*South Afr J Anaesth Analg.* 2023;29(1 Suppl 3):S3-6
https://doi.org/10.36303/SAJAA.2964


South Afr J Anaesth Analg
ISSN 2220-1181 EISSN 2220-1173


SASA REFRESHER COURSE

# Cost-effective anaesthesia and generics – playing the long game

**M Blackburn**

*Co-convenor, SASA PPBU*
***Corresponding author, email:*** *jhb.anaesthetist@gmail.com*

**Topics**

- The big picture
- Playing fair and keeping a seat at the table
- Generics/clones
- Bridion® and other novel/expensive drugs

## Background

It should come as no surprise that financial concerns are creeping ever more into the medical space. With the world heading for a global recession and an inflationary cycle, (almost) everyone is under pressure. Margins are falling, prices are increasing and the average middle and lower class families around the world are poorer than they were five years ago.

This has had a knock-on effect in medicine. Many of us have seen our patients moving to lower medical aid plans, cheaper options, and worse yet, leaving medical aid schemes completely. This has significant effects on us and the medical schemes industry – as often it is the younger patients (who typically provide a lot of the medical scheme reserves due to their low use:contribution ratios) who are leaving or downgrading from or downgrading within schemes.

Medical schemes are required to keep a certain reserve. With reducing numbers of contributors, increased utilisation on a per capita basis, and inflationary increases – against a backdrop of inability to increase contributions significantly above inflation rates – something has to give. Consequently, there is pressure from schemes to provide the same excellent levels of care at the lowest cost possible. Often, the 'anaesthesia bundle' is seen as 'low hanging fruit' when these factors are considered.

It is incumbent on us as frontline anaesthesia providers in the private sector to understand the concept of Value in Health Care.

## Value in Health Care (and elsewhere!)

Value is defined simply as the ratio of Quality to Cost. In the healthcare environment outcome should be added to the equation so it would appear as follows:

$$Value = \frac{Quality + Outcome}{Cost}$$

Quality is not necessarily (strangely) directly associated with Outcome – rather they are a composite. In anaesthesia currently, we find ourselves in an era where the quality and outcomes are generally good, albeit hard to measure. This drives value. However, funders and patients expect more value. Since the variables in the numerator are hard to increase, the big push is for a decrease in the denominator, cost.

## Anaesthesia medication cost

What is the cost of anaesthesia? It comprises professional fees, consumables and drugs/gases. It is helpful to interrogate spending on anaesthesia in the private sector. In 2021 there were 8.95 million lives covered by medical schemes (open and restricted). Total expenditure on health care was R186.15 billion. It is difficult to pick up anaesthesia basket fees but in 2017 anaesthesia drugs accounted for R580 million of expenditure – at 5% inflation this could be reasonably expected to be around R740 million in 2022. Any way you look at it, this is a lot of money, especially when considering the unit price of many of our medications. Adrenaline costs approximately R5.00–R7.00 per amp, paracetamol around R35, propofol around R70 for 20 ml.

According to the CMS, there was on average one anaesthetist encounter per beneficiary in 2020. If we take the 8.95 million beneficiaries, this works out to about R82 per beneficiary per event. While there is obviously some disconnect here between the figures (due to the opacity of the CMS reporting and some liberties taken with the mathematics by the writer of these notes), the message is that anaesthetic drugs are generally not a big line item, especially in the context of surgical implants and consumables. However, it is important to appreciate that every patient gets an anaesthetic drug intervention while not every patient gets an expensive surgical consumable. More on this later.

## Efficiency in private health care

In order to evaluate efficiency in health care in South Africa, it is important to understand how much health care costs elsewhere.

| Country | Cost per capita per year health care (2019) |
|---|---|
| Germany | $5 300 |
| France | $4 700 |
| USA | $11 000 |
| United Kingdom | $4 900 |
| Australia | $5 900 |
| South Africa (state) | $370 |
| South Africa (private) | $1 188 |
| South Africa (total) | $1 157 |

*From World HealthOrganization – Accessed Jan 2023*

The level of care obtained for this money is generally excellent – for an average cost of much less than spent in Europe and other OECD countries. Yes, utilisation is increasing, but there is a lot of political nuance in the reportage of healthcare costs in this country. With NHI looming, it makes sense for reporting to overemphasise the cost of private care. Of note there is a large amount of fraud, waste and abuse in the private medical sector but the target population of this lecture is at best a minor contributor to this.

