SUBSCRIPTION MODEL FOR REIMBURSEMENT: A FAD OR THE FUTURE?

6th November 2019

ISPOR Copenhagen

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Speakers and agenda

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Ex-NICE Appraisal Committee member

Currently Founder and Health Economist, Miller Economics Ltd

Diar Fattah

Ex-Associate Director of Medicines Optimisation NHS DGS & Swale CCGs

Currently Global Director, Innovative Value Strategies & Evidence, AstraZeneca

Erika Turkstra

Ex-PBAC reviewer

Currently Senior Consultant, Pricing & Market Access, Parexel International

Introduction to the subscription model for reimbursement

UK National HTA perspective

Industry & Local payer perspective

Australian national payer perspective

On the opportunities and challenges associated with the subscription-based pricing model

Each panelist will speak for 10 minutes and this will be followed by a 20-minute panel discussion, and 10 minutes of Q&A from the audience

CCG: Clinical commissioning group; DGS: Dartford, Gravesham and Swanley; HTA: Health technology assessment; NHS: National Health Service; NICE: National Institute for Health and Care Excellence; PBAC: Pharmaceutical Benefits Advisory Committee; SMC: Scottish Medicines Consortium

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Introduction

Richard Macaulay

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What is the subscription-based or licensing or 'Netflix' model of medicine reimbursement?

DEFINITION

*Where manufacturers are reimbursed based on a **fixed licensing fee for access,** irrespective of the volume of medicines used*

PRINCIPLE

*Manufacturers are paid based on **how valuable** the medicines are, not the **quantity of medicines** sold*

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The subscription-based model has been widely discussed to incentivise new antibiotic development…
New classes of antibiotic are desperately needed
But physicians will only use these as options of last resort
Lack of uptake & RoI hinders development of new antibiotics
September 14, 2018 01:00 AM
FDA hopes new payment models would spark antibiotic drug development
STEVEN ROSS JOHNSON
10 JULY 2019
NEWS
UK to test subscription payment model for antibiotics
RoI: Return on investment
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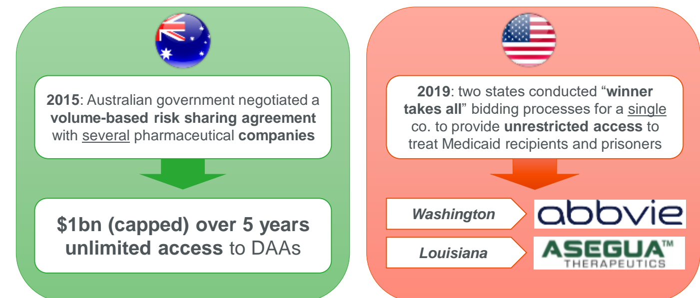
…but has recently been used for competitive reimbursement of HCV therapies in the US & Australia…
2015: Australian government negotiated a volume-based risk sharing agreement with several pharmaceutical companies
$1bn (capped) over 5 years unlimited access to DAAs
2019: two states conducted "winner takes all" bidding processes for a single co. to provide unrestricted access to treat Medicaid recipients and prisoners
Washington
abbvie
Louisiana
ASEGUA THERAPEUTICS
Co: Company; DAA: Direct-acting antiviral; HCV: Hepatitis C virus
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…plus also being proposed by NHS England to help secure access to innovative precision CF therapies

NHS England
NICE
ORKAMBI®
VERTEX

Public deadlock

Vertex calls for changes to NICE as CF drug profits soar
February 6, 2019

Campaigners call for NHS access to Orkambi as MP inquiry gets underway

Vertex destroys nearly 8,000 Orkambi packs amid U.K. pricing standoff
Mar 28, 2019 11:29am

Cystic fibrosis scandal: 116 MPs join our battle to end shameful deadlock over vital drugs

Vertex an "extreme outlier" in pricing and behaviour, says NHS England
31st January 2019

