## PORTABLE ARTIFICIAL KIDNEY

### Overview / summary of the initiative

| Title: | Portable artificial kidney |
| Country: | The Netherlands |
| Thematic area: | Health |

**Objective(s):**

Improve well-being of patients with end-stage renal disease (ESRD) by developing a compact haemodialysis device as an alternative to the current large haemodialysis device that is especially suitable for use in a hospital or dialysis centre. The portable artificial kidney (PAK) becomes smaller and lighter in weight, easy to bring, so patients can use it at home or elsewhere. Furthermore, the portable artificial kidney should provide patients with more choice in treatments, enable a larger group of patients to having dialysis on a daily basis and thereby improve their condition significantly. On the long term the ambition of the initiative is to develop an implantable bio-artificial kidney.

**Timeline:** 2008 - 2020

**Scale of the initiative (resource/budget indication):** Aprr. € 40 million

**Scope of the initiative:**

- Focused on new knowledge creation (basic research, TRLs 1-4): Yes
- Focused on knowledge application (applied research, TRLs 5-9): Yes

**Source of funding:** Public-private

**Granularity of the initiative (initiative, policy approach):** Initiative


### Brief description of the initiative:

Dialysis is heavy and it determines everyday life of patients with end-stage renal disease (ESRD). Each year 1 in 6 dialysis patients die. Despite technological progress and the opportunities to decrease the impact of dialysis on the lives of patients the development of better haemodialysis was not addressed. The Dutch Kidney Foundation (DKF) therefore decided not to wait longer and start developing the portable artificial kidney itself (PAK) in 2008. In collaboration with Dutch health insurers the foundation invested in the development of the PAK, as well as in related research projects to enable breakthroughs that can be applied to the development of the portable kidney (e.g. research into better ways of accessing water (in order to connect the dialysis to the vein there must be good access to the veins).

To ensure that the PAK remains available for kidney patients the intellectual property of the PAK (and resulting innovations) remains at the foundation and the partners involved in the various projects. The marketing of the portable artificial kidney will also be done by companies that specialize in it but they may subsequently do so under license. In order to protect intellectual property the foundation has established the social enterprise NeoKidney Development. The development of the PAK has been formally moved to this company.

Next to improving the well-being of patients the development of the PAK also will contribute to reduce waste (waste from the dialysis fluid are collected in a special cartridge which filters it through which it can be reused) and thereby will allow to reduce water usage from 120 litres to about 5 litres. Moreover, by continually cleaning the device dialysis can run without interruption and the cleaning cycle becomes more reliable and stable. On the long term the ambition of the initiative is to develop an implantable bio-artificial kidney.

### I: Background, origin, mission and ambition

#### Ia: Origin

Due to the waiting list for patients and the limited progress on new legislation on organ donation the DKF searched for other options to improve the well-being of patients with end-stage renal disease (ESRD). The foundation was approached by the Dutch foundation Willem Kolff (named after the Dutch scientist that was a pioneer of haemodialysis as well as in the field of artificial organs) that suggested ideas to increase scientific research related to haemodialysis in The Netherlands in 2005. Based on studies to alternatives for kidney transplantation DKF therefore decided not to wait longer and start developing a PAK itself in 2008.

#### Ib: Initiator

Dutch kidney foundation (Nierstichting)

#### Ic: Mission and ambition

Improve well-being of patients with end-stage renal disease (ESRD) by developing a compact haemodialysis device as an alternative to the current large haemodialysis device that is especially suitable for use in a hospital or dialysis centre. The DKF has set the ambition to develop a PAK that is smaller and lighter in weight and easy to bring and to enable patients to run dialysis at home or elsewhere. The PAK should provide patients with more choice in treatments, enable a larger group of patients to having dialysis-treatments on a daily basis and to improve patients’ condition significantly.
### The following milestones have been defined:

- **2008: Start of the initiative**
- **2009: Concept development**
  - Proof-of-concept: Recycling dialysis concept, Pilot studies, Prototype WAK (NEPRON+)
  - Feasibility/Viability check: User analysis, Market /SOTA analysis, Freedom-to-operate patent analysis - Expert consultation on feasibility
  - Operational plan: Draft Business plan, social enterprise NeoKidney as a vehicle, List of requirements, Request for Quotation
- **2014: Functional model**
  - Functional Model: Development of the dialysis cycler and components, Development of the sorbent cartridge, Software development, In vitro testing, In vivo safety study, In vivo performance testing, Inventory of regulatory requirements
  - Design: User-based Industrial design
  - Joint venture established between Debiotech (Switzerland), AWAK Technologies (Singapore) and NeoKidney Development to complete a functional model in 2015
- **2016: Prototype**
  - Prototype: Final product design, GUI development, Physical implementation, Pre-production prototype, In vitro validation, In vivo performance testing
  - Care Model: User scenarios, Clinical backend applications, Training programme, Cost-benefit analysis
- **2018: Clinical trials**: First-in-man, Phase I and II trials
- **2019: Regulatory Approval**: Document review, Evaluation, Certification
- **2020: Use of PAK 2.0**

On the long term the ambition of the initiative is to develop an implantable bio-artificial kidney.

