

Refractive Surgery Alliance

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November 25, 2014

Sarah A. Collier, MPH, et al
Center for Disease Control
Atlanta GA 30329

RE: Estimated Burden of Keratitis — United States, 2010

Dear Dr. Collier, et al.,

The Refractive Surgery Alliance (RSA) is a private organization of board-certified ophthalmologists in refractive surgery. The RSA does not accept industry funding. The RSA's primary mission is to provide physician-based education about refractive eye surgery and eye care.

As such, the RSA welcomes any and all efforts that work to educate the public regarding vision. Similar to refractive surgery, contact lenses play an important role in the United States and provide an important alternative to glasses, particularly around improved function and performance. Contact lenses enable increased productivity and enable many people to work in occupations and engage in activities that would not be possible wearing glasses. In addition, the contact lens industry is a multi-billion dollar industry that provides jobs at all points in the supply chain. The net impact of contact lenses on society is very positive.

The RSA enthusiastically supports the CDC recommendations for good hygiene associated with contact lens use.

However, the recent study, "Estimated Burden of Keratitis—United States, 2010" published last week in the *Morbidity and Mortality Weekly Report* (Vol. 63, No. 45, pp 1027-39), while mostly accurate, has created the mistaken impression among the media and among many in the public that the cost for reimbursed medical care extending from contact lens misuse approaches \$180 million per year. The data that support the article does not justify that claim.

We recognize that the article carefully specifies "keratitis and contact lens related diagnostic codes," but it appears that the public reader and the media have interpreted this to mean "contact lens related diagnostic codes" only, ignoring that the majority of *keratitis* codes in this study were not directly attributed to contact lens wear, or any other specific etiology for that matter.

The article appears to encourage this misinterpretation, both in the Introduction and in the Discussion, by focusing on contact lens hygiene and issuing guidelines for contact lens use. We question the rationale behind this and do not feel the argument has merit. The fact that the report originated with an agency as esteemed as the CDC adds to our concern, as it frankly does not withstand scientific scrutiny.

Please consider our concerns about the methodology and presentation of this study:

1. The article admits that keratitis is a general condition that may have many etiologies. There is a specific ICD 9 code (371.82) for a “corneal disorder due to contact lens”, and that code accounted for only 249,000/988,000 (25.2%) of the visits in the data reported. Yet the article is used to call for significant interventions in contact lens use:

Increased surveillance capacity, identification of additional preventive measures, and further quantification of the burden of keratitis can help to direct prevention efforts. Development of effective prevention messages for dissemination to contact lens users and eye care professionals, including ophthalmologists and optometrists, is important to reduce microbial keratitis.

We are concerned that this recommendation is based on a conflation of the “corneal disorders due to contact lens” with all other forms of keratitis, and do not feel that it is justified.

2. Similarly, the cause of the 25.2% of visits billed under ICD 9 billing code 371.82 is not clear. Not all corneal disorders due to contact lenses are keratitis, and not all billing records under this code were generated from visits with a corneal complaint. Many of these exams may have been routine annual exams of patients who wear contacts, in which the examiner felt compelled to make an insurance-dictated reimbursable “diagnosis” such as peripheral neovascularization. Some practitioners feel compelled to do this in an effort to “justify” (in the view of 3rd party payers) a medically reasonable and necessary office visit, and perhaps offset out of pocket costs for the patient, even though these “diagnoses” have no medical consequence. In other words, interpreting visits that are billed under this code as contact lens complications is not valid given the real world practices in many contact lens clinics. To set public policy based on unreliable information is not valid.
3. On a fundamental level we object to the use of data that the authors admit themselves are unreliable. There are limitations to using billing data to infer clinical practices as described in detail by the authors in the Discussion. In fact, the description of the data problems comprise more than half 285/555 (51%) of the words that make up the Discussion. These limitations are sufficient to invalidate any conclusions drawn by the article. It is not reasonable to say “we know the data are unreliable, but here is what they show.” If they data are unreliable they should not be used.
4. The presentation of the data is also confusing. Tables 1 – 3 contain two general sets of billing codes: 371.82 and a group of codes (370.0, 370.8, and 370.9), yet the tables list the codes in a way that the casual reader might believe represented six sets of data, not two. Specifically, the tables list the two groups listed above, then list each of the codes individually, and then list the total of all the codes together. We feel this is misleading. We question the author’s intent in presenting the data in this way, as it appears to encourage misinterpretation of the data.
5. The numbers in Table 2 and Table 3 do not add up. We find this interesting and question how it could have survived the review process.

