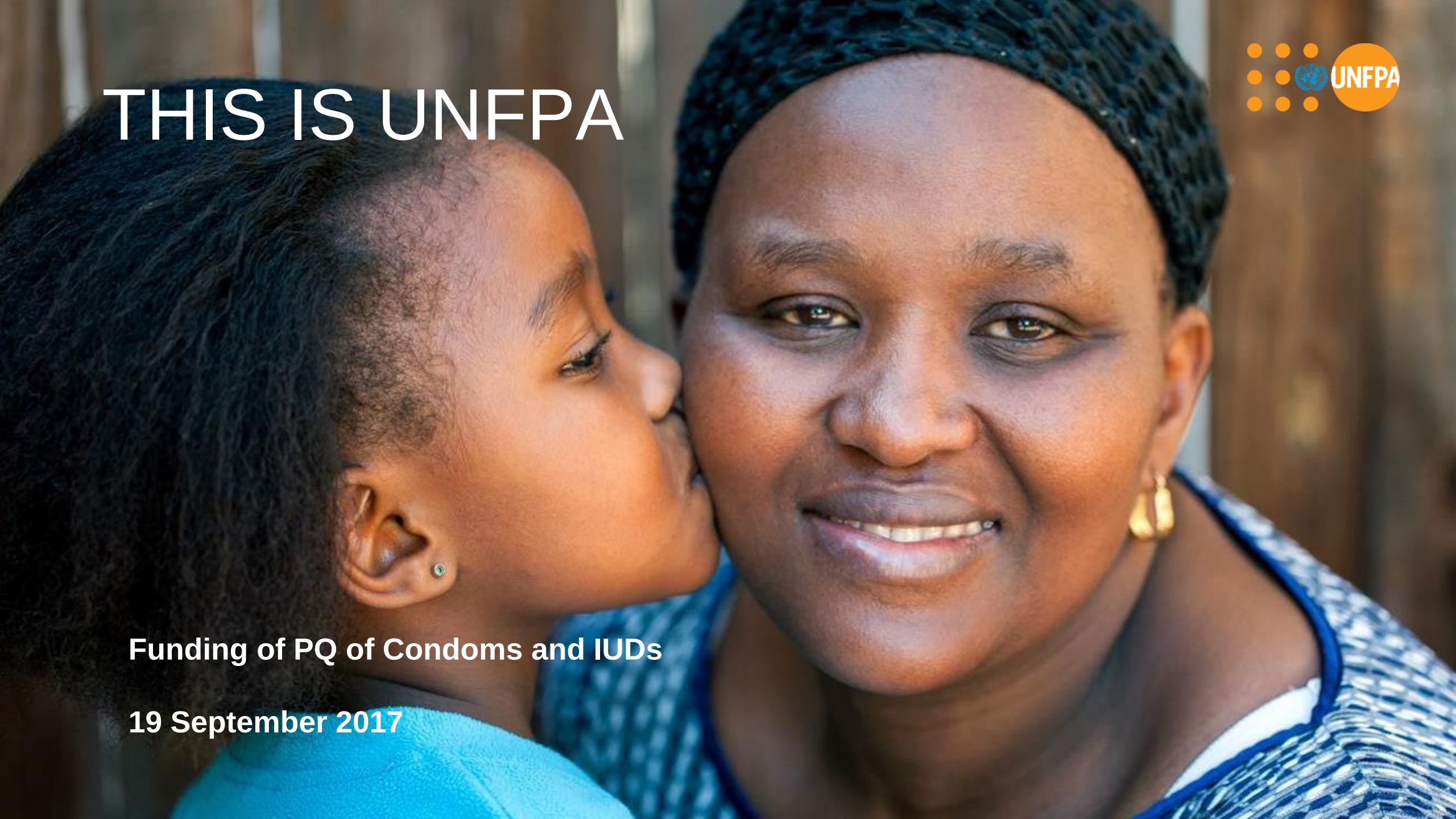

THIS IS UNFPA

Funding of PQ of Condoms and IUDs

19 September 2017

OUR WORK

WHO/UNFPA Prequalification Programmes

- Prequalification programmes started in 2001 (WHO's normative and standard setting role)
- In 2005 it was agreed that UNFPA will manage the prequalification of condoms and intrauterine devices
- UNFPA evaluates all submissions made in response to the expression of interest.

Aims of the Prequalification Programme

- Ensure that manufacturers have effective quality management systems in place and meet product quality standards
- Determine the physical capacity of manufacturers to deliver required quantities of products
- Enhance confidence in ability of manufacturers to meet all requirements and reduce the level of associated risk
- Save time and resources in identification of reliable manufacturers

Major Prequalification Programme Activities

- Management of the Prequalification programmes
- Development of technical specifications for condoms and IUDs
- Development of technical guidance on prequalification of condoms and IUDs
- Assessment of the technical file of the device
- Inspection of the manufacturing site
- Testing of the device for prequalification purposes
- Management of quality complaints

Major Prequalification Programme Activities

- Stakeholder collaboration activities
- Management of the Quality control laboratories for testing devices
- Coordination of a network of national laboratories
- Stakeholder collaboration activities
- Maintenance of Member States collaboration programme

Current funding mechanism

UNFPA Core Resources

UNFPA Supplies

Sustainable Funding

- UNFPA Core resources – reduced and continue to reduce
- UNFPA Supplies – reduced and continue to reduce
- **2020**

Impact of UNFPA Prequalification programme

4

UNFPA holds **4** LTAs with manufacturers

31

UNFPA holds **8** LTAs with manufacturers

6

UNFPA holds **3** LTAs with manufacturers

Partnerships - Key to a Sustainable PQ programme

Immediate strategies

- Increase funding
  - UNFPA Supplies programme,
  - Norway and the Netherlands
  - TGF
  - Unitaid

- Postpone new applications to 2019
  - Currently UNFPA receives about 2 new applications per year,
  - Postponing new applications will not add value.