### Id: Decision making process

DKF set the ambition and objectives of the initiative. In collaboration with the involved partners and on advice of the advisory and medical board of NeoKidney the milestones have been further developed and turned into a concrete roadmap to develop the PAK 2.0.

### Ie: Linkage to other governance levels

The initiative is part of the foundation's overall ambition to improve the well-being of patients with end-stage renal disease (ESRD).

### If: Geographical scope

National focus, but global use/application.

### Ig: Time span

12-15 years, depending on the challenges that might occur during the clinical trials and certification process. On the long term the ambition of the initiative is to develop an implantable bio-artificial kidney.

### II: Formation

#### IIa: Driving forces

- Dutch foundation Willem Kolff: suggested ideas to increase scientific research related to haemodialysis in The Netherlands
- Dutch Kidney Foundation: initiator, funding (€14 million), mobiliser of support and awareness, fundraiser
- Dutch health insurers (Zilveren Kruis, Menzis and CZ): support the mission with expertise, knowledge and funding (€ 6,8 million) for the research projects

#### IIb: Approach

Top-down approach

#### IIc: Citizen involvement

Citizens are mainly involved in fundraising. With (global) campaigns and online updates (webpages, newsletters and short movies on YouTube progress on the initiative is actively communicated.

### III: Technical and political feasibility

#### IIIa: Technical feasibility assessment

The technical feasibility has been assessed at the start with two complementary assessments (patents, market developments, etc.) by University of Twente’s research centre for Biomedical Technology and Technical Medicine (MIRA) and Roland Berger.

In 2014, after the end of the EU NEPRON+ project, an interim feasibility assessment has been carried out (focused on the NEPRON+ patents). Furthermore, four proposals from companies on a tender for the development of the PAK 1, including biomedical feasibility assessment.

#### IIIb: Ex ante technical and risk assessment

With two complementary assessments the technical and risks have been assessed ex ante. In addition an ex ante Cost-Benefit Analysis was done, however due to the lack of precise data on the costs of haemodialysis treatments only with extrapolation indications on the costs and benefits could be calculated.

#### IIIc: Success factors
The following major factors and gaps for success have been identified up-front:

- Collaboration with international renowned leading nephrologists, entrepreneurs and scientists
- Joint venture with experienced private business partners to push forward the development
- Required basic technology is quite mature
- Establishment of social enterprise to secure IPR and speed-up development
- Active push on adaption of technical requirements
- Technical barriers/challenge might arise when the clinical trials start
- Certification of the portable artificial kidney
- Market access (users)
- Barriers with regards to the care-concept

IIIe: Political and societal assessment

In 2016 the DKF launched a global campaign (Help them escape) to raise € 10 million for the development of the PAK project. This campaign resulted in the collaboration with three Dutch health insurers (Zilveren Kruis, Menzis and CZ) that support the initiative with expertise, knowledge and funding (€ 6.8 million) for the research projects.

IIIff: Interim political and societal assessment

There was no assessment made of the political needs to attain the mission vis-à-vis political cycles/re-election/changes in government or societal preferences.

IIIg: Financial risk assessment

A financial risk assessment was made up-front. The assessment led to the conclusion that the social enterprise NeoKidney was established for the development of the PAK, to ensure that the portable kidney remains available for kidney patients and the intellectual property of the portable artificial kidney (and resulting innovations) remains at the foundation and the partners involved in the various projects. Also liability issues in case of expensive legal disputes were addressed by moving the development to NeoKidney.

IV: Governance: organisation, management and coordination

IVA: Governance

DKF established social enterprise NeoKidney for the development of the PAK and funded with a subsidy of DKF. NeoKidney is owner of the IPR of the PAK.

- NeoKidney is managed by a board and advised by an Advisory and Medical board.
- 3 members of the Advisory board are appointed by DKF, the other members are representatives of the participating health insurers and scientists and business partners.
- The Medical board advises on the research projects
- The DKF innovation program manager works part-time for NeoKidney to ensure the DKF research projects are aligned with NeoKidney’s activities

Furthermore NeoKidney is a partner in all related research projects funded with the innovation program of DKF and partner of the joint venture with the business partners Debiotech and AWAK Technologies.

IVB: Progress monitoring

Progress of the to the PAK related research projects funded by DKF is monitored on project basis by external reviewers. Progress of the development of the PAK prototypes within the joint venture is monitored by the board of NeoKidney and the Advisory board on regular basis. The Medical Board monitors the scientific progress on a two-yearly basis.

