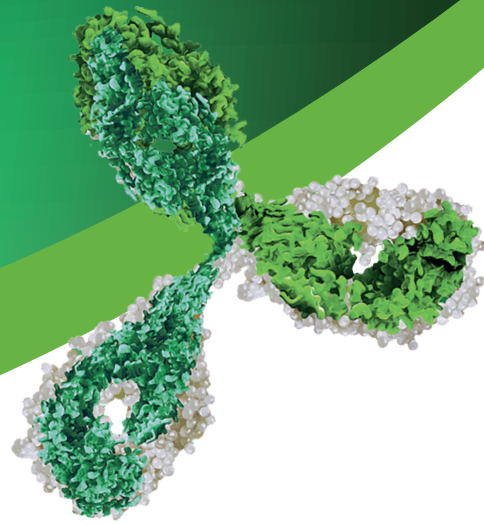


BIOSIMILAR MEDICINES IN AUSTRALIA



FACTSHEET

Patient-Centric Care and the Human Factor

Key points covered in this document

1. Understanding what patients want to know when it come to using biological, including biosimilar, medicines
2. Achieving optimal health outcomes for all Australians through patient-centric care
3. Implementing communication strategies that support patient understanding

GBMA Education acknowledges the provision of funding by the Australian Government in the production of these materials.

PATIENT-CENTRIC CARE AND THE HUMAN FACTOR

Applying Patient-Centric Care in The Context of Biological Medicines

Biological medicines have transformed therapy for certain serious conditions in recent decades, and the market continues to evolve at a rapid pace. To understand what a biosimilar medicine is, and the various concepts that surround biosimilar medicine equivalence compared to the reference product, most patients will require a basic understanding of the difference between biological and small-molecule medicines.

Any change in medication or brand of medication should always be made with the patient experience in mind. Ensuring the patient is confident and invested in the treatment decision will improve patient outcomes.¹

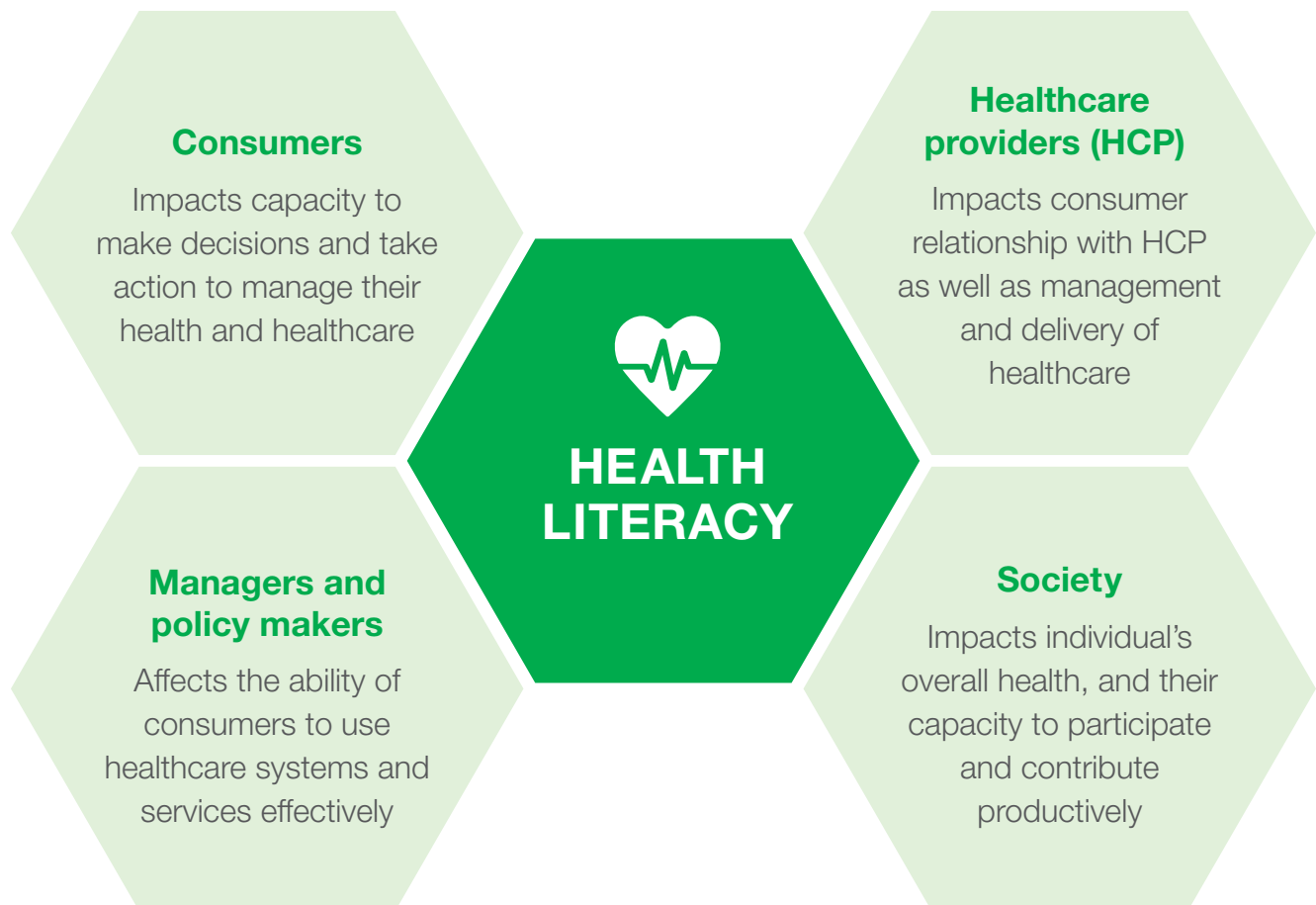
The Patient Experience is at The Heart of Better Healthcare

