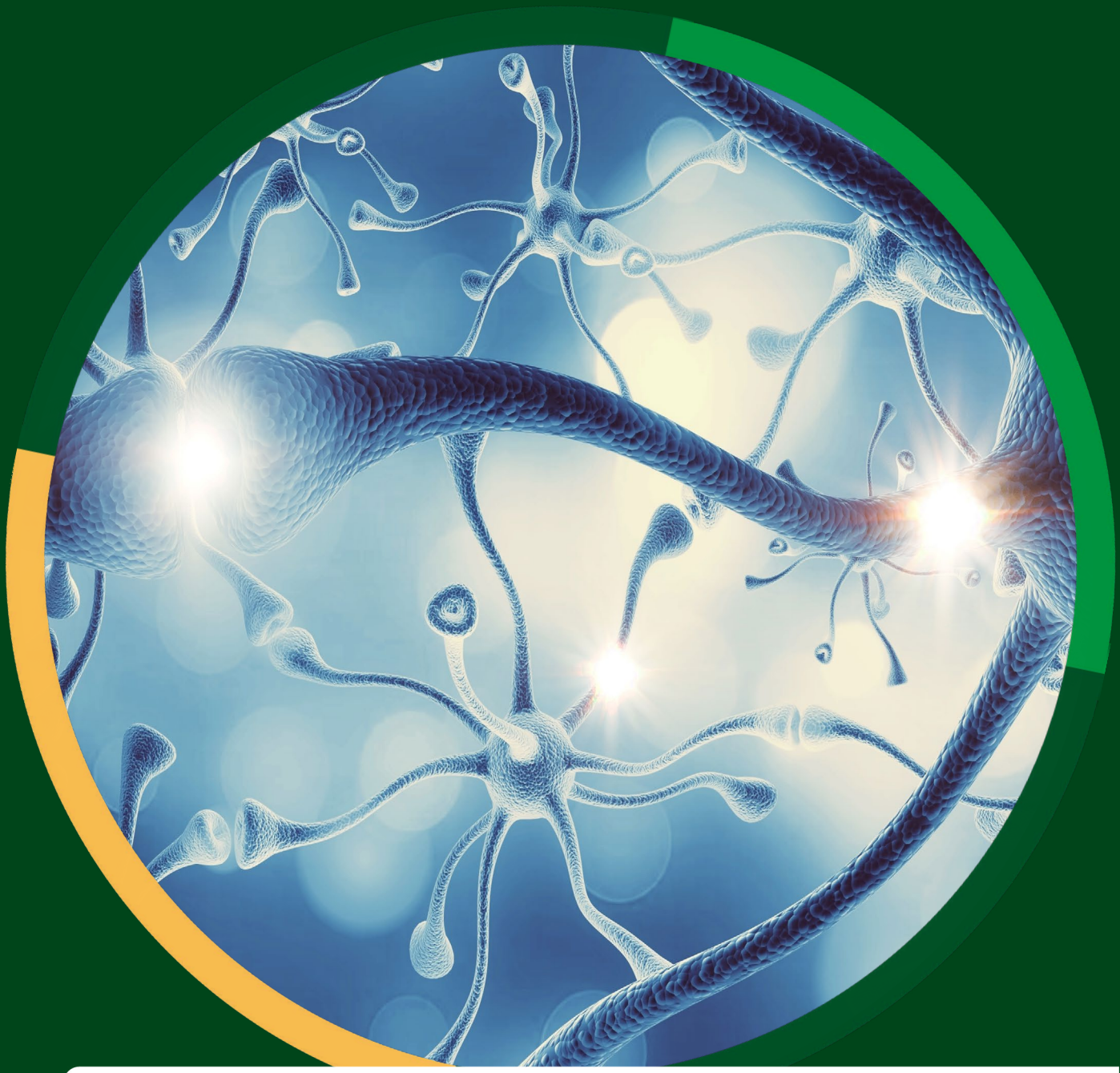

Neurotechnology Innovation Network

Biodesign workshop series episode 1: Neuropathic pain
19 September 2019 | Workshop outputs

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ktn | UKRI Innovate UK

Connecting for Positive Change.

