



Oral Presentation to Health Market Inquiry

25 February 2016



SAMED

south african medical device industry association

advancing **innovation** responsibly

Items for discussion

1. **SAMED** vision
2. **SAMED**: who we are and what we do
3. **Medical Device** contribution to **SA** cost of care
4. **Price** regulation will affect access
5. **Medical Device** Industry are price takers
6. **Innovative** medical technology reduces cost of care
7. **Challenges** faced by the **Medical Device** Industry

SAMED VISION

To develop a sustainable medical device industry by responsibly improving patient access to innovative medical technology

SAMED is committed to:

- safeguarding and promoting the interests of its members;
- encouraging ethical principles and practices;
- promoting innovation and better patient outcomes; and
- ensuring effective representation with all relevant authorities whether public or private.

SAMED – Who we are and what we do

One voice for the South African Medical Device Industry

- **Established 1985, grown significantly in recent years**
- **Recognised as important stakeholder in the South African Healthcare Industry**
- **169 member companies, 4 associations, 12 associate members**
- **The majority of medical device companies in South Africa are small to medium in size**
- **Engages stakeholders, advocates members' interests and continually works towards benchmarking professional conduct for its members**
- **SAMED members must comply with two Codes of Practice ie the SAMED Business Code (which prohibits rebates) and the Marketing Code for Health Products**

Medical Device Contribution to the Cost of Care – are Medical Devices really a cost driver?

- **Medical Device Industry is characterised by so-called “value adds” which are unique to the Industry, the cost of which are borne by the companies themselves and are often ‘unacknowledged’.**
- **Examples include:**
 - **ensuring training, retraining and skills development of Healthcare Professionals and other users of devices to ensure correct use of devices (at least R31.7m for 47 companies participating in a survey)¹;**
 - **cost of delivery of products used in emergency cases e.g. trauma surgery due to accident; and**
 - **cost of keeping stock, cost of maintenance and support.**

1- “Industry Overview and economic impact assessment for the South African medical technology industry” – prepared for SAMED by KPMG, 2014

Medical Device Contribution to the Cost of Care – are Medical Devices really a cost driver?

- **Medical Devices account for only 6 to 7% of overall healthcare spend**

Reference:

Council for Medical Schemes 2013/2014 report, wherein medical devices are stated to constitute only 7% of total hospital expenditure, reported under consumables and equipment. See:

https://www.medicalschemes.com/files/Annual%20Reports/AR2013_2014HR.pdf

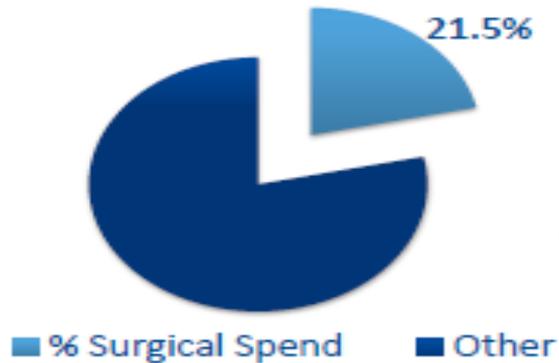
Medical Device Contribution to the Cost of Care – are Medical Devices really a cost driver?

Surgical spend driven by supply and demand side pressures



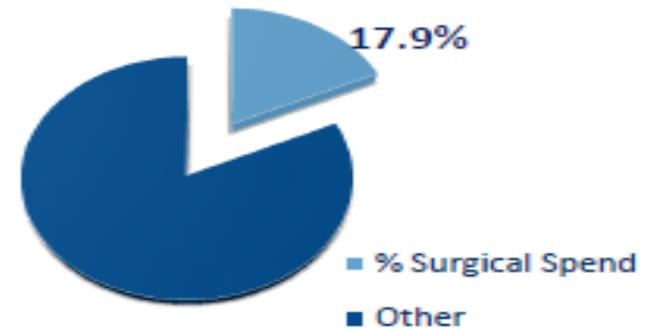
Proportion of Surgical Spend of Hospital Spend

2008



Overall hospital spend has increased however 3.6% decrease in overall Surgical Spend as a proportion of Hospital Spend

