GoNano Stakeholder Workshop about nanotechnology and diabetes

Information material

Date
12 February, 2019
11:00 – 15:00h
University of Twente, Designlab
Enschede

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UNIVERSITY OF TWENTE.

About the meeting

Thank you for participating in this GoNano stakeholder workshop on nanotechnology and diabetes. Professional stakeholders (researchers, engineers, industry, civil society organisations and policy) will work together to co-create new solutions for future nanotechnology innovation, with a specific focus on diabetes research.

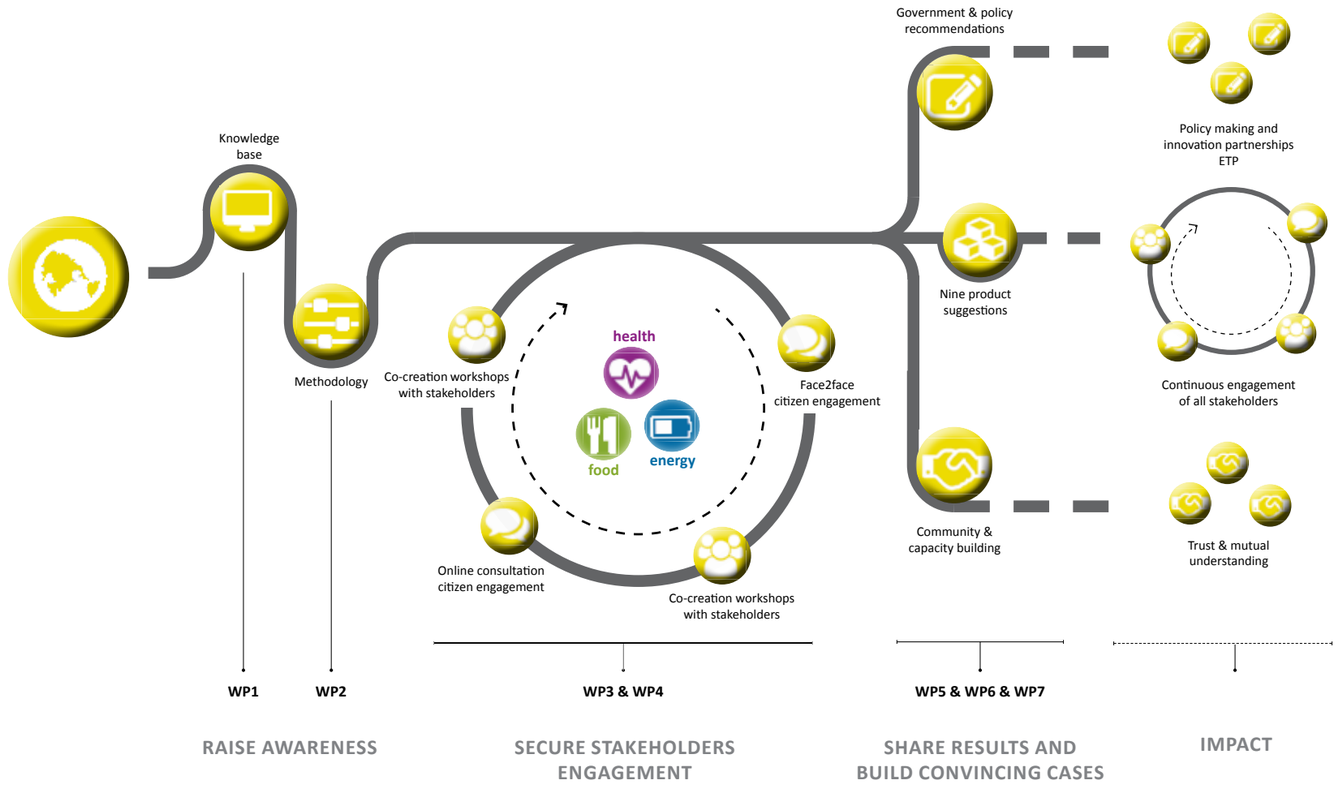
About the Gonano project

GoNano is an EU-funded project that enables co-creation between citizens, civil society organizations, industry, researchers, and policy makers across Europe to align future nanotechnologies with societal needs and concerns. GoNano aims to explore how researchers can work with citizens and professional stakeholders to create novel suggestions for future nanotechnology products.

