**Methodological challenges and opportunities in evaluating clinical safety in primary eyecare services**

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The recent paper by Swystun and Davey1 is a welcome addition to literature on clinical safety in acute eyecare services in primary care. Their research raises important questions about how clinical safety in such services, and indeed primary eyecare services in general, should be determined. Evaluations of effectiveness of UK primary eyecare services have typically focussed on false positives, for example, false positive referrals to the Hospital Eye Service (HES), with false negatives rarely being considered. Indeed, there are interesting methodological challenges in examining for false negatives, but also, we suggest, some novel opportunities with the advent of greater digital interconnectedness in eyecare pathways.

In terms of challenges, one difficulty is defining what constitutes a false negative, with different methodologies and their consequent different criterion options for what comprises a false negative potentially being a major source of difference when investigating similar services. In the absence of an established definition of what constitutes a COVID-19 Urgent Eyecare Service (CUES) optometrist's incorrect diagnosis or an unsuccessful recommendation, Swystun and Davey1 were obliged to set their own definitions. They used direct patient contact via telephone following access to CUES, quantifying cases of missed pathology and/or failure to appropriately manage patients’ symptoms in a sample of over a thousand episodes. Their “incorrect” diagnoses were determined by patients’ accounts, but they also went on to define "major errors", a definition which included errors or omissions judged to have potential to cause harm. While the precise definitions of CUES misdiagnoses and unsuccessful recommendations might be open for debate, consensus is more likely to be found regarding a potential for harm category. While the authors describe some limitations of reliance on patient reported outcomes, their point that the purpose of acute eyecare relates to resolving patients’ symptoms highlights the advantage such a direct approach can have in the context of urgent eyecare.

Examining clinical records is another approach sometimes employed to establish safety. Interestingly, Sheen et al’s study2 examining clinical safety in an urgent eyecare schemeused a combination of clinical records review and telephone interview outcomes to establish inappropriate management, reporting a substantially lower false negative rate than Swystun and Davey1, albeit in a different service (not reliant on the substantive telemedicine element within CUES during the pandemic). Konstantakopolou et al3 also employed clinical record review to examine clinical safety in a minor eye conditions scheme (MECS), examining not only referred but also non-referred patients’ records to assess for appropriate management; however, while this approach can be used to capture clinical management against guidelines, it is reliant on the veracity of recorded details, with potential for documentation inconsistencies versus actual presentations4, over- and under-reporting of tests/examinations, and/or symptoms evaluated, and/or advice and management provided. In a recent evaluation of false negatives in CUES (and within the same service and pandemic timeline as Swystun and Davey), Williams et al5 tracked a large population of over 1000 cases seen in primary care, monitoring the potential for *non-referred* cases to attend an HES’ emergency eye department within 28 days. Williams et al offered this criterion as a proxy for possible false negatives following CUES assessment, with the large sample size and single within area HES provider accommodating urgent eyecare permitting interrogation of safety. Their analysis compared both primary care clinical records for non-referred cases and secondary care clinical records for those non-referred primary case cases subsequently re-presenting to the emergency eye department. Although this method was advantageous in utilising routine data sources within the parameters of service evaluation and audit, it would not have captured non-referred CUES cases presenting to other providers. In contrast, the method of Swystun and Davey1 did partially illuminate the outcome of cases directed to care by their GP and NHS111, including for example cases of stroke, which may not otherwise have attended ophthalmology. Notably, however, the difference in findings between Williams et al5 and Swystun and Davey1 for CUES is very striking, but potentially somewhat less so when considering those cases with the potential for harm.

Primary care services for usually non-urgent and/or often asymptomatic conditions, for example glaucoma, present different methodological challenges when examining clinical safety. In particular, the absence of acute symptoms and/or the timeline for potential changes in status require different methodologies. As is the case for primary eyecare services in general, evaluation of referral pathways for glaucoma, for example, have also usually centred on estimating the false positive rate, while establishing false negatives has been far less widely researched. Retrospective analysis of notes and optic nerve images of patients not referred was the method employed by Devarajan et al6. In contrast, Ratnarajan et al7 included consultant clinical examination of non-referred patients but for a limited sample of discharged participants willing to attend for review. The largest study of false negatives in a glaucoma referral filtering scheme8 also used a methodology where non-referred patients were examined in a reference standard clinic, an approach resulting in a significantly more restricted sample size, for feasibility, when compared to data on CUES reported by Swystun and Davey1 and Williams et al4.

The coronavirus pandemic has thrown the mismatched capacity and demand in eyecare into stark relief. As eyecare providers deal with burgeoning capacity issues in secondary care, there is rightly an increased focus on transforming pathways to better utilise skills in primary care. Establishing clinical safety in such services is a pressing requirement. Different clinical services accommodating populations requiring eyecare for either acute or chronic conditions reasonably might require different approaches to the what, the when, and how, of measuring clinical safety. The advent of greater digital interconnectedness in eyecare pathways creates opportunity to explore clinical data within both primary and secondary care, alongside data on attendance, non-attendance, re-attendance, and health care episodes falling outside of ophthalmology. If appropriate information governance and relevant legal frameworks can be satisfied, and data sharing arrangements agreed, this approach could permit detailed exploration of routine data sources. Such an approach could have the benefit of scale and regularity within clinical safety monitoring, with reduced dependency on potentially challenging research methods, ethical approval processes, and sampling methodologies in those consenting to participate. Data interrogation of integrated eyecare pathways within the framework of audit, quality improvement, and service evaluation should be to the benefit of patients, providers, and commissioners, complementing research methodologies where these are required.

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