‘Terminal Sedation’
The Rights and Wrongs…?

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Sept 2018
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Jobbing Consultant
Not Philosopher, Lawyer...

• Princess Alice Hospice, Esher, 1995 -
  – Medical Director, clinical ethics committee
• University of Surrey, Guildford, 2012 -
  – Visiting Reader, ex-ethics committee

• Association for Palliative Medicine
  – Ethics Committee, 2009 - 2018
• Royal College of Physicians
  – SCE QWG, Exam Board 2010 - 2016, SSG, 2016 -

• Publications / teaching
  – Ethics BMJ, JME, IJPN, CE, NE
  – Ethics MSc University of Surrey, MA St Mary’s University
The **Place** of ‘Terminal Sedation’

To sedate, or not to sedate... that is the question...?

Benedict Cumberbatch as Hamlet, Skull as Yorick, 2015
Plan
Terminal / Palliative Sedation

• Background ‘sedation’ in palliative care / terminal care
  – Systematic review, literature since 2015
  – 106 papers, Apr 2018

• Clarification
  – Symptom control
  – Sedation
  – [Assisted suicide]

• Ethics / good practice…?
  – Rights
  – Wrongs
Hands Up Time Already…!

- **How many** people have ever seen ‘terminal sedation’ used in clinical practice…?
Okay Now…?

- How many people have ever seen ‘terminal sedation’ used in clinical practice…?
- How many people would be comfy writing in notes:
- Plan: “please start terminal sedation”
Terminal Sedation *is...*

Challenging

Yikes...!
Terminal Sedation *Should* Be… Challenging

Whatever...?!
Terminal Sedation: Ethical Challenges

- **Lack of consensus on rights / wrongs**
  - In general
  - Individual cases

- **Polarised stances:**
  - **No** — *never*, crosses a *moral* line
  - **Possibly** — *sometimes*; only if defined *preconditions*
  - **Yes** — *whenever*, ‘a must’... *on demand*
Terminal Sedation: Ethical Challenges

- **Diverse stakeholders / perspectives**
  - Patients
  - Family
  - HCP – personal / team
  - Clinical – evidence base
  - Organisation
  - Professional requirements
  - Legal boundaries
  - Public and media image
Terminal Sedation Decisions…

Wider Ethical Issues

• Stakeholders
  – Who benefits from sedation…?

• Power
  – Who decides to sedate…?

• Proportionality
  – How much / when start sedation…?

• Morality
  – If we do it / say it’s right, does that make it right…?
Terminal Sedation Decisions…
Wider Ethical Issues

• Consequences
  – Does sedation *shorten life*…?
  – Ramifications if no *food* / *fluid*…?

• Justice…
  – Is sedating *cheaper*…?
  – Less training, is sedation *easier*…?
Terminal Sedation: Clinical Challenges

- Lack of clinical clarity… we don’t mean same thing…!
  - Inconsistent terminology
  - Diverse interventions
  - Different clinical / medico-legal settings
  - Evidence base lacking
Terminal Sedation: Clinical Challenges

• **Compounded** at bedside:
  
  – Distressing scenarios – **emotive**
  – Clinically **complex** decisions
  – **Uncertainty** leads to ‘**different**’ practices
  – Doubts / **discord** across MPT… spreads to patient / family
Any Treatment Comes with Risks Including Terminal Sedation…

- **Fatal** consequences
  - Not just theoretical risks
  - More in non-expert hands
  - Mustn’t overlook at bedside

- **Media** coverage…
  - National level
  - Acute Trusts
  - Community Trusts
Media Concern that End-of-Life Patients ‘Heavily Sedated’

- **UK**, 2009… brewing
- **1 in 6 died** as **continuous deep sedation**
  
  » Telegraph, Sept 2009
Media Concern that End-of-Life Patients ‘Heavily Sedated’