Jul 2018: NHS England offer licensing deal

Guaranteed **£1 bn** Over 10 yrs — in return for — **Unlimited access** to Vertex's existing & **future** CF therapies (Symdeko, Orkambi, Kalydeco)

Initially rejected by Vertex (**≈90% discount** per patient)

UPDATE 24 Oct 2019 — NHSE announced a **definitive agreement** with Vertex

CF: Cystic fibrosis; NHS: National Health Service

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Subscription-based pharmaceutical renumeration offers access opportunities but also some significant challenges

Potential benefits	Potential drawbacks
Payers can offer **broad patient access** whilst securing **substantial cost savings**	Only suitable in **certain circumstances**
Cost of goods is often a **small component** of total price – i.e. company **return on investment** may not be compromised	Challenges in **multi-company negotiations**
Predictable budget impact for payers and **long-term 'de-risked' revenue** for co.s	**Existing price regulations** may preclude these being set up – or need a waiver
Incentivise treatment not payers rationing	Replacing **traditional HTA criteria** – opportunity costs? ICER thresholds?
Easier to **set up & manage** vs. other RSAs	**Supply chain management** for companies
	Reverse company incentives - negate sales force impact in driving prescribing

HTA: Health technology assessment; ICER: Incremental cost-effectiveness ratio; RSA: Risk sharing agreement

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We will attempt to discuss the viability, uses, and limitations of the subscription-model for reimbursement

SUBSCRIPTION MODEL FOR REIMBURSEMENT: A FAD OR THE FUTURE?

We will hear perspectives from

UK National HTA	***Local payer & industry***	***Australian national HTA***
Paul Miller	**Diar Fattah**	**Erika Turkstra**

HTA: Health technology assessment

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UK National HTA perspective

Paul Miller, Miller Economics Ltd

Ex-NICE Appraisal Committee member,

Founder & Health Economist, Miller Economics

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What potential does the SUBSCRIPTION MODEL offer HTA/ NHS?

1. Wider definitions of value (more relevant to decision-making)?

2. Wider scope for budgetary management?

3. Price reductions (commensurate with the value assessment)?

4. Flexibility to achieve market access agreement?

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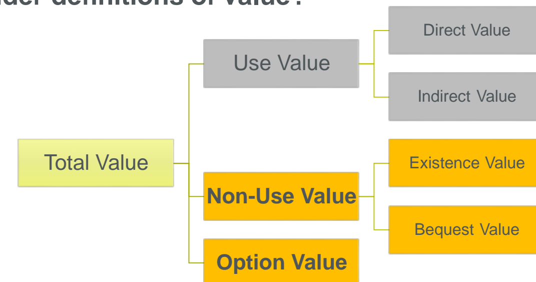
1. Wider definitions of value?



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2. Wider scope for budgetary management?

- Subscription model used as a financially-based contractual agreement: **a fixed fee**
- Directly seeks to manage r.h.s of equation (through explicit agreement)
  - PRICE x VOLUME = **BUDGET IMPACT**
  - More 'flexible'/ vague on l.h.s of equation – still may not be 'fully independent' of volume
- Essentially a type of '**budget cap**' agreement
  - Potential for all the well-rehearsed advantages: smooth, predictable affordability etc.
- **BUT**……How to set the fixed fee?
  - Related to concept of value: cost-effectiveness?
  - Still need estimates of PRICE (even if this varies by VOLUME)
  - Good epidemiology data may be pivotal
  - Competitive tendering for contracts

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3. Price reductions?

- Potential that a subscription model is just a '**bigger deal**'
  - Larger patient coverage
  - Multi-faceted
  - Multi-year
- Leverage **purchasing power** to ensure better 'unit price' is achieved vs. other contractually arrangements
- Scope for 'bundling' portfolio-based contracts
  - Economies of scale?
  - Cross-subsidy of products within a 'bundle'?

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4. Flexibility to achieve market access agreement?