The **'patient experience'** is a crucial consideration in quality healthcare. Health literacy has a substantial impact on patients' health and wellbeing, as well as the Australian healthcare system overall (Figure 1).² Almost **60% of adult Australians have low individual health literacy**, meaning they may not be able to effectively exercise their choice or voice when making healthcare decisions.³ Low individual health literacy is associated with the higher use of health services, low levels of consumer knowledge, poorer health outcomes,⁴ and a **higher likelihood of experiencing an adverse outcome**.⁵

Patient-centric care is consistently linked to **improved patient safety and treatment outcomes**. This inclusion of clear information, empathic, two-way communication and respect for patients' beliefs and concerns during consultation can lead to patients being more informed and involved in decision-making, and create an environment where patients are more willing to **disclose information** and feel more **ownership of clinical decisions**.⁶

Increased patient engagement can encourage greater **participation** in personal care, **compliance** with medication, **adherence** to recommended treatment, **monitoring** of prescriptions and doses, and **motivation** to accurately report adverse events.^{7,8,9}

Figure 1. Effective communication is fundamental in the provision of safe and high-quality healthcare²



Impact of Negative Expectations and The 'Nocebo' Effect

What is the 'nocebo' effect?

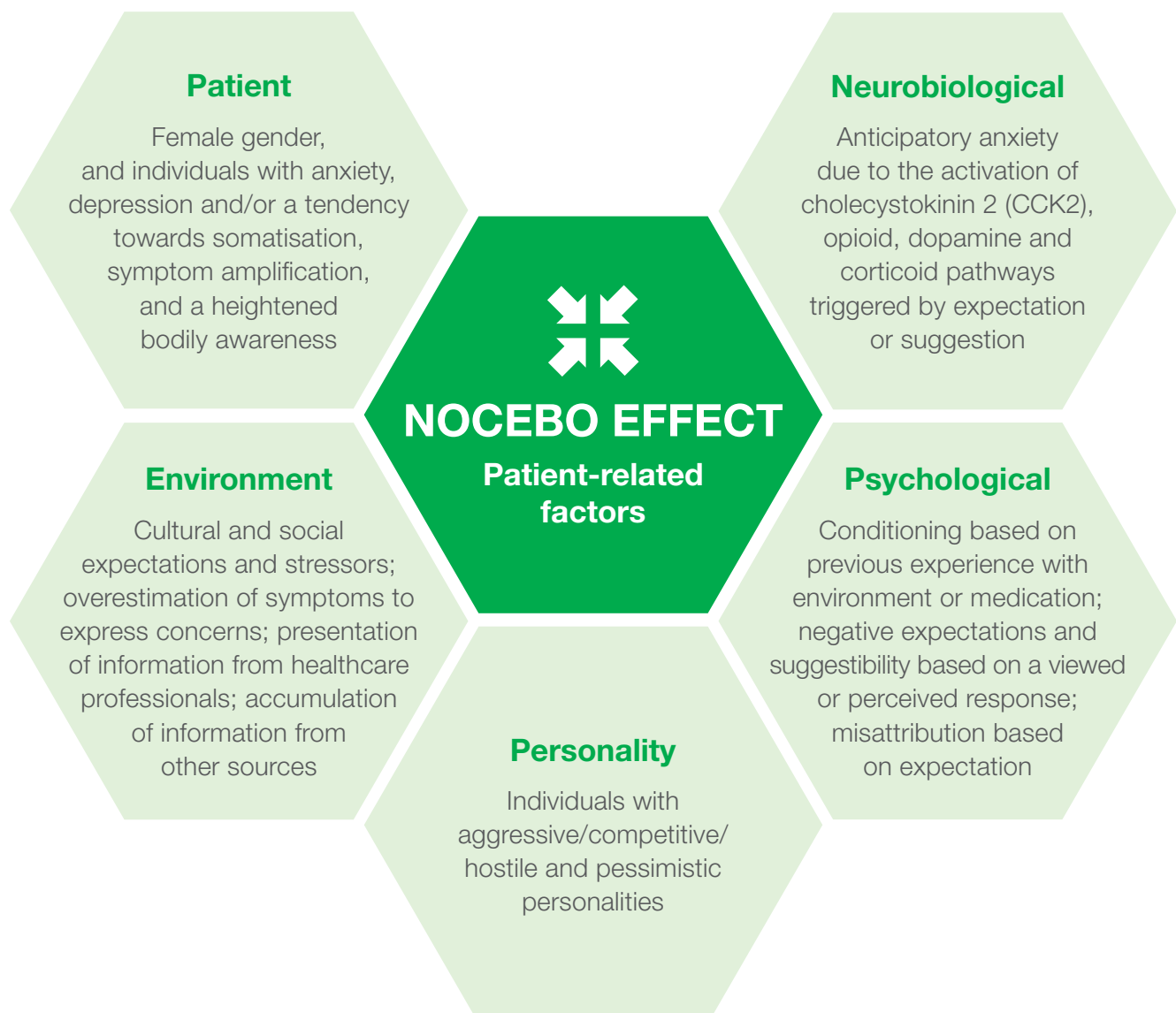
Any pharmacological or non-pharmacological treatment has two components: one related to the specific effects of the treatment itself and the other, nonspecific and related to the perception of the therapy being administered. The nonspecific effects of a treatment are referred to as **placebo effects** when they are beneficial and **nocebo effects** when they are detrimental.

PATIENT-CENTRIC CARE AND THE HUMAN FACTOR

