



June 9, 2009

Joint Council of Allergy, Asthma and Immunology

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Mr. Patrick Conway
Office of the Secretary
Federal Coordinating Council on Comparative Effectiveness Research
Email: Patrick.conway@hhs.gov

Dear Mr. Conway:

The Joint Council of Allergy, Asthma and Immunology, representing the allergists and immunologists in the country, is pleased to submit the following comments for the Coordinating Council on Comparative Effectiveness Research to consider as it embarks upon its work.

It is clear that we support good practice guidelines, good medicine, and what effectively works, but it is important to consider the individual in the situation. It is important to be mindful of couple of important issues when analyzing the effectiveness of a specific treatment:

1. What is the effectiveness rate of the treatment?
 - a. Can it help all the patients it is targeted to?
 - i. The minority cannot be excluded or denied treatment
2. Who will it specifically help?
 - a. If it does not help someone what can?
3. How will the treatment have an effect on the patient's quality of life?
 - a. Emotionally
 - i. Burden on the family
 - ii. Hurt relationships between patient and others
 - b. Socially
 - i. Hurt the patient's financial situation
 - ii. Permanently change the patient's way of life
 - c. Physically
 - i. Cause the patient to feel constant pain

These factors should not only be decided by doctors, but by the patients. The patient's point of view is critically important here as well, so therefore the public should be able to submit their comments for consideration. Often patient's point of view is overlooked and it is the most important part of the treatment.

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Also, another point of view that is missing are the product and service representatives. For example, if a patient is taking an allergy medication, then the allergy company should be there to provide their comments. A panel made up of product and service representatives is important to include when evaluating one's treatment.

The minority of the people are over looked when testing a drug's effectiveness. If the treatment worked on the majority of the people, then it would be approved to use and the minority would be ignored. There still needs to be treatments in which the Doctors can provide individuals based on their specific situation.

In addition, treatment still needs to be discussed with the Doctor and the patient on a one-on-one basis specific to the patient's need. By discussing the options, a few factors would be discussed:

1. Benefits and Risks
 - a. Each would be laid out in front of the patient
2. Cost Benefit Analysis
 - a. After this analysis the patient could then take into account expense before making their decision

Another point made is that right now there is no standard definition for effectiveness. There is no criterion set up to say if something works or if it does not work.

There are several points of views that can inevitably yield different results. With different results there will also be different effects. These perspectives includes; the patient, the employer, and the doctor.

As of now there is not a single way to conduct the study. The strategy that one should employ is dependent on who is asking the question, the patient population under evaluation and for what purpose the answer will be utilized.

In addition, patients place different values on different levels of health status. Therefore, when evaluating different patients show different tolerance levels for side effect treatment options, it is important to recognize the diversity within the patient community. People are at different points in their lives, so different preferences and utilities could affect the patients' preference and assessment of the value of a particular treatment.

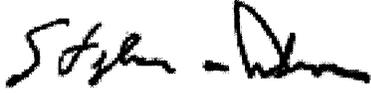
There are 4 perspectives to look at this situation from:

1. Societal- Which deals with the costs and benefits of the treatment on society. It tries to capture the whole society's effect. If the treatment helped, it would increase the patient's productivity and get them back to work, but it could also keep them out of work. Time cost is also something that needs to be taken into consideration.
2. Patient - This differs from societal in that the costs and benefits only affect the patient, not the entire society. Time horizon is also associated with the patient perspective because if a patient would not be able to, for example go on a daily run, the illness would be a preventative to this activity.
3. Employer- These are the costs and benefits of that effect the employer.
4. Payer- These are the costs and benefits that impact the payer.

This research analyzes the fact that not all perspectives are taken into account when deciding on a treatment, though each treatment does have profound effects.

If you should have any questions or need further information, please do not hesitate to let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen - Imbeau". The signature is fluid and cursive, with a long horizontal stroke at the end.

Stephen A. Imbeau, MD
President
JCAAI