Neuropathic pain – Needs identification

It is essential that the development of neurotechnologies start with the end in mind, so a needs-based approach should be taken. Similarly, an understanding of risk must continuously be at the forefront of any development. There must be clarity around needs, risks and benefits.

Central to the development of all treatments for neuropathic pain is improving patient outcomes. There are several, interconnected, high level needs which need to be met to achieve this:

- Better understanding of pain mechanisms and treatments
- Reduce infection rates for invasive systems
- Better non-invasive pain relief
- Better data and clinical/QALY evidence
- Better communication among stakeholders
- Reduce time to market
- Reduce costs to NHS

Implanting devices pose a significant risk; 1-2% of all surgeries result in infection which both threatens the health of the patient and greatly increases costs. In the short term, antimicrobial materials will help reduce infection rates but ultimately, reducing the number of surgeries or their invasiveness could have the largest impact. Many implanted neurotechnology devices need repairing or replacing within 5 years, for example, changing their batteries. More energy efficient devices, longer lasting batteries or removing batteries altogether and instead using energy harvesting technologies will increase the longevity of devices. Conductive polymers and stretchable polymers will increase durability and also help limit problems of movement restrictions seen with current devices.

To reduce the chance of infections to zero, non-invasive pain relief must be improved. Externalised stimulation removes the need for surgery; however, they potentially trade off the efficacy of implanted stimulators. An important goal, therefore, must be the development of new non-invasive stimulation therapies with increased efficacy. Neurofeedback therapies using brain-computer interfaces, also provide a non-invasive treatment for neuropathic pain. Problems that exist with the current hardware include the high price of consumer grade electroencephalogram (EEG) devices, no CE marking and the difficulty of self-directed use by patients (e.g. correct placement of electrodes). Moreover, better evidence is required, particularly through randomised trials.

Better data and evidence are crucial for the development of new treatments for neuropathic pain. There need to be effective measures of efficacy which could be achieved by better feedback technologies, more randomised trials, patient-programmable devices and improved pain assessments.

There need to be better defined mechanisms of neuropathic pain, at the cellular and network level, which requires a better mechanistic understanding of the process. Wearable technologies may help collect information which could be used to address patient level variability. Artificial Intelligence could provide a powerful approach to unlock this data. Data scientists (e.g. climate scientists) could help shed new light on neural data. Implantable systems with research capability, or the ability to perform functional MRI, might also provide key insights into how therapies work today, and how they might be improved.

Bringing together a wider group of expertise will help gain a better understanding of the needs, risks and benefits of new technologies. Clear communication between trial designers and marketing teams is required so that claims and trials are aligned, helping define and agree clinical outcomes. Risk analysis must be at the centre of the development process and broader teams will help prevent a narrow view of risk.

Expanding teams will also help spread the knowledge amongst clinicians and patient groups around what technologies are available. They will also then have the opportunity to better communicate unmet needs back to the technology developers.