The GoNano project is built on the assumption that nanotechnologies are more likely to gain broad acceptance if they take public values and concerns into account at early stages of innovation. Therefore, a co-creation methodology has been designed, which will be conducted in three different thematic areas (Food, Health, and Energy). In this co-creation process, wishes, needs and product suggestions of both citizen and professional stakeholders are taken into account by means of a face-to-face citizen consultation, a stakeholder workshop, an online citizen consultation and a second stakeholder workshop (see Figure 1 for a visual representation). The aim of the co-creation process is to end up with nine products and/or research suggestions (three for every thematic area). This information brochure serves as input for the first stakeholder workshop in the area of health.

GoNano project

Governing Nanotechnologies through societal engagement



GoNano co-creation process

What do we expect from you?

During the workshop, stakeholders with varying backgrounds will discuss and explore possibilities for new product design in the health area and ways to include the needs and values expressed by citizens. Every stakeholder has its own perspective, knowledge and expertise, directly or indirectly linked to nanotechnology. By linking different perspectives and expertise, we aim to come up with new insights and specific suggestions for future development of health technologies.

What will happen after this meeting?

1. GoNano researchers will analyse the outcomes of this stakeholder meeting about requirements for designing future nanotechnologies for applications in healthcare.
2. In Spring 2019 citizens across Europe will receive an invitation to evaluate the innovation ideas from the stakeholder workshops.
3. In another round of stakeholder workshops, researchers, engineers, industry, civil society and policy representatives will re-work the design suggestions.
4. GoNano researchers will present the results to EU policy-makers and make the results available online, together with teaching material that show how people could work with citizens to develop innovative product designs.

Organization

The co-creation process in the health area is led by the University of Twente (UT). Based on interviews with various stakeholders from all over Europe, three application areas of health and nanotechnology were defined: health monitoring, diagnostic devices and regenerative medicine. In October 2018, 50 citizens from the Netherlands provided suggestions and ideas for the development of nanotechnology in these application areas (please see a summary of the results below). This stakeholder workshop builds on the outcomes of the citizen consultation and explores how structured interactions between stakeholders can lead to specific design suggestions. This is the first of two workshops: the second workshop will be organised in October 2019.

Nanotechnologies and health

Nanotechnology is the study, design, creation, manipulation and use of materials, devices or systems at extremely small scales of 1-100 nanometer (nm). By way of comparison, a human hair is approximately 80,000 - 100,000 nm wide.

By working on such a small scale properties of existing materials can be manipulated and improved, or new materials with novel properties can be designed. These properties can be physical, chemical, electrical, mechanical optical or magnetic. Nanotechnology offers great promises for solutions on environmental, health and food challenges. In the area of health it is applied for detection of symptoms, monitoring, tissue regeneration, drug delivery and imaging. Various nanomaterials and structures are used, such as:

- Nanomaterials to make smart skin patches for wound healing;
- Nano-encapsulation for targeted delivery of drugs;
- Nanoparticles used as contrast agents improving MRI signals, or as drug delivery systems;
- Nanosensors enabling non-invasive measurements of large number of parameters, e.g. biomarkers from urine or breath;
- Nano-bio and synthetic technologies enabling regenerative medicines.

Based on these nanosystems and structures, which all are labelled as 'nanotechnologies', various potential applications are developed in the health area.

Application areas

Interviews with various stakeholders conducted across Europe as part of the GoNano project, highlighted three important application areas for nanotechnology in health: monitoring devices for health, early-diagnostic devices and regenerative medicines.

