# TRANSCRIPTION WEBINAR:
# THE LONG AND WINDING ROAD TO HEALTH TECHNOLOGY ASSESSMENT (HTA) IN SOUTH AFRICA.

*Presented by Mark Blecher. December 4, 2019*

BID

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Social Protection and Health Division

Inter-American Development Bank

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# THE LONG AND WINDING ROAD TO HEALTH TECHNOLOGY ASSESSMENT (HTA) IN SOUTH AFRICA.

**December 4, 2019**

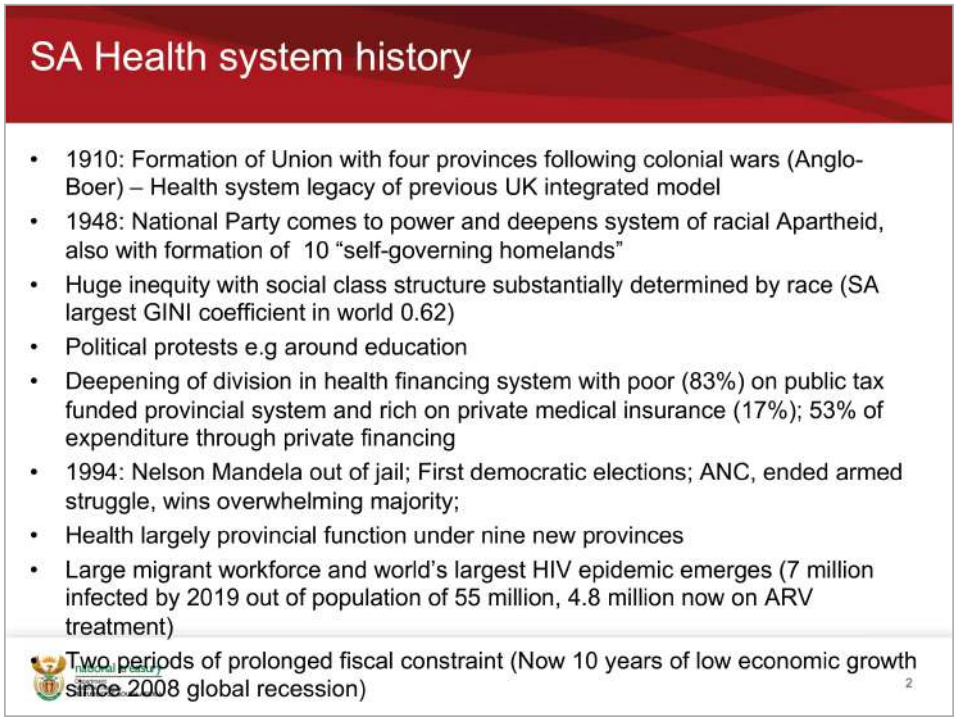
Presented by **Mark Blecher**

**ENCUENTRA EL WEBINAR EN REDCRITERIA.ORG**

# INTRODUCTION

## Minute 00:04:28

Thank you to Red Criteria Network for inviting me to give some perspectives on this interesting topic. I work in the Ministry of Finance in South Africa on health and social development and I am currently doing a short project with WHO in Geneva, where we are trying to work on a book on budget structures. The topic I will be speaking on is regarding the long and winding road to Health Technology Assessment in South Africa.




# SA HEALTH SYSTEM HISTORY

## Minute 00:05:05

I will start with some very quick history of South Africa. South Africa used to be, many years ago, a British colony, which I mention only because our health system has some features of the old UK integrated services model, which some of the ex-Commonwealth countries still have. And of course South Africa went through a very long period of racial Apartheid, which cemented huge inequities. South Africa is one of the most unequal countries in the world with one of the highest GINI-coefficients in the world, substantially determined by race. And that is reflected in a health system where there have been very deep divisions with the poorer 83% of the population on a public tax funded system and a richer 17% of the population on a private medical insurance system.

The country reached democratic transition in 1994 in a time of lot of instability, with a large migrant work force, a large HIV epidemic in the world emerged with 7 million people infected and the country experienced two periods of fiscal restraints, particularly after the 2008 recession.

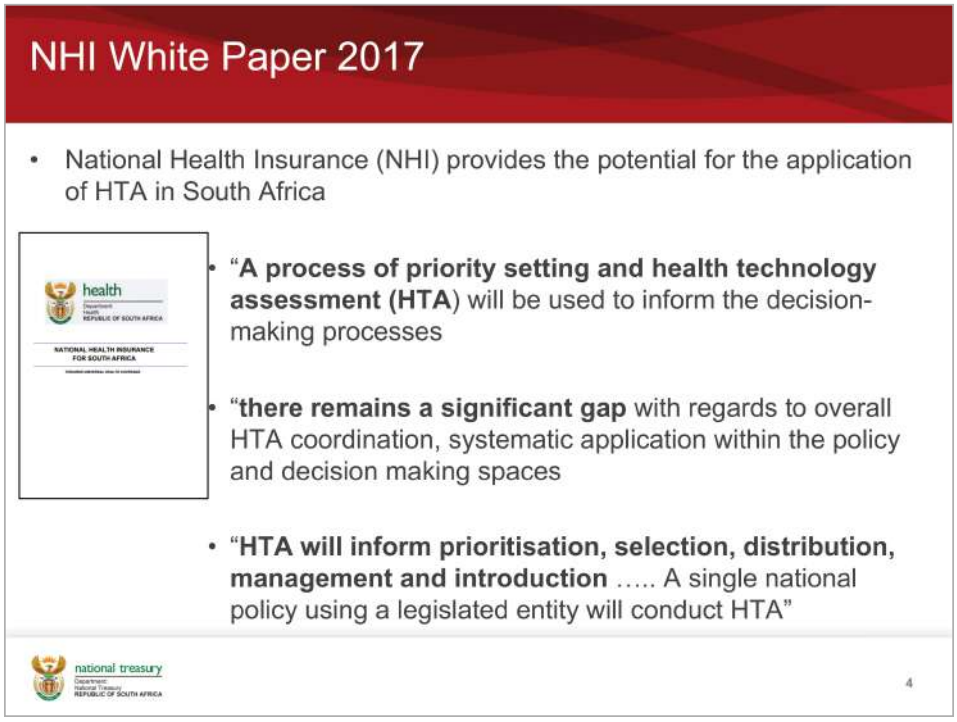
# NATIONAL HEALTH INSURANCE

## Minute 00:06:24

Party because of this history of inequity the country has tried to move forward with a policy of National Health insurance with the idea of creating a large universal coverage with the NHI Fund covering all citizens. Currently public spending for health in the country is around 4% of GDP. With a potential new payroll tax, surcharges on PIT and a potentially increased value-added tax this can potentially reach 6% of GDP over around 15 years.

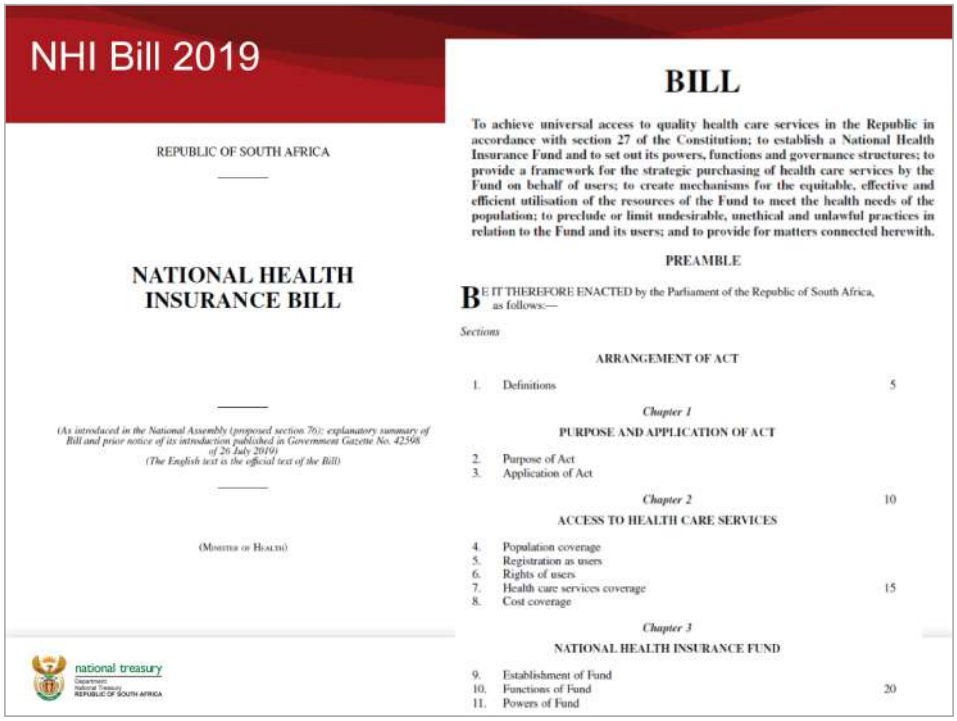
Two difficult policy areas, which we are experiencing are the intergovernmental issues of redirecting funds and functions from the provincial to the national sphere and secondly on the future of private medical schemes, which currently compromise about 15% of health financing.

Initially the proposals were around a more limited social health insurance system for employed persons but the policy shifted to a universal national health insurances system and this changes has also, in some senses, caused some delays. Currently the NHI bill is before Parliament, particularly to establish the National Health Insurance Fund.




## Minute 00:07:43

A White Paper on National Health Insurance was released in 2017 and that talked about a process of priority setting and health technology assessment used to inform decision-making. I won't talk too much about that now.



