

Helicobacter pylori (*H. Pylori*)

- Discovery Led to Nobel Prize (Barry Marshall & Robin Warren)
- Major risk factor for ulcer disease (costs US several \$B annually)
- Major risk factor for gastric cancer (~1M deaths annually worldwide)
- Acquired early in life – mother to child, crowding, can be water borne
- Dramatically decreased incidence & prevalence in western countries
- Continued need for a vaccine
 - Uncertain in developed countries
 - Would be cost-savings in developing countries
- Protective immune response, if any, unknown -> Field trials
- Low incidence precludes field trials in US
- Ex – US field sites necessary, the following are two examples
 - ✓ Nile Delta
 - ✓ Bangladesh

High Quality Field Trials: Essential Ingredients

- High incidence population
- Tractable / understandable national regulatory process
- 3rd Party 'Broker' which has the trust of the local population & regulators
 - o Nile Delta: Naval Medical Research Unit #3 (NAMRU3)
 - o Bangladesh: ICDDR,B (International Center for Diarrheal Disease Research)
- Prior safety in a western population
 - o Studies in developing countries must build on safety in developed countries

IN SEARCH OF FIELD TRIAL SITES

مشروع دراسة وبائيات الأمراض المعوية بأبوحمص

بالتعاون مع

وحدة الأبحاث الطبية للبحرية الأمريكية نامرو-٣ القاهرة

Enteric Disease Epidemiology Project At Abu Homos

In Collaboration With

U.S. Naval Medical Research Unit No.3 Cairo

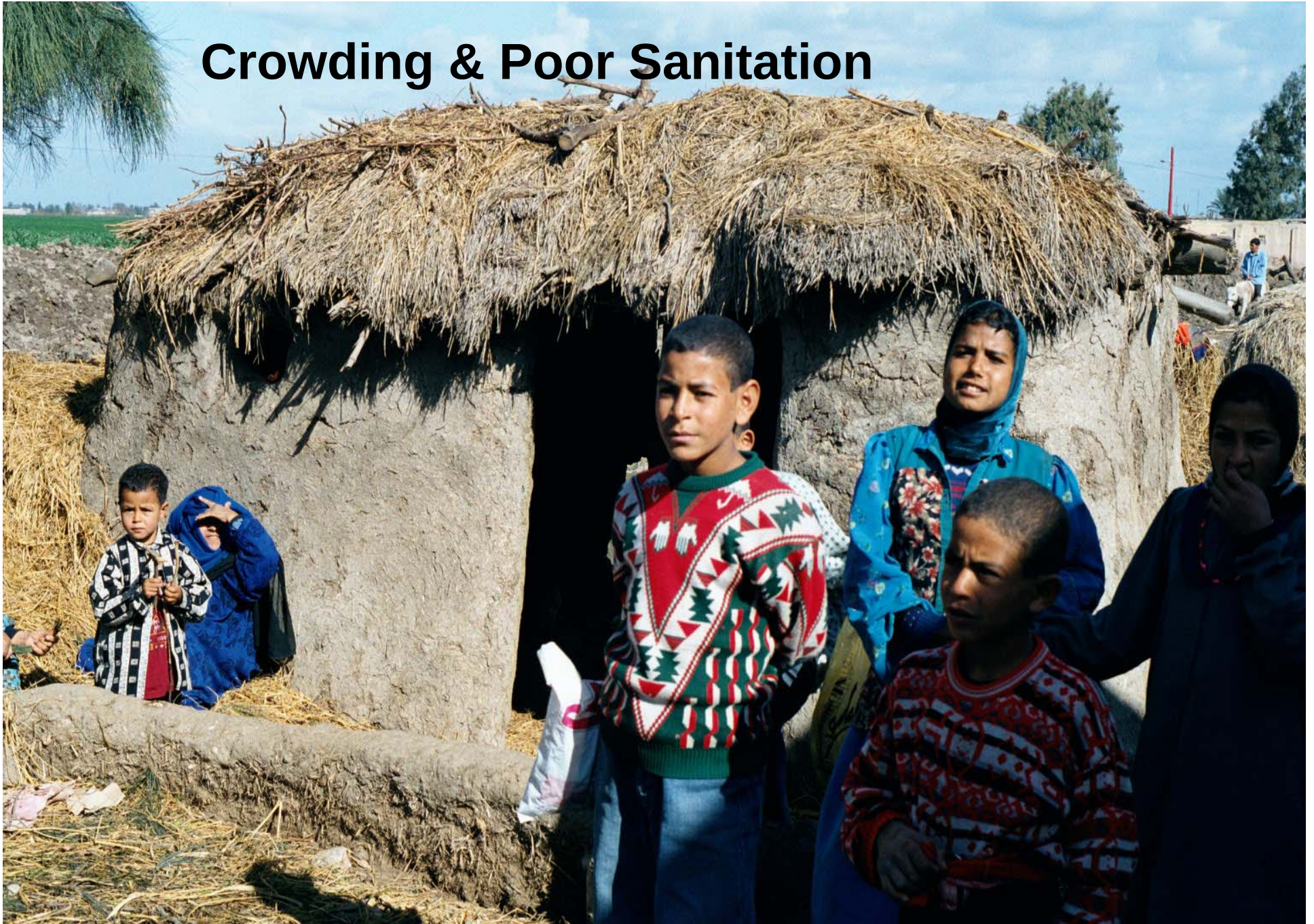
U.S. NICHD-WHO

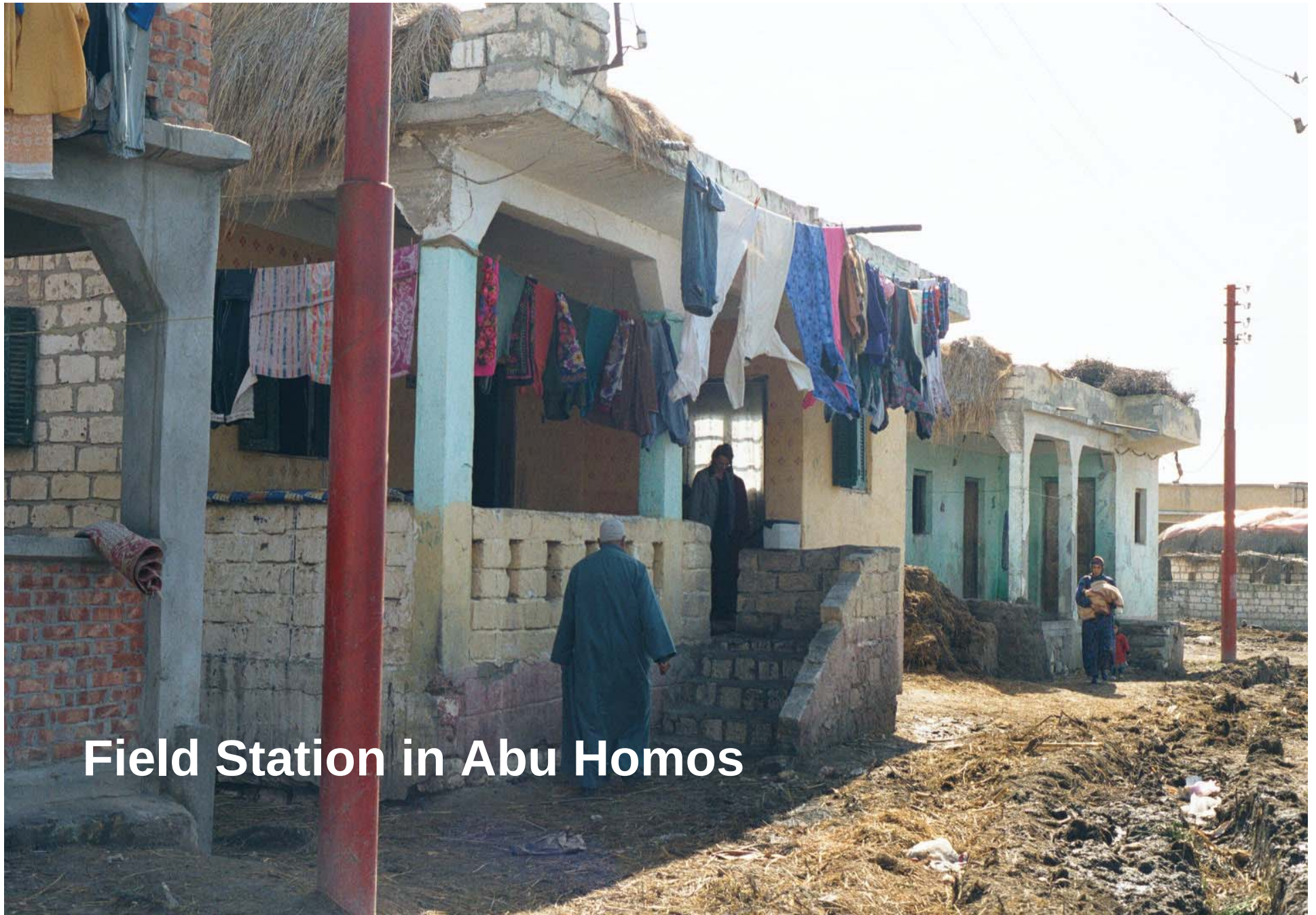
THE NILE DELTA: ABU HOMOS

High Incidence Of Schistosomiasis & *H. pylori*



Crowding & Poor Sanitation



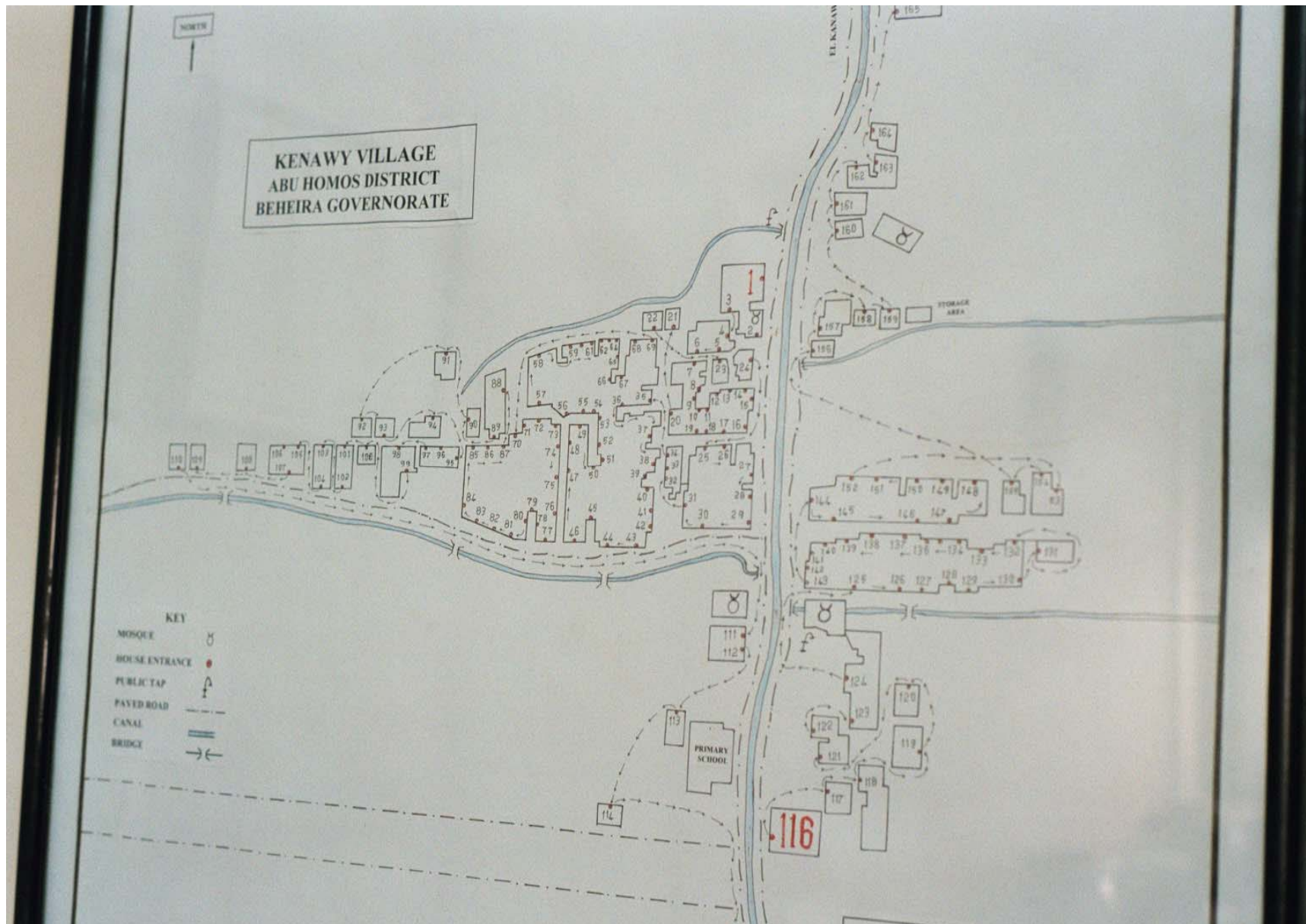


Field Station in Abu Homos

Egyptian Mothers Bring Their Children For HP Testing



House to House Route For Clinical Staff in Abu Homos



Abu Homos Clinical Research Associates



ICDDR,B: Had It's Start As A US Cholera Study Unit During the Viet Nam War (Then East Pakistan)



Capable and Motivated Investigators