- A subscription model (under the right circumstances) potentially offers a mutually agreeable pricing & market access solution where otherwise this can not be reached:
- Why?
  - Is it addressing a market failure, lack of incentives in given areas based on low volume?
  - Is it offering more certain budget management by agreeing a fixed-fee for a given period?
  - Is it driving down unit price(s) by raising the stakes of the deal?
- Subscription model is not only a 'fad' since much of what it might offer has always been an inherent part of contracts….

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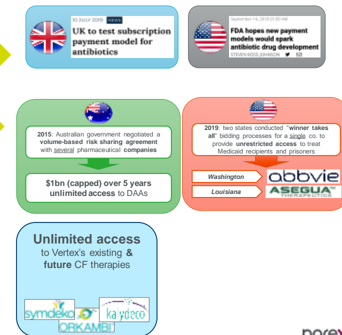
What potential does the SUBSCRIPTION MODEL offer HTA/ NHS?

1. Wider definitions of value (more relevant to decision-making)?
2. Wider scope for budgetary management?
3. Price reductions (commensurate with the value assessment)?
4. Flexibility to achieve market access agreement?



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Key Issues

- Does 'innovative contracting' (such as subscription model) need to be a more explicit part of the HTA value assessment stage rather than the commissioning, implementation and deal-making stage?
  - Where the nature of a contract may materially impact the value of the product…..
- Will there always be a need to demonstrate how any 'innovative contract' (such as subscription model) is better (however defined) than x% discount to the list price?
  - Health systems may inherently prefer simple deals unless alternative is very convincing!

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Industry and Regional payer perspective

Diar Fattah *MPharm MSc*

Innovative Value Strategies and Evidence Global Director (AstraZeneca)

Former – Associate Director of Medicines Optimisation NHS CCG and NICE TA member

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Objectives

1. Industry Perspective
2. Regional Payer Perspective
3. Is it really a win for all?

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Industry

- Promote patient access
- Affordability vs cost effectiveness
- Trend towards multiple indication products being manufactured e.g. Lynparza, Humira.
  - Each indication requires resources for HTA preparation
  - Variation in value between indications
  - Launch sequencing delays = bad for patients!
- Incentivises previously commercial unattractive clinical areas e.g. antibiotics (NHS example)
- Critical to have access to accurate epi data

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Netflix for Antibiotics – NHS/NICE July 2019

- Volume to Value reimbursement
- Upfront payment even if volume not used
- Encourages R+D and manufacturing in previously commercially non-viable areas

News story

Development of new antibiotics encouraged with new pharmaceutical payment system

The NHS will test the world's first 'subscription' style payment model to incentivise pharmaceutical companies to develop new drugs for resistant infections.

Published 9 July 2019
From: Department of Health and Social Care

Health Secretary Matt Hancock "Today we are **sending a strong signal to the rest of the world** that there are **workable models** to stimulate investment in these vital medicines"

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Regional/National Payer

- Incentive to treat more patients but what about medical care costs e.g. hospital time?
- High budget impact – need to prepare to fulfil contract length
- Slow uptake of disruptive technology if "locked" into long term contract
- If long term outcomes not realised – poor investment but already tied into contract
- How does accounting/finance deal with this?
  - Will national subtract a set % from all regional budgets?
  - Will regions with higher prevalence pay more from their budget?

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Regional/National Payer Considerations

- Various issues depending on clinical area

1. Rare diseases:
   a) Epidemiology data inaccuracy
   b) Data uncertainty
   c) High costs
   d) Mixed with value guarantees

Small errors in assumptions can lead to large risk realisation

2. Non rare:
   a) Budget impact
   b) Tender exercises
   c) Tracking of finance

Work closely with national bodies to share patient data and to improve diagnosis rates

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Can everyone win?

Drug X for treatment of Isporitis costs $30,000 per patient.

