TAENIA SOLIUM TAENIASIS/CYSTICERCOSIS DIAGNOSTIC TOOLS

REPORT OF A STAKEHOLDER MEETING

Geneva, 17–18 December 2015

World Health Organization

TDR For research on diseases of poverty
UNICEF • UNDP • World Bank • WHO

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LIST OF ABBREVIATIONS

WHO: World Health Organization
TDR: Special Programme for Research and Training in Tropical Diseases
TPP: target product profile
MDA: mass drug administration
NTD: neglected tropical diseases
FAO: Food and Agriculture Organization of the United Nations
OIE: World Organisation for Animal Health
ILRI: International Livestock Research Institute, Nairobi, Kenya
UNICEF: United Nations Children's Fund
FERG: WHO Foodborne disease burden Epidemiology Reference Group
DALY: disability-adjusted life-years
Ab: antibody
Ag: antigen
ELISA: enzyme-linked immunosorbent assay
LAMP: loop-mediated-isothermal-amplification
PCR: polymerase chain reaction
CIETUS: University of Salamanca, Salamanca, Spain
CNM: Instituto de Salud Carlos III, Madrid, Spain
CDC: Centers for Disease Control and Prevention
EDCTP: European & Developing Countries Clinical Trials Partnership
ITM: Institute of Tropical Medicine, Antwerp, Belgium
TUM: Technical University Munich, Munich, Germany
HIV: human immunodeficiency virus
POC: point of care

EXECUTIVE SUMMARY

The World Health Organization (WHO) Special Programme for Research and Training in Tropical Diseases (TDR) and the Department of Control of Neglected Tropical Diseases convened a meeting at WHO headquarters in Geneva, Switzerland on 17–18 December 2015 to identify mechanisms to improve tools for diagnosis of *Taenia solium* taeniasis/cysticercosis for programme implementation in endemic low-resource settings. The two-day meeting was attended by participants from endemic countries and further experts (see *Annex 1*: List of participants). Country representatives from China, Madagascar, Mexico, Peru, Vietnam and Zambia presented situation analyses which informed the discussion on the process needed to acquire optimal tools for diagnosis in resource-limited settings, and an overview of tests used. Veterinary public health (pig/food safety) and mental health aspects and pathways from development to usage of diagnostic tools were also discussed (see Annex 2: Meeting agenda).

The participants identified the priorities for diagnostic tests and three working groups discussed the possible settings of use and drafted a target product profile (TPP) for each setting. Seven diagnostic test priorities were defined. A work plan was generated and the participants confirmed their support for continued cooperation in generating appropriate diagnostic tools for control of *T. solium* taeniasis/cysticercosis.

KEY MESSAGES

Common country needs for diagnostic tests

- Base the prioritization of test characteristics on setting (clinical versus research versus control).
- Design tools for evaluation of control programmes.
- Develop diagnostic tools for surveillance of taeniasis and asymptomatic neurocysticercosis for screening of patients before and after mass drug administration (MDA) with praziquantel.
- Devise rapid, easy-to-use diagnostic tests for 1) diagnosis of neurocysticercosis in epileptic patients in resource limited settings and 2) those able to differentiate neurocysticercosis from general cysticercosis.
- Implement new, validated diagnostic tests in national health and distribution systems in countries with full transmission including pigs and humans.
- Endorse political and international partner commitment for implementation.
- Define clinical implications of positive test results and provide decision trees for clinicians.
- Integrate control programmes with other neglected tropical disease programmes e.g. schistosomiasis control programmes (including development of tests with multiple targets coordination and harmonization of ethics).

Common needs expressed by diagnostic tool developers

- Focus on diagnostic tools for control and elimination programmes, on the short term first. Define tools/components/reagents already approved and available for potential further use.
- Evaluate and validate diagnostic tools based on the evidence and according to common protocol and standards.
- Elucidate factors causing false–positive and false–negative test results.
- Determine the geographical distribution of cross reacting parasitic infections.
- Conduct more profound studies on the specificity of existing tools (e.g. for cysticercosis tests in pigs confirmed by necropsy).
- Exchange test reagents and protocols, and share expertise between developers and industry.
- Define the role of point-of-care (POC) tests within the control toolbox.
- Conduct innovative research in order to develop new POC tests appropriate for field settings.

The development of an appropriate test requires that several steps to be followed. In order to overcome challenges with this process, it will be necessary to:

- define clear product standards and setting-specific target product profiles;
- share resources, such as targets and reagents;
- standardize and publish evaluation protocols;
- establish networks of evaluation sites pre-approved for standardized protocols; and
- accelerate policy development through modelling of health impact and cost-effectiveness.

DECLARATIONS OF INTEREST

All invited country representatives and experts completed the WHO declaration of interest form before the meeting. The forms were submitted to and reviewed by the WHO Secretariat. No conflicts of interest were identified.