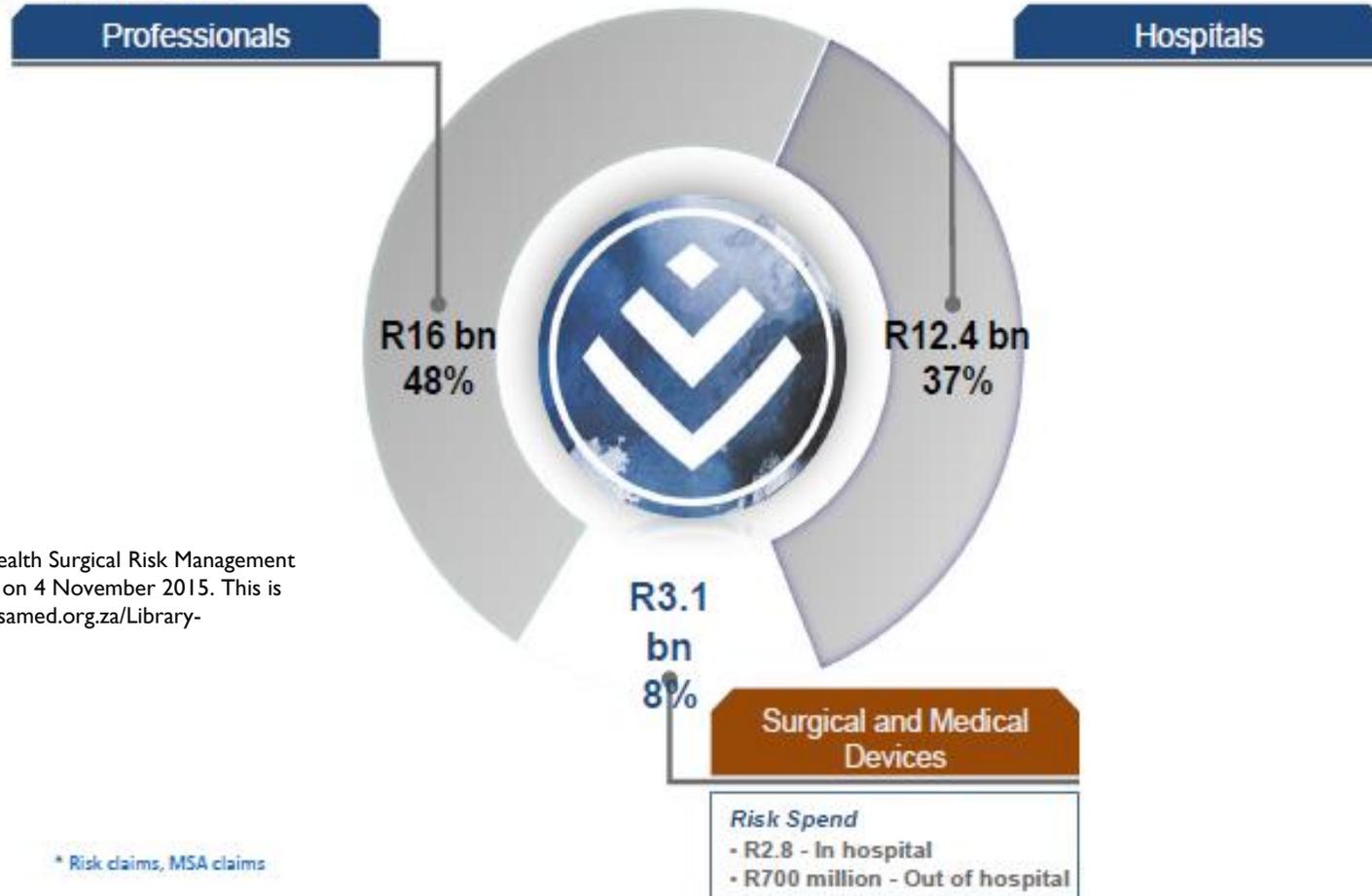
2013



Reference: Discovery Health Surgical Risk Management presentation to SAMED on 5 August 2014. This is available at: <http://www.samed.org.za/Filemanager/userfiles/SAMED%20-%20Surgical%20Risk%20Management%20-%20final.pdf>

Medical Device Contribution to the Cost of Care – are Medical Devices really a cost driver?

