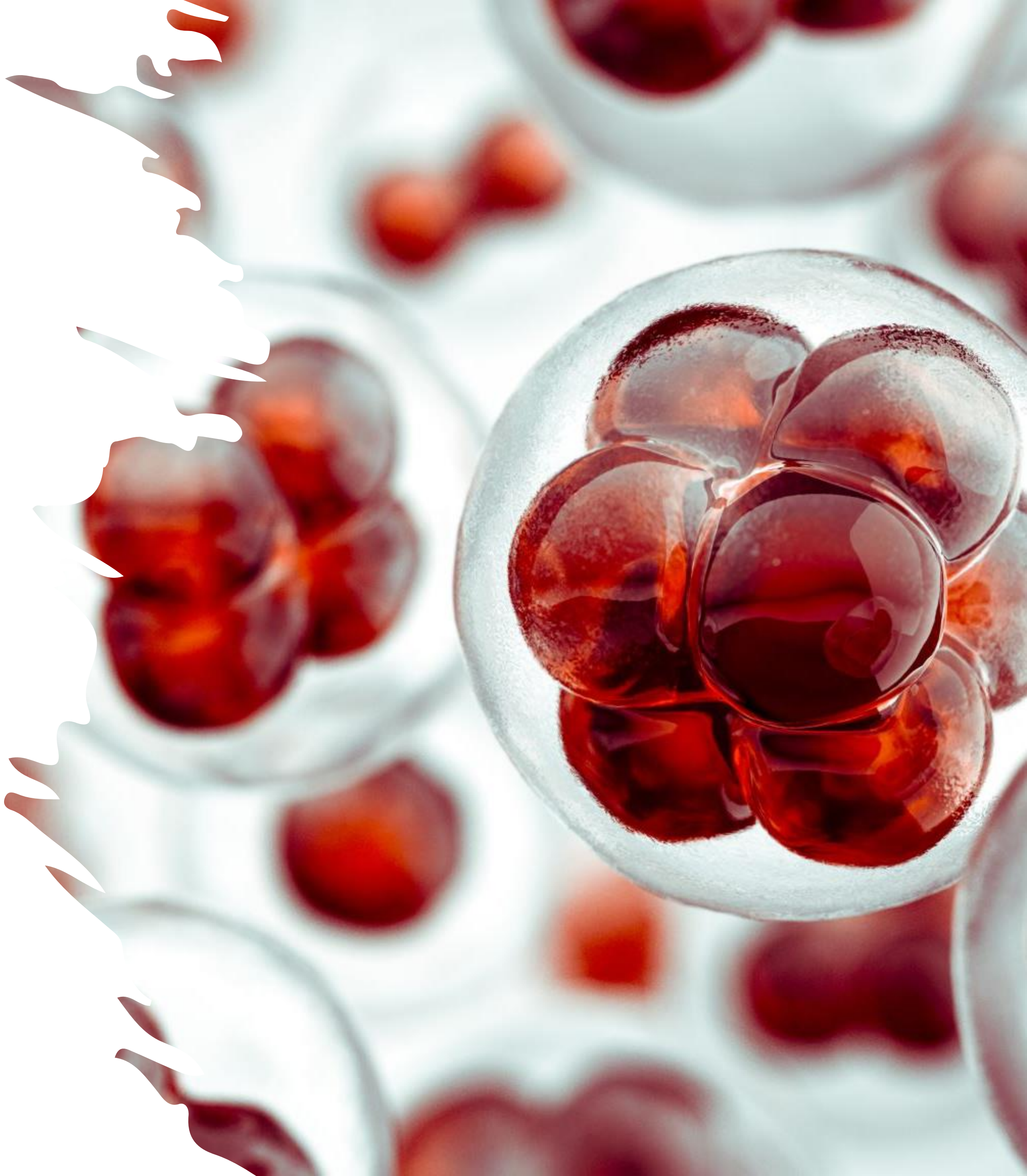
Pain, expectations and stem cells:

the socio-ethical challenges of novel treatments for arthritis

Allegra Schermuly, Alan Petersen,
Claire Tanner, Sian Supski
(Monash University)

Megan Munsie
(University of Melbourne)



Background

- Access to stem cell interventions (SCIs) is via clinical trials, clinical innovation, standard clinical practice.
- *Only* haematopoietic stem cell transplants (HSCT) for treatment of haematopoietic malignancies, immunodeficiencies, metabolic & genetic disorders considered standard clinical practice in Australia.
- Possible cell therapies derived from embryonic (ESC), induced pluripotent (iPSC) & mesenchymal stem cells (MSCs) are being investigated for a range of conditions, including arthritis.
- PRP (platelet rich plasma), not stem cell derived but a popular treatment for arthritis with contested evidence base.
- PRP is not captured under the current biologicals framework so falls outside the remit of the TGA.

