Mapping an emerging framework for regenerative medicine reimbursement

The development of regenerative medicines (RMs) carry substantial risks for companies because production costs are often large and products are yet to show effective long-term results. A broad examination of published literature in the field of RM shows there is a growing discussion about policies that aim to encourage the development of RMs through risk-sharing policies. Interviews with numerous organisations in the field of RM showed that trade associations are the most active in considering ways to structure financial reimbursement for the RM industry.

What questions & challenges are raised?

Many companies are hesitant to risk investing large amounts of money into regenerative medicine (RM) research and development. Treatments may not work as hoped, may not pass expensive clinical trials, or might be too expensive for payers (health insurance providers or government health programs) to provide to patients. On the other hand, RM treatments are very different than standard drugs; they have the potential to cure. This may make RMs cheaper for payers in the long run because patients won't require future drugs or treatments - that is - as long as RM treatments work. There could be a lot to gain for companies and for patients, so finding ways to reimburse companies for their investments in RMs is important to move things forward. Dr Aurélie Mahalatchimy and Professor Alex Faulkner from the University of Sussex conducted a study to examine the growing number of published discussions on RM reimbursement that provides an overview of how prevalent the issue of RM reimbursement has become and who is discussing it. The types of publications (journals, books, etc.), geographical location, disciplines of journals, and the publishers all provide new insight into who the contributors and audiences are and what interests they have in reimbursement policies. The authors' analysis of publications is complemented with interviews from institutions, organisations and government agencies that highlight what some think are the current obstacles to RM reimbursement and ideas that will help resolve these issues.

diseases and would not be developed without regulatory and other incentives or reimbursement programs). The authors' interviews indicate that the RM industry would benefit from future discussions on how to develop better ties and collaborations between government agencies, payers and other industry stakeholders. Trade associations feel that determining ways to better orchestrate dialogue and cooperation among organisations and agencies is essential to solve reimbursement issues and spur the development of RMs for the clinic.

What background and point are discussed?

The authors' analysis of RM literature shows a growing number of publications on the topic of RM reimbursement and "risk-sharing" policies. Additionally, their work sheds light on who the contributors are, who the audiences are, where publications and authors are from geographically, and where texts are being published. The US had the highest average number of texts per month discussing RM reimbursement for 2015 (416). The next four countries were Japan(239), Germany(237), France(188), the UK(183) and South Korea(56). The authors found that most of the publications appeared in academic journals rather than books, chapters, dissertations or other texts. The literature on RM reimbursement was primarily directed at clinical audiences (46%), followed by social and human sciences (28%), business (10%), economics (8%) and others. Data show that RM literature is widely spread among different journals and publishers. To better understand the current climate and dynamics of the RM reimbursement discussions, the authors interviewed 43 different organisations and stakeholders (national agencies, service providers, trade associations, funding bodies, research institutions, consultancy companies, and others). Of all the interviewees, trade associations appeared to be the most involved and knowledgeable on issues surrounding RM reimbursement. The general message the authors received from trade associations was that there needs to be better collaboration between government agencies and the primary health care agencies in the UK (specifically NICE and the NHS) to reduce the time and costs of developing RM products. The assessment, evaluation and value of RM treatments with a curative nature is another topic also discussed, including calls for greater use of data obtained outside of randomised clinical trials. There was also some interest by trade associations to change the current reimbursement and incentive methodologies, such as establishing government funding initiatives, but associations primarily emphasised better collaboration.

What insight & direction does this give for research policies?

Currently there are many different ideas being discussed for reimbursing RMs. Some individuals are proposing risk-sharing programs for RMs, requiring payers to make annual payments to companies of RMs based on the performance of the treatment. Alternatively, some individuals are proposing better incentive programs to off-set reimbursement issues and encourage investment. Discussions for solutions need to continue, and indeed Dr Mahalatchimy and Professor Faulkner's analysis of RM publications shows that the discussion of RM reimbursement is growing around the world with contributors from many different fields. However, the data also suggest that the topic is still relatively new. The UK could greatly benefit from increasing its involvement in reimbursement discussions that will ultimately shape the RM industry. The authors' data also shows how topics of RM reimbursement and risk-sharing are being associated with other topics, such as 'orphan drugs' (drugs that are for rare