor (anti-VEGF) therapy before or at the time of cataract surgery.
- 9 Patients with diabetes presenting with severe NPDR should have laser photocoagulation or receive close follow-up (every 4 months or more frequently).
- 10 Patients with diabetes presenting with PDR, AND NO maculopathy should have panretinal photocoagulation (PRP) scheduled.
- 11 Patients with diabetes presenting with PDR (excluding high risk PDR and advanced PDR), AND CSME should have macular laser treatment OR anti-VEGF treatment BEFORE PRP.
- 12 Patients with type 1 diabetes AND PDR should have PRP.
- 13 Patients with NV at iris (rubeosis) should have PRP.

**Recall Period**

- 14 Patients with diabetes AND NO DR should have been advised to have their eyes examined at least every 2 years.
  - 15 Patients with diabetes AND mild non-proliferative diabetic retinopathy (NPDR) should have been advised to have their eyes examined at least every 1 year.
  - 16 Patients with diabetes AND moderate NPDR should have been advised to have their eyes examined at least every 6 months.
  - 17 Patients with diabetes AND severe NPDR should have been advised to have their eyes examined at least every 3 months.
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# BMJ Open

## Can the appropriateness of eyecare be measured through cross-sectional retrospective patient record review in eyecare practices in Australia? The iCareTrack feasibility study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-024298.R1
Article Type:	Research
Date Submitted by the Author:	11-Dec-2018
Complete List of Authors:	Ho, Kam; University of New South Wales Faculty of Science, School of Optometry and Vision Science Rahardjo, Dian; The University of New South Wales, School of Optometry and Vision Science Stapleton, Fiona; The University of New South Wales, School of Optometry and Vision Science Wiles, Louise; Macquarie University Faculty of Medicine and Health Sciences; University of South Australia Division of Health Sciences, Centre for Population Health Research Hibbert, Peter; Macquarie University Faculty of Medicine and Health Sciences; University of South Australia Division of Health Sciences, Centre for Population Health Research White, Andrew; Cambridge University Teaching Hospitals NHS Foundation Trust, Cambridge, ; Centre for Vision Research, Westmead Millennium Institute, Hayen, Andrew; University of Technology Sydney Faculty of Health Jalbert, Isabelle; The University of New South Wales, School of Optometry and Vision Science
<b>Primary Subject Heading</b>:	Health services research
Secondary Subject Heading:	Ophthalmology
Keywords:	appropriateness of care, record audit, record review, preventative eyecare, Glaucoma < OPHTHALMOLOGY, Diabetic retinopathy < DIABETES & ENDOCRINOLOGY

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## Title page

**Title:** Can the appropriateness of eyecare be measured through cross-sectional retrospective patient record review in eyecare practices in Australia? The iCareTrack feasibility study

**Authors:** Kam Chun Ho<sup>1</sup> ([kam.ho@unsw.edu.au](mailto:kam.ho@unsw.edu.au)),  
Dian Rahardjo<sup>1</sup> ([d.rahardjo@unsw.edu.au](mailto:d.rahardjo@unsw.edu.au)),  
Fiona Stapleton PhD<sup>1</sup> ([f.stapleton@unsw.edu.au](mailto:f.stapleton@unsw.edu.au)),  
Louise Wiles PhD<sup>2,3</sup> ([louise.wiles@mq.edu.au](mailto:louise.wiles@mq.edu.au)),  
Peter Hibbert<sup>2,3</sup> ([peter.hibbert@mq.edu.au](mailto:peter.hibbert@mq.edu.au)),  
Andrew White PhD<sup>1,4,5</sup> ([andrew.white@sydney.edu.au](mailto:andrew.white@sydney.edu.au)),  
Andrew Hayen PhD<sup>6</sup> ([Andrew.Hayen@uts.edu.au](mailto:Andrew.Hayen@uts.edu.au)),  
and Isabelle Jalbert PhD<sup>1</sup> ([i.jalbert@unsw.edu.au](mailto:i.jalbert@unsw.edu.au))

<sup>1</sup>School of Optometry and Vision Science, UNSW Sydney, Australia

<sup>2</sup>Faculty of Medicine and Health Sciences, Australian Institute of Health Innovation, Macquarie University, Sydney, Australia

<sup>3</sup>Centre for Population Health Research, School of Health Sciences, University of South Australia, Adelaide, Australia

<sup>4</sup>Save Sight Institute, University of Sydney, Westmead Hospital, Sydney, Australia

<sup>5</sup>Centre for Vision Research, Westmead Institute for Medical Research, University of Sydney, Westmead Hospital, Sydney, Australia

<sup>6</sup>Faculty of Health, University of Technology Sydney, Australia

**Corresponding Author:** A/Prof Isabelle Jalbert

1  
2  
3  
4 [i.jalbert@unsw.edu.au](mailto:i.jalbert@unsw.edu.au)  
5

6 +61 2 9385 9816  
7

8 School of Optometry and Vision Science, UNSW Sydney, Sydney  
9

10 NSW 2052, Australia  
11

12  
13 **Word count:** 3398  
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15 **Keywords:** appropriateness of care, record audit, record review, preventative  
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17 eyecare, glaucoma, diabetic retinopathy  
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## Abstract

**Objectives:** The CareTrack study found that a wide range of appropriateness of care (i.e. care in line with evidence-based or consensus-based guidelines) was delivered across many health conditions in Australia. This study therefore aimed to demonstrate the feasibility of using the CareTrack method (a retrospective onsite record review) to measure the appropriateness of eyecare delivery.

**Design:** Cross-sectional feasibility study.

**Setting and Participants:** Two hundred and thirteen patient records randomly selected from eight optometry and ophthalmology practices in Australia, selected through a combination of convenience and maximum variation sampling.

**Methods:** Retrospective record review designed to assess the alignment between eyecare delivered and 93 clinical indicators (Delphi method involving 11 experts) extracted from evidence-based clinical practice guidelines.