## Playing the game and keeping a seat at the table

SASA has spent many years building a brand that is trusted. We were extensively involved in COVID-19 and people listened to our input. We have cordial to good relationships with most funder and facility groups. All of this is premised on the principles of fair play.

What is fair play? This is an ethos whereby we attempt to engage with funders and stakeholders in such a way that engenders respect, team spirit, equality and respect for the unwritten rules of the game – integrity, solidarity, tolerance, care and excellence. It sounds trite but failure to play fairly reduces the credibility of the organisation (SASA). Our credibility is our ticket to the negotiating table – our seat.

We are in a position where, to a large extent, SASA is consulted by medical schemes and we have a collaborative relationship with most administrators. Unfortunately, some schemes have abused this relationship but that is a topic for another discussion.

## Generics and clones

It is important to understand what we are talking about when we discuss generic drugs and clones.

- Originator drugs ('Ethicals')
  - These are the original drug.
  - Designed by the pharmaceutical company, developed, tested, patented.
  - Development costs borne by the originator company.
  - Patent usually lasts 20 years but it takes 8–10 years to bring a drug to market.
  - Originator can market agent and sell agent exclusively until the patent expires.
- Generic drugs
  - These are drugs made by other pharmaceutical companies using previously patented molecules.
  - Because they do not bear the development costs they can be sold for lower prices.
  - Generics are generally intended to be interchangeable with the originator product, are manufactured without a license from the originator company.
  - There are different rules around the world with respect to quality and efficacy of generic drugs.
  - They must contain the same ingredient at the same dose and the same presentation as the original.
  - SAHPRA is in the process of aligning their guidance to the European Medicines Agency (EMA).
  - Essentially, bioequivalence must be demonstrated.
  - Bioequivalence is not the same as therapeutic equivalence.
  - In South Africa there is currently no need to demonstrate therapeutic equivalence. Only bioequivalence needs to be demonstrated. This is important and may explain the varying effects seen with some generic agents.

**Bioequivalence** is a term in pharmacokinetics used to assess the expected in vivo biological equivalence of two proprietary preparations of a drug.

If two products are said to be **bioequivalent** it means that they would be expected to be, for all intents and purposes, the same.

**Bioequivalence** is **determined** based on the relative bioavailability of the innovator medicine versus the generic medicine. ... In order to **determine** that two medicines are **bioequivalent** there must be no more than a 20% difference between the AUC and Cmax.

**Therapeutic equivalence**. **Drug** products are considered to be "**therapeutic equivalents**" only if: they are **pharmaceutical equivalents** and they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labelling.

> A drug that is a **therapeutic equivalent** may or may not be chemically **equivalent**, bioequivalent, or generically **equivalent**.

**Bioavailability** is a measurement of the rate and extent to which a therapeutically active chemical is absorbed from a drug product into the systemic circulation and becomes available at the site of action.... If two drugs are **bioequivalent**, there is no clinically significant difference in their **bioavailability**.

- Clones
  - These are drugs produced by the originator company – same dose, presentation, molecule and strength.
  - They are generally sold at a lower price than the original and are a way for the originator to continue to profit from the original molecule.

The concern with generic drugs is that of cheating – provide sufficient incentive and economists tell us that there will be an "army of people, clever and otherwise, who spend more time trying to cheat it". While this lecture will at no point indicate or name specific companies, there are numerous examples of cases where this is a problem.

The market for generic drugs is massive, especially in the developing world. Unscrupulous suppliers dump their poor quality drugs in markets where oversight is less rigorous, while selling their high-quality generics (often the same brand) in first

world countries. There has recently been an exposé about the quality of drug manufacturing plants in India (the world's largest supplier of generic drugs), indicating that quality control is often very poor.

While many generic agents are excellent drugs, this will always be the concern. There are numerous papers in the South African and overseas literature confirming poor function of some generic drugs, particularly generic antibiotics – one study demonstrated treatment failure in half of a sample of generic gentamycins despite 96% bioequivalence.

Thus it can be seen that not all generics are equal and there is pecuniary benefit to someone in the supply chain to use them over the originator. This benefit was meant to be for the patient but failure of treatment may be a high price to pay for cheaper drugs.

### *The law and generic agents/substitution*

The Medicines and Related Substances Control Act stipulates that:

A pharmacist shall inform members of the public who he/she dispenses to of the benefits of generic substitution. If the patient agrees to the substitution, the pharmacist shall take reasonable steps to inform the prescribing clinician. There may be no substitution if the patient refuses or if the clinician writes "no substitution" on the script.