Example 1: In Table 2, the number of emergency department visits for 371.82 is listed as 19,000. The number for the other three codes (370.0, 370.8, and 370.9) is listed as 41,000. The combined sum is listed as 58,000, not 60,000.

Example 2: In Table 2, the counts for the three “370” codes is listed as 41,000, but the individual codes add to 40,000.

Example 3: In Table 3, the Total dollars spent for 371.82 is listed as 33.5. The Total for the three “370” codes is listed as 135.3. These two numbers add to 168.8, but the total displayed is 174.9.

There are several other addition errors in these tables for the derivative columns. One is left to question which, if any, of the numbers provided are reliable.

6. As noted above, the authors provide reasonable transparency to the limits and problems with the study design and the data used for the study in the Discussion. As such, informed readers would be inclined to dismiss the findings as non-interpretable, which we believe they are. However, the authors seem to encourage misapplication of the report with their concluding statement:

Keratitis associated with poor contact lens hygiene is preventable. Prevention efforts should include surveillance, improved estimates of the burden of disease, and vigorous health promotion activities focused on contact lens users and eye care professionals (ophthalmologists, optometrists, and opticians). Increased surveillance capacity is needed for microbial keratitis, in particular data from optometrist visits.

While conceptually true, this statement has no relationship to the data presented in this study. Of course poor hygiene can have adverse health effects (not limited to keratitis) and we should encourage everyone to have better hygiene. But that is irrelevant to this report. Nothing in the billing data cited in the report attribute any office visit to poor hygiene. This is sensationalist and has no place in a CDC publication.

The remainder of the statement is a transparent call for increasing intrusion into medical practice. For one to justify “increased surveillance” it would first be necessary to demonstrate that surveillance would lead to practices that reduce morbidity from keratitis. There are many leaps of faith between that hope and reality, and even more between the billing data used for this study and any suggestion that surveillance would do better than practitioners who are caring for patients. It is hard to imagine why this statement is even included.

7. The authors valiantly attempt to tie the keratitis visits to infectious keratitis from misuse of contact lenses. The logical path they follow is tortuous and, in our opinion, intellectually dishonest. Let us summarize:

First, they conflate billing codes for 371.82 (corneal disorder due to contact lens) and the general codes for keratitis in an apparent attempt to generate a large dollar amount to drive the argument—especially since only 25.2% of the office visits were for 371.82.

Second, they cite an article from Moorfields Eye Hospital in London from 1991 (reference 1) that looked at 91 eyes in 61 patients and found that contact lens wear accounted for most of the

cases of a subtype of keratitis caused by microbial infections. The authors that wrote the 1991 reference have published several other articles since. Why rely on a 1991 article, which evaluated patients using very old contact lens technologies and drew from such a small sample size? Why apply the findings from a non-US country to US data?

Next, the article cites other studies that looked at specific types of keratitis. These were interesting reports but they bear no relationship to present study, which looked at billing codes for office visits that had no documented relationship to contact lens wear. This is the comment:

Among the estimated 38 million contact lens wearers in the United States (8), poor storage case hygiene, infrequent storage case replacement, and overnight lens wear are established preventable risk factors for microbial keratitis, contact lens-related inflammation, and other eye complications (3,6,7).

The Discussion clearly tries to leave the reader with the impression that the financial burden of keratitis is due to contact lens use, and in particular to contact lens misuse. We find no support for this argument in the data presented.

We see no ophthalmologists listed in the long list of authors. Had an ophthalmologist been consulted, it might have resulted in more insightful consideration of the many reasons why keratitis billing codes are used. Furthermore, several of the references were based on “telephone interviews” with contact lens patients, which are even softer data than billing codes. Far better literature exists on the topic. We question why it wasn’t referenced.

In summary, the CDC report has led to a public misconception about the risks associated with contact lens use. We agree that contact lenses have risks, but vehemently disagree with any attempt to inflate the actual risks beyond their actual level. We are disappointed with the lack of scientific rigor in this study.

Therefore, we respectfully demand that the CDC issue a public retraction to this study that addresses the concerns cited above.

We look forward to your reply.

Sincerely,

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