**Primary Outcome Measure:** Number of eligible patient records, sampling rates, and data collection time. This feasibility study also tested the ability of 93 clinical indicators to measure percentage appropriate eyecare for preventative, glaucoma, and diabetic eyecare. A secondary outcome was the percentage of practitioner-patient encounters at which appropriate eyecare was received.

**Results:** A median of 20 records (range 9 to 63) per practice were reviewed. Data collection time ranged from 3 to 5.5 hours (median 3.5). The most effective sampling strategy involved random letter generation followed by sequential sampling. The appropriateness of care was 69% (95%CI, 67%-70%) for preventative eyecare, 60% (95%CI, 56%-58%) for glaucoma and 63% (95%CI, 57%-69%) for diabetic eyecare.

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4 **Conclusions:** Appropriateness of eyecare can be measured effectively using retrospective record  
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6 review of eyecare practices and consensus-based care indicators.  
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10 **ARTICLE SUMMARY**  
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13 **Strengths and Limitations of this Study**  
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- 16 • The feasibility of a systematic approach (based on CareTrack method) to measure  
17 appropriateness of eyecare on site in eyecare practices was demonstrated.
- 18 • Appropriateness of eyecare was in line with previously measured healthcare but this may  
19 represent a slight overestimation of true appropriateness of eyecare.
- 20 • Measurement of appropriateness of eyecare was limited to those aspects for which clinical  
21 indicators could be derived.
- 22 • The small convenience sample used in this study may introduce selection biases.
- 23 • The study findings support the conduct of a larger trial to determine the percentage of  
24 eyecare encounters at which appropriate care is received. This study identified the best  
25 patient record sampling methods, potential issues associated with recruiting eyecare  
26 practices, and with accessing, extracting, recording and analysing clinical records.  
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## INTRODUCTION

Globally, 285 million people of all ages suffer from visual impairment with the major causes from both chronic eye conditions, including ocular diseases (e.g. glaucoma, diabetic retinopathy, age-related macular degeneration, cataract) and uncorrected refractive errors such as myopia and presbyopia.<sup>1,2</sup> The prevalence of vision problems is strongly associated with ageing,<sup>3</sup> hence the burden of ocular health problems will increase with an ageing population. Due to the growing demand for eyecare and in the context of resource scarcity worldwide, interest in measuring and enhancing the quality of eyecare delivery is growing.<sup>4,5</sup> Translation of best available evidence into clinical practice can improve the efficacy and cost-effectiveness of patient management.<sup>6</sup> In theory, evidence-based clinical practice guidelines aim to translate research findings into easy to apply care recommendations that are intended to guide practitioners to improve their professional practice and optimise patient care.<sup>7</sup> However, there is mounting evidence that such evidence-based clinical practice guidelines are not always adhered to or fully implemented in the clinical setting.<sup>8</sup>

The measurement of care quality is complex and multidimensional. In Australia, quality is considered as the guiding principle for assessing the health system's performance and this includes nine-dimensions: appropriate, effective, responsive, continuous, sustainable, accessible, capable, efficient and safe.<sup>9</sup> In this study, we focused on appropriateness of care defined as "care/intervention/action that is relevant to the patient's needs and based on established standards" (see Box 1).<sup>10</sup> Assessment of the appropriateness of eyecare delivery requires that recommendations from evidence-based clinical practice guidelines or expert-based consensus be transformed into measurable clinical indicators which are designed to assess, compare and determine the potential to improve care.<sup>11</sup>

### Box 1. Definitions used.

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4 **Condition** means clinical ocular conditions (e.g. glaucoma and diabetes) or preventative care.  
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6 **Evidence-based care** involves clinical decision making based on the existing best evidence for the  
7 care (including eyecare) of individual patients.<sup>12</sup> The practice of evidence-based care means the  
8 integration of the clinical expertise of the practitioners with the best available clinical evidence  
9 and patient's preferences.<sup>13</sup>  
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14 **Appropriateness of eyecare** is care/intervention/action provided is relevant to the patient's  
15 needs and based on established standards.<sup>10</sup> In this study, appropriate eyecare is clinical care for a  
16 condition considered to be evidence-based or consensus-based by a panel of clinical experts in  
17 Australia in the context in which it was delivered in the years 2013 and 2014.  
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23 **Clinical practice guidelines** are evidence-based statements that include recommendations  
24 intended to optimise patient care and assist health care practitioners to make decisions about  
25 appropriate health care for specific clinical circumstances. Clinical practice guidelines should assist  
26 clinicians and patients in shared decision making.<sup>14</sup>  
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33 **Clinical indicator** is a measurable component of a standard or guideline, with explicit criteria for  
34 inclusion, exclusion, time frame and setting.<sup>15</sup> It is a condition-specific process measurement of  
35 healthcare management, appropriate for Australian eyecare practice in 2013-2014.<sup>16</sup>  
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40 **Record review** is a method using pre-recorded, patient-focused data as the primary data source  
41 to assess quality of care.<sup>17</sup>  
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44 **Eyecare practice** refers to practice or clinic (e.g. optometry and ophthalmology practice) where a  
45 service related to the eyes or vision is provided.  
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48 **Eyecare provider** is an individual who provides a service related to the eyes or vision.  
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50 **Surveyor** is a person with appropriate clinical and review experience to review patient records  
51 against clinical indicators.  
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4 There are indications that the appropriateness of care is at times suboptimal. For example, the RAND  
5 study conducted in 2000 in the United States evaluated performance on 439 clinical indicators for 30  
6 acute and chronic health conditions and preventative care. American adults received recommended  
7 health care only 55% of the time.<sup>18</sup> More recently, the CareTrack study showed similar results with  
8 57% of Australian adults receiving appropriate care across 22 health conditions.<sup>15</sup> Very little  
9 information can be found on the quality of delivery of eyecare specifically, as ocular conditions were  
10 not included in the CareTrack study<sup>15</sup> and only small components of eyecare such as senile cataract  
11 were evaluated in the RAND study. According to the National Eye Health Survey (NEHS),<sup>19</sup> more than  
12 50% of Australians with visual impairment are undiagnosed. To meet the eyecare needs of the  
13 ageing population and optimise the health care spending in this area, it is important to ensure that  
14 eyecare is delivered appropriately. To do this requires a deep understanding of who is getting what  
15 eyecare from whom and why in Australia.