Medium-term strategies

- Reduce the target number of prequalified suppliers
  - Possible reduction in programme running costs
  - Requires a review of the programme – determine adequate number of manufacturers to meet the unmet need

- Risk-based Requalification
  - Requalification is standard 3 years
  - Current approach does not take into consideration the performance of the manufacturers.
  - Requalification period may be higher or lower based on performance.
  - May not necessarily reduce costs of running the programme.

Long-term strategies

- Market Research
  - Benefits
    - provide factual information about the value of the WHO/UNFPA PQ
    - indicate resources required to ensure an efficient programme.
  - Challenges
    - activity funding will be required
    - might be complex as there are many stakeholders.

Long-term strategies

❖ Prequalification Fees

- Benefits
  - In-line with other UN PQ e.g. vaccines charging fees, medicines charging nominal fees
  - Sustainable funding
- Challenges
  - Manufacturers may be reluctant to pay fees as the services (assessments, inspections and product testing etc.) used to be free of charge
  - Will require assessment of the running cost which might be costly
  - Will require gradual implementation and consultation with other partners

A Fee model is required

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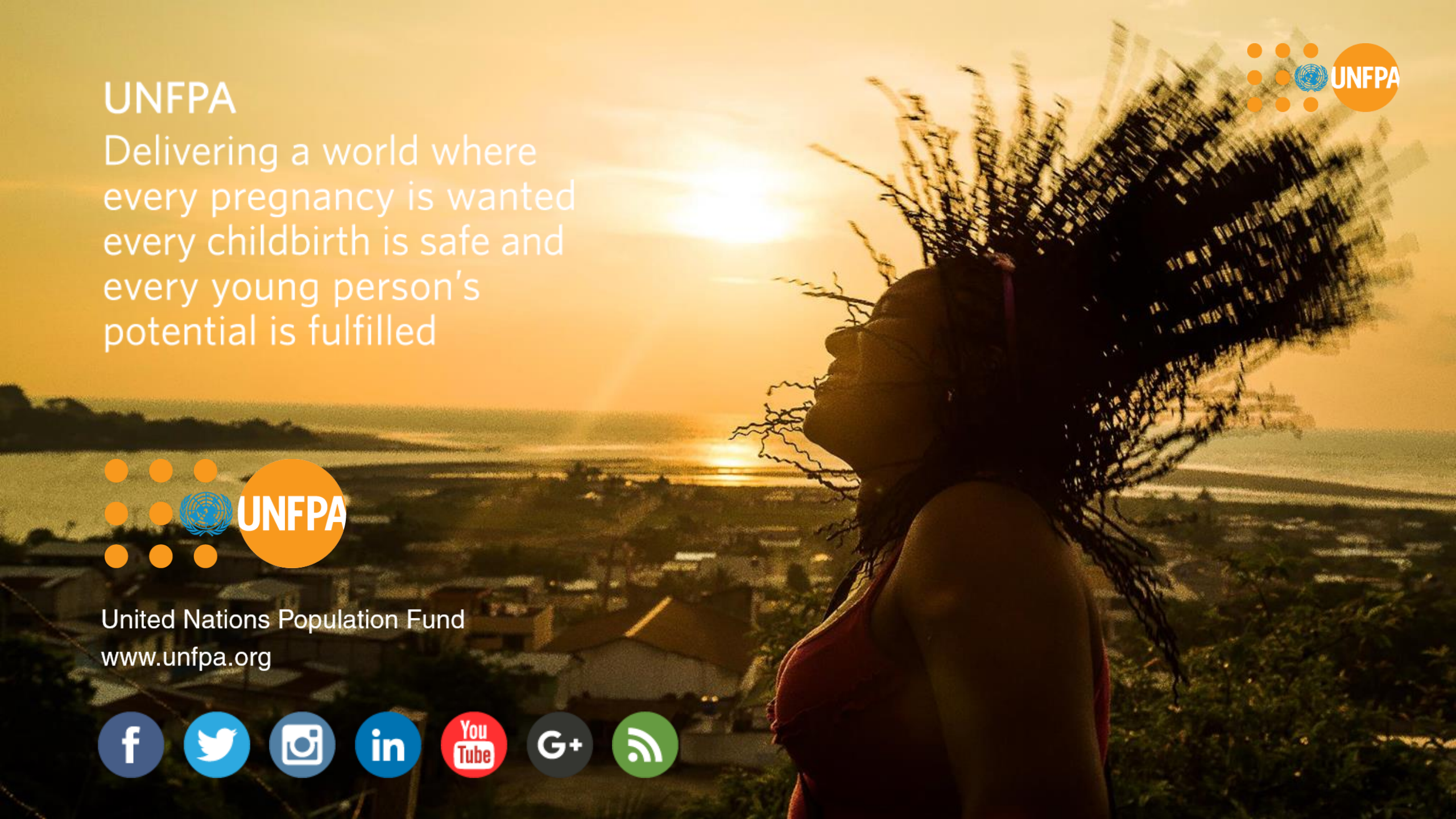
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