A scientific approach to measuring clinical practice

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Full list of publications at end; summary & all papers available from rakheeshah19@gmail.com

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  – David Austen; David Burghardt; Deacon Harle; Lynne Weddell

Plan

Why?

How?

So what?

Why?

• 45 year old, first eye exam.
  What proportion of optoms would:
  – Test visual fields
  – Measure intraocular pressure
  – Carry out ophthalmoscopy
  – Test motility
  – Record their results

Plan

Why?

How?

So what?

Why?

• Optometric practice legislated by:
  – Opticians Act (1989)
  – NHS regulations

• Additional guidelines:
  – General Optical Council
  – College of Optometrists
  – Association of Optometrists

• But what happens in the consulting room?
Clinicolegal issues

- Recent example
  - 116 charges
  - Included, at age 4y:
    (i) you did not record ...
    (ii) Bolam/Bolitho defence
      - Body of reasonable competent optometrists
      - Profession has no evidence-based data on typical standards in optometric practice

Why?

- To evaluate the service we provide
- Clinicolegal issues
- Continuous Education & Training (CET)
  - Determine priorities
  - Measure outcome
- Policy decisions
  - Governmental
  - Professional
- Show what we provide for GOS
- Drafting professional guidelines
- Consumer complaints

Plan

The use of standardised patients to assess the content of optometric eye examinations

Lessons from other healthcare professions

- Questionnaires
- Clinical vignettes
- Record abstraction
- Standardised patient (SP)
  - Trained to:
    - Simulate a real patient
    - Give consistent responses
    - Use checklists to provide objective report of exam
  - Used in medical training & to assess clinical activities
  - Evidence based studies demonstrate the SP approach to be the “gold standard”

The content of optometric eye examinations in England

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Plan

Why?

How?

What for?

Recruitment of sample

• Recruitment of participating optometrists:
  – Selected randomly from GOC register
  – 1.5hrs travelling radius of London
  – Sent letter of invitation, with consent form enclosed
  – Only recruited if consent received
  – 600 letters sent
  – 102 agreed to participate
  – Participation rate of 27% of those optometrists who could be contacted

Recruitment of sample

• Encouraged high participation rate by offering:
  – Full anonymity OR
  – Feedback for CET

• Optometrists must be unaware of who is the SP
  – > 3 new patients a week
  – No visits within one month of consent form being received
  – An unannounced actor would visit at any time over 2 years
  – SP must be a convincing actor

How?

• Three Standardised Patients
  – SPs were actors
  – One for each scenario
  – Thoroughly trained
  – Regularly monitored using video-recording
  – Audio recording
  – 300 SP encounters

Defining the checklist

• College of Optometrists’ Code of Ethics and Guidance for professional conduct:

“The optometrist has a duty to carry out whatever tests are necessary to determine the patient’s needs for vision care as to both sight and health. The exact format and content will be determined by both the practitioner’s professional judgement and the minimum legal requirements.”
Defining the checklist

• Legal requirements are defined in part 4 of the Opticians Act 1989:

(1) When a doctor or optometrist tests the sight of another person it shall be his duty
(a) to perform for the purpose of detecting signs of injury, disease or abnormality in the eye or elsewhere
(i) an examination of the external surface of the eye and its immediate vicinity
(ii) an intraocular examination, either by means of an ophthalmoscope or by such other means as the doctor or optician considers appropriate
(iii) such additional examinations as appear to the doctor or optician to be clinically necessary.

(b) immediately following the test to give the patient a written statement—
– that he has carried out the examinations required by subparagraph (a) of this section, and
– that he is or (as the case may be) is not referring him to a registered medical practitioner

The Act also requires that the statement should say if the patient is being referred to a registered medical practitioner and if s/he is being referred, the reason for referral.

Defining the checklist

• General Ophthalmic Services Contracts Regulations: Part 5, Section 13 relating to Testing of Sight:

A contractor shall, having accepted an application from or on behalf of a patient for the testing of sight
(a) secure the testing of the patient’s sight to determine whether the patient needs to wear or use an optical appliance; and
(b) in so doing, shall secure the fulfilment of any duty imposed on a tester of sight by, or in regulations made under, section 26 of the Opticians Act 1989

(3) Where a contractor or an ophthalmic practitioner employed by it to perform the contract is of the opinion that a patient whose sight was tested pursuant to paragraph (2)
(a) shows on examination signs of injury, disease or abnormality in the eye or elsewhere which may required medical treatment; or
(b) is not likely to attain a satisfactory standard of vision notwithstanding the application of corrective lenses,

Defining the checklist

the contractor shall, if appropriate, and with the consent of the patient—
(i) refer the patient to an ophthalmic hospital, which includes an ophthalmic department of a hospital,
(ii) inform the patient’s doctor or GP practice that it has done so, and
(iii) give the patient a written statement that it has done so, with details of the referral

Scenario 1

• Is the eye examination appropriate for:
  – the identification of headaches of a suspicious nature?
  – and the appropriate management of these?
Why?