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32 Record review is commonly used to measure adherence to practice guidelines, the translation of  
33 clinical education into practice, and the effect of interventions intending to improve care  
34 delivery.<sup>15,20-22</sup> The greatest advantage of a record review is that the data are already collected,  
35 making it relatively inexpensive and easy to obtain a large amount of data over an extended  
36 period.<sup>17</sup> However, patient records are not designed for research purposes, so the data can be  
37 incomplete, unavailable, or difficult to interpret.<sup>23</sup>

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46 This paper describes a cross-sectional feasibility study to test whether retrospective onsite reviewing  
47 patient records from eyecare practices can be used to assess the appropriateness of eyecare delivery  
48 in Australia. The feasibility study therefore aims to determine patient record sampling methods for  
49 the main trial, and explore potential issues associated with recruiting eyecare practices and with  
50 accessing, extracting, recording and analysing clinical records.

## 51 52 53 54 55 56 57 58 **METHODS**



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4 An onsite cross-sectional retrospective record review of eyecare practices was designed to  
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6 determine the types of problems that might be encountered and to inform the future main study;  
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8 this included testing the selection of eye conditions, their clinical indicators and the logistical and  
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10 practical aspects of recruiting eyecare practices, assessing patient records and extracting, recording,  
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12 storing and analysing the data. The feasibility study was designed to assess the alignment between  
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14 eyecare delivered and consensus-based care indicators (see below) extracted from evidence-based  
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16 clinical practice guidelines for three representative eye conditions. The representative eye  
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18 conditions glaucoma and diabetic retinopathy were selected based on prevalence (sufficiently high  
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20 to be measured using the proposed methodology), burden of disease, and the availability of  
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22 Australian and international evidence-based clinical practical guidelines against which to measure  
23  
24 appropriateness of eyecare delivery.<sup>24-27</sup> Preventative eyecare was also selected as effective  
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26 prevention is a key policy initiative for all health care delivery.  
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### 31 32 **Study settings**

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34 A sample of eight optometry and ophthalmology practices located in Sydney, Australia were selected  
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36 by the investigators based on convenience and maximum variation sampling, ensuring  
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38 representation from a variety of eyecare practice settings using different record types (e.g. paper or  
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40 electronic records), electronic document and records management system (EDRMS)<sup>28</sup> and business  
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42 models (e.g. franchisee, corporate and independently owned practices).  
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### 47 48 **Eligibility**

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50 A random sample of adult patient records (aged over 18 years old) from each of the selected eyecare  
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52 practices who attended for eye examination between 1st January 2013 and 31st December 2014  
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54 were reviewed. Visits were included if they were billed as a comprehensive eye examination (i.e.  
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56 Medicare item numbers 10900, 10907, 10912, 10913, 10914 or 10915),<sup>29</sup> representing consultations  
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58 longer than 15 minutes in length of time, or those categorised as comprehensive eye examination by  
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4 the billing eyecare practitioner. Post-operative visits, contact lens fitting or aftercare, unscheduled  
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6 visits due to acute conditions, and subsequent follow-up visits (e.g. visual field test) were excluded  
7  
8 from the sample.  
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11 To assess the appropriateness of glaucoma eyecare, patients were included if they were diagnosed  
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13 with glaucoma, ocular hypertension, were at risk of glaucoma, or were categorised as glaucoma  
14  
15 suspects. According to the NHMRC guidelines for the Screening, Progress, Diagnosis, Management  
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17 and Prevention of Glaucoma,<sup>30</sup> a glaucoma suspect is a person suspected of having glaucoma who  
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19 has some but not all of the criteria required for a glaucoma diagnosis. They may have one or more of  
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21 the following: suspicious optic disc, optic disc margin haemorrhage, occludable drainage angle,  
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23 peripheral anterior synechiae or elevated intraocular pressure. A person at risk of glaucoma may be  
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25 someone with a positive family history of glaucoma, or a history of chronic steroid use, or some  
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27 other known risk factors for the disease. To assess the appropriateness of diabetic eyecare, patients  
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29 were included if they were diagnosed with type 2 diabetes mellitus (both with and without diabetic  
30  
31 retinopathy). Pregnant patients were excluded from all appropriateness assessments and patients  
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33 with type 1 diabetes mellitus were excluded from the assessment of appropriateness of diabetic  
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35 eyecare. This was because different sets of clinical indicators were expected and the prevalence  
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37 might be too low to measure the appropriateness of eyecare for pregnant patients and patients with  
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39 type 1 diabetes mellitus.  
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#### 46 **Protocol and Sampling**

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49 The study protocol was based on the CareTrack Australia protocol and the RAND methodology.<sup>18,31</sup>  
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51 Eight clinical indicators for preventative eyecare (Appendix 1), 13 for glaucoma eyecare (Appendix 2)  
52  
53 and 17 for diabetic eyecare (Appendix 3) were developed –by the investigators based on  
54  
55 recommendations extracted from relevant published national and international clinical practice  
56  
57 guidelines (Table 1) –using the Delphi method. The purpose of the clinical indicator development  
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was not to create new sets of clinical practice guidelines or care recommendation, but to facilitate quantitative measurement of appropriateness of eyecare. This rigorous Delphi review process involved a panel of three to five nationally recognised clinical experts from the relevant fields who were invited to review and rate the clinical indicators for feasibility, acceptability and impact. Experts were identified as clinical leaders in their field and typically were employed in an eye department in a large hospital or a large teaching clinic and/or held an adjunct academic appointment. Experts were invited to comment and score the indicators for their appropriateness, in the context of eyecare delivered in Australia from 2013 to 2014. Experts from both the optometry and ophthalmology field were involved in the Delphi review process for all clinical indicators.

