

Design of an Informed Assent Form in Comic Strip Format for Minors

Supplementary file 1.

Figure S1 shows examples of comic strips from different sections. The corresponding sections of the original document are the following:

Image A corresponds to the following text of the original informed assent form (Aims):

“(…) You are asked to participate in this study to help us better understand the bivalent XXXX vaccine and its efficacy in healthy children, adolescents and young adults. Type B meningococcal disease is caused by a germ named meningococcus B. The vaccine is called bivalent IIII (…)”

Image B corresponds to the following text of the original informed assent form (Randomization):

“(…) You will be assigned to one of two groups. Group assignment will be at random, like the toss of a coin, and you won't know what medication you are receiving while participating in the study. A placebo is a similar substance to the study vaccine, but it does not contain any active component. In two out of three cases, you will receive the bivalent YYYY vaccine. Based on the group you are assigned to, you will receive three doses of the bivalent YYYY vaccine or two doses of XXYY and one dose of placebo.”

Image C corresponds to the following text of the original informed assent form (Placebo):

“During the study, you will be given YYYY or XXYY (vaccine against the hepatitis A virus) and placebo. XXYY is an approved vaccine used to protect against the infection with the hepatitis A virus. The placebo is a dummy vaccine that looks identical to the real one but does not contain any active component. In this study, the placebo is salty water (normal saline).”

Image D corresponds to the following text of the original informed assent form (Risks):

“Things that may make you feel discomfort or fear: injections with the bivalent YYYYY vaccine, XYYY or placebo may cause redness, swelling or pain in the area of the arm where the injection has been given. You may also experience fever, headache or tiredness after receiving the vaccine.”

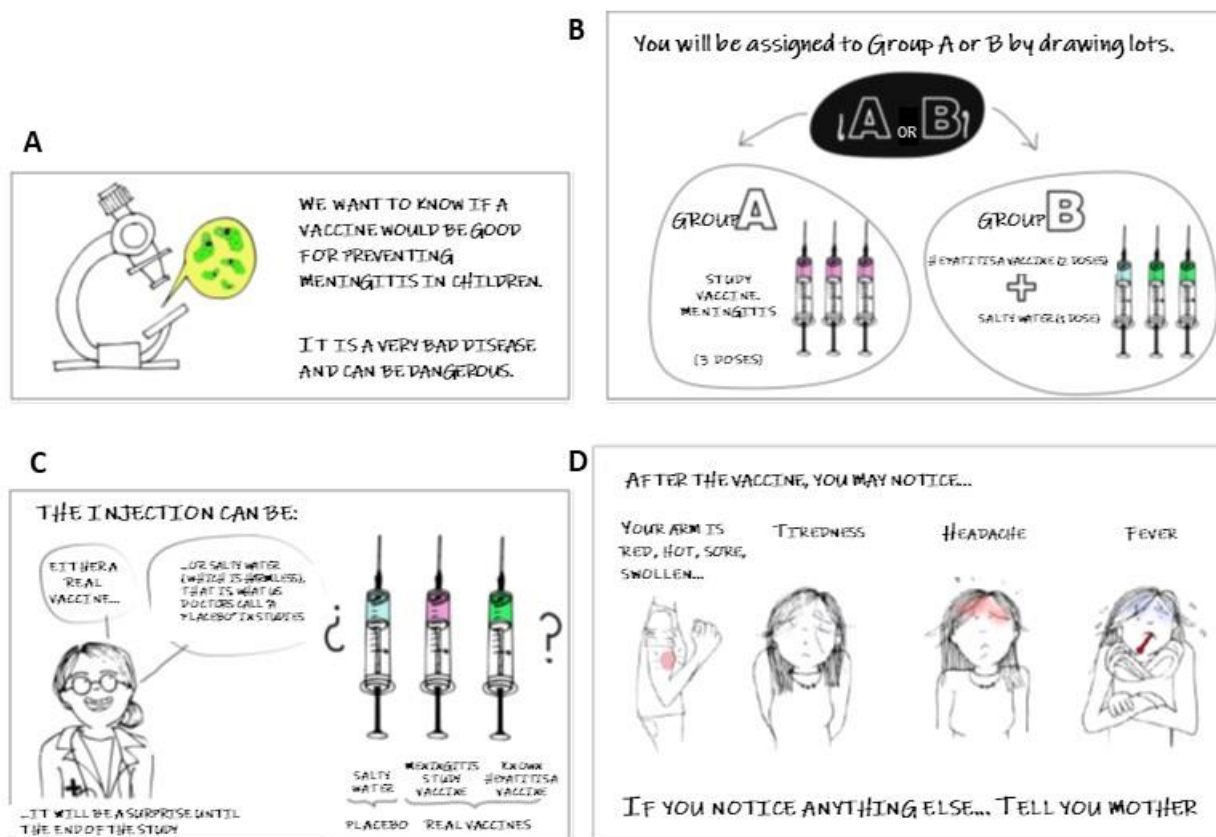


Figure S1. Examples of comic strips from different sections of the new assent form. **A)** Aims; **B)** Randomization; **C)** Placebo; **D)** Risks.