- Common condition
- Frequent reason for the public to consult healthcare practitioners (Gutteridge & Cole, 2000)
- 9% of the population present to their GP with a headache every year (Latinovic et al., 2006)
- Of patients consulting optometrists, about one in ten men and one in four females have migraine (Gutteridge & Cole, 2000)

Methods

- Actor (SP) presented as:
  - 20 year-old student
  - Seeking a private eye examination
  - “to see if my spectacles are ok”
- SP instructed to report:
  - Headaches of a recent onset only if asked reason for visit or if asked specifically about headaches
  - First ever headache 4 weeks ago resembling a migraine

Defining the checklist

- Detailed history relating to the headaches
- Gold standard questions for primary care headache investigation based on Diagnostic Screening Questionnaire and mnemonic LOFTSEA
- Ocular exam to include fundus exam, measuring visual acuities, pupil reaction, visual fields and external eye movement (Davies, 2007)

Questions appropriate for identifying the significant nature of the headaches

<table>
<thead>
<tr>
<th>Questions appropriate to identifying the significant nature of the headaches</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Has the pattern of your headaches been generally stable (i.e., no change or small changes) in frequency (and severity) over the past few months?</td>
<td>9%</td>
</tr>
<tr>
<td>2. Have you had the headaches for longer than six months?</td>
<td>50%</td>
</tr>
<tr>
<td>3. Are you aged between 5 and 50 years?</td>
<td>100%</td>
</tr>
<tr>
<td>4. Does the headache interfere to a noticeable extent with your normal daily life (work, education and/or social activities)?</td>
<td>14%</td>
</tr>
<tr>
<td>5. On average, how many days with headache do you have per month?</td>
<td>68%</td>
</tr>
<tr>
<td>6. On average, how long do the headaches last, if left untreated?</td>
<td>41%</td>
</tr>
<tr>
<td>7. On average, how many days per week do you take analgesic medication?</td>
<td>7%</td>
</tr>
<tr>
<td>8. Do changes in your senses (light, taste, smell or touch) occur in the period immediately before the headache starts?</td>
<td>40%</td>
</tr>
</tbody>
</table>

Scenario 1: Results

- 98% detected headache
  - 82% simply by asking reason for patient’s visit
  - 16% by asking the patient specifically about headaches
- 8 gold standard questions for primary care headache investigation
  - 22% asked at least four questions
- 48% proactively identified the patient’s symptoms of flashing lights
  - 15% asked specifically about flashing lights
  - 33% asked if the SP was experiencing visual disturbances prior to the headache

Questions appropriate for identifying the significant nature of the headaches

- Tests for investigation of the headaches
  - Proportion of recommended tests performed varied from 33-89%
- 99% carried out examination of the fundus
- 61% carried out visual field examination
- 69% asked the patient to seek a medical opinion
- 14% advised the patient to keep a headache diary
- SP’s headache symptoms strongly suggest migraine
  - 20% suggested or diagnosed migraine
- Duration of eye exam 5 to 50 minutes
Advice provided by the optometrists regarding the nature of the patient’s headache diagnosis

<table>
<thead>
<tr>
<th>Further advice provided regarding the headache diagnosis (n=49)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosed migraine</td>
<td>2%</td>
</tr>
<tr>
<td>Indicated the headache may be a migraine</td>
<td>12%</td>
</tr>
<tr>
<td>Indicated the headache may be a tension type headache</td>
<td>25%</td>
</tr>
<tr>
<td>Indicated the headache may be a migraine and/or tension type headache</td>
<td>6%</td>
</tr>
<tr>
<td>Indicated the headache may be of another type</td>
<td>4%</td>
</tr>
</tbody>
</table>

Discussion

- 14% of optometrists asked about severity of headaches
  - Significant headaches are sometime identified by severity (Goadsby, 2004)
- Presence of headache identified in 98% of cases
  - 49% offered further advice regarding migraine diagnosis

Scenario 2

To determine whether the eye examination performed by optometrists in England is appropriate for the detection of primary open angle glaucoma (POAG)

Why?