**Table 1. Evidence-based clinical practice guidelines used to develop clinical indicators**

Guideline	Year	Publisher	Country
<b>Preventative eyecare</b>			
NHMRC guidelines for the Screening, Progress, Diagnosis, Management and Prevention of Glaucoma <sup>†27</sup>	2010	National Health and Medical Research Council (NHMRC)	Australia
Guidelines for the Management of Diabetic Retinopathy <sup>†26</sup>	2008	NHMRC	Australia
Canadian Ophthalmological Society evidence-based clinical practice guidelines for the periodic eye examination in adults in Canada <sup>32</sup>	2007	Canadian Ophthalmological Society (COS) guidelines	Canada
Preferred Practice Pattern <sup>®</sup> guidelines. Comprehensive Adult Medical Eye Evaluation <sup>33</sup>	2010	American Academy of Ophthalmology (AAO)	United States of America
<b>Glaucoma eyecare</b>			
NHMRC guidelines for the Screening, Progress, Diagnosis, Management and Prevention of Glaucoma <sup>27</sup>	2010	NHMRC	Australia
Canadian Ophthalmological Society Evidence-based Clinical Practice Guidelines for the Management of Glaucoma in the Patient Eye <sup>34</sup>	2009	COS guidelines	Canada
Diagnosis and Management of Chronic Open Angle Glaucoma and Ocular Hypertension <sup>35</sup>	2009	National Institute for Health and Care Excellence (NICE)	United Kingdom
Preferred Practice Pattern <sup>®</sup> Guidelines. Primary open-angle glaucoma <sup>36</sup>	2010	AAO	United States of America
<b>Diabetic eyecare</b>			
Guidelines for the Management of Diabetic	2008	NHMRC	Australia

Retinopathy<sup>26</sup>

Canadian Ophthalmological Society evidence-based clinical practice guidelines for the management of diabetic retinopathy <sup>37</sup>	2012	COS guidelines	Canada
SIGN Management of diabetes A national clinical guideline <sup>38</sup>	2010	Scottish Intercollegiate Guidelines Network	United Kingdom

†Only the recommendations related to preventative eyecare were considered

It was initially intended that 10 records per condition per practice be reviewed, however in practice the number of records sampled varied based on the time available and the complexity of the on-site record review. Records of preventative care patients were first reviewed, followed by records of glaucoma and diabetic eyecare patients. When a list of eligible patients or eligible visits could not be automatically generated, a range of possible sampling methods were used to identify eligible records, as appropriate. These methods varied between different eyecare practice settings with the final method determined based on how the records were stored. Briefly, this involved the surveyors (KCH, DR) generating either “a list of patients” who were examined at the eyecare practice within the study period or “a list of visits” conducted within the study period (i.e. multiple visits from the same patient could be included) and taking a random sample from this generated list. For practices with EDRMS that could not generate any of the types of lists mentioned above, “a list of random dates” was generated with eligible visits on those dates included in the sample pool. For practices without EDRMS where paper records were used, ten random letters from the alphabet were generated anew each time and sampling started from the patient whose surname starts with the letter selected; sequential records were then checked until one eligible patient per letter was identified. For one practice, only records from patients who visited the practice between September 2016 and March 2017 were available for sampling due to the practice having undergone extensive renovation during the mandated sampling period and their patient records having been relocated to other premises and not being accessible. Sampling for that practice therefore occurred from the pool of patients examined in 2013 or 2014 who happened to have been re-examined in the period

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4 between September 2016 and March 2017. In instances where sampling occurred by patients and  
5 not by visits, only the first eligible visit was included. In one practice, patients with diabetic mellitus  
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7 could best be identified using the Medicare item 10915 (comprehensive consultation of more than  
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9 15 minutes duration for a patient with diabetes mellitus including dilation<sup>29</sup>) but this was not the  
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11 case for other practices sampled.  
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16 Random sampling was achieved by using a random number generator. First, a range of number  
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18 started from '1' was assigned to each patient or visit between 1st January 2013 and 31st December  
19  
20 2014. A list of random numbers was then generated and the records with the corresponding number  
21  
22 was sampled.  
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26 In order to facilitate the progress of this feasibility study, clinical indicators from different but  
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28 advanced stages of the drafting and Delphi method review process were used for certain conditions.  
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30 For preventative eyecare, clinical indicators drafted based on the clinical practice guidelines but that  
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32 had not undertaken Delphi expert review were used in this feasibility study. For glaucoma and  
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34 diabetic eyecare, streamlined clinical indicators which had been reviewed in the first but not the  
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36 final round of the Delphi process by the panel of experts were used.  
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#### 40 **Data extraction**

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42 Patient age, gender, ethnicity and date of visit were extracted from each patient record selected.  
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44 Records were also reviewed for appropriateness by one of two trained surveyors (K.C.H. and D.R.),  
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46 recording whether individual indicators and sub-indicators were met with 'yes' (care provided during  
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48 the encounter was consistent with the indicator), 'no' (care provided during the encounter was not  
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50 consistent with the indicator) or 'not applicable' (the indicator was not relevant to the encounter) in  
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52 a secure Microsoft Excel spreadsheet.  
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4 Every effort was made to minimise the occurrence of missing data. For example, for occurrences  
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6 where data for an indicator were consistently missing (e.g. instrument used for intraocular pressure  
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8 measurement), the practice manager or the eyecare practitioner were interviewed and relevant  
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10 information (e.g. only a single tonometer type available in the practice) used to record answers to  
11  
12 relevant indicators. In other instances, for example where the practices' EDRMS only retained a  
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14 record of the last recommended recall period, information about the recommended review period  
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16 could not be verified retrospectively and therefore any indicators related to recommended review  
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18 period were noted as 'not applicable'.  
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23 The extracted data from two records were cross-checked at each eyecare practice to ensure the  
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25 inter-reliability of the two data surveyors and any differences were resolved by discussion. Kappa  
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27 score will be calculated to test the level of agreement between the two surveyors. Percent  
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29 appropriateness of care for each indicator was averaged across all eligible records.  
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### 32 33 **Patient and Public Involvement**

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35 In this study, patients were not involved. All data were collected from the patient records. Ethics  
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37 approval (Approval no.: HC15336) was obtained from the University of New South Wales (UNSW)  
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39 Sydney's Human Research Ethics Committee and a waiver of consent to access patient records  
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41 retrospectively from eyecare practices was granted. Informed consent was obtained from the  
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43 eyecare practices.  
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### 48 49 **RESULTS**

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51 Nine eyecare practices were invited and eight agreed to participate in the feasibility study. One  
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53 practice refused to participate as the practice owner did not feel comfortable giving access to the  
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55 patient records. This diverse convenience sample included two franchises, one corporate, one  
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57 teaching clinic, one referral clinic, two independent optometry clinics and one private  
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ophthalmology clinic (Table 2). Although all eight practices used some form of EDRMS, four of the practices predominantly used paper records.