A nocebo effect is defined as ‘a negative effect of a pharmacological or non-pharmacological medical treatment that is induced by patients’ expectations, and that is unrelated to the physiological action of the treatment (both in a clinical and routine care setting)’.¹⁰ This can mean new and worsening symptoms that can arise as a result of negative verbal and nonverbal communications from anyone in the patients wider health support network, which can lead to the mistrust in healthcare professionals and/or lack of confidence in the treatments prescribed.¹¹

A nocebo effect is a result of the complex interactions between the patient, their psychosocial framework, their healthcare professionals(s), and the way the information is delivered and received (Figure 2).¹²

Figure 2. Mechanisms of nocebo effect¹²



What are the impacts of the nocebo effect?

The placebo effect is a well-accepted phenomenon and has been widely studied.¹³ In general, the **placebo effect** conveys positive beliefs that may translate to beneficial outcomes as a result of a **positive psychosocial context** about a sham treatment or medication that a patient is or will be receiving.

Conversely, the **nocebo effect** can have a distinct and noticeable impact on the effectiveness of treatment and overall healthcare. **Negative treatment expectations** and/or **distrust** or **lack of confidence** can result in **non-compliance** leading to **an increased burden** of disease, as well as an **increased cost of care**.¹²

Germain V *et al.* 2018, looked at the potential impact of the nocebo effect in Norway's infliximab switch study (NOR-SWITCH). When comparing retention rates between patients receiving the reference product versus the biosimilar, results suggest that a nocebo effect may occur soon after the switch and initially lower the retention rate for biosimilar medicines. Thereafter, retention rates appear to be identical, confirming the safety, efficacy and acceptability of the switch in the long term. These results support the importance of waiting to perform objective measures of treatment response.¹ Furthermore, prescriber confidence and patient information provided prior to switching appears to be crucial for patient acceptance of biosimilar medicines, and therefore reducing the nocebo effect.¹