- Prevalence of POAG in UK population aged over 40 is estimated to be 2% (Azuara et al., 2007)
- 542,000 estimated to have the disease (Azuara et al., 2007)
- 65% of cases undetected (Azuara et al., 2007)
- Higher prevalence in Afro Caribbean and West African populations with onset at a younger age than in Caucasians (Rudnicka et al., 2006)
- Population screening not performed in the UK
  - POAG detected by “case finding”
- Detection methods vary widely across profession
  - criteria for using screening tests vary
  - criteria for referral of suspects varies widely between optometrists (Vernon & Gosh, 2001)

Is the eye examination appropriate for the investigation of Primary Open Angle Glaucoma?

- To aid early detection of glaucoma: CoO guidance recommends at least two of the following three tests:
  - Ophthalmoscopy (Disc Assessment)
  - Tonometry
  - Perimetry
- AOP takes the view “for at risk groups” basic visual field screening and tonometry are “core units” of the Regular Eye Examination

Methods

- Actor (SP) presented as:
  - 44 year-old patient
  - African racial origin
  - Requesting new reading spectacles
  - No personal or family history of glaucoma
  - SP instructed not to mention (or indicate any knowledge of) the increased risk of glaucoma in patients of African racial origin
Results

<table>
<thead>
<tr>
<th>Tests and questions from the checklist</th>
<th>% of optometrists that asked the question/ performed a test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of last eye examination</td>
<td>98%</td>
</tr>
<tr>
<td>Reason for visit</td>
<td>7%</td>
</tr>
<tr>
<td>Previous ocular history, do you have glaucoma?</td>
<td>37%</td>
</tr>
<tr>
<td>a) Have a family history of glaucoma?</td>
<td>95%</td>
</tr>
<tr>
<td>Anterior segment examination using a slit lamp</td>
<td>37%</td>
</tr>
<tr>
<td>a) Gonioscopy</td>
<td>8%</td>
</tr>
<tr>
<td>Fundus Examination</td>
<td></td>
</tr>
<tr>
<td>a) using direct ophthalmoscopy</td>
<td>80%</td>
</tr>
<tr>
<td>b) using slit lamp biomicroscopy</td>
<td>22%</td>
</tr>
<tr>
<td>c) using head mounted indirect ophthalmoscopy</td>
<td>2%</td>
</tr>
<tr>
<td>d) using a fundus camera</td>
<td>8%</td>
</tr>
<tr>
<td>No Fundus Examination</td>
<td>1%</td>
</tr>
<tr>
<td>Visual Fields</td>
<td></td>
</tr>
<tr>
<td>a) Using full threshold testing</td>
<td>12%</td>
</tr>
<tr>
<td>b) Using supra threshold testing</td>
<td>84%</td>
</tr>
<tr>
<td>No Visual Field</td>
<td>35%</td>
</tr>
</tbody>
</table>

Scenario 2: Results

83% recommended a re-examination interval
- 76% advised 2 years
- 22% advised 1 year
- 2% advised 18 months

Duration of eye exam varied from 20 to 30 minutes

Discussion

- Measurement of IOP alone is inadequate (Weinreb & Khaw, 2004) 
- Disc assessment in isolation is inadequate (Harper et al. 2000)
- Combined strategy is necessary (Harper 1999; Vernon & Gosh, 2001)
  - Repeating visual fields reduces false positive referrals
  - Repeating tonometry using a contact tonometer: improved accuracy of referrals (Salmon et al., 2007)

Scenario 3

To determine whether the eye examination performed by optometrists in England is appropriate for the detection of recent onset flashing lights

Why?
Why?

- Differential diagnosis
  - Are the flashing lights as a result of migraine, posterior vitreous detachment, or retinal detachment?

- Posterior Vitreous Detachment
  - Monocular
  - Dim rather than bright light (Kanski, 2000)
  - Induced by eye movement
  - Perceived as a swift flash temporally in arc fashion

- Migraine
  - Flashing lights (Aura) almost always binocular (Harle & Evans, 2004)
  - Central black patch, bordered by luminous zig zags
  - Enlarges into half the field and fades out into the periphery

Methods

- Actor (SP) presented as:
  - 59 year-old patient
  - Seeking a private eye examination
  - Complaining of recent onset flashing lights over the previous week

- SP instructed to report:
  - Flashing lights in one eye in the dark, but only if the optometrist asked for the “reason for visit” or if the optometrist specifically asked the SP regarding symptoms of flashing lights

Results: Was the History and Symptoms taking appropriate for the investigation of recent onset flashing lights in one eye?