Monitoring devices for health

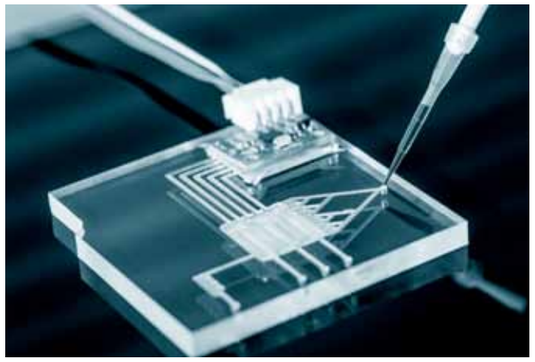
Nanosensors may help to create better insight in an individual's health status by measuring health values. Proponents of this technology expect that through the collection of health data, nanosensor might be promising for leading to a shift in the healthcare system from curing diseases to preventive healthcare. In the context of diabetes, nanosensors could increase the awareness of the consequences of an unhealthy lifestyle. For diabetes patients, nanosensors could make life easier by continuously monitoring their glucose levels. The devices could be designed in such a way that patients are automatically warned when their glucose levels are off, and that insulin get injected without the patient even noticing. Researchers or working on improving sensor technology in a way that it becomes smaller, and therefore more wearable, and in a way that it become more reliable and can even measure insulin levels.

Diagnostic devices

This area typically includes analytical systems for both in vitro and in vivo Devices for early diagnosis typically include the development of integrated multifunctional devices allowing for fast and cheap medical diagnostics. Based on nanotechnology, devices are being developed that can measure biomarkers in blood, urine or breadth in a cheap, fast and sensitive way. Devices are now being developed to be implemented in hospitals, but might be available for citizens in the future. In the context of diabetes, a lab-on-a-chip device could be developed to allow people to diagnose for diabetes (both type 1 and 2) at home.

Regenerative medicine

Regenerative medicine focuses on the development of systems able to replace lost or impaired body functions such as engineering of artificial skin tissue, cartilage and bones for autologous implantation. Regenerative medicine also explores biocompatibility of implants through the development of efficient strategies based on nano technology to disrupt and prevent biofilm formation associated with a number of infectious diseases and implant-associated infections as well as through nano-functionalization of surfaces and intelligent, non-toxic, biodegradable or bioactive materials. In the context of diabetes type 1, researchers of RegMedXB are working on a proof-of-concept to regenerate insulin-producing β-cells in the islets of Langerhans of the pancreas.



Ethical, legal, social and regulatory issues

These promising developments in nanomedicine also carry a range of ethical, social, legal and regulatory questions in their wake. Ethical questions include privacy, autonomy (e.g. regarding brain implants) and the patient's right to decide whether to be informed about diagnosable but incurable diseases. Social issues include the affordability of the healthcare system, changing notions of health and disease, or potential shifts in responsibility from centralized hospitals to general practitioners and from healthcare professionals to the individual patient.

European regulations define the regulatory context for nanotechnologies. The medical devices regulation is the only regulation dealing with health products that contains specific nano provisions. It provides a definition of nanomaterials and contains approval procedure, safety assessment and labeling provisions on nanomaterials. This regulation stresses the need for special care when devices contain nanomaterial that can be released in the user's body. Special care must be taken when using nanoparticles with high or medium potential for internal exposure. Such devices should be subject to the most stringent conformity assessment procedures..

Other regulations, including regulation on the authorization and supervision of medicinal products for human and veterinary use, the directive on good clinical practice or the regulation on clinical trials on medicinal products for human use also apply to healthcare products although none of these regulations include nano-specific provisions.

Outcomes of the citizen workshop

On 24 November 2018, 50 citizens from all over the Netherlands gathered at the Designlab at the University of Twente to discuss the future of nanotechnology in healthcare. The session was divided in three rounds: 1) citizens gave their views on the use of nanotechnologies in healthcare by discussing different scenarios that included health monitoring, diagnostic devices and regenerative medicine, 2)citizens designed their ideal health technology, and 3) citizens came up with specific messages to stakeholders.

Based on the output of the citizens, various overarching concepts could be detected, including: safety, well-being, autonomy, accessibility, privacy and security of data, and costs. These concepts will be shortly described by giving a summary of the comments citizens made and linking design suggestions to them which were mentioned by the citizens during the workshop.

Safety

Participants questioned whether some invasive technologies (e.g., implanted nano-chips) might be harmful or not. However, they emphasized that it was not a deal-breaker, in when these technologies could improvement treatment of diseases. This was also the case with regenerative medicines: participants had doubts about its safety as they were not familiar with the effects and working principles of the technology, but in general they could see the benefits of it.

Suggestion/requirements mentioned by the participants:

- Inform and educate people about working principles of nanotechnology and its potential risks;
- If possible, try come up with a non-invasive alternative.