NHI Bill 2019

REPUBLIC OF SOUTH AFRICA

NATIONAL HEALTH INSURANCE BILL

(As introduced in the National Assembly (proposed section 76): explanatory summary of Bill and prior notice of its introduction published in Government Gazette No. 42598 of 26 July 2019)
(The English text is the official text of the Bill)

(MINISTER OF HEALTH)

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Department: National Treasury
REPUBLIC OF SOUTH AFRICA

BILL

To achieve universal access to quality health care services in the Republic in accordance with section 27 of the Constitution; to establish a National Health Insurance Fund and to set out its powers, functions and governance structures; to provide a framework for the strategic purchasing of health care services by the Fund on behalf of users; to create mechanisms for the equitable, effective and efficient utilisation of the resources of the Fund to meet the health needs of the population; to preclude or limit undesirable, unethical and unlawful practices in relation to the Fund and its users; and to provide for matters connected herewith.

PREAMBLE

BE IT THEREFORE ENACTED by the Parliament of the Republic of South Africa, as follows:—

*Sections*

ARRANGEMENT OF ACT

1. Definitions 5

*Chapter 1*

PURPOSE AND APPLICATION OF ACT

2. Purpose of Act
3. Application of Act

*Chapter 2* 10

ACCESS TO HEALTH CARE SERVICES

4. Population coverage
5. Registration as users
6. Rights of users
7. Health care services coverage 15
8. Cost coverage

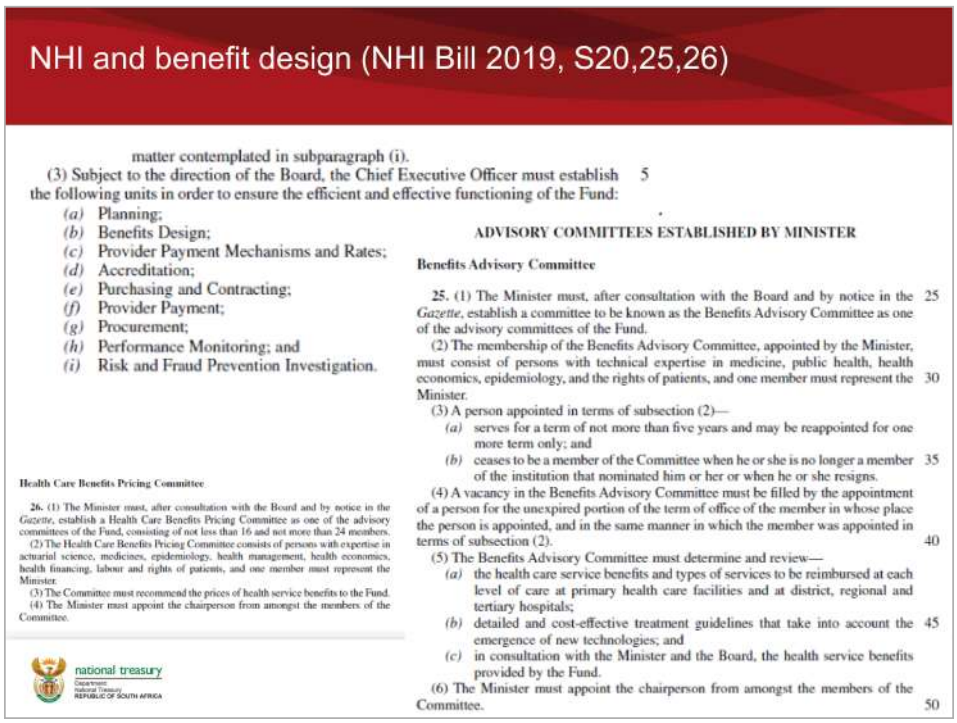
*Chapter 3*

NATIONAL HEALTH INSURANCE FUND

9. Establishment of Fund
10. Functions of Fund 20
11. Powers of Fund

## Minute 00:08:00

The National Health Insurance Bill was published recently for public comment. And this is currently before our parliament. This is just an extract from the bill, the front cover of the bill. On the right are some of the sections of the bill, including the sections on population coverage, registration of users, rights of users, health care coverage issues, and so on.



NHI and benefit design (NHI Bill 2019, S20,25,26)

matter contemplated in subparagraph (i).

(3) Subject to the direction of the Board, the Chief Executive Officer must establish the following units in order to ensure the efficient and effective functioning of the Fund:

(a) Planning;
(b) Benefits Design;
(c) Provider Payment Mechanisms and Rates;
(d) Accreditation;
(e) Purchasing and Contracting;
(f) Provider Payment;
(g) Procurement;
(h) Performance Monitoring; and
(i) Risk and Fraud Prevention Investigation.

**Health Care Benefits Pricing Committee**

**26.** (1) The Minister must, after consultation with the Board and by notice in the *Gazette*, establish a Health Care Benefits Pricing Committee as one of the advisory committees of the Fund, consisting of not less than 16 and not more than 24 members.

(2) The Health Care Benefits Pricing Committee consists of persons with expertise in actuarial science, medicines, epidemiology, health management, health economics, health financing, labour and rights of patients, and one member must represent the Minister.

(3) The Committee must recommend the prices of health service benefits to the Fund.

(4) The Minister must appoint the chairperson from amongst the members of the Committee.

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**ADVISORY COMMITTEES ESTABLISHED BY MINISTER**

**Benefits Advisory Committee**

**25.** (1) The Minister must, after consultation with the Board and by notice in the *Gazette*, establish a committee to be known as the Benefits Advisory Committee as one of the advisory committees of the Fund.

(2) The membership of the Benefits Advisory Committee, appointed by the Minister, must consist of persons with technical expertise in medicine, public health, health economics, epidemiology, and the rights of patients, and one member must represent the Minister.

(3) A person appointed in terms of subsection (2)—

(a) serves for a term of not more than five years and may be reappointed for one more term only; and
(b) ceases to be a member of the Committee when he or she is no longer a member of the institution that nominated him or her or when he or she resigns.

(4) A vacancy in the Benefits Advisory Committee must be filled by the appointment of a person for the unexpired portion of the term of office of the member in whose place the person is appointed, and in the same manner in which the member was appointed in terms of subsection (2).

(5) The Benefits Advisory Committee must determine and review—

(a) the health care service benefits and types of services to be reimbursed at each level of care at primary health care facilities and at district, regional and tertiary hospitals;
(b) detailed and cost-effective treatment guidelines that take into account the emergence of new technologies; and
(c) in consultation with the Minister and the Board, the health service benefits provided by the Fund.

(6) The Minister must appoint the chairperson from amongst the members of the Committee.

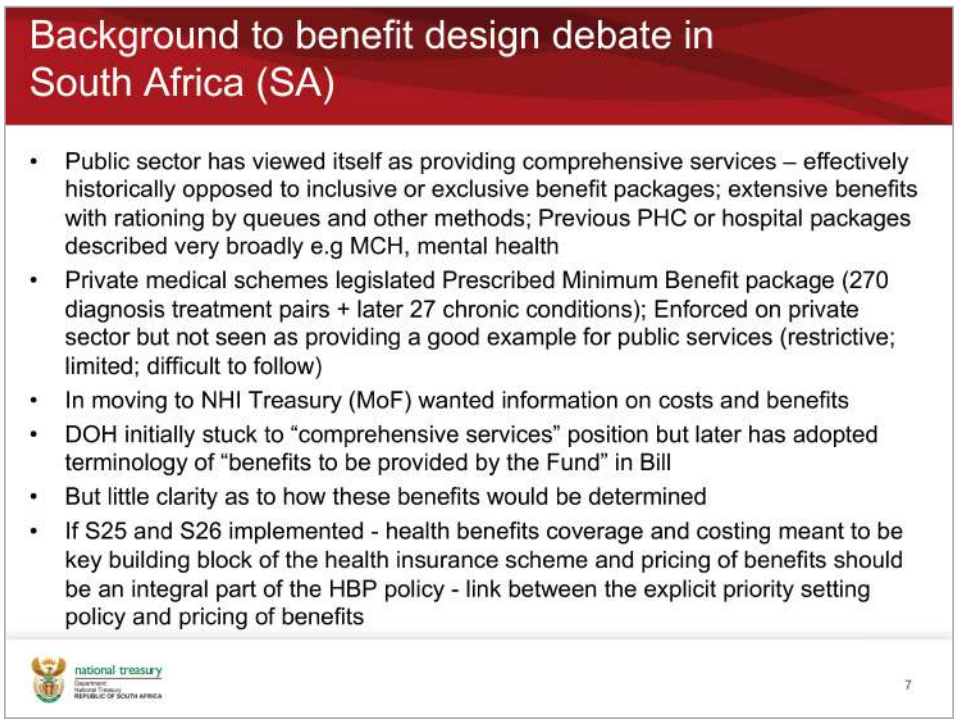
# NHI AND BENEFIT DESIGN

## Minute 00:08:25

The next slides start getting more into the meat of the benefit design and benefit packages. There are three sections from the Act that I am showing here on the slide.

The first one from section 20 of the Act says that the Fund itself will have a unit, unit 3B here on the benefits design. So there will be a unit in the Fund on benefits design. Then section 25 of the Act talks about a Benefits Advisory Committee, which the Minister will appoint. Subsection 5 says that this Committee will determine health care benefits and the types of services to be reimbursed at different levels of care and determine detailed and cost-effective treatment guidelines and consider the emergence of new technologies, and so forth.

And then section 26 talks about an addition to this Benefits Advisory Committee, the establishment of a Benefits Pricing Committee, which will recommend prices for different benefits to be paid to providers.




# BACKGROUND – DESIGN DEBATE IN SOUTH AFRICA

## Minute 00:09:43

I would like to give you a bit of a background to this debate around benefit design in South Africa. Historically the public health sector has viewed itself as providing comprehensive services and it has not really been structured around benefit packages in the sense that it hasn't a typical insurance system. Historically there has been opposition both to the national inclusive or exclusive benefit package and rationing has happened by queues or other methods. Previous primary health care packages or hospital packages have been described very broadly like in terms of 'maternal and child health' or ' mental health' but not really getting into the detail of benefits.