- Presence of flashes identified in 87% of examinations:
  - 80% by asking for “reason for visit”
  - 7% by specifically asking if any symptoms of flashing lights were present

- But 13% of optometrists in this sample did not identify the key presenting symptoms

Other results for History and Symptoms taking

- 85% of optometrists asked about floaters
- 36% asked about a “curtain” or “shadow” in the SP’s vision

- Expert panel listed a “Gold standard” set of 7 questions appropriate for identifying the nature of the flashing lights symptom:
  - No optometrists asked all 7 gold standard questions
  - 35% asked at least four of the seven questions

Tests performed

- Expert panel identified 9 tests appropriate for the investigation of the patient’s symptoms
  - 2 optometrists performed all the recommended tests
  - The proportion of recommended tests performed varied from 33-100%
  - On average, six of the nine tests were performed
  - 13% of optometrists examined the anterior vitreous for pigment cells (Shafer’s sign)
  - 38% of those who dilated the patient

### Results for “gold standard” questions

<table>
<thead>
<tr>
<th>Questions appropriate to identifying the nature of the flashing lights</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where in your vision do you see the flashing lights?</td>
<td>53</td>
</tr>
<tr>
<td>Are the flashing lights in one eye or both eyes?</td>
<td>72</td>
</tr>
<tr>
<td>Describe the flashes?</td>
<td>26</td>
</tr>
<tr>
<td>Is there a pattern to the occurrence of the flashes?</td>
<td>83</td>
</tr>
<tr>
<td>Is there a change in this pattern of occurrence?</td>
<td>39</td>
</tr>
<tr>
<td>How long ago did you first notice them?</td>
<td>94</td>
</tr>
<tr>
<td>How long do they last?</td>
<td>34</td>
</tr>
</tbody>
</table>

The proportions quoted are based on the entire sample (n = 102). The totals do not add up to 100% because many optometrists asked more than one of these questions.
Dilated fundus examination?

- 66% recommended dilated fundus examination either by themselves or by another eyecare practitioner
- Of the 102 SP visits:
  - 24 visits included a dilated fundus examination
  - 76 visits included an undilated fundus examination
  - 1 practitioner did not examine the fundus
  - 1 practitioner referred the SP directly to Moorfields

Results: “What proportion of optometrists would have referred this patient to the Hospital Eye Service (HES) and with what urgency?”

- 30 optometrists referred the standardised patient to the HES
  - 20 optometrist out of 77 who did not dilate the SP
  - 10 optometrists out of 24 who did dilate the SP
- 70% of those who referred asked for the patient to be seen in the HES on the same day or within a week

Results: Some odds and ends

- Examination duration
  - Mean 26 mins. (if undilated). Range 12 – 50 mins.
  - Mean 36 mins. (if dilated). Range 25 – 50 mins.
- Of those 69 optometrists who recommended a re-examination interval:
  - 81% recommended 2 years
  - 17% recommended 1 year
  - 2% recommended 18 months
- No practitioners performed a purely symptom-led examination

Discussion: College of Optometrists guidance 2010 (revised 2005):

- If a retinal break is suspected the minimum examination should include:
  - History and Symptoms looking for particular risk factors
  - A dilated fundus examination using an indirect viewing method
  - An examination of the anterior vitreous to look for pigment cells
  - Appropriate advice to the patient (supported by a written information sheet)

Discussion: College of Optometrists guidance 2010 (revised 2005):

- If a retinal break is suspected the minimum examination should include:
  - A dilated fundus examination using an indirect viewing method
  - 34% of this sample of optometrists did not recommend a dilated fundus examination to be performed either by themselves or another practitioner (nor made an urgent referral)
  - 94% of optometrists who recommended dilated fundus examination advised this should be done on the same day

• Notable points to emerge from our sample of optometrists:
  - 13% did not identify symptom of flashing lights
  - 15% did not ask about floaters
  - 51% asked if there had been a recent increase in the number of floaters
  - 64% did not ask about a “curtain” or “shadow” in vision
Discussion: College of Optometrists guidance 2010 (revised 2005):