Well-being

Participants were positive about the potential for preventive healthcare with monitoring technologies. However, they emphasized that they did not find it an attractive idea to be constantly aware of health indicators in case of monitoring devices and or diagnostic devices. Also, they had concerns regarding the interpretation of data when these devices were used by citizens without a health professional, and how citizens could deal with a margin of error. Furthermore, participants emphasized that being aware of having a risk of getting a particular disease or being diagnosed with a disease in an early stage could negatively influence mental well-being, especially, when there is no treatment available.

Suggestions/requirements mentioned by the participants:

- Try to make a shift to prevention of diseases instead of focusing on curing of diseases in the healthcare system;
- Only give a signal when an anomaly is detected (monitoring devices);
- Connect the sensor technology to a device that is being monitored by a health professional or make sure that people use a (diagnostic or monitoring) device under supervision of a health professional;
- Only make early diagnostic tests and monitoring devices available for high-risk groups;
- Don't try to monitor and detect as many diseases as possible, but always keep human's well-being in mind.
- Limit the accessibility of home-test devices;
- Educate and inform people about how to use the devices, and how to interpret the data.

Autonomy

Participants strongly felt that they should be able to decide themselves which diseases are being monitored or diagnosed for. They also were very clear that they wish to have autonomy over their health data in terms of collection, storage and sharing. Furthermore, participants emphasized that there should always be freedom of choice in whether to use a technology or not.

Suggestions/requirements mentioned by the participants:

- When designing a monitoring device, make sure that people can adjust the settings in the indicators that are being measured and the type of data that is being shown (e.g., set the margin of error, define signalling references, etc.);
- Make sure that regarding diagnostic devices that citizens can decide what types of diseases is being tested for;
- Make sure that it in the design of the device it is clear for users how to use their data / what happens with the data (in terms of collection, storage, and sharing);
- Learn from the lessons of the electronic medical record, and give citizens the choice whether they want to share their data with a health professional or not, but let hem always be the owner of the data;
- Never make a health technology obligatory to use.

Accessibility

Participants were afraid that health technologies could polarize society in terms of rich vs. poor, digital skilled vs. non-digital skilled, and religious vs. non-religious. They posed their concerns, that a considerable group of people would not know how to use monitoring and diagnostic devices, and that the digital gap would influence accessibility to health technologies. Furthermore, regarding regenerative medicines, citizen emphasized that this could lead to a differentiation between religious and non-religious people. They made a comparison with vaccinations.

Suggestions / requirements mentioned by the participants:

- In case of expensive treatments, such as regenerative medicines, availability should be based on health criteria, not financial criteria (similar to donor organs);
- Don't let religious principle be leading in the development of health technologies, but always give freedom of choice;
- Focus on the user experience when designing the reading device of monitoring and diagnostic devices. Make sure that results are easy to understand, and not multi-interpretable;
- Educate and train people in how to use monitoring and diagnostic devices.

Privacy and security of data

Participants posed major concerns regarding the privacy and security of personal data that would be collected with monitoring and diagnostic devices. They were especially afraid that data would be available for health insurance companies. Participants were ambiguous about the role of the government in this regard. On the one hand, they thought the government should take the lead in the implementation and regulatory framework of monitoring and diagnostic devices. On the other hand, they thought these devices should be implemented by the market and they would feel less inclined to use a monitoring device when the government would actively encourage these to use.

Suggestions / requirements mentioned by the participants:

- Make sure that in the design of the device it is clear for users how to use their data / what happens with their data (in terms of collection, storage, and sharing);
- Include IT-specialists in the development of sensor technologies, and make sure data is collected and stored in a secure way;
- Anticipate in regulations on all data that might be available with monitoring and diagnostic devices;
- Be careful when communicating from a governmental perspective about these devices (similar with electronic medical record).

Costs

Participants emphasized in several discussions that it was important to take into account the costs of the healthcare system. They were ambiguous whether nanotechnology would limit the costs, or increase the costs. On the one hand, they saw possibilities with prevention of diseases instead of focusing on curing of diseases. Also they saw the potential of personalized medicines. On the other hand, they were afraid that processing all health data could lead to an increase of costs, and that people might become too much focused on their health (including misinterpretations of data). These monitoring and diagnostic technologies might lead to an increase of visits to the GP.