DISCOVERY HEALTH MEDICAL SCHEME – TOTAL EXPENDITURE



Reference: Discovery Health Surgical Risk Management presentation to SAMED on 4 November 2015. This is available at: <http://www.samed.org.za/Library-List.aspx?library=3>

* Risk claims, MSA claims

Medical Device Contribution to the Cost of Care – are Medical Devices really a cost driver?

- **If extrapolate a 10% reduction in, or put a freeze on Medical Device prices, the impact at a 7 to 10% weighting would be minimal ie 1%**
- **Therefore it doesn't make sense to regulate the prices of Medical Devices**

Price Regulation will affect access - SA Medical Device Market Share in USD

Russia: \$6bn in 2013.⁵

US: \$110 bn in 2014, expected to reach \$133 bn by 2016.¹

EU: \$122.5 bn³ in 2013.⁴

China: \$304 bn in 2013.⁹

India: \$4.4 bn, grow to \$7 bn by 2016.⁷

Japan: \$31 billion in 2014.⁸

Brazil: \$4.2 bn in 2015.³

SA: \$1.2bn in 2013.²

Australia: \$11.8 bn in 2012-13.⁶

1- <http://selectusa.commerce.gov/industry-snapshots/medical-device-industry-upted-states.html>

2- Wesgro "2014 Western Cape Medical Devices sector", 2014: <http://wesgro.co.za/publications/publications/2014-western-cape-medical-devices-sector>

3- <http://www.espicom.com/brazil-medical-device-market.html>

4- <http://www.emergogroup.com/resources/market-europe#Market>

5- <http://www.mddionline.com/article/russias-medtech-market>

6- <http://www.mtaa.org.au/about-the-industry/industry-statistics>

7- <http://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/indian-medical-device-industry-can-grow-to-7-billion-by-2016-usibc/articleshow/48213378.cms>

8- <http://www.pacificbridgemedical.com/target-asian-markets/japan-medical-market/>

9- <http://www.china-briefing.com/news/2014/12/03/market-overview-medical-devices-china.html>

Medical Device Industry are price takers

- **Medical Schemes exert enormous influence on prices and price increases of Medical Devices:**
 - **A Medical Scheme has indicated in discussions with Medical Device companies that they will review and possibly reject any increases that are above the inflation rate, so they are clearly not taking exchange rate effect on imported products into account**
 - **They also threaten to delist non-conformers from their list of reimbursed products**
 - **This affects procurement decisions by hospital groups as it becomes difficult to get patients to pay for Medical Devices not reimbursed / partly reimbursed by the major schemes**

Medical Device Industry are price takers

- The impact of managed care as cost-reduction objectives, sometimes without consideration for patient outcomes and with no or little emphasis on evidence-based medicine and cost-effectiveness (as opposed to cost-reduction), sometimes defaulting to the availability or not of devices and services in the state sector as the standard of care to be applied to medical scheme beneficiaries. This results in patients having to pay out of pocket
- Medical Schemes focus primarily on price to set reimbursement levels for devices. They also set reference prices, and then keep on pushing everyone to average, thereby creating a 'skewed' or new average
- For certain Medical Devices that are reimbursable, Medical Device companies are not involved in the final setting of prices for the use of Medical Devices in the private sector – the way in which, and the amount at which, prices are set (i.e. in per use cost of device) is negotiated separately between Medical Schemes and Hospital Groups

Medical Device Industry are price takers

Discovery Admission, page 98 of 17 November 2014 submission:

Discovery Health's role in managing medicine costs

- DH has developed a number of tools and assets in the management of medicine prices and utilisation.

[confidential]

These tools include benefit design to increase the usage of preferentially priced medicines; active SEP price negotiation; clinical protocols to manage medicine utilisation; drug utilisation reviews; and the use of DSP arrangements and pharmacy networks to managed medicine expenditure.

Although medicines are mentioned above, it is our members' experience that Discovery also influences prices for Medical Devices.