In contrast legislation referring to the private medical scheme legislated 270 prescribed minimum benefits, which were diagnostic treatment pairs and later 27 chronic conditions. So this was enforced in the private sector but was not seen as a good example for the public sector because it was seen as restrictive.

Moving to the National Health Insurance, the Ministry of Finance wanted more information on costs and benefits and so was, in a sense, putting some challenge to the Ministry of Health

around this process on comprehensive benefits, and was asking: “what are the benefits and the cost-effectiveness of benefits?”

Although the Department of Health initially stuck to the approach on comprehensive services, over time it has adopted in the bill this terminology that I showed in the previous slide of “benefits to be provided by the Fund”. But there has been little clarity on how these benefits would be determined. If the sections 25 and 26 of the bill are implemented then it does appear that health benefits coverage and costing are meant to be the key building block of the health insurance scheme and the pricing of benefits should be an integral part of this policy. So there could be a link between the priority setting and the pricing of benefits.

# STG AND EDL

## Minute 00:12:05

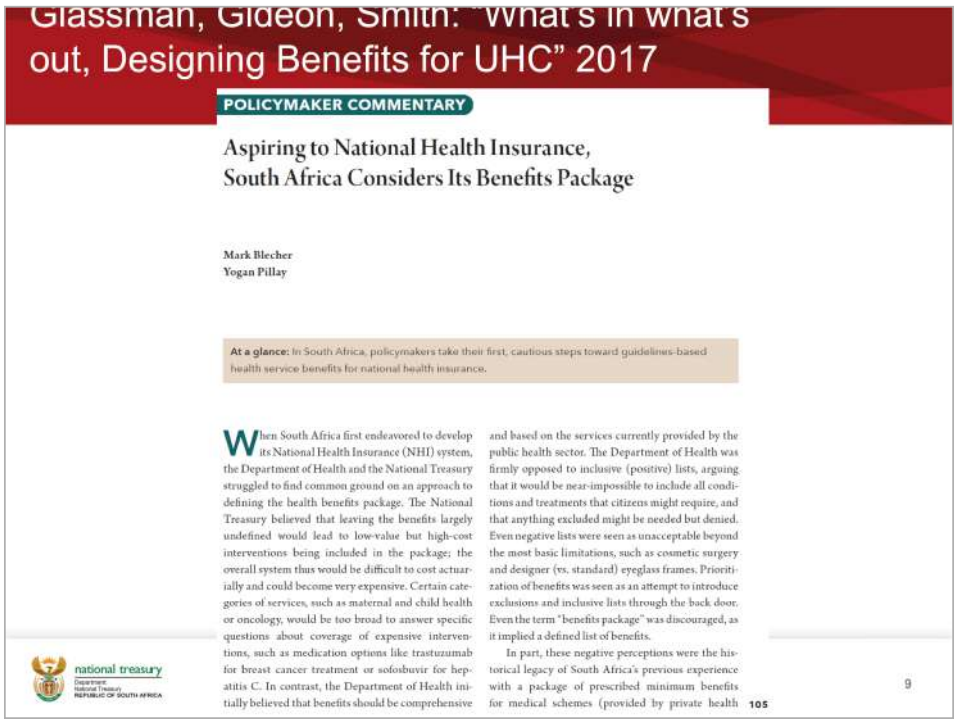
We are at the point now where South Africa needs to develop a benefits package for the National Health Insurance. And despite not currently having a clear national benefits package, South Africa has got a lot of experience with standard treatment guidelines and also essential drug lists. But often there are multiple standard treatment guidelines for one condition, like the national department or a province, a hospital, a university, or an insurance company; they have different treatment guidelines. So there is not a census around one national guideline. And there is not really a process to set one single national guideline. Although some of these might reach the heads of the Health Committee and get some national acceptance.
The essential drug lists for medicines are a bit more binding as they tend to influence the medicines procurement process. They tend to focus mainly on medicines and not on other technologies. And even here a standardized HTA process and economic evaluation is often weak.

There is one national attempt now to collect these standard treatment guidelines into a software tool as a collection of benefits but this mainly covers primary health care and is not yet complete.

Given that we do not currently have a benefits package for South Africa this is a pragmatic approach but one of its limitations is that many of these STGs may have been designed by clinicians or have passed some effectiveness research or looking at a Cochrane reviews but typically there would have been inadequate economic evaluation.

And for those who are interested in the South African case, you can look at some of the South African treatment guidelines at this link on the Department of Health website:

http://www.health.gov.za/index.php/component/phocadownload/category/197/



Glassman, Gideon, Smith: "What's in what's out, Designing Benefits for UHC" 2017

POLICYMAKER COMMENTARY

Aspiring to National Health Insurance, South Africa Considers Its Benefits Package

Mark Blecher
Yogan Pillay

**At a glance:** In South Africa, policymakers take their first, cautious steps toward guidelines-based health service benefits for national health insurance.

When South Africa first endeavored to develop its National Health Insurance (NHI) system, the Department of Health and the National Treasury struggled to find common ground on an approach to defining the health benefits package. The National Treasury believed that leaving the benefits largely undefined would lead to low-value but high-cost interventions being included in the package; the overall system thus would be difficult to cost actuarially and could become very expensive. Certain categories of services, such as maternal and child health or oncology, would be too broad to answer specific questions about coverage of expensive interventions, such as medication options like trastuzumab for breast cancer treatment or sofosbuvir for hepatitis C. In contrast, the Department of Health initially believed that benefits should be comprehensive and based on the services currently provided by the public health sector. The Department of Health was firmly opposed to inclusive (positive) lists, arguing that it would be near-impossible to include all conditions and treatments that citizens might require, and that anything excluded might be needed but denied. Even negative lists were seen as unacceptable beyond the most basic limitations, such as cosmetic surgery and designer (vs. standard) eyeglass frames. Prioritization of benefits was seen as an attempt to introduce exclusions and inclusive lists through the back door. Even the term "benefits package" was discouraged, as it implied a defined list of benefits.

In part, these negative perceptions were the historical legacy of South Africa's previous experience with a package of prescribed minimum benefits for medical schemes (provided by private health

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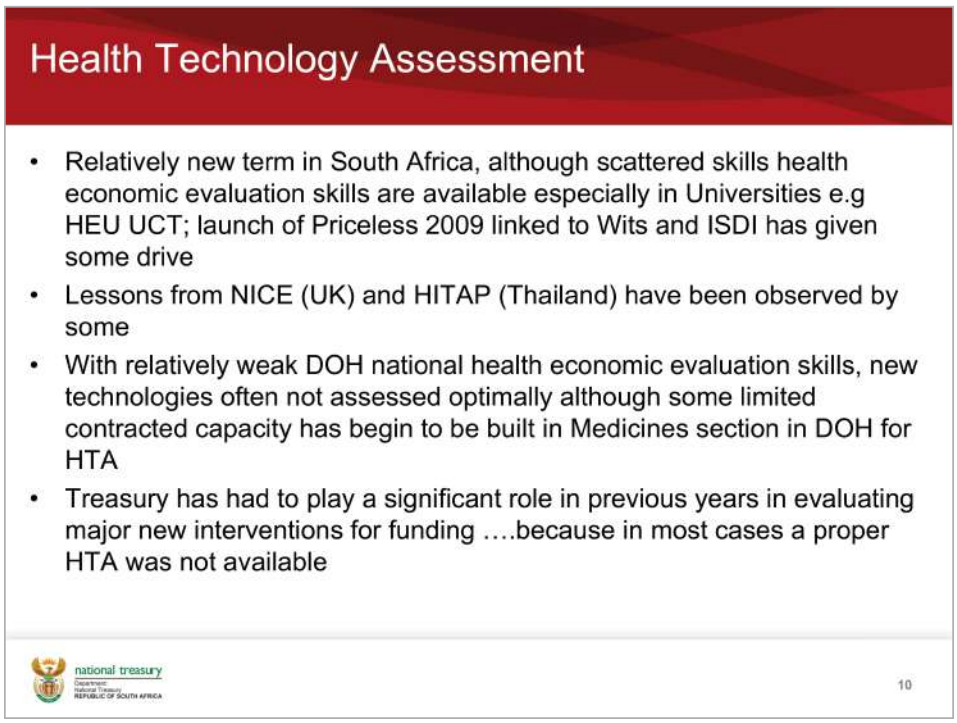
# GLASSMAN, GIDEON (2017)

## Minute 00:14:03

This is just something we wrote on this between ourselves and the Department of Health. This was in the book some of you know by Ursula Gideon, Amanda Glassman and Peter Smith wrote on benefits packages. We wrote a little bit about a policy approach to a benefits package in South Africa.



