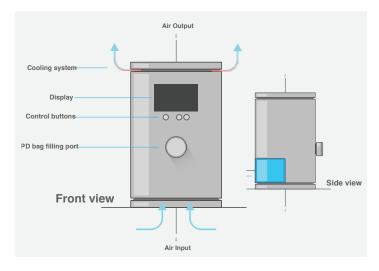


As we approach the summer holidays in Sydney, we look back on 2019 as a year of major milestones for Ellen Medical Devices, the home of the Affordable Dialysis Project. We're proud to report that we are moving steadily closer to making our treatments available to the millions of kidney patients around the world who need them.

# New workshops making new prototypes

Thanks to a generous anonymous donation from an Australian philanthropic family we built and equipped two new workshops at the George Institute, which our engineering team has been using to build new prototypes. Our 3D printers can make new parts in a matter of hours instead of the usual days or weeks. We have built seven different prototypes of our pure water distiller, each smaller, simpler and more inexpensive than the last. The water they produce is of WFI (water for injection) quality, the highest grade of medical water, and contains no bacteria or pyrogens. It is the ideal water for filling peritoneal dialysis bags at home.



# New partners with just the right chemistry

During the year we signed partnership agreements with Brandwood CKC, the leading regulatory consultant for medical devices in Australasia, and the Monash Medicines Manufacturing Innovation Centre, a Victorian group of academic pharmaceutical chemists who helped us define the chemistry in our peritoneal dialysis bags.



After a rigorous evaluation process we also appointed Sydney-based Design and Industry (D+I) as our design-for-manufacturing partners in a multi-million dollar contract, supported by key strategic grants from the Medical Devices Fund of the NSW Government and the Paul Ramsay Foundation. D+I will manufacture 50 pure water distillers and 10,000 bags to be tested with local volunteer dialysis patients in 2020. Their subcontractors Genesys are looking after the software and electronics design. Both companies have the essential ISO13485 certification required to build medical devices for human use.





The George Institute staff conduct a home visit to screen for kidney disease in the Indian state of Andhra Pradesh.

## Clinical advisors and clinical trials

Our new Clinical Advisory Board had its first meeting in November in Washington DC during the American Society of Nephrology annual meeting - the world's biggest kidney conference, attended by over 8000 people. The Board comprises leading kidney specialists from China, India, Mexico, Thailand, Europe and North America and is chaired by Prof Vlado Perkovic (yes, another kidney man), formerly Executive Director of The George Institute, Australia and now Dean of Medicine at UNSW Sydney. Vlado has been part of our project since the beginning and helped create the Affordable Dialysis Prize back in 2015 which started it all. It was a landmark meeting - so exciting for us to hear from the clinical coal face about how our dialysis systems could play a key role in different parts of the world, and an important reality check as we move forward to test our system with patients.

So 2019 has been an important year of milestones and successes, and 2020 promises more, as we launch our clinical program and commence the essential processes for regulatory approval. Warm thanks to our many supporters around the world. We look forward to keeping you informed, and partnering with you as we move from the laboratory and the factory into the clinic and the home.



The latest Ellen Medical prototype



The Hon Brad Hazzard MP, NSW Minister for Health and Medical Research, awarding Vincent Garvey and Professor John Knight of Ellen Medical Devices, the developer of The George Institute's affordable dialysis system, a grant from the 2018 NSW Medical Devices Fund. Photo: NSW Health.

#### Contact:

To find out more about the Affordable Dialysis Project or The George Institute for Global Health, please contact: +61 8052 4500 <u>info@ellenmedical.com</u>

### The George Institute For Global Health:

We're improving the lives of millions of people worldwide through innovative health research. Working across a broad health landscape, the Institute conducts clinical, population and health system research aimed at changing health practice and policy worldwide.