Innovative Medical Technology reduces the cost of care

The rate of innovation is markedly different:

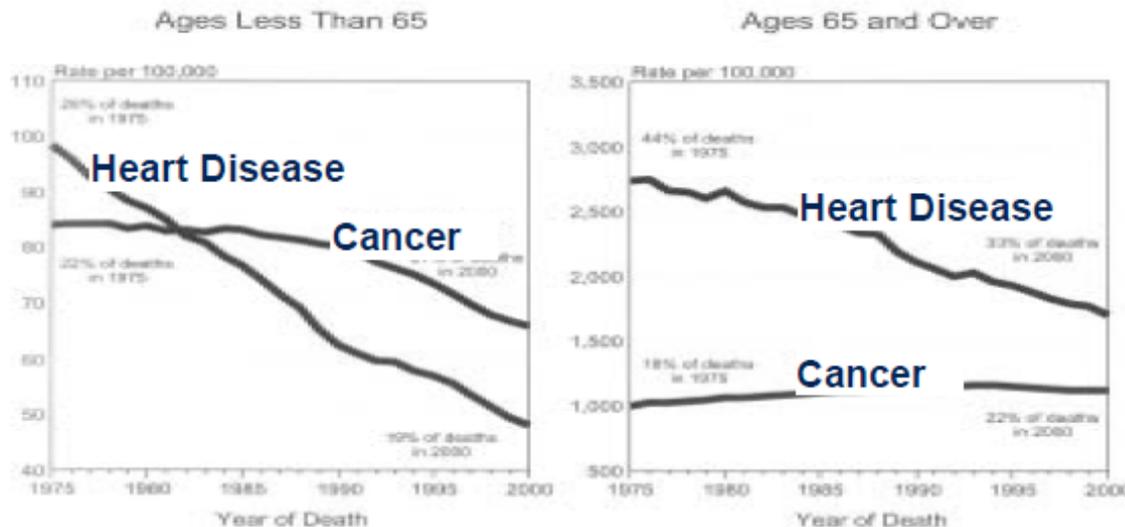
- On average in the Medical Device Industry, devices are superseded by new / improved devices within 18 – 24 months. This means that certain devices have a much shorter life cycle (2 – 4 years) than pharmaceuticals, within which the research and development costs involved have to be recouped
- The short life cycle involved in the development / innovation of Medical Devices (“fast followers”) is a further factor ensuring that barriers to entry in the Medical Device Industry are relatively low and stimulates competition

Innovative Medical Technology reduces the cost of care

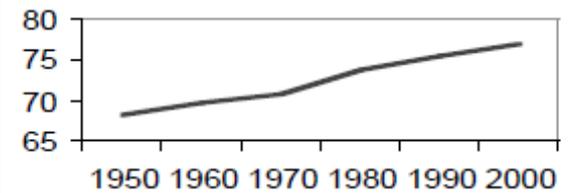
Medical Technology has greatly improved Healthcare

Significant
INCREASE in value

US Death Rates
1975-2000



US Life Expectancy at Birth
1950-2000



Source: NCHS

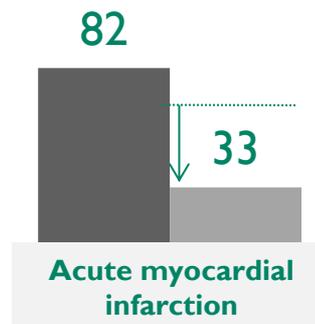
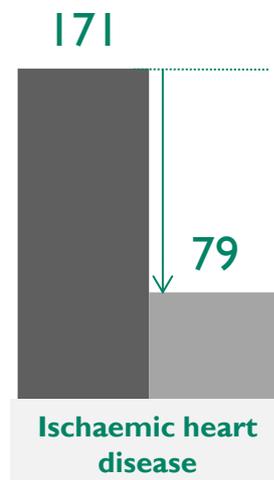
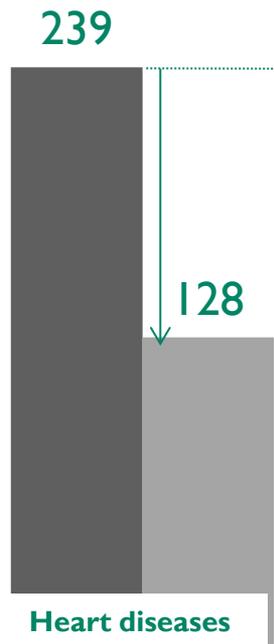
Around 70% of the survival improvement in heart attack mortality is a result of changes in technology.” Cutler & McClellan, 2001