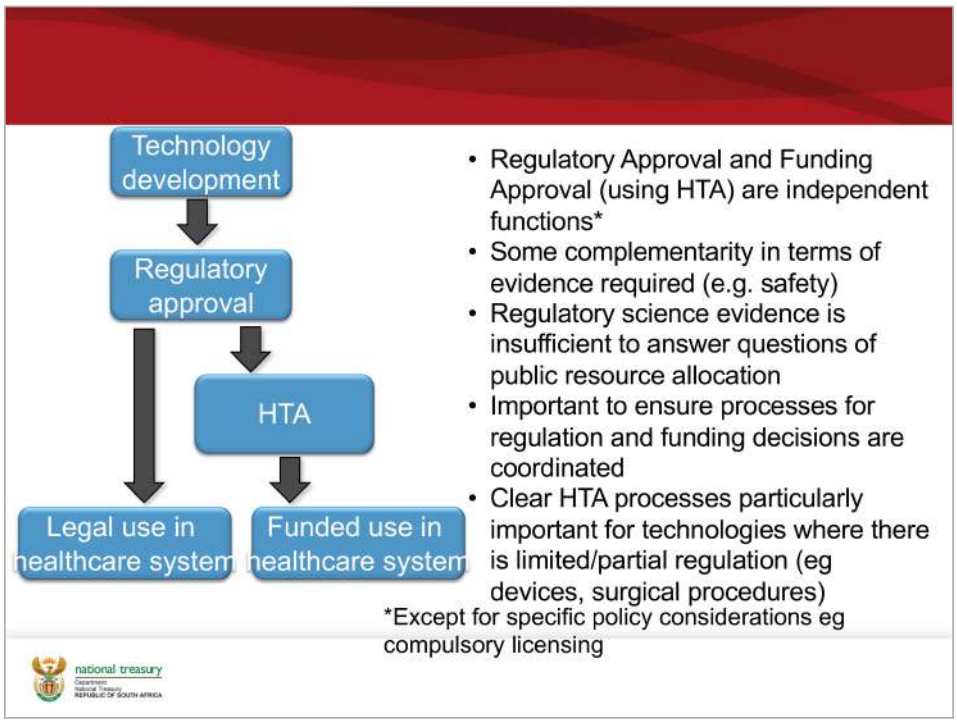

# GLASSMAN, GIDEON (2017)

## Minute 00:14:24

The notion of Health Technology Assessment (HTA) is a relatively new term in South Africa. Although there are scattered skills in HTA and in health economic evaluation available, especially in some of our universities, for example at the Western Cape Province Health Economics Unit or the University of Cape Town. Also the Priceless unit was launched in 2009 linked to the WITS University and also linked to the international ISDI network. They have given some drive to the process. And some in the country have observed the lessons from NICE in the UK and HITAP in Thailand as well as other lessons.

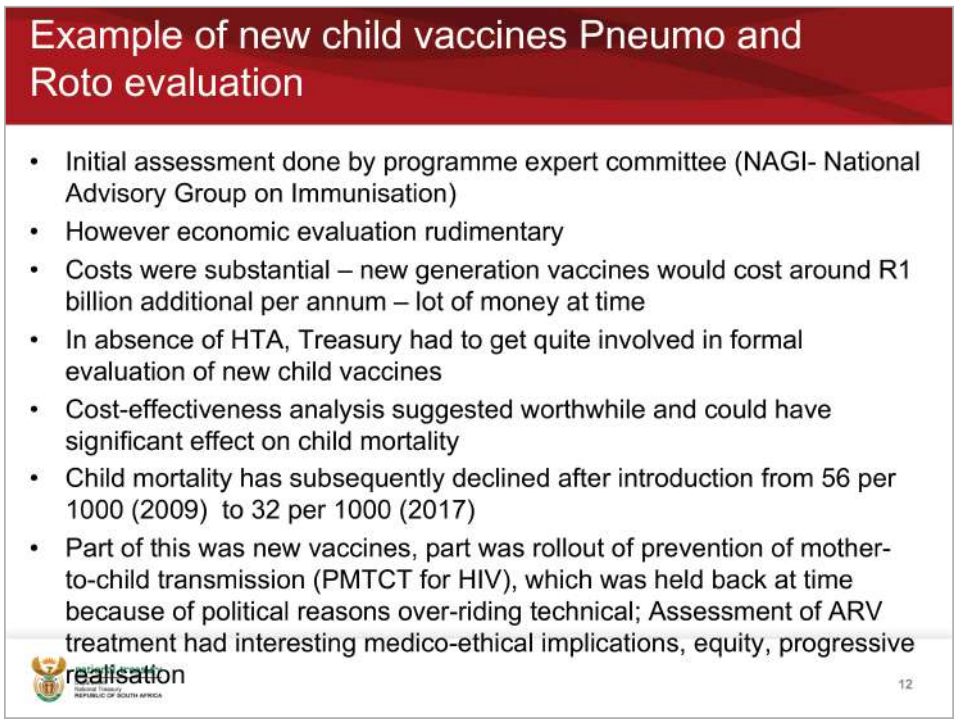
But there has been relatively week skills in HTA and economic evaluation at the Health Department and often technologies have not been assessed optimally from an economic perspective. Although some limited capacity has begun to be built in the Medicines Section in the Department of Health for HTA.

In previous years the treasury has had to play some role in evaluating of new interventions for funding, mostly because in several cases a proper Health Technology Assessment was not available.




## Minute 00:15:40

Typically, in South Africa we have a Medicines Control Council which gives regulatory approval for the approval of a new medicine for its introduction, but ideally, we would want a HTA to decide whether this new medicine should be funded in the health care system.



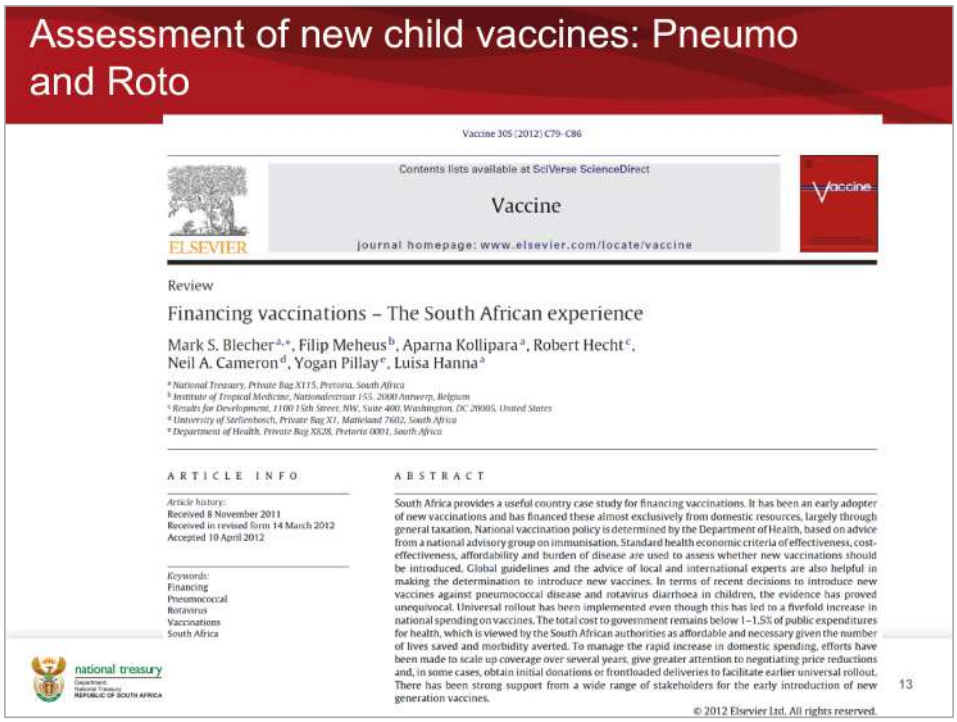

# EXAMPLE: NEW CHILD VACCINES

## Minute 00:16:01

So this is an example, which I was personally involved with, on the evaluation of new child vaccines for Pneumoconiosis and for Rotavirus. The initial assessment was done by an expert committee in the Department of Health, which is called the NAGI committee (National Advisory Group on Immunization). But the economic evaluation of these new vaccines was rudimentary. The costs were substantial. New generation vaccines would have cost around 1 billion Rand, a lot of money for the country at that time. And in the absence of HTA the Treasury had to get quite involved in the formal evaluation of the vaccines. The cost-effectiveness analysis suggested that they were worthwhile and could have a significant effect on child mortality. The joint analysis between the Department of Health and ourselves lead to the instruction of the vaccines and child mortality has declines fairly substantially from 56 per 1000, in 2009, to 32 per 1000 in 2017.

Part of this was due to these new vaccines and part of it was due to the rollout of prevention of mother-to-child transmission for HIV, which was also a very interesting case in HTA because it was very clear from a technical perspective that this was a very important and cheap intervention but the intervention was held back at the time for political reasons, which was kind of a lesson in

HTA. Even the introduction of antiretroviral (ARV) treatment was very interesting technically because at the time the process was greatly assisted by medical ethicists in the acceptance of the intervention and there were issues around equity and progressive realization and other factors that had to be taken into account in the assessment.



Assessment of new child vaccines: Pneumo and Roto

Vaccine 30S (2012) C79–C86

Contents lists available at SciVerse ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Review

Financing vaccinations – The South African experience

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ABSTRACT

South Africa provides a useful country case study for financing vaccinations. It has been an early adopter of new vaccinations and has financed these almost exclusively from domestic resources, largely through general taxation. National vaccination policy is determined by the Department of Health, based on advice from a national advisory group on immunisation. Standard health economic criteria of effectiveness, cost-effectiveness, affordability and burden of disease are used to assess whether new vaccinations should be introduced. Global guidelines and the advice of local and international experts are also helpful in making the determination to introduce new vaccines. In terms of recent decisions to introduce new vaccines against pneumococcal disease and rotavirus diarrhoea in children, the evidence has proved unequivocal. Universal rollout has been implemented even though this has led to a fivefold increase in national spending on vaccines. The total cost to government remains below 1–1.5% of public expenditures for health, which is viewed by the South African authorities as affordable and necessary given the number of lives saved and morbidity averted. To manage the rapid increase in domestic spending, efforts have been made to scale up coverage over several years, give greater attention to negotiating price reductions and, in some cases, obtain initial donations or frontloaded deliveries to facilitate earlier universal rollout. There has been strong support from a wide range of stakeholders for the early introduction of new generation vaccines.