**Table 2. Characteristics of the sample eyecare practices**

<b>No. of Optometry practices : No. of Ophthalmology practices</b>	7 : 1
<b>Electronic document and record management system (EDRMS):</b>	
• <b>Commercially available (e.g. Optomate, Sunix)</b>	3
• <b>Bespoke</b>	5
<b>Record types:</b>	
• <b>Electronic record only</b>	4
• <b>Structured paper record</b>	2
• <b>Semi-structured paper record</b>	1
• <b>Unstructured paper record only</b>	1
<b>Sampling method:</b>	
• <b>By patients</b>	5†
• <b>By visits</b>	1
• <b>By dates</b>	2
<b>No. of records sampled per practice§:</b>	
• <b>Preventative eyecare, median (range)</b>	23 (21 to 50)
• <b>Glaucoma eyecare, median (range)</b>	10 (8 to 20)
• <b>Diabetic eyecare, median (range)</b>	4 (1 to 10)
<b>No. of practitioners sampled per practice, median (range)</b>	3 (1 to 14)
<b>Time taken (hours per practice), median (range)</b>	3.5 (3 to 5.5)

†One practice was able to provide a list of all eligible patients (i.e. patients with glaucoma, glaucoma suspects and diabetic patients).

§Appropriateness of preventative eyecare was assessed in 3 of 8 practices; appropriateness of glaucoma and diabetic eyecare was assessed in 7 of 8 practices.

The purpose of this study was to explore potential issues associated with accessing, extracting, recording and analysing clinical records. Eligible records for preventative eyecare were easily identified, so time was preferentially allocated to reviewing of these over the other two conditions, to identify the optimal sampling method. As a result, a median of 23 records (range: 21 to 50 records) were reviewed for preventative eyecare within the allowed time in three practices, which was more than the intended 10 records.

Patient records for glaucoma and diabetic eyecare were randomly sampled using different methods among the practices to determine the best feasible sampling strategy to use in the main trial as a diversity of EDRMS and record types were used in the eyecare practices sampled. One practice

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4 categorised patients based on diagnosis (e.g. glaucoma and diabetes) and visit types (e.g. initial and  
5 follow-up visits) and a list of eligible patients was therefore provided by the practice and could be  
6 used for random sampling. Another practice categorised patients by diagnosis and a list of eligible  
7 patients could be generated from the EDMRS for random sampling. For the other five settings, the  
8 eligibility had to be checked consecutively for each randomly sampled individual patient record, until  
9 the required number of records was found; this process proved to be much more time consuming  
10 but was necessary in a majority of sampled practices.

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21 For preventative eyecare, ten record review was completed within 1 hour for all methods, but more  
22 time was required to identify eligible records for glaucoma and diabetic eyecare. If a list of patients  
23 eligible for random sampling could not be generated, sampling by patients was the most feasible (for  
24 both paper and electronic records) and least time-consuming method of identifying the eligible  
25 records for glaucoma and diabetic eyecare. Ten eligible records related to glaucoma eyecare could  
26 be identified and reviewed within 1 to 1.5 hours for most methods. For diabetic eyecare, up to 4  
27 eligible records could be identified and reviewed within 1.5 to 2 hours whereas only 1 or 2 eligible  
28 records could be identified if sampling occurred by visits or dates. Sampling of diabetic patients by  
29 Medicare Item 10915 was therefore suggested as a potentially more feasible option. This was  
30 attempted in the last practice where diabetic eyecare was measured for the feasibility study. The  
31 overall time spent to review the records per practice ranged from 3 to 5.5 hours.

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46 Two hundred and thirteen records were reviewed in the feasibility study, and the characteristics of  
47 the randomly selected records (patients) are shown in Table 3. Appropriateness of preventative  
48 eyecare was assessed in 3 practices; appropriateness of glaucoma and diabetic eyecare was assessed  
49 in 7 practices. The glaucoma and diabetic patients randomly sampled were older and a majority of  
50 the visits reviewed for these patients occurred in 2013. Three quarters of glaucoma patients were  
51 glaucoma suspects, followed by 17% with moderate glaucoma, 7% with severe glaucoma and 1%  
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with early glaucoma. Nearly 80% of diabetic patients did not have diabetic retinopathy, followed by 7% with moderate diabetic retinopathy and 4% mild diabetic retinopathy.

**Table 3. Characteristics of the record review's random sample**

	Preventative eyecare	Glaucoma	Diabetic eyecare
<b>No of practices sampled</b>	3	7	7
<b>No of records sampled</b>	94	82	37
<b>Patient age (mean <math>\pm</math> SD, years)</b>	43.1 $\pm$ 17.6	56.2 $\pm$ 15.2	61.6 $\pm$ 10.6
<b>Patient gender:</b>			
• <b>Male</b>	39 (41%) <sup>†</sup>	44 (54%)	22 (59%)
• <b>Female</b>	53 (56%) <sup>†</sup>	38 (46%)	15 (41%)
<b>Year of the sampled visit:</b>			
• <b>2013</b>	39 (41%)	53 (65%)	30 (81%)
• <b>2014</b>	55 (59%)	29 (35%)	7 (19%)
<b>Eyecare provider:</b>			
• <b>Optometrist</b>	94 (100%)	72 (88%)	36 (97%)
• <b>Ophthalmologist</b>	0 (0%)	10 (12%)	1 (3%)

<sup>†</sup>Gender was missing from 2 records.

