Topic idea submitted to IHI - Reference Number: TI_001215

Are you submitting the idea:
☐ in your personal capacity?
☑ on behalf of an organisation?

Please indicate the name of the group organisation: Paneuropean Region of the International Association for Dental Research

Please select from the list below the type of stakeholders your organization represents: Research/higher or secondary education organisation (private or public)

1 Title of your idea

Please provide a short title that accurately reflects the objective(s) of your idea:

Replace, repair and regenerate oral tissues using medical devices with new and non-compromised chemistry and new digital techniques

2 Scope

Explain the specific challenges/problems to be addressed by your idea and how these affect relevant stakeholders, taking into account what is already known and/or available in the field: Globally, dental disease treatment costs amount to about 280 billion Euros per year, and the indirect costs, e.g. due to productivity losses, to 134 billion Euros a year (Kassebaum et al., 2017). Dental caries affects 2.5 billion adults (untreated caries) and 560 million children worldwide per year and is thus still the most widespread non-communicable disease (Listl et al, 2015). Within the EU oral health varies greatly, with 20-90% of European 6 year olds having dental caries (WHO Data and Statistics), which especially affects disadvantaged and underprivileged patient groups (Public Health Res, 2022) with major economic impacts. The new migration situation will place a further burden for oral health care systems in Europe. Furthermore, oral diseases including gum diseases are linked with other non-communicable diseases such as Diabetes or CVDs (WHO, 2021) and affect appropriate food digestion.

Treatment modalities using medical devices are presently subject to extreme controversy due to the use of so-called compromised chemicals affecting general health (e.g. the immune system) but also related to their possible impact on the environment (e.g. microplastic). Presently, EU regulations are banning dental amalgam in the near future. As alternative, resin-based materials are proposed, which, however, may also release compromised chemicals such as resin monomers or endocrine disruptors (e.g. BPA). Furthermore, they are cost intensive compared to amalgam treatment, which places economic burden especially on low-income vulnerable patient groups and overall on the health care system. Finally, biologically based treatment approaches aiming at healing and regeneration of oral tissues are underrepresented.

Please indicate which IHI specific objective(s) (SO), as described in the IHI Strategic Research and Innovation Agenda (SRIA), your idea addresses:

["SO2: integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treat- ment and management of diseases, meeting the needs of end-users" "SO4: exploit the full potential of digitalisation and date exchange in heath care"]

Please select the keywords that are most relevant to your idea:

- ["Non-communicable diseases"
- "Immune system diseases"
- "Prevention"
- "Treatment"
- "Disease management"
- "Health technology"]

In alignment with the IHI specific objective(s) selected above, specify the objectives of your idea:

SO2: So far, research on (oral) medical devices is fragmented, some being done by health industry (e.g. technical improvement of materials), others by academic institutions (preclinical and clinical evaluation). Focussing on unmet public health needs (see above) needs a close cooperation of industrial partners and academia at an early stage of device development. The aim is to develop innovative tools for improved treatment and management of oral diseases, which respect patients' health and the environment, but also the specific challenges of the oral tissues, such as a humid environment with high bacterial loads; they also shall prevent disease progression, withstand biting forces, adhere to adjacent tissues and induce and support tissue repair/regeneration. New and innovative bioactive molecules shall be combined with technologies from other fields (e.g. glasses, whiskers or cements industry).

SO4: Furthermore, new digital technologies involving cost-effective chairside 3D printing systems exploiting the potential of digitalization shall be supported.

3 Expected impacts to be achieved by your idea

Briefly describe the expected impacts to be achieved by your idea, ensuring that they contribute to IHI general and relevant specific <u>objectives</u>, as described in the IHI SRIA:

Impacts are wider long-term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments. Impacts generally occur sometime after the end of the project, e.g. successful implementation of digital solutions supporting people-centred care.

IHI general objectives: 1. contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations; 2. foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contribution to 'Europe's Beating Cancer Plan'; 3. drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.

The expected impact will the creation of an EU-wide new research strategy and leading to an improvement of the oral and therefore also the general health of the population, especially for disabled and underprivileged groups. Furthermore, contamination of the environment with compromised substances such as BPA or microplastic, when such materials are applied or removed, shall be avoided. Of special importance is the impact on the healthcare systems, which today are under strong financial pressure, by improving the cost-effectiveness for new treatment approaches. Suitable tools can easily be implemented into the existing health care systems for treating and management of oral diseases such as tooth decay, dental pulp inflammation, regenerating and repair of hard and soft oral tissue, and for minimally invasive treatment of Molar-Incisivi-Hypominerlization (MIH), a disease, which shows increasing prevalence in the EU, and of trauma/fractures and erosion/abrasion of teeth.

4 Why should your idea become an IHI call topic?

Explain why collaboration through a cross-sectoral and multidisciplinary public private partnership is needed in particular:

Why does it require collaboration among several industry sectors (e.g. pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging health ICT)?

Why does it require collaboration between private (industry) and public partners (e.g. academia, healthcare practitioners, patients, regulators)?

Industrial partners from the oral health field, which may so far not be partners of IHI, have expertise in the technical development of medical devices mainly by applying or modifying existing chemistry. Experiences from other industries (e.g. on antifouling technologies, glass/ceramic and cement technologies or 3D digital printing technologies) are essential for developing new treatment platforms. However, the financial capacities of industrial partners in the oral health field for the development of for such new and innovative tools is limited due to the comparatively small market segment. On the other side, university partners can contribute with basic chemical and biological expertise and they have the expertise in testing and evaluating the basic biological and mechanical properties of new constructs. Testing has become complex, also due to the recent medical device regulations. IHI is therefore the unique platform for such innovations because it has broad experience to guide such complex partnerships.

Why is the contribution of industry needed to achieve the expected impacts?

Contribution of industry: Large companies that are members of the IHI industry partners (i.e. COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe) contribute to the programme, primarily through 'in-kind' contributions (e.g. their researchers' time, laboratories, data, compounds). At least 45% of each project's total costs have to be in-kind contribution.

Contribution of industry from the health sector is needed because of existing experience about special market needs such as the delivery system or shelf life stability. Furthermore, they have extended experiences in upscaling such devices, which means the transition from laboratory specimens to industrial production of a new device. Contributions of partners from other industrial fields (by cross-sectional health innovation) are needed to participate from their experiences e.g. in the ship hull industry on antifouling strategies, which are also important for the prevention of disease progression in the bacterially contaminated oral cavity. Glass, ceramic or cements technologies contribute to mechanical and chemical stability. 3D digital printing/workflow industry experiences are needed for developing new approaches e.g. printing organic but also inorganic devices.