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## ASSESSMENT OF NEW CHILD VACCINES

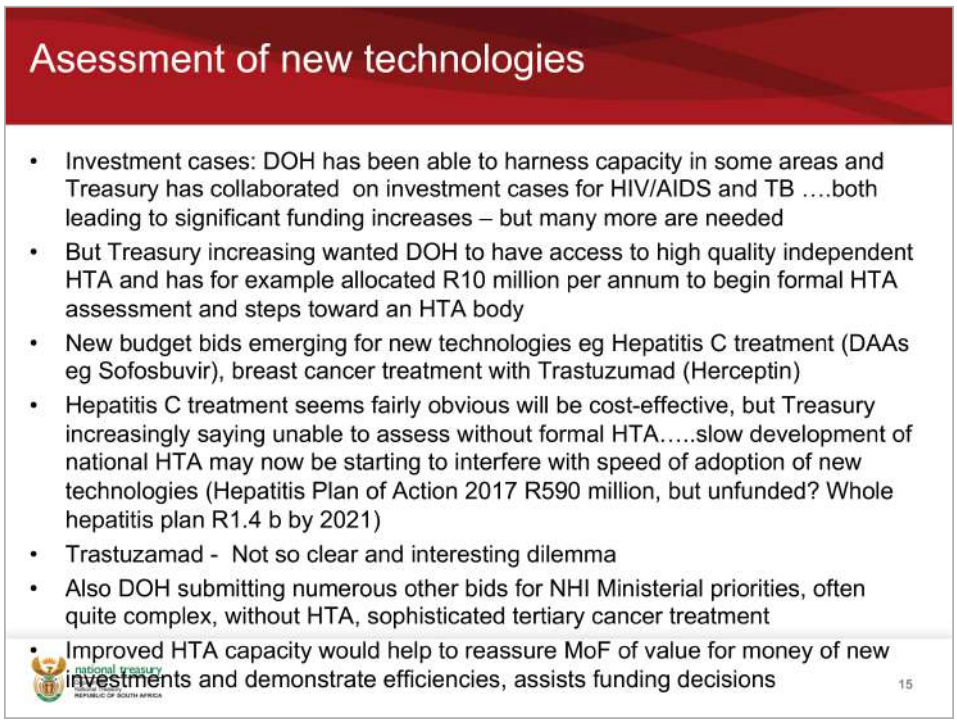
### Minute 00:18:04

This was a paper we wrote looking into the introduction of these new child vaccines regarding the South African experience. This reflects the joint work between the treasury and the Department of Health and the need at that time because there was no national HTA process for the Treasury to become involved in these issues.

# HIV/AIDS FINANCING IN SOUTH AFRICA

## Minute 00:18:23

This was a paper we did looking at some aspects of HIV/Aids assessment, a bit more broadly than an HTA evaluation, in the context of an investment case. It is also linked to issues of sustainability and fiscal space. This investment case was driven substantially by numerous colleagues at the Department of Health and Gesine Meyer-Rath in the “Hero-unit” in South Africa. It is quite an interesting tool, which brings together a number of different HTA methodologies into a wider assessment of a bigger problem like how to deal with an area like HIV/AIDS. It is another interesting methodological approach.




# ASSESSMENT OF NEW TECHNOLOGIES

## Minute 00:19:09

Respect to these investment cases the Department of Health has been able to harness capacity in some areas. And Treasury has collaborated, for example, in some HIV/AIDS and TB investment cases, both of which led to very significant funding increases. I mean, the HIV/AIDS investment case, for example, would add an additional around 1 to 1.5 billion per year as a result, partly, of this work. But the treasury wanted the Department of Health to have access to high quality independent HTA, not to be drawn in so much ourselves as an organization each time we have to be asked to fund a new intervention. We want the Department of Health to have access to the skills and the independent assessment. We have also due this technical assessment, which is obviously quite difficult and requires a lot of skills. So we allocated around 10 million Rand a year for the Department of Health to begin building formal capacity in HTA and taking some steps toward establishing an HTA body.

In the meantime new budget bids started emerging for new technologies, like Hepatitis C treatments, like Sofosbuvir or breast cancer treatment, for example with Trastuzumad. Both of these

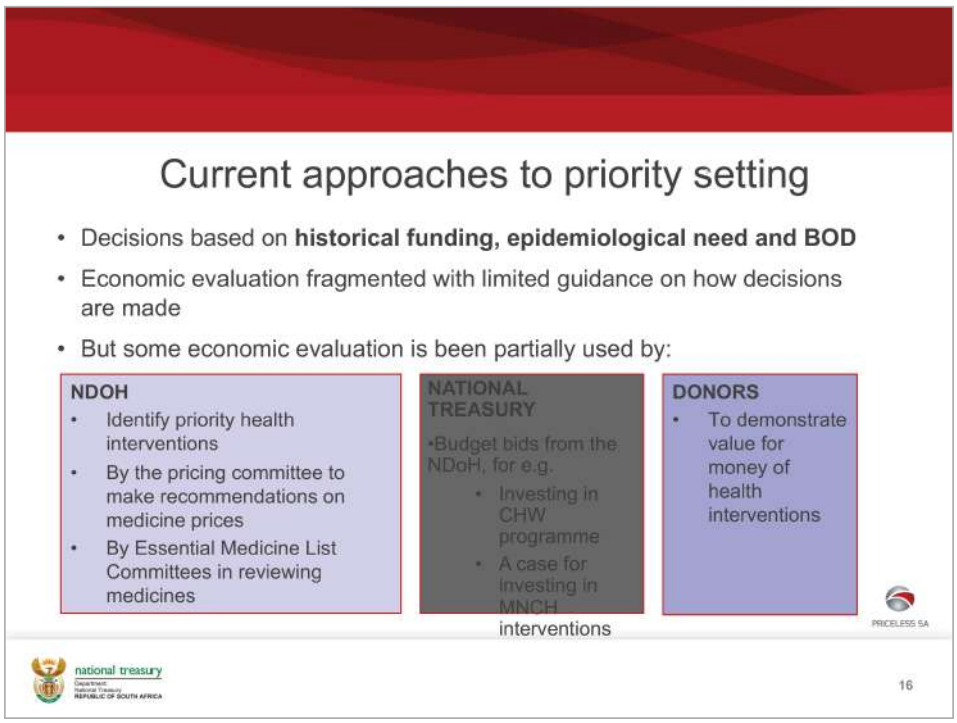
were fairly interesting cases. The Hepatitis C treatment seemed fairly obvious that this would be cost-effective but the Treasury was starting to get a bit inpatient and saying: “Look, we cant just keep funding these new interventions. The Department needs to do a formal HTA.” And the Department moved ahead and they included this also in a national Hepatitis Plan for Action, which was released in 2017, and this plan said that the cost for Hepatitis C treatment would be around 590 million and the whole Hepatitis Plan would cost around 1.4 billion by the year 2021.

But because the department was not able to put forward to the Ministry of Finance a full HTA assessment of Hepatitis C treatment, it meant that although the plan was released it was not funded. And this put a lot of pressure on provinces in delivering the intervention. It is an example where, in a sense, slowness to do the HTA has partly delayed the rollout of the intervention, which seems to be a very sensible intervention. It almost certainly would pass HTA but the HTA capacity has not been there to formally do it.

The case of Trastuzamad was also quite interesting because it was not so clear and interestingly HTA was done but it was not a very complete HTA but the HTA was not shared with the Treasury. The Treasury was asked to fund Trastuzamad and two years later, in preparing for this presentation, the Department of Health finally sent me a copy of this HTA of Trastuzamad. For time reasons I won’t go into all the findings now but it is interesting that they were not shared at the time when the bid was made and although Trastuzamad is, to some extent, coming to the guideline policies in South Africa some provinces have not gone ahead with providing it partly because of the extents of cost of Trastuzamad and there hasn’t been additional national funding allocated for it.

Also the Department of Health has submitted numerous other bids for, so called, NHI Ministerial priorities, often quite complex, without HTA some involving sophisticated tertiary cancer treatment.

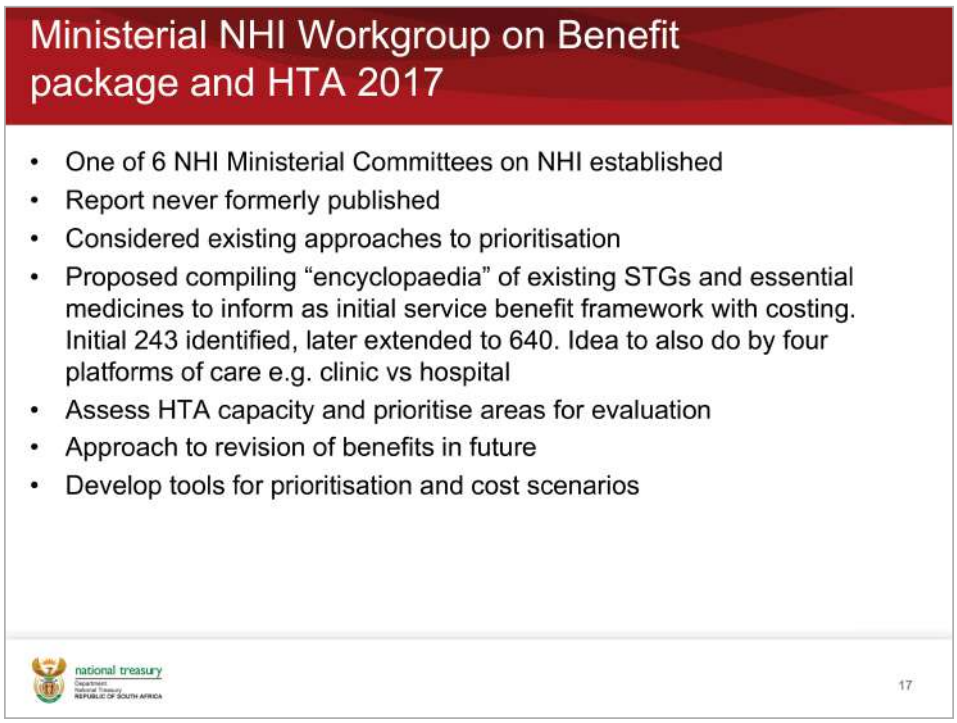
Improved HTA capacity would help to reassure the Ministry of Finance of value for money of new investments and demonstrate efficiencies and would assist in funding decisions. So there is a strong case why small investments in HTA would be useful in our context.