Records review in eyecare practices often required that 'judgment calls' be made by trained surveyors. For example, non-standard ocular acronyms were also often encountered, which required specialist knowledge in the area to decipher. A review manual was drafted and continuously updated, to devise a consistent and explicit set of rules that can be employed by trained surveyors to conduct a full record review in the future.

In this feasibility study, the overall appropriateness of preventative, glaucoma and diabetic eyecare was 69% (95%CI 67%, 70%), 58% (95%CI 56%, 60%), and 61% (95%CI 55%, 66%), respectively (Figure 1). Overall, preventative eyecare showed the highest appropriateness, most particularly for the indicator related to history taking. Only seven of 82 glaucoma patients reviewed met the inclusion criteria for clinical indicators related to glaucoma management (Appendix 2, indicators 4 and 5). It was notable that none of the records reviewed in this feasibility study recorded ethnicity, a common risk factor for many eye conditions including glaucoma<sup>39,40</sup> and diabetic retinopathy.<sup>41</sup> Substantial

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4 inter-rater agreement between the two surveyors was shown with a kappa score equal to 0.76  
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6 (95%CI 0.74, 0.78).  
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## 9 **DISCUSSION**

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12 Using a small, diverse sample of eyecare practices (i.e. different business models, practice size,  
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14 EDRMS systems, record format, professions and specialties) located in Sydney, this study  
15  
16 demonstrated the feasibility of reviewing optometry and ophthalmology records to measure  
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18 appropriateness of eyecare delivery. Based on these findings, a larger, more comprehensive review  
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20 of appropriateness of eyecare in Australia is feasible and indicated. Whilst indicators were  
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22 developed, and appropriateness of eyecare assessed for three conditions only (preventative,  
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24 glaucoma and diabetic eyecare), there were no indications from this study that feasibility was  
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26 condition specific.  
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31 Given that most of the EDRMS were not designed for record review and diagnostic coding was not  
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33 commonly used, identification of eligible records was challenging. Different sampling strategies were  
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35 used based on how the records were stored and the EDRMS design. The most feasible and efficient  
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37 sampling method that could be used in a majority of practices was to sample randomly by patient.  
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39 Other recommendations derived from this feasibility study include the use of surveyors with an  
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41 eyecare background, and a time allocation of 4 to 5 hours per practice for measurement of  
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43 appropriateness of eyecare in three conditions.  
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48 A very low proportion of diabetic patients were found in the eyecare practices that were selected for  
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50 this feasibility study. This may be partially attributed to their location as the prevalence of diabetes is  
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52 very low in many eastern suburbs of Sydney, <http://www.diabetesmap.com.au/#/>, to the patients'  
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54 profile in the sampled practices and to the speciality of the practitioners in these practices. Some  
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56 practitioners also may have only recorded the presence of disease (e.g. the patient having diabetes  
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58 mellitus) rather than documenting both absence and presence of all relevant diseases covered  
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4 during the history taking. Patients with an established diagnosis of diabetes mellitus may also be  
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6 more likely to consult a secondary care specialist in diabetic eye diseases such as a medical retina  
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8 ophthalmologist. Some of these patients might also have had other health conditions which required  
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10 hospital care and prevented them from attending primary eyecare practices.  
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14 The appropriateness of preventative, glaucoma and diabetic eyecare found in this feasibility pilot  
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16 study was in line with the overall appropriateness of other health care previously measured in the  
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18 CareTrack Study.<sup>15</sup> Regular diabetic eye checks were recommended 89% of the time in this study, a  
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20 slightly higher frequency than that of 78% found by the NEHS.<sup>19</sup>  
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24 Despite evidence showing ethnicity as a risk factor for a multitude of ocular disease<sup>42-44</sup>, none of the  
25  
26 eight settings audited in this feasibility study systematically recorded ethnicity. Although further  
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28 investigations are needed to determine whether ethnicity might factor in care decisions without  
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30 being recorded, it should be noted that criticisms exist regarding the use of ethnicity as a risk  
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32 factor.<sup>45-47</sup>  
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36 The process of conducting a record review and the reporting of findings to individual practices  
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38 following the study completion appeared to at times induce some beneficial changes. These  
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40 anecdotal findings originated from a single practice where the following changes were reported post  
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42 study: 1) modification of record form plus staff training to reinforce the importance of addressing  
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44 the chief complaint and history taking of driving status; and 2) add diagnostic coding for new  
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46 patients with diabetes to improve patient management and promote a strong care evaluation  
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48 culture.  
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### 51 52 **Strengths and Limitations** 53

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55 Important questions were answered with this feasibility study such as the sufficiency of the number  
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57 of eligible patients, data collection time and preferred sampling strategy. Since the purpose of this  
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4 study was to test the feasibility of reviewing patient records from Australian eyecare practices to  
5 assess the appropriateness of eyecare delivery, eyecare practices with diverse settings were audited  
6 using convenience sampling, but this may have limited the generalisability of the results. In addition,  
7 all sampled practices were located in Sydney for convenience purposes; the appropriateness of  
8 eyecare measured may thus not be representative of the rest of Australia. The majority of the  
9 patients sampled in this feasibility study were glaucoma suspect or diabetics without diabetic  
10 retinopathy and the appropriateness of eyecare measured for these two conditions may therefore  
11 not reflect that of more severe presentations of disease. The unequal number of records obtained  
12 from each practice may skew the results towards the performance of the practice or practices with  
13 the most records reviewed. Finally, the indicators used were still in development and it is therefore  
14 possible that any significant changes to the indicators that occurred in the final round of review may  
15 affect the validity of these results.

## 31 **CONCLUSION**

32 This study demonstrated that appropriateness of eyecare can be measured using record review of  
33 eyecare practices. Variations from best eyecare practices were identified in this feasibility study  
34 however this was in line with care previously measured for other health conditions. Different  
35 sampling strategies were tested to cater for the diverse nature of eyecare practices, EDRMS and  
36 record types and random sampling proved to be at times challenging and time consuming. It is  
37 recommended that the personnel involved in extracting data from the clinical records should have  
38 eyecare backgrounds to be able to make 'judgement calls' during the review process.