- Shafique Sarker, M.D, Ph.D
- Pradip Bardhan, M.D.
- > 20 publications on *H. pylori*

ICDDR,B: Major Focus On Safety



**All subjects observed
at ICDDR,B
headquarters for 7-
days after 1st exposure
to ensure no AEs go
undetected**

ICDDR,B: Nandipar Field Site Is In Low-Lying Area in Dhaka And Serves A Local Population of 23,000



IF YOU WANT A TWO YEAR COURSE ON VACCINES

- Go to Tuscany
- Established while at Novartis/in collaboration with University of Siena



THANK YOU

Credits: Drs. Derek O'Hagan & Emanuela Palla



Derek O'Hagan, Ph.D., is Head of Vaccine Delivery Research and Vice President Novartis Vaccines and Diagnostics, based in Cambridge, MA. He previously spent 10 years at Chiron, Emeryville. Past positions that he has held include a lecturer in Drug Delivery, School of Pharmaceutical Sciences, University of Nottingham



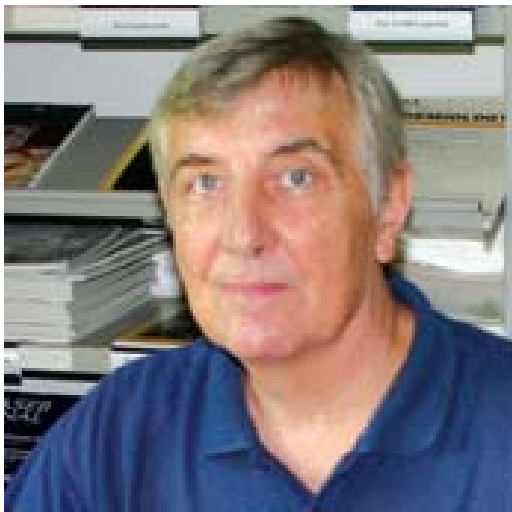
Emanuela Palla Ph.D., is Head of 'Early' Vaccine Projects for Novartis. Dr. Palla has nearly 35 years of vaccine development. Particularly expert at moving projects from research into development, she played a central role in the approval of FluAd, the 1st adjuvanted flu vaccine.

And – she taught me all I know about vaccines!!

Credits: Drs. John Telford & Rino Rappuoli



Dr Rino Rappuoli is Novartis Global Head of Vaccines Research. Previously, he was Chief Scientific Officer and VP, Vaccines Research, Chiron Corporation. Rino has been elected to the US National Academy of Sciences, the European Molecular Biology Organization and was awarded the Gold Medal by the Italian President for contributions to public healthcare. He is the author of 321 original papers.



Dr John Telford has a PhD in Molecular Biology from Zurich University. He has worked at Novartis Vaccines & Diagnostics in Siena for over 24 years in a number of roles, recently as Project Leader for GBS vaccines. He is currently Head of Microbial Molecular Biology overseeing antigen discovery for a number of vaccine projects including GBS.