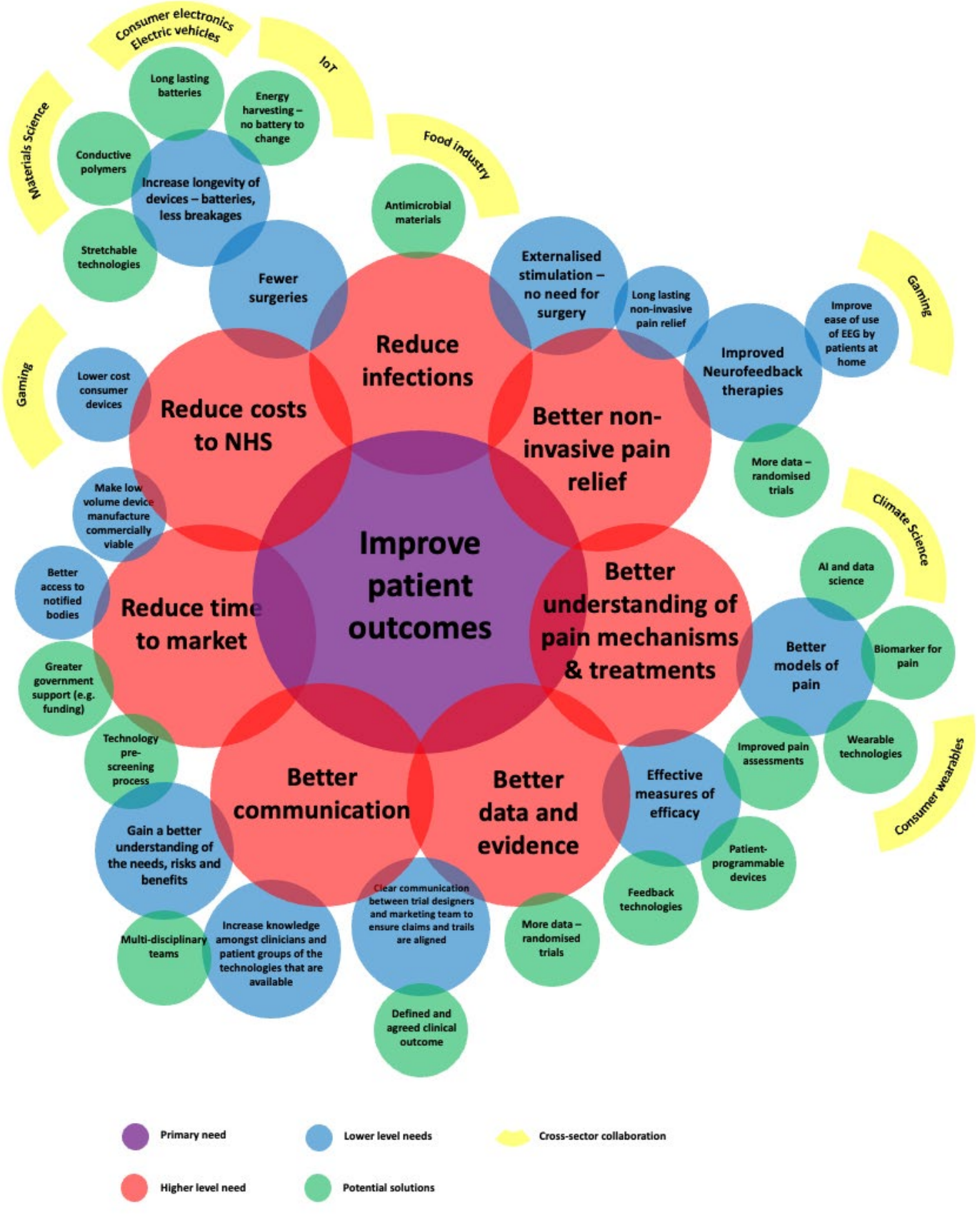

Figure 1. Needs and potential solutions for neuropathic pain treatment.

While teams comprised of a wider set of expertise will certainly help provide a sense-check for early stage device development, a more structured technology pre-screening process would make sure that resources are directed at device development that has the greatest chance of success and therefore reduce their time to market. An example of an independent review process is that of Innovate UK applications, where assessors provide feedback on the viability of technology (both commercially and scientifically). However, there is no official pre-screening method, particularly where IP is sufficiently protected within the review process. Greater government support could help facilitate this and would also ensure the best allocation of government funding. Other structural changes are required, for example, the small number of notified bodies has created a backlog, resulting in longer times to gain regulatory approval. Better access to notified bodies would greatly improve the regulatory approval process.

Reducing the cost of devices and treatments will help reduce the time to market and increase the number of patients benefiting from these new therapies. However, there is a significant challenge in manufacturing small volumes of devices at commercially viable rates. New manufacturing processes may be one answer, but collaboration with other sectors, particularly for non-invasive devices may be the key to mass market production. EEG has the potential to be used, not only in healthcare applications, but much broader (and larger) markets like entertainment and gaming. The intersection of these two sectors could yield greater technological developments and cost saving possibilities.

Another opportunity is for innovators to work more closely with NICE and the NHS to test new devices in a collaborative manner. An example of one pathway is the “managed access” which can enable devices and treatments to be piloted to gather key clinical data to support eventual commercialisation – pending the outcomes meet the pre-agreed metrics for success. Novel public-private partnerships could help catalyse new innovations in a resource-constrained business environment.