IVC: Public-private involvement

The development of the PAK is public-private organized: with DKF (via NeoKidney), health insurers and business partners Debiotech and AWAK Technologies as partners.

IVD: Communication and dissemination

- With (global) campaigns and online updates (webpages, newsletters and short movies on YouTube) the progress is actively communicated to the broader public.
- Results and findings of research projects are published and shared within the research community

V: Resources and budget needs/availability

VA: Scale

The initiative has a budget of appr. €40 million. In total appr. 90 FTE researchers are involved in projects contributing to the development of the PAK. The NeoKidney company employs 1,2 FTE and the two business partners (Debiotech (Switzerland) and AWAK Technologies (Singapore) employ both 10 FTE to the project.

VB: Funding sources

The initiative funded with the following sources:

- Funding via the DKF (€ 8 million)
- Not-for-profit health insurers (€ 6.8 million)
- (global) public fundraising campaigns (#Helpthemescape, sponsor runs, etc.) organised by the foundation (€1,4 million in 2016)
- Donations from foundations and private persons (legates) (€1 million in 2016)
- Debiotech (Switzerland) and AWAK Technologies (Singapore) private investments

**Vc: Allocation of the budget**
- NeoKidney: € 20-30 million (including business partners Debiotech and AWAK Technologies)
- Related research and innovation projects DKF: appr. € 10 million

**VI: Policy mix and integral ('holistic') use to deploy mission-oriented R&I-initiatives**

**Via: Policy mix**
- Research projects funded via DKF and co-financed by the Dutch STW and Dutch Topsector Life Sciences & Health Innovation Agenda
- EU FP7 (NEPRON+ project, Marie Curie International Training Network project BioArt and the STELLAR consortium
- User studies
- Development of the PAK prototype is a joint effort of NeoKidney and the selected two business partners Debiotech and AWAK Technologies.
- IPR of the PAK is owned by NeoKidney

**Vib: Engagement of citizens**
Citizens are mainly engaged to the initiative via fundraising and awareness campaigns. With (global) campaigns and online updates (webpages, newsletters and short movies on YouTube progress on the initiative is actively communicated. Furthermore, citizens are engaged with users studies to the test the ease of use of portal device and impact of home dialysis on patient life. Moreover, patients will be involved during the clinical trials that are required.

**VII: Embeddedness of and connectivity with related initiatives (regional, national, supranational, global)**

**VIIa: Relationships/links/synergies to similar initiatives elsewhere**
- On EU level a consortium worked within the NEPHRON+ project to develop ICT based solutions for home dialysis. The project started in 2010 and has been funded under FP7-ICT-2009-4 in 2009 with € 5 million and will run 57 months. The DKF was a member of the consortium.\(^1\)
- In the USA research is running to develop a wearable artificial kidney (WAK) carried out by Dr. Victor Gura\(^2\) and is supported by the Wearable Artificial Kidney Foundation (WAKFUND).\(^3\)

**VIIb: Links to UN Sustainable Development Goals**
The initiative contributes to Goal 3 – Ensuring healthy lives and promoting well-being.

**VIII: SWOT analysis**

**VIIIa: Strengths**
- Collaboration with international renowned leading nephrologists, entrepreneurs and scientists
- Joint venture with experienced business partners
- For the initiative required basic technology is quite mature
- Participation in EU project NEPHRON+
- Spin-out NeoKidney to secure IPR and speed-up development
- Active push on adaption of technical requirements
- Contacts with the dialysis industry

**VIIIb: Weaknesses**
- The foundation is a charity and as such depends on its fundraising income
- Funding for next phase is not fully secured

**VIIIc: Opportunities**
- If 10% of the 6,300 Dutch dialysis patients switch to the PAK, the Netherlands will save 27 million annually in direct healthcare costs.
- This figure does not include the effects of higher participation and productivity in society. Worldwide, savings could be up to 10 billion.

**VIIIId: Threats**
- Unknown which technical barriers/challenge might arise when the clinical trials start
- Unknown if and which development of the prototypes and production challenges might occur
- Certification of the portable artificial kidney
- Market access (users)
- Potential barriers with regards to the care-concept

**VIIIe: Lessons learned**
IPR has been moved to social enterprise NeoKidney to ensure the PAK remains available for kidney patients
Public private collaboration is key to push forward the development and create concrete solutions

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\(^1\) [http://www.nephronplus.eu/en](http://www.nephronplus.eu/en)

\(^2\) [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2736696/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2736696/)

\(^3\) [http://www.wakfund.org/](http://www.wakfund.org/)
User studies are key to ensure that the developed solution suits the needs of the end-user

References

Phone interview with program manager Jasper Boomker from the Dutch Kidney Foundation on 13 November 2017. Mr Boomker is program manager of the innovation program at the Dutch Kidney Foundation and works part-time for Neokidney.
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