# CURRENT APPROACHES TO PRIORITY SETTING

## Minute 00:23:13

So currently at the Department of Health we are doing certain interventions while at the Treasury, for example, budget bids are playing a role. All of these need to be put together more in whatever the new dispensation is and the structure of a new HTA authority or process.




# NHI WORKING GROUP

## Minute 00:23:31

The Ministry of Health then established a working group on benefits packages and on HTA in 2017. It was one of six NHI Ministerial Committees established by the Ministry of Health. Its report was never published, which was a pity because it was a helpful report and I think it would have helped a transparent debate about the way forward on the benefits package and on HTA. It considered existing approaches to prioritization and proposed compiling and encyclopedia of existing standard treatment guidelines and essential medicines to form a basis of an initial benefits framework with costing. Initially that identified around 243 treatment guidelines. I think it was later extended to about 640 across different platforms of care. And the idea was to use HTA capacity to prioritize areas for future evaluation and also reconsider some of the older guidelines.

## NHI Bill on HTA 2019 (S7,57)

(3) In Phase 1 the Minister may establish the following interim committees to advise him or her on the implementation of the National Health Insurance:

*(d)* The Ministerial Advisory Committee on Health Technology Assessment for National Health Insurance, which must be established to advise the Minister on Health Technology Assessment and which must serve as a precursor to the Health Technology Assessment agency that must regularly review the range of health interventions and technology by using the best available evidence on cost-effectiveness, allocative, productive and technical efficiency and Health Technology Assessment.

(4) Treatment must not be funded if a health care service provider demonstrates that—

*(a)* no medical necessity exists for the health care service in question;

*(b)* no cost-effective intervention exists for the health care service as determined by a health technology assessment; or

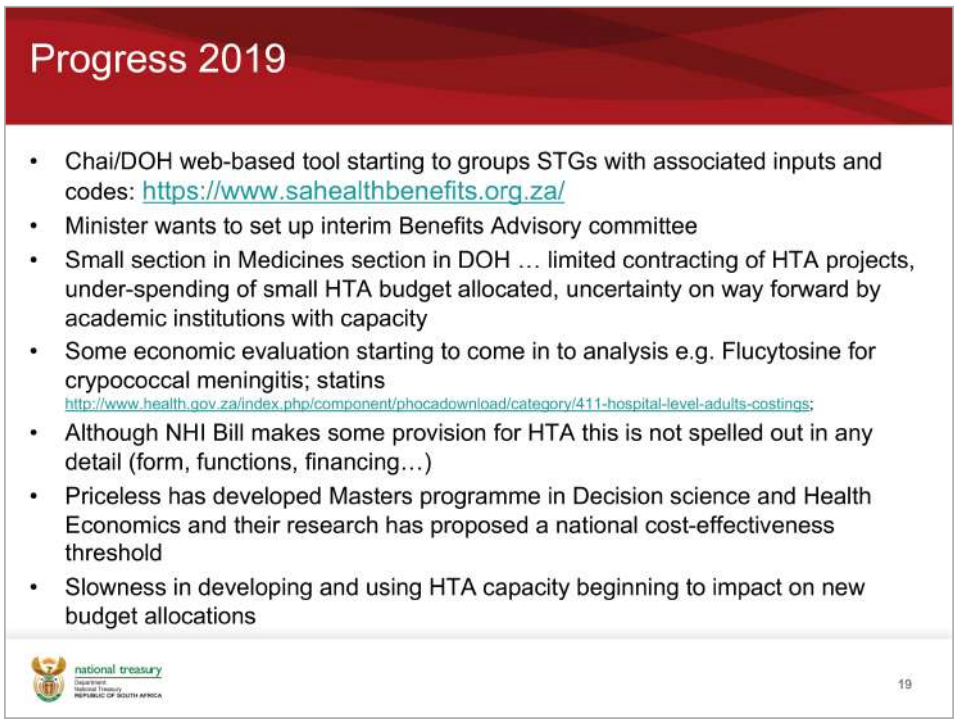
*(c)* the health care product or treatment is not included in the Formulary, except in circumstances where a complementary list has been approved by the Minister.

REPUBLIC OF SOUTH AFRICA

# NHI BILL ON HTA 2019

### Minute 00:24:36

The NHI bill also has some things to say about HTA in section 7 and 57 of the bill. The bill says that in phase one the Minister will establish and Advisory Committee on HTA, which must serve as a precursor to the HTA Agency, which must regularly review the range of health technologies and interventions using the best available evidence. Treatment must not be funded if there is no cost-effective intervention for that. So the bill made some provision for HTA but this provision is really soft from a legislative perspective.




# PROGRESS 2019

## Minute 00:25:24

By 2019 there has been some progress. Chai, the Clinton Health Access Initiative, has been working with the Department of Health on a web-based tool trying to put these standard treatment guidelines together as a basis of some kind of treatment package. Some of this can be picked up on this website, although it is necessary to register to access the website. (https://www.sahealthbenefits.org.za/)

The new Minister of Health wants to set up an interim Benefits Advisory committee. And the small section in Medicines section in the Department of Health has been doing some limited contracting of HTA. But they are under-spending on the budget of 10 million per year that has been allocated to them. So there has been some progress but it has been slow and there has been slow and there has been uncertainty on way forward by academic institutions with capacity to do HTA assessment. So we have some very good health economists in the country who could do great work but there is some underutilization of that capacity.

If one looks at the assessment of medicines which a lot of those early assessments that you will see on this website of the Department of Health don't really have economic evaluation. They are starting with clinical evaluation or effectiveness evaluation and many of them have no economic evaluation. But one starts seeing a new generation of evaluation which are starting to include a health component as, for example, those on Flucytosine for crypococcal meningitis or the one on statins. Those interested in these cases can look at this website: http://www.health.gov.za/index.php/component/phocadownload/category/411-hospital-level-adults-costings

One will see that an increasing numbers of these are starting now to get some economic analysis into them. Not necessarily always a completely strong analysis or a full HTA analysis but one sees a direction of some improvement of bringing in economic evaluation and HTA into medicine assessment.

Although the bill makes some provision for HTA this is not spelled out strongly. For example the form, functions, financing are not really strong. They are not strong enough from a legislative respective to establishing a statutory authority on this. They would need stronger legislative provisions to really create a new part substantially.

In the meantime Priceless at FITS University has developed a Masters program in Decision Analysis and Health Economics and some of their research has started to propose a national cost-effectiveness threshold for South Africa.

But overall there has been some slowness in developing and using HTA capacity and this is beginning to impact on new budget allocations from the Ministry of Finance.

## HTA: Status 2019

| Issue | Status |
|---|---|
| Mandate | Bill suggests interventions in benefit package should be cost-effective; Increasingly being required for budget bids for new technologies |
| Legal framework | Advisory Committee; No clear legal form and powers; Talk of precursor to HTA Agency, but not binding |
| Institutional arrangements | Small function in Medicines section in DOH; Minister seting up interim Benefits Advisory Committee; Prioritisation framework still to be developed. Proposes to contract out, but various University expert units uncertain of role |
| Assessment and appraisal framework eg CEA, equity, affordability, impact... | Framework seems still largely driven by old EDL assessment approach. Seems as if HTA framework still to be developed, several recent medicine evaluations still limited even in economic evaluation component |
| Monitoring evaluation: Independent, fair, quality of evaluations | Appears not developed yet |

national treasury
Department: National Treasury
REPUBLIC OF SOUTH AFRICA

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# HTA STATUS 2019

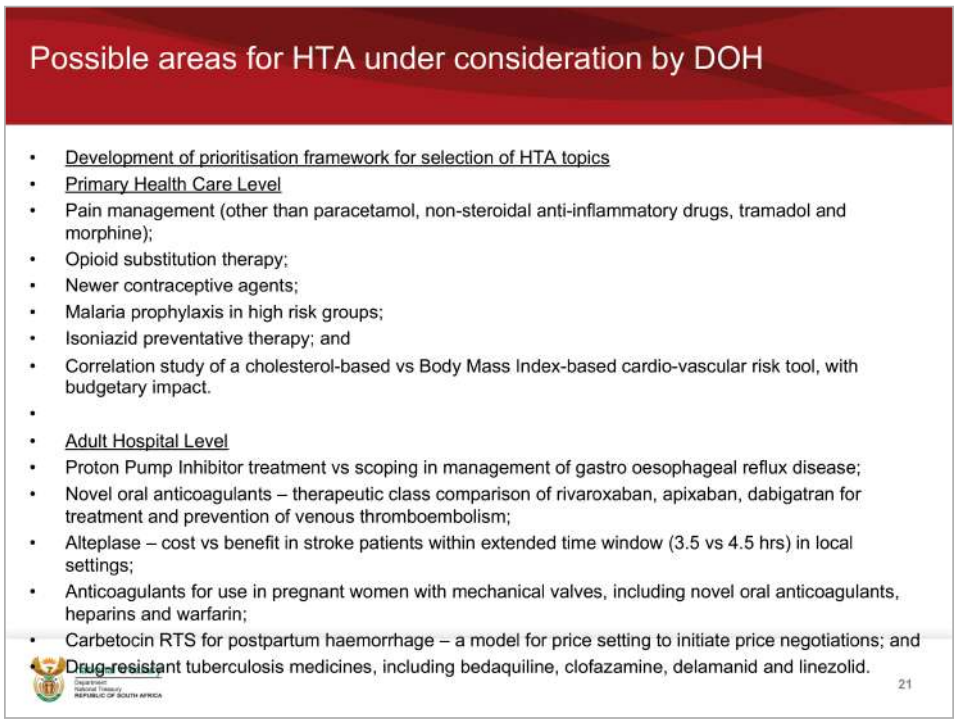
### Minute 00:28:10

This is just to summarize the status. Regarding the mandate for HTA, the bill does suggest that there should be a role of HTA in benefit package development and is increasingly required by the Ministry of Finance for budget bids.