Balancing obtaining informed consent while minimising nocebo-related risks

While healthcare professionals have a duty to inform patients of all possible adverse events, they are also tasked with minimising the risks of a medical intervention for that patient. If we look at the contributing patient-related factors to the nocebo effect, we can recognise that some patients may be more susceptible to nocebo-related risks than others. We can therefore identify patients at risk. This includes patients who may be susceptible to conditioning (e.g. prior experience adverse reactions) and patients with psychological symptoms (e.g. anxiety and depression) or a tendency for somatisation.¹²

PATIENT-CENTRIC CARE AND THE HUMAN FACTOR

Creating an Environment of Confidence

Effective communication is a fundamental requirement for safe and high-quality healthcare. Communication failures are one of the most commonly cited underlying causes of adverse events and complaints about the healthcare system.⁹ In order to overcome this hurdle, information disseminated should be:

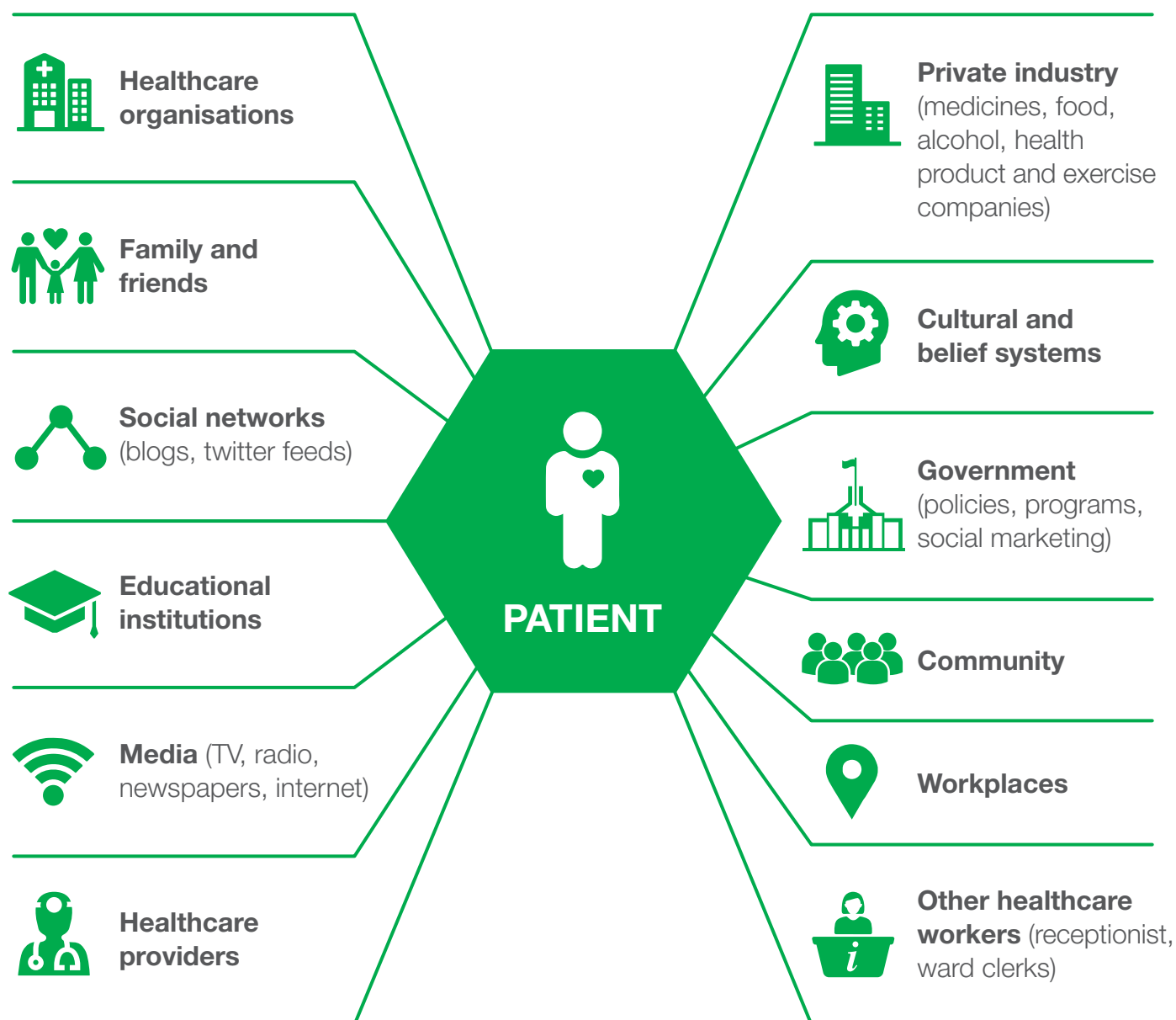
- Presented in a **clear, focused and useable** format; for this to be effective it should be individually contextualised to the patient needs.
- Delivered with **effective interpersonal communication** strategies.²