## 51 **ACKNOWLEDGEMENT**

52 We thank the expert reviewers for their contribution towards the Delphi rounds of review of the  
53 clinical indicators.

## 58 **FUNDING**

1  
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3  
4 This work was supported by a UNSW Sydney Tuition Fee Scholarship [to KCH]; a UNSW Sydney  
5  
6 Faculty of Science June Griffith Fellowship [to IJ]; and a UNSW Sydney Faculty of Science Research  
7  
8 Program Grant.  
9

#### 10 **CONFLICT OF INTERESTS**

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13 The authors declare no conflict of interest.  
14

#### 15 **AUTHOR STATEMENT**

16  
17 Substantial contributions to the conception or design of the work [KCH, IJ, FS, LW, PH]; acquisition,  
18  
19 analysis, or interpretation of data for the work and drafting the work [KCH, DR, AH]; developing  
20  
21 clinical indicators through the Delphi method [KCH, IJ, FS, LW, PH, AW]; revising it critically for  
22  
23 important intellectual content and final approval of the version to be published [KCH, IJ, FS, DR, AH].  
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25

#### 26 **DATA STATEMENT**

27  
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29 Technical appendix, statistical code, and dataset available from the Zenodo repository, DOI:  
30  
31 [10.5281/zenodo.1196760].  
32

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7 **FIGURE LEGENDS**  
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10 **Figure 1. The percentage of appropriate eyecare delivery measured by domains of care.** 95%  
11 confidence interval around the mean is displayed. Preventative eyecare: 94 records from 3 practices  
12 were reviewed; glaucoma eyecare: 82 records from 7 practices reviewed; diabetic eyecare: 37  
13 records from 7 practices reviewed. None of the records reviewed met the inclusion criteria for the  
14 domain of care "referral", hence this was not plotted.  
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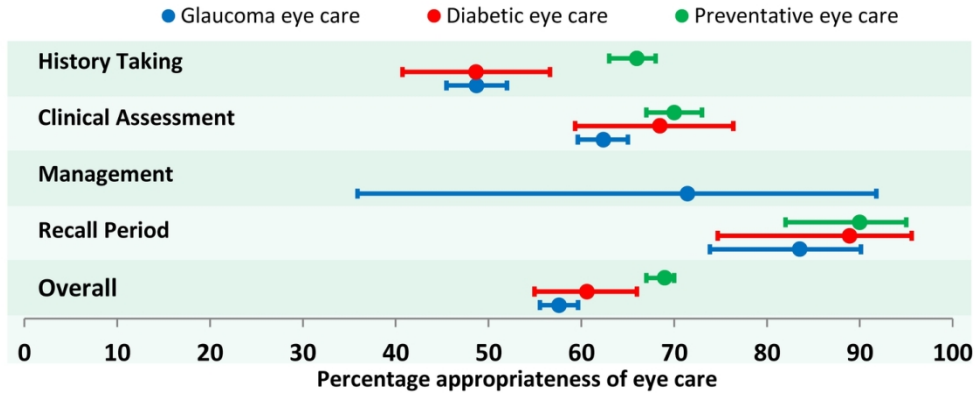


Figure 1. The percentage of appropriate eyecare delivery measured by domains of care. 95% confidence interval around the mean is displayed. Preventative eyecare: 94 records from 3 practices were reviewed; glaucoma eyecare: 82 records from 7 practices reviewed; diabetic eyecare: 37 records from 7 practices reviewed. None of the records reviewed met the inclusion criteria for the domain of care “referral”, hence this was not plotted.

64x26mm (600 x 600 DPI)

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**Appendix 1. Preventative eye care clinical indicators**

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**History Taking**

**1** Patients presenting for initial comprehensive eye exam should have the following documented:

- name, AND
- age, AND
- ethnicity, AND
- gender, AND
- driving status, AND
- chief complaint, AND
- current medication and allergies, AND
- ocular history, AND
- medical history, AND
- Presence of diabetes mellitus, AND
- ocular family history, AND
- medical family history.

**Clinical Assessment**

**2** Patients presenting for comprehensive eye exam should have the following assessments performed and documented:

- habitual visual acuity (VA) at distance, AND
- habitual VA at near, AND
- best corrected monocular VA with refraction at distance, AND
- best corrected binocular VA with refraction at distance, AND
- best corrected binocular VA with refraction at near, AND
- anterior eye examination, AND
- intraocular pressure (IOP) taken more than once, AND
- IOP instrument recorded, AND
- IOP time recorded, AND
- optic nerve head examination, AND
- fovea examination.

**Recall Period**

- 3** Patients aged  $\geq 19$  and  $\leq 39$  with no identified risk are advised to undertake comprehensive eye examination checks at least every 5 years.
- 4** Patients aged  $\geq 40$  and  $\leq 64$  are advised to undertake comprehensive eye examination at least every 2 years.
- 5** Patients aged  $\geq 65$  are advised to undertake comprehensive eye examination at least 1 year.
- 6** Patients with diabetes should be advised to undertake comprehensive eye examination at least every 2 years.
- 7** Caucasians, aged  $>50$  are advised to undertake regular comprehensive eye examination.
- 8** Africans, aged  $>40$  are advised to undertake regular comprehensive eye examination.
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**Appendix 2. Glaucoma clinical indicators**

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**History Taking**

- 1 Patients assessed for OR with glaucoma should have the following documented during the initial visit:
  - age, AND
  - ethnicity, AND
  - personal ocular history, AND
  - general health history, AND
  - history of migraine, AND
  - smoking status, AND
  - current ocular medication, AND
  - current systemic medication, AND
  - current and past steroid use, AND
  - family ocular history, AND
  - diabetic status, AND
  - high blood pressure, AND
  - low blood pressure, AND
  - Raynaud's syndrome.
- 2 Patients assessed for OR with glaucoma should have the following documented during the glaucoma follow-up examination:
  - interval ocular history, AND
  - interval systemic medical history, AND
  - side effects of ocular medications, AND
  - frequency and dosage of medication use, AND
  - time of last IOP-lowering medications, AND
  - review of use of medications.