Innovative Medical Technology reduces the cost of care

New treatments & technology enable shorter lengths of hospital stay

Avg decrease in number of hospital days over 13 years

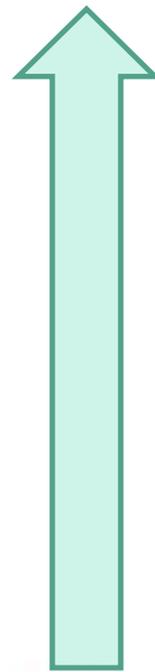
Hospital days per 10 000 patients



■ 1985
■ 1998

~50% decrease in hospital days in only 13 years

Significant INCREASE in value



Source: Health United States 2000, National Center for Health Statistics, Table 92

Innovative Medical Technology reduces the cost of care

EVOLUTION OF THE ICD *Smarter Over the Years*



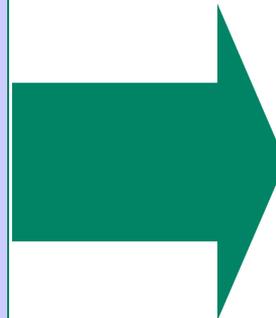
1989

Size: 209cc

Procedure: 2-4 hr, open chest

Hospital Days: 12

Battery Life: <2 years



Today

Size: 36cc

Procedure: 1 hr, small incision

Hospital Days: 2

Battery Life: >7 years

Incremental Medical Device Innovation: Value for Patients and Funders

Innovative Medical Technology reduces the cost of care

Cost of ICD* Therapy – Down 81% since 1990

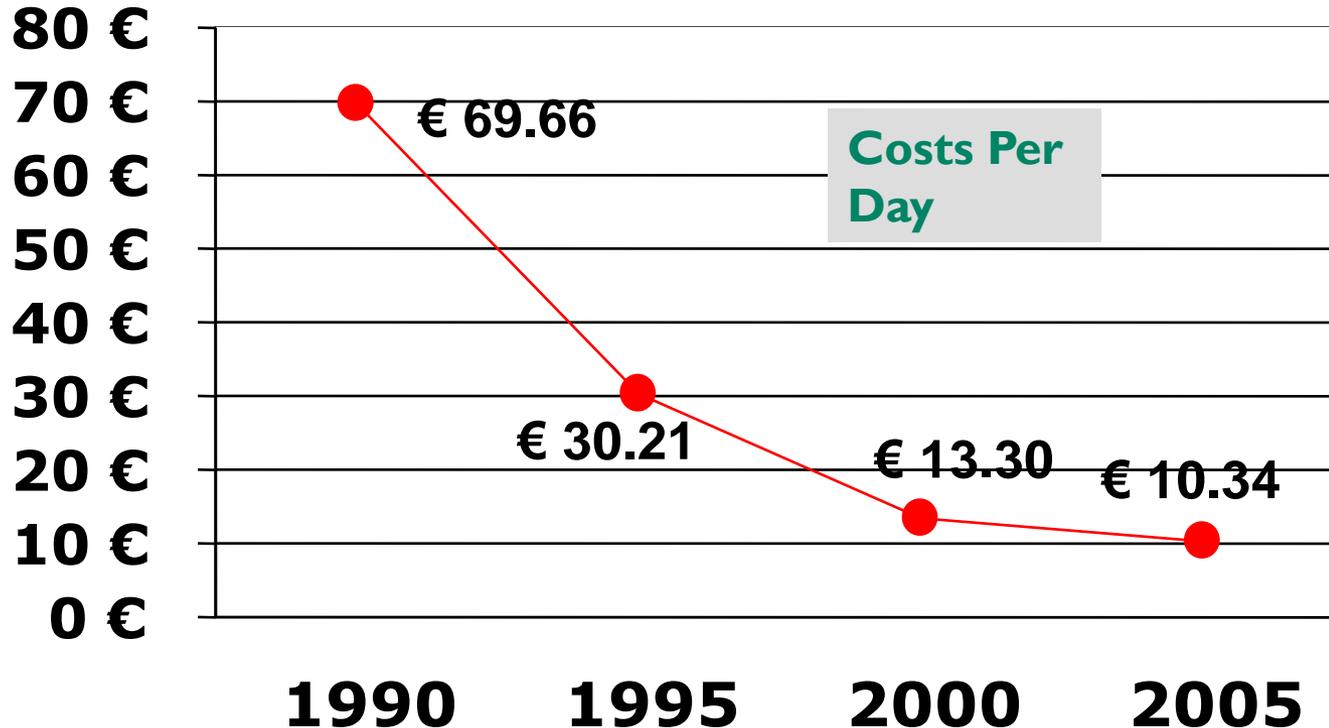


*Implantable Cardiac Defibrillator

reduced procedure costs
reduced length of stay
increased battery life



Major improvement
in Cost per Day



Innovative Medical Technology reduces the cost of care

SAMED proposes *Best Value* concept:

- **Value needs to be assessed over time, with considerations for successful outcomes, rather than focused on costs of a single procedure or patient encounter**
- **A payment system that fails to incorporate appropriate systemic incentives for best value is likely to incur not only higher long-term costs, but poorer patient outcomes**
- **Such an improperly designed system could inhibit the adoption of new and improved technologies, as value is underestimated**

Challenges faced by the Medical Device Industry

Exchange rate:

- **At the outset it must be noted that the Medical Devices market is extremely vulnerable to exchange rate volatility (more than 76% of Medical Devices are imported into SA)**
- **As Medical Devices are in most instances not sold directly to Consumers, the Industry is vulnerable to the way in which Funders (Medical Schemes) and Hospitals budget for, procure and reimburse Medical Devices**

Challenges faced by the Medical Device Industry

Lack of regulatory requirements to ensure Safety, Quality and Effectiveness:

- The Medical Device Industry is by and large unregulated, which poses a serious concern to patients, **SAMED** and its members