	Current Method	Netflix
Per patient cost	$30,000	N/A
Population cost	Year 1: $760m Year 10: $60m	$350m/year
# patients in 10 years	140k	260k
# patients cured by Y2	45k	144k
# of deaths @ Y10	22k	7k
10Y System Cost	$4.5bn	$1.3bn
10Y Pharm Revenue	$3.25bn	$3.55bn

Continuous rebate negotiations **avoided**

Payer gatekeeping exercises **avoided**

More patients treated and quicker

Reduced burden on system so reduced cost

Increased Pharma revenue

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Australian experience: HCV subscription model

Erika Turkstra,

Senior Consultant, Parexel

Former Associate Professor at Griffith University, Australia, involved in reviews of PBAC submissions

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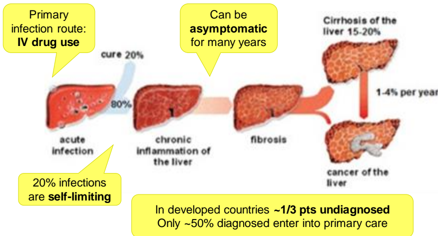
Hepatitis C is the most common cause that can lead to liver cirrhosis and transplantation

Hepatitis C is a type of liver inflammation caused by a virus
Chronic infection with the virus may lead to severe health complications, including irreversible scarring on the liver (cirrhosis) and cancer of the liver



Primary infection route: **IV drug use**

Can be **asymptomatic** for many years

20% infections are **self-limiting**

In developed countries **~1/3 pts undiagnosed**
Only ~50% diagnosed enter into primary care

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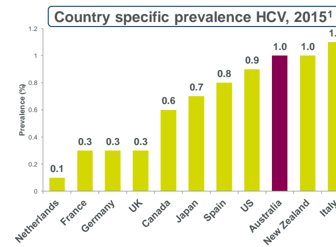
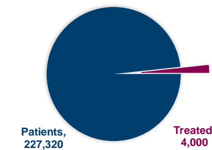
In 2015, Australia had a high prevalence of HCV, with few patients treated before DAAs came available

Country specific prevalence HCV, 2015[1]



HCV prevalence in Australia in 2015 with only 2% of population treated [2,3]



[1]Blach, S, et al. "Global prevalence and genotype distribution of hepatitis C virus infection in 2015: a modelling study." *The Lancet Gastroenterology & Hepatology* 2.3 (2017): 161-176.
[2] The Kirby Institute. (2016). Hepatitis B and C in Australia Annual Surveillance Report. Supplement. [3] Drug utilization sub-committee (DUSC) Direct acting antiviral medicines for the treatment of chronic hepatitis C, September 2018
DAA: Direct-acting antiviral; HCV: Hepatitis C virus;

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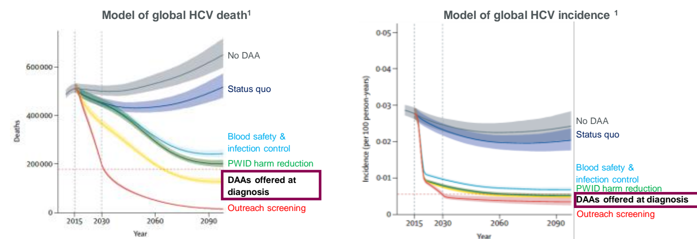
Modelling indicates that DAAs offered at diagnosis may be very effective in reducing HCV disease burden



- Heffernan (2019) developed a model to predict the HCV epidemic in each of 190 countries and analysed the impact of six interventions

[1]Heffernan, Alastair, et al. "Scaling up prevention and treatment towards the elimination of hepatitis C: a global mathematical model." *The Lancet* 393.10178 (2019): 1319-1329.

DAA: Direct-acting antiviral; HCV: Hepatitis C virus; PWID: People who inject drugs; WHO: World Health Organisation

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The Australian government came with a unique scheme to address the HCV burden in Australia…

THE HON SUSSAN LEY MP
MINISTER FOR HEALTH
MINISTER FOR AGED CARE
MINISTER FOR SPORT

MEDIA RELEASE

20 December 2015

TURNBULL GOVT INVESTS OVER $1B TO CURE HEP C

The Turnbull Government will invest more-than $1 billion to give all Australians with Hepatitis C access to breakthrough cures that could all but eradicate the deadly and debilitating disease within a generation.

