

## Efficacy, effectiveness, immunogenicity - are not the same in vaccinology

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portant issues regarding immunisation in inflammatory bowel disease patients. However, in our opinion, definition of vaccine efficacy is misused. In fact this article is on vaccine immunogenicity. Here, we emphasise the differences between the definitions of efficacy, effectiveness and immunogenicity, differences that are fundamental in vaccinology.

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### Abstract

Manuscript of Carrera *et al* is devoted to immunization in inflammatory bowel disease (IBD) that is very important issue in gastroenterology. However, some specific definitions used in the article need clarification. Efficacy of vaccine is measured in a randomised, placebo-controlled studies, that are expensive and difficult to plan. Moreover, it is unethical to offer a placebo instead of vaccine. For all of these reasons, efficacy of vaccine is measured in IBD patients rarely. Effectiveness of vaccine is measured as an epidemiological affect from observational studies. These studies are also uncommon in IBD because it would be difficult to perform a study that assess the prevalence of one rare disease (vaccine-preventable) in patients with a chronic rare condition, such as IBD. Immunogenicity of vaccine refers to the ability of a vaccine to induce an immune response in a vaccinated individual that is, in fact, the matter of the article.

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**Key words:** Efficacy; Effectiveness; Immunogenicity; Vaccine

**Core tip:** The Carrera *et al*'s article presents some im-

### TO THE EDITOR

We read with interest the manuscript of Carrera *et al*<sup>[1]</sup>, devoted to immunisation in inflammatory bowel disease (IBD) patients. However, we would like to clarify the definitions used in the article.

The title of the article suggested that the body of the manuscript is focused on the efficacy of vaccines in IBD. Moreover, the authors defined efficacy as "percent risk reduction for clinically significant infection in a vaccinated group *vs* a control group", but there is nothing in the article about efficacy. The entire article is about the immunogenicity of vaccines. These two words are not synonyms.

How well a vaccine works can be measured through different types of studies<sup>[2]</sup>. The measurement of a vaccine's effect in a randomised (placebo-controlled) study is referred to as efficacy. Randomised studies are expensive and are not always conducted after a recommendation for vaccination has been issued because withholding the vaccine from people recommended to receive it would place them at risk for infection, illness and possibly serious complications. The measurement of a vaccine's epidemiological effect from observational studies is referred

to as effectiveness. Apart from ethical and economic considerations, it would be difficult to perform a study that assessed the prevalence of one rare disease (vaccine-preventable) in patients with a chronic rare condition, such as IBD. The efficacy of a vaccine may indirectly predict cases of that one rare disease when the protecting level of antibodies is known from previous epidemiological studies. Immunogenicity refers to the ability of a vaccine to induce an immune response (antibody- and/or cell-mediated immunity) in a vaccinated individual. Until now, neither efficacy nor effectiveness has been assessed in IBD patients for any vaccine. All of the vaccine studies in IBD patients have instead assessed the immunogenicity of the vaccines.

Proper use of these terms is not just an academic issue, as the level of antibodies does not always predict real protection against a disease. Immunogenicity can be low, as observed in hepatitis B virus vaccine (*i.e.*, in the

Gisbert *et al.*<sup>[3]</sup> study, only 36% of IBD patients on immunosuppressive and biological therapy achieved adequate hepatitis B surface antibody levels), but hepatitis B cases are extremely rare in a vaccinated IBD population.

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