The legal framework talks about this Advisory Committee, but it is a little bit weak and not necessarily binding in some cases. The institutional arrangements are really just emerging. The institutional arrangements include the small functions in the Medicines section of the Department of Health (DOH) and the Minister is wanting to set up this Interim Committee, but the actual prioritization framework for what functions to do in HTA has to be developed. In fact that is one of the projects that the Department wants to contract out, and it proposes to contract out several of these evaluations but where there is expertise is in some if the expert units a lot of the individuals are uncertain of what role there are being asked to play in this or whether they will have a role.

On assessment and appraisal frameworks, if you look at the DOH website, the framework really seems to be largely driven by the old Essential Drug List assessment approach. It seems as if the proper HTA framework still needs to be kind of formally developed and several recent medicines

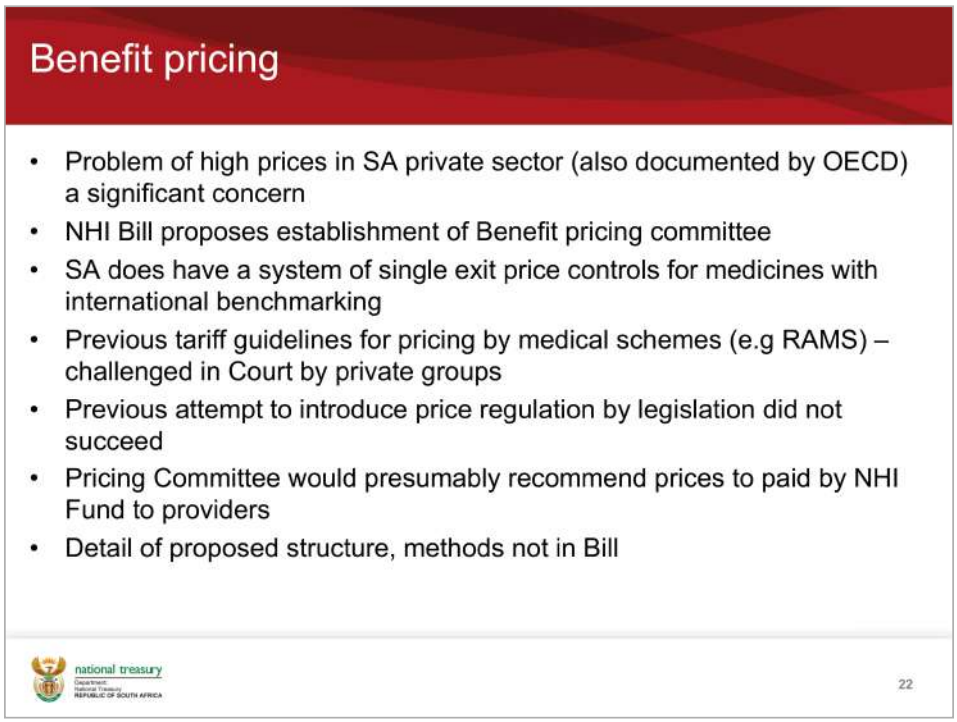
evaluations are still somewhat limited in their economic evaluation component. It does not yet seem to be a monitoring and evaluation framework yet of HTA as a discipline in the country.




# POSSIBLE AREAS FOR HTA

## Minute 00:29:42

Some of the areas the DOH was thinking of for doing HTA are listed here. I am not going to go through these. This is just a short list, which I have distracted. Interestingly some of the first things they wanted to put out is a guidance from experts on how to develop a prioritization framework for the selection of HTA topics.




# BENEFIT PRICING

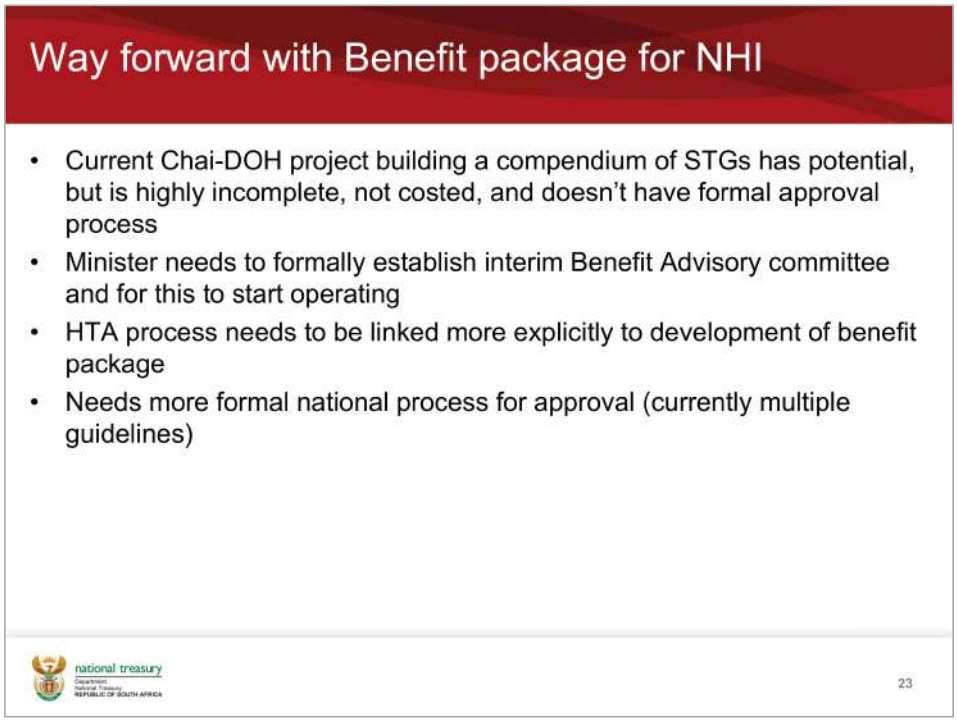
## Minute 00:30:04

I would just like to say a word or two on benefit pricing. You have seen that the NHI Bill makes some provision for an advisory committee on benefit pricing. There is a big problem with high prices of services in the South African private sector. This was also documented by a cross-country OECD review. The NHI Bill proposes the establishment of a pricing committee. South Africa does have quite a good system though of single exit prices on medicines, which uses international benchmarking. So there is a bit of experience.

But the previous tariff guidelines for pricing by medical schemes, for example put out by a body which is known as RAMS at the time, was challenged in Court by private groups. There has been lot of opposition from the private sector to any price controls of any form. The Department was unable to move forward on this. So this may have to then be reintroduced back.

Previous attempts to introduce private price regulation by legislation did not succeed. The Pricing Committee would presumably recommend prices to paid by NHI Fund to providers but

the detail of the benefits pricing committee, its structure and its methods are not yet in the Bill. We are quite far away from this although there are some early legislative provisions for this.




# WAY FORWARD WITH BENEFIT PACKAGE FOR NHI

## Minute 00:31:18

These are some of the issues for the way forward for the benefit package.
The current Chai-DOH project is trying to build a compendium of STGs and it has potential, but it is still at quite an early phase but that is starting to build what might merge as a benefit package. The Minister is in a process of trying to establish this interim benefits advisory committee.

The HTA process needs to be linked more explicitly to development of these benefits. And all of this needs a more formal national process for approval because there are currently multiple guidelines and there is no clear process of national approval.

# WAY FORWARD WITH HTA IN SOUTH AFRICA

## Minute 00:32:01

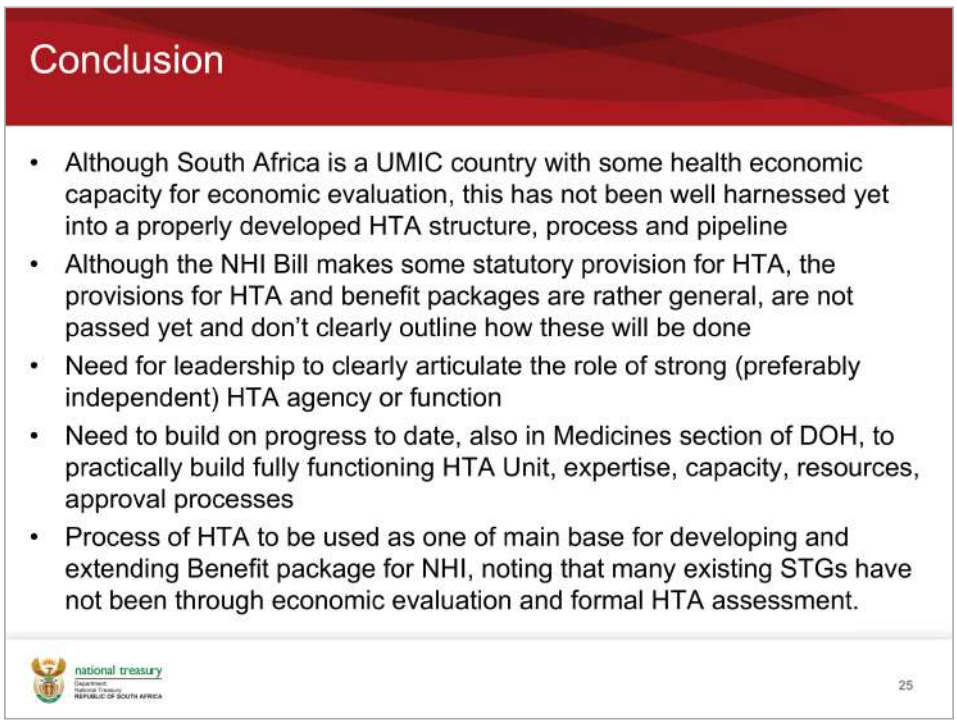
On HTA there are still a lot of debates around future institutional form in SA. Are we just building capacity, would it just be the small unit in the NHI Fund or is it an independent structure, which is hinted at in the bill? The bill is quite week on this. It is not necessarily convincing as a way forward.