In a "watershed moment" in Australian history, Minister for Health Sussan Ley today announced Australia would become one of the first in the world to publicly subsidise these cures – currently costing patients up to $100,000 – for the nation's entire population of Hep C sufferers, no matter what their condition or how they contracted it.

Pharma initially involved: GILEAD, Bristol-Myers Squibb

Subsequent joiners: abbvie, MERCK

- Australia became the first in the world to publicly subsidise HCV treatment (DAAs) with a **capped cost of over AU $1bn over 5 years**
- Treatment is available to **all patients diagnosed with HCV**, within TGA indication
- Treatment can be provided by **various healthcare providers** (e.g. GPs)
- Estimated number of patients treated 61,500 for a price per patient of **AU$16,260**
- **Guaranteed revenue for pharma over 5 years** (no details on how money distributed to pharma)

DAA: Direct-acting antiviral; HCV: Hepatitis C

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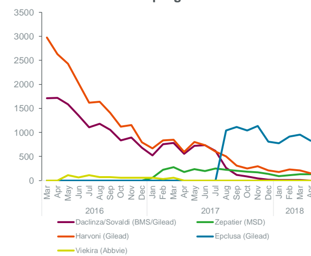
… which has resulted in high initial uptake of DAAs …

- In the first 26 months 58,941 patients received treatment (~26% of HCV patients)
- After high uptake when the program started (mainly severe patients), uptake has reduced
- Prescribing has moved from specialists to GPs over time, which may indicate early access
- Initially, Harvoni (Gilead) and Daclinza/Sovaldi (BMS/Gilead) had the largest market share, moving to Epclusa (Gilead) mid-2017

Number of patients initiating treatment per month since start of program in March 2016



[1] Drug utilization sub-committee (DUSC) Direct acting antiviral medicines for the treatment of chronic hepatitis C, September 2018

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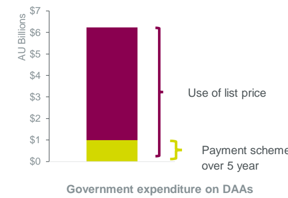
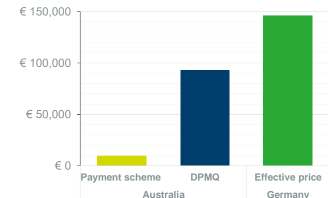
… and substantial savings for the government, and lower treatment cost than using discounting in Germany

Subscription model has resulted in substantial reductions in government cost (March 2016-April 2018)



12-weeks Harvoni treatment per patient is substantially lower using Australian payment scheme than German ex-manufacturer price



1 Drug utilization sub-committee (DUSC) Direct acting antiviral medicines for the treatment of chronic hepatitis C, September 2018
Payment scheme, based on assuming that 61,500 patients would receive treatment over 5 year, Public summary document — March 2015 PBAC meeting: Sofosbuvir 400 mg, tablet; Sovaldi
DPMQ: Dispensed price maximum quantity, equates to list price; 28 tablets multiplied by 12, currency exchange 8th October 2019; PBS.gov.au
German effective price is the APU/HAP (Herstellerabgabepreis) Lauer-Taxe 8th October 2019, multiplied by 12 to estimate total treatment cost

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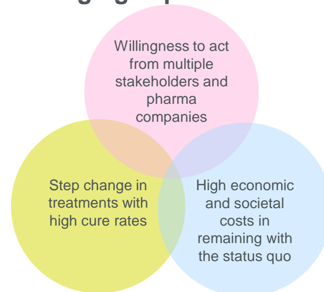
The Australian subscription model has effectively expanded access to HCV whilst managing expenditure

- This example in Australia demonstrates that this new subscription model can **work in certain circumstances**
- Requires **synergy with other initiatives** to maximise benefits
  - The uptake has **slowed down after the first year**, which may indicate that hard-to reach populations may not be reached without further efforts
- Of note, **all pharma companies have opted into the scheme**



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Panel discussion and Q&A

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Thank you

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