Choice of delivery is important. Healthcare professionals need to be attentive to their patients' needs and recognise which form of communication is best for delivering health messages on an individual basis. Some patients may prefer verbal, face-to-face discussions, while others may prefer printed or online material that they can digest in their own time. Regardless of the medium, communication should be easy to understand and tailored at low levels of individual health literacy.²

While information about health and healthcare is developed and distributed by a range of healthcare-related organisations, patients will also seek information from a variety of other sources.² Healthcare professionals should be aware of the potential impact of subsequent sources of information, particularly in relation to nocebo-related risks.

Nonverbal communication is equally important to verbal, and may unintentionally convey negative messages when discussing therapy options, which may lead to a nocebo response.¹³ It's therefore important that healthcare professionals are conscious of their body posture, tone of voice, and mannerisms (shrug of shoulders, frown, or furrowed brow). Healthcare professionals should acknowledge any personal biases and actively work to minimise the impact of those biases on the patient's decision.¹²

Figure 3. Sources of health and healthcare information available to patients¹



Australia focuses on a patient-centric view in the uptake of biological medicines, maintaining patient choice with the support of healthcare professionals, who also retain choice.

YOUR PATIENTS, YOUR GOVERNMENT

References

1. Germain V, *et al.* Long-term follow-up after switching from originator infliximab to its biosimilar CT-P13: the weight of nocebo effect. *Ann Rheum Dis* 2018; doi: 10.1136/annrheumdis-2018-214374.
2. Australian Commission on Safety and Quality in Health Care. Health literacy: Taking action to improve safety and quality. Available at: <https://www.safetyandquality.gov.au/sites/default/files/migrated/Health-Literacy-Taking-action-to-improve-safety-and-quality.pdf>. Accessed August 2019.
3. Australian Bureau of Statistics. Health Literacy, Australia. Canberra: Australian Bureau of Statistics, 2008.
4. Berkman ND, *et al.* Health Literacy Interventions and Outcomes: an Updated Systematic Review. Evidence Report/Technology Assessment No. 199. (Prepared by RTI International– University of North Carolina Evidence-based Practice Center under contract No. 290-2007-10056-I) AHRQ Publication Number 11-E006. Rockville, MD: Agency for Healthcare Research and Quality, 2011.
5. DeWalt D, *et al.* Literacy and health outcomes: systematic review of the literature. *Journal of General Internal Medicine*. 2004;19:1228–1239.
6. Doyle C, *et al.* A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open*. 2013.
7. Vincent CA, *et al.* Patient safety: what about the patient? *Qual Saf Health Care*. 2002;11:76–80.
8. Coulter A. Engaging patients in healthcare. Maidenhead, Berkshire: Open University Press, 2011.
9. Rathert C, *et al.* Acute care patients discuss the patient role in patient safety. *Health Care Manag Rev*. 2011;36:134–44. 10.1097/HMR.0b013e318208cd31.
10. Colloca L, *et al.* Nocebo effects, patient-clinician communication, and therapeutic outcomes. *JAMA*. 2012;307:567–568.
11. Teixeira MZ, *et al.* The placebo effect and homeopathy. *Homeopathy*. 2010;99: 119–129.
12. Planes S, *et al.* The nocebo effect of drugs. *Pharmacol Res Perspect*. 2016;4(2): e0028.
13. Hróbjartsson A, *et al.* Placebo interventions for all clinical conditions. *Cochrane Database of Systematic Reviews* 2010, Issue 1. Art. No.: CD003974. DOI: 10.1002/14651858.CD003974.pub3.