We have allocated some seed funding which needs to be better used to accelerate building capacity, processes, systems, standardization, formal approval processes.

We need to make better use of national expertise in some of the units like Priceless, University Health Economics Units, because we do have some good national capacity in this regard.

We need to build a pipeline of annual HTA projects and we need HTA to be used and it needs to be increasingly as a basis for budget decisions.
HTA needs to be a key basis for inclusion of new technologies in benefit package and review of

existing benefits. We need to build capacity outside medicines area where this discipline is emerging from in South Africa. And we need to build institutions and get closer to decision on institutional form.




# CONCLUSION

## Minute 00:33:06

I think what you can see from this is why I called it the long and winding road. This is still kind of an emerging discipline in our country. It seems to be potentially an important discipline and something that could contribute a lot to getting better value for money, help to guide some of the things we do and help us to be fast on the uptake of new technologies. We have, in some cases, been fast in the past but we are now starting to fall behind on some new technology. We are an upper-middle income country and we do have some health economic capacity we can use for HTA but it has not yet been well harnessed.

Although the NHI Bill makes some statutory provision for HTA, the provisions for HTA and benefit packages are rather general and could be strengthened. They don't clearly outline how these

will be done and we need leadership to clearly articulate the role of strong, preferably independent, HTA agency or function. We need to build on progress to date, also in Medicines section of DOH, to practically build fully functioning HTA Unit, expertise, capacity, resources and approval processes.

The process of HTA should be used as one of main base for developing and extending the benefit package for NHI, noting that many of the existing STGs have not been through formal economic evaluation and formal HTA assessment.

# QUESTIONS AND ANSWERS

## Minute 00:35:49

***Question:***

***If you got the HTA system working and put it into place, then you are in a situation where the DOH might come in with a HTA that says that this is cost effective but the Finance Ministry can come back and say that there is no budget for it. What do you see ahead? If the HTA assessment becomes formal how does the DOH and the Treasury handle that kind of issue? There is just not enough money in the budget.***

***Answer:***

That is obviously an important question in all countries. What some colleagues may not be aware of, particularly those who have not worked in the Ministry of Finance is something I will describe by giving you an example from our Ministry. As many countries do now we do multi-year budgeting, like a three medium term expenditure cycle. The main thing that drives the availability of additional funding is economic growth. If one is projecting, for example 2 % economic growth in the third year then typically 2% additional resources will become available in that year. So every single year the Ministry of Finance (MOF), except in a really bad period like after the 2008 recession, this allocation happens because most countries have some economic growth – even if it is slow economic growth – this economic growth feeds through to revenue, which feeds through to expenditure. One of the interesting things about working in the MOF is that every year you have to do a budget process and this economic growth is generating some revenue. Typically when you work in the MOF you receive budget bids from departments (maybe 5, 10 or 15 budget bids for next year budget cycle) and one uses scoring systems to assess which of these are potentially worth funding. But those of good evidence are clearly going to higher onto the list of likely funding.

In the literature around budgeting a lot is given to the political role in budgeting implying that a lot of budgeting decision are driven by political decisions. To some extent this is true but in my experience, working in the MOF, there is a lot of technical work that goes into the budget. So well developed effectiveness analysis can often be brought into the budget process. Not to say that they always do and obviously a lot of the decisions of HTA may not necessarily need to come to the MOF because a lot analysis will be part of the decisions that the DOH makes within its own budget process. But something like these new child vaccines that cost over a billion a year, is quite difficult for the DOH to have done this without additional funding.

Good examples are also the Hepatitis and Trastuzumad examples that I gave. The Hepatitis action plan is going to cost 1.4 billion to implement the best sort of interventions for Hepatitis A, B and C. That is a lot of money for the DOH to find. But because in that case they never tabled the HTA the MOF was not in the position to assess the bid at all. And that led to trying to implement it but under greater funding constraints. So yes, Joseph is correct, obviously not all cost-effective interventions will be affordable but the better the evidence the greater the chance for them being funded.

## Minute 00:40:36

***Question:***

***The related questions are about whether you anticipate setting a cost-effectiveness threshold for what other criteria do you think are going to come in for priority setting beyond the HTA?***

***Answer:***

Let me say firstly that we have never had an official threshold in South Africa. I think both the MOF and the DOH have, in a sense, almost have to rely on the 1:3 per GDP threshold, which initially came from the WHO or the Bank, I am not sure where it initially came from. We actually used this threshold when we did our analysis of the new child vaccines. More recently Priceless has published a paper trying to calculate a potential threshold for South Africa. I think they might have drawn partly from the new methodologies that the York Unit in the UK is using for looking at potential thresholds, potentially there are other thresholds coming out then the previous 1:3. But that research has not yet been adopted as a national guideline. Clearly for Treasure cost-effectiveness is an important factor but there are a lot of other factors that are also important in making a budgetary decision and as the Ministry of Finance we have a number of criteria we use in trying to make allocative decisions. Some of those we laid out in that vaccine paper. I have tried to mention some of them already here. Clearly is an important factor. I have pointed out in the antiretroviral case that the medical-ethical issues and the equity issues are very important. But it is kind of surprising because South Africa is an upper-middle-income country but it hasn't yet put together a clearly defined framework of the criteria to use when evaluating an HTA. It is a gap and we need to address and one of the first things that the HTA Agency needs to do, to lay out what are the criteria that we need to use as a country when evaluating a new intervention. And when you look at those DOH analysis you will see that many of them historically are relying

largely on effectiveness. It is almost like the pre-HTA era. As a country, even though we are not a middle-income country, we are emerging and starting to use HTA more broadly. We have quite strong political forces in South Africa, which sometimes overrule the HTA finding. I guess to some extent that's inevitable. I have mentioned at least three of the cases that are presented today. I look forward to future work where we have a more clear, sound and national set of criteria for making a recommendation.

## Minute 00:44:46

***Question:***

***We have a question regarding the role of patients associations in the process. Is the HTA likely to just be the technical side that's providing information and then there is a separate process for broader consultation or what role could patient associations and other stakeholders be playing?***

***Answer:***

I think that is a very important question. I personally would really want to see that. I have seen in Thailand, for example, the way that HITAP, for example, looks at inputs from a wider range of different groups. I would hope that we would do that. As I said, because the process in South Africa is really emerging, it has not been clearly laid out how and who they would consult with. I think the question points to a very important gap in our existing HTA in process. It is clear that one can't make these decisions based on effectiveness and affordability alone. There is a range of other criteria including, for example what patient associations have to say around this. But as a country we need to put these together and I think this is an important challenge for the DOH, for the emerging NHI fund, for the emerging ministerial advisory committee on benefits, to start to put these together in a sensible and structured way that doesn't ignore these stakeholder groups. I think we have seen some good practices in South Africa. Fore example on AIDS treatment the government was really behind the curve, the Treatment Action Campaign and civil society really played the leading voice in getting the country to start ARV treatment. We have seen other cases where civil society has really been completely excluded from such decisions. We have seen both, good and bad cases, and I think we need to learn from those.

## Minute 00:47:10

***Question:***

***How about the relationship with the political opposition? Is it something that is negotiated in this broad support or is that also part of the dynamic?***

***Answer:***

In South Africa the African National Congress had, historically, quite an overwhelming majority, except in one of the nine provinces. The political process tends not to play such a big role in executive decisions of cabinets etc. The NHI bill obviously currently before Parliament and will be discussed in Parliament with all the political parties. There have been a lot of inputs, I think a hundred thousand inputs that have been received so there will be a very wide range of comments and Parliament will have to deliberate and make decisions on the bill.

## Minute 00:48:31

***Question:***

***Regarding the benefit package you mentioned that South Africa came out of this more NHS style without a distinct benefits package. The UK has gone into an incremental process of priority setting rather than en explicit benefit package. Do you think South Africa will continue the same track as the UK or do you think that something more explicit is likely to come out early in the process?***

***Answer:***

I think the DOH has been struggling with the notion of an explicit benefit package because their thinking is very much rooted in a human rights approach, in a comprehensive benefits approach in which the public sector is providing everything to everybody. And previously benefits packages have been very broadly defined.  The wording in the bill does suggest that they need to start trying to define aspects of the benefits package. And as I say these are the current attempts by the DOH to pull the benefits package form the existing standard treatment guideline and essential drug list. They are trying to develop some kind of encyclopedia of benefits, which might form a basic benefits package. But I think that the role of HTA will be particularly helpful for the new technologies, particularly also where they require additional funding. This is where the MOF comes in because the MOF increasingly will want to see HTA before allocating funds.
I have personally found even preparing for the seminar useful because within Africa there is

some deliberations as to how we should move forward with our benefit package approach. I think the work that has been done by CHAI and the Department of Health does potentially provide a useful base. But we need to find ways of presenting this. One of the difficulties I have found when looking at the package that has been put together to date, is that you end up with these extremely long lists of with quotes and numbers that can extend into hundreds of pages, which are technically quite difficult to understand and to follow. I think we have to think through how do we present the benefit package in a way that is usable to people, to civil society, to clinicians etc. But I think there is a very strong human rights approach in South Africa. I haven't said anything about legal challenges. We haven't yet seen in South Africa the extent of legal challenges that many South American countries have seen. We had one interesting case on retinodialysis where the court ruled that the government was entitled to limit access but we have seen several decisions of the constitutional court which have that government must extend benefits on, for example, housing or various other social benefits. So it is very interesting to see the role that legal cases also en up playing in this. But I am hoping that HTA will at least give us a lot of direction on new technologies and that over time we will have a clearer set of benefits.

CRITERIA
Regional Network on Explicit Priority
Setting and Health Benefits Plans