Specifications for Copper IUDs - variations

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Specifications for Copper IUDs - variations

Current status:

- **WHO/UNFPA technical specification for TCu380A intrauterine device, WHO TRS 1044, Annex 10, 2022.**
- **Discussion on development of Specifications for TCu375 held in Delhi in 2014. Project kept in abeyance.**
- **Variations of designs of Cu IUDs available in public health programmes, social marketing programmes and commercial markets**

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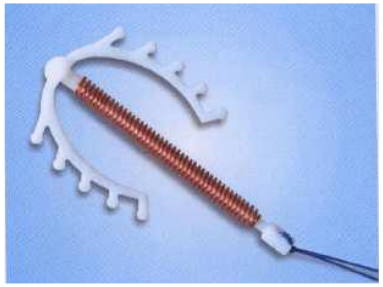
Considerations for other IUDs for PQ (e.g.Cu375 and other innovations like using Cu wires with Ag cores) - e.g Do we need to develop new specifications and what does that look like in practice?



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Considerations:

1. **Clinical :**

- **Duration of contraception protection**
- **Conditions for specific use – post partum, miscarriage, abortion etc**
- **Variations in dimensions of Female reproductive organs in specific populations**

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Considerations:

2. Product characteristics and applications:

- **Design, Shape and Dimensions of the device**
- **Materials involved in composition**
- **Applicator design – materials, shape and dimensions**
- **Packaging materials**
- **Sourcing of materials**

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Considerations:

3. Programme considerations:

- **Population characteristics**
- **Family planning practices**
- **Prevalence of use and preferences**

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Background for TCu380A:

- **Cochrane Review of the effectiveness and safety of copper containing IUDs was published in 2006 and updated in 2007.**
- **Of the IUDs considered in the review, TCu380A had a lower pregnancy rate than MLCu375, MLCu250, TCu220C and TCu200**
- **Longer protection years – 10 years**

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<u>Development of other variants:</u>

<u>TCU380A variants:</u>

Post partum – Modified insertion tube design

<u>Multi load, TCu375</u>: Used in many national family planning programmes – history and usage data and clinical evaluation

- Umbrella shaped winged frame, claims of lower expulsion rates and minimal probability of puncture of fundus

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Development of other variants:

Multi load, TCu375:

- **Standard and Sleek (shorter stem length)**
- **Contraceptive protection – 5 years**

TCu250:

- **Contraceptive protection – 3 years**
- **Useful in anaemic women and in cases of excessive bleeding**

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Development of other variants

Design: Umbrella shaped, 'Y ' shaped, - Flexibility and dilatation of cervix copper surface area (e.g. 380 mm 2, **200 mm** 2 **etc**.) **– winding patterns**

Materials:

- **Device: HDPE, LDPE copolymer**
- **Thread(Suture): HDPE, Nylon 66**
- **Core: Silver core – avoids fragmentation of copper**

Specifications for Copper IUDs - variations

Development of other variants

Applicators: (appropriate for the design of the device, flexibility and insertion techniques)

- **Preloaded,**
- **Graduated applicator**
- **Materials**
- **Flange – materials and positioning**

Specifications for Copper IUDs - Requirements

- Compliance with requirements of ISO 7439
- Preclinical and clinical evaluation
- Additional requirements from TCu380A specifications, as applicable
- Specific design and dimensions tolerance
- Shelflife claim substantiation
- Packaging and labelling
- Specific programme and customer requirements

Specifications for Copper IUDs - Requirements

- **Compliance with Regulatory requirements e,g as applicable for**

  Class III medical device and sterile

Clinical Investigations - ISO 11249:2018

- Clinical evaluations will be required by most regulatory bodies for modified or new designs of copper bearing IUDs
- ISO 11249:2018 provides Guidance on the design, execution, analysis and interpretation of clinical studies
- The standard references ISO 14155, Clinical investigation of medical devices for human subjects — Good clinical practice, for general guidance on clinical trials
- Parallel, randomised trials using a TCu380A IUD as the control are recommended
- Primary and secondary end points are recommended
- Other specific end points may apply for new deigns of IUDs

Primary End Points

- The upper 95 % confidence level, two-sided confidence interval for the one-year pregnancy rate computed using life table methods;
- The one-year expulsion rate computed using life table methods;
- The one-year discontinuation rate computed using life table methods.

Secondary End Points

Ectopic pregnancies
All pregnancies
Expulsions
Uterine or cervical perforations
Removals subdivided by reason for removal
Discontinuations subdivided by reason for discontinuation
Loss to follow up
Effects on bleeding patterns
Pregnancy outcome when IUD is in situ
Other side effects and complications

Specifications for Copper IUDs - Requirements

Thank you

Any questions ?