**Clinical Assessment**

- 3 Patients assessed for glaucoma OR with ocular hypertension (OHT) OR newly diagnosed glaucoma should have a glaucoma examination performed and documented or referral for the following procedures is organised:
  - habitual VA, at both distance, AND
  - pupil reaction, AND
  - intraocular pressure (IOP), AND
  - the time of IOP measurement, AND
  - type of IOP measurement (applanation/Goldmann/non-contact tonometer), AND
  - central corneal thickness at regular intervals, AND
  - anterior ocular health by slit lamp, AND
  - peripheral anterior chamber configuration by gonioscopy OR van Herick's peripheral anterior chamber depth assessment, AND
  - size of optic disc, AND
  - cup/disc ratio, AND
  - pattern of the neuroretinal rim, AND
  - presence of disc rim haemorrhage, AND
  - presence of thinning of the nerve fibre layer, AND
  - imaging of optic disc AND/OR optic nerve fibre AND/OR fundus photography, AND
  - visual field examination.

**Management**

- 4 Patients with glaucoma AND asthma should NOT be treated with non-selective beta-blockers

(Timolol OR Tenopt OR Timoptol OR Ganfort OR Combigan OR Azarga OR Cosopt OR Xalacom OR Latanocom OR Duotrav).

- 5 Patients with newly diagnosed glaucoma should be treated with topical prostaglandin analogue (Bimatoprost/Latanoprost/Tafluprost/Travoprost), unless contraindicated, OR selective laser trabeculoplasty

#### Recall Period

- 6 Patients with suspected glaucoma should be advised to have a glaucoma follow-up examination within 6 to 18 months.
- 7 Patients with suspected glaucoma (low risk) should be advised to have a glaucoma follow-up examination within 6-24 months.
- 8 Patients with suspected glaucoma (high risk) AND are treated AND archiving target should be advised to have a glaucoma follow-up examination within 3-6 months.
- 9 Patients with suspected glaucoma (high risk) AND are treated AND without archiving target IOP should be advised to have a glaucoma follow-up examination within 4 months.
- 10 Patients with early glaucoma should be advised to have a glaucoma follow-up examination within 12 months.
- 11 Patients with moderate glaucoma should be advised to have a glaucoma follow-up examination within 6 months.
- 12 Patients with advanced glaucoma should be advised to have a glaucoma follow-up examination within 4 months.

#### Referral

- 13 Patients (assessed for glaucoma OR with OHT) AND are treated AND NOT achieving target IOP should be referred to ophthalmologist.
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**Appendix 3. Diabetic eye care clinical indicators**

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**History Taking**

- 1 Patients with diabetes should have the following documented:  
duration of diabetes, AND  
most recent HbA1c result OR self-reported level of blood glucose control, AND  
presence of history of high blood pressure (hypertension), AND  
presence of history of dyslipidaemia (high cholesterol).

**Clinical Assessment**

- 2 Patients with diabetes should have the following assessments performed and documented:  
visual Acuity, AND  
examination of iris, AND  
a dilated fundus exam OR retinal photography with grading.

**Referral**

- 3 Patients with diabetes with a suspicion of macular ischemia AND clinically significant macular oedema (CSME) should have or be referred for fluorescein angiography.
- 4 Patients with diabetes presenting with any reduction in best corrected visual acuity that is suspected to be due to diabetic retinopathy (DR) should be referred to an ophthalmologist within 4 weeks.
- 5 Patients with diabetes presenting with suspected diabetic macular oedema (possible/suspected thickening, hard exudate, oedema) should be referred to an ophthalmologist within 4 weeks.
- 6 Patients with diabetes presenting with proliferative diabetic retinopathy (PDR) should be referred to an ophthalmologist within 4 weeks.
- 7 Patients with type 1 diabetes presenting with persistent vitreous haemorrhage should be referred to an ophthalmologist.

**Management**

- 8 Patients with diabetes AND cataract presenting with diabetic macular oedema should have macular laser before cataract surgery if possible OR intravitreal anti-vascular endothelial growth factor (anti-VEGF) therapy before or at the time of cataract surgery.
- 9 Patients with diabetes presenting with severe NPDR should have laser photocoagulation or receive close follow-up (every 4 months or more frequently).
- 10 Patients with diabetes presenting with PDR, AND NO maculopathy should have panretinal photocoagulation (PRP) scheduled.
- 11 Patients with diabetes presenting with PDR (excluding high risk PDR and advanced PDR), AND CSME should have macular laser treatment OR anti-VEGF treatment BEFORE PRP.
- 12 Patients with type 1 diabetes AND PDR should have PRP.
- 13 Patients with NV at iris (rubeosis) should have PRP.

**Recall Period**

- 14 Patients with diabetes AND NO DR should have been advised to have their eyes examined at least every 2 years.
  - 15 Patients with diabetes AND mild non-proliferative diabetic retinopathy (NPDR) should have been advised to have their eyes examined at least every 1 year.
  - 16 Patients with diabetes AND moderate NPDR should have been advised to have their eyes examined at least every 6 months.
  - 17 Patients with diabetes AND severe NPDR should have been advised to have their eyes examined at least every 3 months.
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For peer review only



STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1, 3
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5-7
Objectives	3	State specific objectives, including any prespecified hypotheses	7
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	8-9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8, 12-13
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	12-13
Bias	9	Describe any efforts to address potential sources of bias	12-13
Study size	10	Explain how the study size was arrived at	11
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	12-13
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	13
		(b) Describe any methods used to examine subgroups and interactions	n/a
		(c) Explain how missing data were addressed	12
		(d) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(e) Describe any sensitivity analyses	n/a
<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	13-15
		(b) Give reasons for non-participation at each stage	13
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	13-15
		(b) Indicate number of participants with missing data for each variable of interest	15-16
Outcome data	15*	Report numbers of outcome events or summary measures	14-16
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	14-16

		(b) Report category boundaries when continuous variables were categorized	n/a
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	16-17
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	18-19
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).