Regulatory tension

- Human research ethics committees, Therapeutic Goods Administration, consumer protection (e.g. ACCC), practitioner regulators.
- Hospitals regulated by state laws leading to clinical data being either publicly unavailable or difficult to access, oversight in the hands of bodies responsible for clinical conduct.
- Commonwealth laws on special access systems lack clarity and consistency.
- Governance rules and decisions are often contested, e.g. how much evidence is enough to justify providing interventions in the clinic.
- Lack of clarity around when interventions should be considered standard care.

Qualitative interviews

Consumers (n=17)

- People living with or caring for people with different types of arthritis
- Ages 45–83
- None had undergone SCT, many had heard of stem cells, some had considered stem cell therapy in 2012/13
- 2 had sought access to a current Australian clinical trial and were ineligible
- Many knew about PRP, some had undertaken it

Professionals (n=13)

- Sports medicine physicians (n=4), including clinicians giving PRP (n=2)
- Physios/researchers (n=2)
- Consumer advocates (n=2)
- Policy professionals (n=1)
- Researchers (n=3)
- Director of a biologicals company (n=1)

Significant themes

- Pain
- SCIs as ‘quick fixes’ in arthritis treatment
- Placebo effects - the power of belief

Pain

…someone can have terrible looking X-ray and really have very little pain or symptomatic bother. But it can go the other way around. Someone’s knee can look really good and yet they have… So it’s not just about the structure of the joint. (Prof. 45)

‘quick fix’ – professionals

…we’re trying to say to people, ‘Well, there’s this whole range of conservative management that’s going to benefit you…’, but it’s not always the message they receive. And so, ‘If I can have something that’s a quick fix, that I’m not going to have to do all the physio and dieting and losing weight and exercising and all the stuff that’s harder…’. (Prof. 1)

There’s a lot of hope and patients really want to have a really quick fix, so I think it’s incredibly important to answer those questions as quickly as we can, so that people know whether we’ve actually got a cure for osteoarthritis or something, at least to make them feel better. Because, at the moment, the treatments we have don’t have wonderful effect sizes … the strongest evidence we have for effects is in exercise… it’s really powerful but it’s really hard to achieve. That’s why people like the quicker fixes of having something squirted into their joint or take a tablet or something, because and weight loss is, in a lot of people’s view, not very much fun or easy to do. And a lot of people have tried to do it before and failed as well, so it’s not easy. (Prof. 41)

‘quick fix’ – consumers

One consumer said their rheumatologist was ‘very adamant’ in dissuading them against SCT, saying it was a ‘waste of time’ but indicated that ‘If it had been peer reviewed and there were real studies, I would jump at the chance to try something.’ (Consumer 35) The individual who expressed ‘ethical concerns’ said that ‘accessibility [to SCTs] is a huge issue’, but that ‘if there’s clinical trials that I’m eligible for, yes, please.’ (Consumer 46)

Placebo effects

The difficulty in the space from an ethical perspective for me has been that if you look at – people have sort of been injecting these random – what looks like a random sort of soup mix into a knee and saying, well, ‘We think this works’. And then you get a clinical outcome, and it looks great, and then you kind of wonder, well, how did that work? What is that? Is it a placebo response? Is that real? Is that something that we should find out? So, in a funny kind of way, the clinical sciences come before the laboratory science, and now it’s almost going backwards, and trying to understand what the mechanism of action is, because we didn’t get to that part first, which is backwards in terms of the way the science has progressed, I guess. (Prof. 36)

Reflections on findings

- Arthritis is an interesting case to explore the interaction between patients' and clinician's hopes and expectations for novel/clinically unproven treatments and established standards of clinical efficacy.
- This painful, often-debilitating condition is surrounded with competing ontologies of aetiology, tools of diagnosis and effective treatments.
- Definition of and language used to describe the condition is critical for responses; e.g. Aust. Commission on Safety and Quality in Health Care (2024) *Osteoarthritis of the Knee: Clinical Care Stan*dard.
- In a context of persistent pain and few clinical options that experimental/clinically unproven treatments, such as SCT, are seen to offer hope—the 'quick fix'.
- Yet, uncertainty surrounds the efficacy and safety of SCT—raising socio-ethical questions regarding the clinical management of arthritis.

Some socio-ethical questions

- Is it appropriate for SCTs to be offered to those living with arthritis when considerable uncertainty surrounds their benefits and safety—even if they report improvements?
- If patient reported benefits can be attributed to placebo-effects, does this matter? To whom does it matter? Concept of ‘benevolent deception’ .
- To what extent does the performativity of medical practice contribute to creating ‘false hope’: treatment decisions based on incorrect assumptions.
- On what basis should competing ontologies of ‘treatment’ for arthritis (e.g. exercise, lifestyle changes, weight loss, novel treatments) be assessed as more or less ‘true’ or valid?