- If a retinal break is suspected the minimum examination should include:
  - An examination of the anterior vitreous to look for pigment cells
  - 13% of optometrists in our sample examined the anterior vitreous for pigment cells (Shafer’s sign)
    - 38% of those who dilated

Discussion: Some limitations of the study

- The optometrist might have identified the SPs and modified their approach accordingly
- Was this a representative sample of UK optometrists?
- Geographical bias

Differences in approach across the UK

- All practices visited were located within 1.5 hours travelling of London
- The NHS contract in Scotland since 2006 and the PEARs (Primary Eyecare Acute Referral) scheme in Wales facilitate a symptom-led approach to the eye examination
  - Scenario 3

General conclusions of SP study

- SP approach is valuable for measuring clinical care
- Substantial differences exist in duration and depth of clinical investigations
- Not all eye examinations are the same
  - No such thing as ‘standard sight test’

Specific conclusions

- Future CET could usefully focus on:
  - The importance of determining the patient’s prime symptom
  - Migraine diagnosis and assessment
  - Glaucoma screening
  - Risk factors for Primary Open Angle Glaucoma
  - Examination techniques and referral guidelines for patients presenting with symptoms of PVD

Do clinical records tell us what happens in an eye examination?

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Record Abstraction

- Two levels of anonymity:
  - Full anonymity
  - Partial anonymity and feedback for professional development
- 1/3rd chose full anonymity
- 2/3rd chose partial anonymity or did not state preference

Record abstraction: Results

- Using data from SPs as gold standard, information gathered from clinical records classified as:
  - True Positive
  - False Negative (under-recording)
  - False Positive (over-recording)
  - True Negative
- Compared to the gold standard:
  - False positives identified in 4.4% of cases
  - False negatives identified in 17.2% of cases

Record Abstraction: Examples

- 46-65% of optometrists do not record retinoscopy
- Up to 18% of optometrists under-record motility, but up to 16% can over-record this!
- 3-10% under-record visual fields
- 18-27% under-record slit lamp biomicroscopy

Record Abstraction: Conclusions

- Records are an imperfect representation of eye examinations
- Presence of false positives and false negatives
- Subject to recording bias
  - under-estimation
  - over-estimation
- Record keeping a priority for future CET
Plan

The use of standardised patients to assess the content of optometric eye examinations in the UK

The use of computerised clinical vignettes to assess the content of optometric eye examinations in the UK

Clinical Vignettes

• Same three scenarios (SP study)
  – Three clinical vignettes

• Published on IoO website
  – Expert system
  – Individualised feedback upon completion
  – 2 CET points awarded for each vignette

• Whole profession was invited to participate
  – 233 first vignette
  – 187 second vignette
  – 167 third vignette

Clinical Vignettes

• Computerised vignettes
  – Novel
  – Cost effective

• Useful for assessing clinical practice

• Accuracy and validity is debatable

A Comparison of SPs, Record Abstraction and Clinical Vignettes

• Different methods capture different elements of clinical practice and are prone to different biases

• A three way comparison shows that compared with the SP “gold standard”:
  – Clinical records under-estimate the actual care provided
  – Vignette scores over-estimate clinical performance

Outcomes: potential applications of SP research in Optometry

• Evaluating the quality of primary eyecare in the UK

• Evaluating outcomes of CET

• Setting professional guidelines

• Determining the typical scope of current NHS GOS
  – NHS fee negotiations
  – PCT fee negotiations for additional services

• Defining equitable decisions in:
  – Clinicolegal cases
  – NHS complaints
  – Consumer complaints

• Determining priorities for the future
  – Undergraduate training
  – CET
  – General professional development
Outcomes: Clinico-legal Issues

• Malpractice accusations
  – disciplinary hearings
  – Litigation
• Bolam/Bolitho defence
  – Body of reasonably competent optometrists
  – Profession had no directly observed evidence-based data on typical standards in optometric practice
  – Redefined by this research

Outcomes: Clinico-legal Issues

• The argument “if it is not in the notes, then it was not done” is unsafe
• But, if it is in the notes, then it is much easier to defend

Outcomes: Professional Guidelines

• College of Optometrists Code of Ethics and Guidance for Professional Conduct
  – Not a set of instructions
  – Practitioners expected to exercise their professional judgement
• Our research highlights that these are “an aspiration to best practice” and do not reflect current typical practice

Outcomes of research

• 8 publications in refereed journals

THANK YOU

Questions?

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