Suggestions / requirements mentioned by the participants:

- Make sure technologies are used in a way that they unburden the health professional, not give an extra burden to them;
- Make sure technologies complement the health professional, and not substitute the professional;
- Make monitoring and diagnostic devices only available for high-risk groups;
- Use technologies to educate and demonstrate people how lifestyle influences their health.

Conclusion

Based on the input of citizens several dilemmas can be detected to take into account when further developing health technologies:

- Autonomy and accessibility to health technologies vs. availability for high-risk groups
- Focus on prevention of diseases vs. limited use of monitoring/diagnostic devices
- Shift to prevention of diseases vs. autonomy of citizen to make use of a technology
- Easy understanding and usable interface vs. possibility to adjust setting and custom-made technology
- Ownership of data vs. inclusion of health professional in monitoring data
- Educate and inform citizens about health technologies (deficit model) vs. creating autonomy, empower citizens and including them in the design (RRI)

Timetable

Stakeholder workshop

10:30 – 11:00	Registration, coffee
11:00 – 11:15	Welcome

EXPLORATION

11:15 – 11:30	Introduction + motives participants
11:30 – 11:45	3 pitches of participants - Sensor technologies for diabetes - Early diagnostics of diabetes - Artificial pancreas

IDEATION

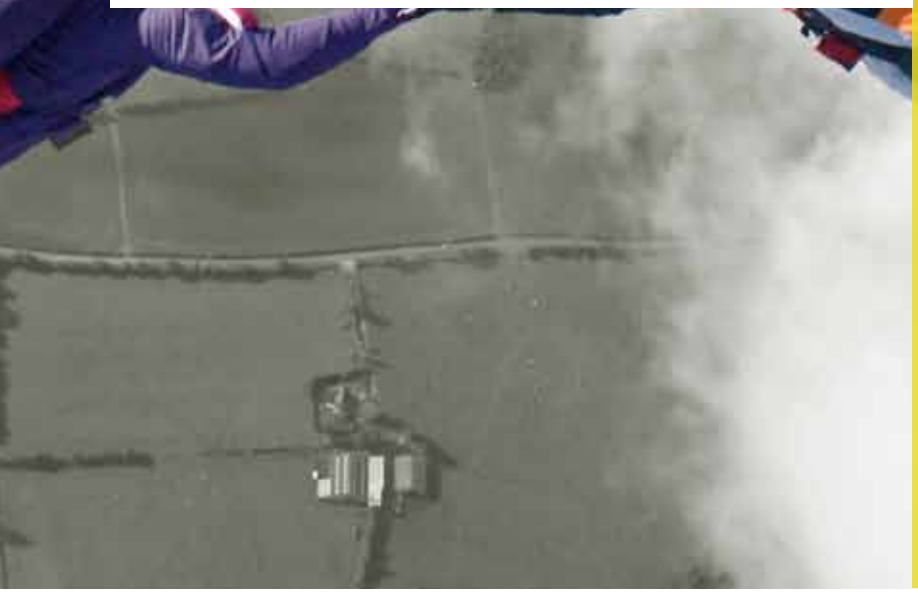
11.45 – 12.10	Results and debate citizen consultation
12.10 – 12.30	Impact citizen consultation on own work

12.30 – 13.15	Lunch, networking

PROTOTYPING / REFLECTION

13:15 – 14:15	Concrete design suggestions for product/ technology
14:15 – 14:45	Presentation storyboards + reflection

14.45 – 15.00	Closure



Methodology

The programme is based on the four pillars of co-creation:

Exploration, where participants get to know each other and their work and explore the wishes, needs and values and messages expressed by the citizens as well as their own needs and interests.

Ideation, where participants imagine and co-create responses to the wishes, needs and values and messages expressed by the citizens by imagining revisions/adaptations of ongoing research and innovation trajectories, building on the varied expertise around the table.

Prototyping, where participants generate a storyboard that visualizes how the resulting research lines and product suggestions are modified in relation to the wishes, needs and values and messages expressed by the citizens and suggests concrete actions to be taken by the stakeholders present to realise this vision.

Reflection, where participants present and reframe their storyboards, reflect on the ways in which the citizen's needs have shaped the storyboards, identify actions to be taken in preparation for the next workshop and reflect back on the overall workshop objectives.

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