- This means that fair competition, specifically on price for quality products, is negatively affected, and leads to the use of substandard quality products (which are imported at a fraction of the cost of good quality products), thereby not only increasing costs in the long run owing to the use of less effective, substandard products but also potentially endangering patients' lives

Challenges faced by the Medical Device Industry

Two different sets of tariff codes hinder Medical Devices entry into the market; and has an impact on competition and access:

- **Equipment Code:** there is no clear mechanism to generate a new code for innovative new equipment looking to come into the market. This forces Medical Device companies to either piggyback on existing codes (resulting in onerous placement agreements) or alternatively not enter the market
- **Professional Fee Tariff:** there is no mutually acceptable mechanism to determine the actual professional cost for a new procedure technique / equipment. Therefore, often the Medical Scheme and Doctor Association will determine different pricing codes
- **No adequate code and tariff = disincentive to adopt a new technology**

Challenges faced by the Medical Device Industry

The impact of the current status on Prescribed Minimum Benefits (PMB):

- **Medical Devices are still not included in the general descriptors of PMB Diagnosis and Treatment Pairs, or included in the Chronic Disease List (CDL) algorithms. Medical Devices form an integral part in the treatment of many PMB conditions and form the basis for a number of disputes at the Council**
- **With no mechanism to create new codes for new technology, means schemes do not have to reimburse the technology, reverting to the 2006 National Health Reference Price List (NHRPL) for the maximum of the PMBs. which does not assist. This also leads to co-payments or the patient paying for full price of the technology or sometimes the company giving the product free of charge**

Challenges faced by the Medical Device Industry

Procurement processes by the Public Sector:

- The effect of the Public Sector on the Private Sector cannot be ignored
- Several SAMED Members have withdrawn supply of Medical Devices to the Public Sector due to ongoing issues related to non-payment, opaque and inconsistent tender and procurement processes and corruption
- The slow payment or non-payment by government for the purchase of medical devices has a direct impact on suppliers working capital / cash flow
- Smaller companies (unlike Multi-Nationals) cannot afford the forward cover and hence then do not sell into the Public Sector, thus lessening competition. This impacts Public Sector patients access to both existing and innovative Medical Devices

Thank you
Any Questions?