Substitution may also not occur if the generic is more expensive than the prescribed medication or if substitution of the prescribed medicine is forbidden by Council.

This is somewhat difficult to apply to the theatre situation where there is one source for the medications, they are provided without scripting and are generally time sensitive – i.e. one cannot wait for the ethical to be sourced from another hospital.

However, the MCC in 2003 ruled that substitution can not take place for agents with:

- "a narrow therapeutic range",
- those used in the treatment of geriatric, paediatric and critically ill patients, and
- those with a varied inter-patient response.

It would be reasonable to posit that almost all of the medications used in modern anaesthesia practice are included in the above. However, the list provided by the MCC included in this document does not include drugs in the typical anaesthesia drug basket.

## Where does this leave us in 2023?

Clearly there are constraints on the healthcare budget – whether that be provided by medical aids or the state.

The goal as practitioners is to use our preferred drug for patient care.

This is 'entitled use' – clinical superiority trumps the financial cost. It is however, non-collaborative and drives the narrative of 'the entitled clinician practising in a silo where money is no object'.

The pendulum can swing the other way though… Where purchasers and facility groups deny doctors the right to choose their drugs. Possible drivers for this include *per diem* fees, pharmacist KPIs, profit motivation on the part of facility groups and simple budgetary constraints on the part of National Health.

While as practitioners we have the right to insist on a generic-free theatre, in practice this isn't ideal or desirable. We need to keep long-term sustainability in mind and be 'reasonable' when it comes to making drug choices. However, our primary responsibility is to our patient and it should go without saying that choosing drugs which are known to be problematic or not to work adequately isn't defensible.

In many cases we aren't empowered to choose the drugs or the generic we want to use – we arrive at a theatre stocked with certain drugs. An advance directive provided stating which drugs we are prepared to substitute should be binding – a template is available on the SASA website.

As has been pointed out on numerous occasions at various SASA congresses, an imbalance of knowledge reduces one's ability to negotiate and disempowers. It is important for members to investigate the actual cost of drugs supplied to their workplace in order to make informed choices. It is easy for pharmacy managers to simply state "oh, the originator is very expensive" and use this as justification for unilateral replacement – often the originator drug has been reduced in price and no longer has a large price differential – this information should be provided to anaesthetists on request.

There is a fine line to walk between sustainability and choice with respect to generics. There are no hard and fast rules – the only guidance is to always put the patient first, and develop one's own defensible policy with respect to generic drugs.

## Bridion® – The elephant in the room?

Bridion® has been a thorny issue since it was released. A single drug intervention costing well over R700 has a major impact on the drug basket price. As such, schemes and funders have targeted Bridion® extensively.

SASA has engaged many funders over Bridion® because we, like you, see the benefits and clinical utility of the drug. There has obviously been some give and take, with no schemes currently requiring motivation for the use of Bridion®. However, the drug remains a thorn in the side of the schemes and as a result, the association.

We are continually having to engage with schemes and facility groups. In 2022, a pharmacist at one of the facility groups erroneously stated that GEMS would not fund Bridion®. This was proven to be a false statement – however, the need to keep drug basket costs down often trumps truth.

Currently, it is critical that members are aware that funders are closely monitoring the use of Bridion®. We get detailed breakdowns of the ratio of rocuronium to sugammadex use, by surgical specialty and area. Some of the data are contaminated by the failure of schemes to understand the penetration of generic rocuronium (initially we were presented with Esmeron:Bridion® usage) and failure to appreciate that some patients require two vials.

It has also been difficult to convince funders of the theatre time benefits of a rapid reversal from deep muscle relaxation – some refuse to accept that there is benefit.

Certain schemes are trying to roll out sugammadex governance programmes, however none of these is at a stage where we can contemplate engaging with them – as an association we are not able to govern our member's use of drugs. It is very apparent though, that continued unregulated use of sugammadex will result in more onerous requirements on the part of funders before payment for the drug is contemplated. This has the potential for negative patient interactions.

It behoves us to practise and use drugs in a responsible fashion. While nobody doubts the efficacy of sugammadex, it is manifestly not required for every single reversal, and continued use in this fashion is irresponsible. There definitely exists a scenario in the future where providers will be investigated and/or penalised if they use more than the average. How this will be policed is unclear and it should go without saying that SASA will not agree to any unfair regulation on drug use.

The aim is to self correct and prevent this scenario.