• **UK**, 2012
• Full **LCP** media storm
  » Daily Mail, June / Nov 2012

• **BUT**…
• Unclear if / when this was *perceived* or *actual* sedation…?
• And then, unclear if / when was *good* or *bad* practice…?
Damning Public Reports: Poor Practices re Sedation at EoLC

Neuberger Review, 2013

Francis Report, 2013
>450 Hospital Deaths
...Inappropriate Drugs / Doses

- >450 died after being given drugs inappropriately
  - Misuse of diamorphine
  - Dangerous ranges without ‘clinical indication’ (20-200mg/24h)
  - Compounded dangerous range Midazolam (20-200mg/24h)
    » Report of the Gosport Independent Panel, 2018

- Dr Jane Barton, Gosport War Memorial Hospital, 1988-2000
  - Husband: she was “doctor doing the best for her patients”
    » https://www.bbc.co.uk/news/uk-england-hampshire-44628013

Dr Jane Barton and her husband
We Need a Shared Definition of Sedation…

- ‘We need to sedate the patient in room 18’
We Need a Shared Definition of Sedation…

• ‘We need to sedate the patient in room 18’

• What does ‘sedate’ in hospice corridor mean…?
Formal Definitions of Sedation

• Sedation = noun, Medicine/Medical
  – 1. the **calming** of mental **excitement** or **abatement** of physiological function, especially by administration of a drug
  – 2. the state so induced
    » Dictionary.com, 2018

• The **reduction of irritability or agitation** by administration of sedative drugs, generally **to facilitate** a medical **procedure** or diagnostic **procedure**
  » Wikipedia, 2018
Formal Definitions are Not Helpful Enough…

- **Reassuring** dictionary definitions
  - Reduce physiological **over-activity** to **normal**
  - **Transient +/-** to cover intervention

- **Misses** nuances / **complexity** of EoLC interventions
  - Intention… what next…?
  - Degrees

- **Don’t** reflect **everyday use** of term…
  - Professionals
  - Public
Must be More than ‘Abatement of Physiological Function’…!

- Technically…
  - All drugs…?
  - B-blocker in hypertension is ‘sedation’…!

- Possibly…
  - Non-sedating but sedation is side effect
  - Opioids, anti-emetics etc…?

- Yet, implicitly…
  - Flattening patients
  - Night sedation, general anaesthetic etc…?
Everyday Understanding is Being ‘Knocked Out’

- Ethical / clinical **conflicts** in hospice
  - Some patients / families / HCPs **want full** sedation
  - Others **fear** sedation just as much...

Amir Khan “brutally knocked out” in sixth round by Saul Alvarez, Las Vegas, 2016
**Increasingly Less Ambiguity around the Aim in Literature...!**

- THEN... ‘**Palliative Sedation**’ ‘preferred term’ since
  - Sedative medicines relieve intolerable / refractory distress
  - **Reduction** patient **consciousness**
    » Morita et al, Systematic Review, JPSM, 2002
    » De Graeff & Dean, EAPC Consensus, J of Pall Med, 2007

- NOW... ‘**Palliative Sedation**’
  - Administering sedating agents *induce* unconsciousness
  - **Take away** dying patient's **perception** persisting symptoms

- INCLUDES... **Continuous Deep Sedation**
  - Continuously and deeply sedated or **kept in coma until death** by use of one or more drugs
Little Ambiguity around Aim in 2018 Literature...!

• THEN... ‘Palliative Sedation’ ‘preferred term’ since
  – Sedative medicines relieve intolerable / refractory distress
  – Reduction patient consciousness
    » Morita et al, Systematic Review, JPSM, 2002
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Palliative Sedation 2018: Induce coma...
• NOT symptom relief
• NOT targeted
• NOT proportional
In >25 Years, Literature **Unclear**: Still Hasn’t Clarified ‘**Practice**’

- Palliative sedation appeared in literature from **1990**
  - Henry, CO in SPC, 2016

- But **still** ill-defined… relatively meaningless:
  - Only a **concept**; clinically ‘**not a thing**’ in practice…!
  - **Unclear**; why, what, when, who…?

- