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Development of a Rapid Bedside Test to Detect the Presence of a Copper-IUD

Over 100 million women worldwide rely on the copper intrauterine device (CuIUD) for contraception making it the most common form of long-acting reversible contraception used. CuIUDs are desirable for their "forgettable" nature and can be placed at any time, including immediately after the birth of a child. CuIUDs do not alter menstrual cycles and have no overt signs of use except for two monofilament threads that can only be seen or felt during a pelvic exam. If the strings are missing, the IUD can still be in perfect position, or it may have 'fallen out' (expulsion). The prevalence of missing strings is common in IUDs placed immediately postpartum (20-60%) as is expulsion (as high as 20%). Outside of this period, missing strings are less frequent (4-18%). In both cases, users and clinicians may be unsure if the IUD is present, presenting a common clinical dilemma.

In high-income countries, such as the US, we utilize non-invasive imaging such as an ultrasound to confirm IUD position, but this is costly and may not be immediately available especially in primary care settings. In low- and middle-income countries, this option is not readily available and women must undergo a painful 'blind' exploration of the uterus where IUD position is checked by removing it. Thus, a rapid, low cost, bedside test for determining CuIUD placement would be a clinically important tool for clinicians and women. We estimate that over 4 million women could benefit this test. In this application, we propose the development of a low-cost, point of care test for determining if a CuIUD is in situ by sampling cervical mucus. Our team is uniquely positioned to produce this commercial product and bring it to market as we have laboratory expertise in cervical mucus (Han), copper chemistry and biology (Ralle) as well as clinical research experience in contraception and reproductive health care in LMIC (Edelman).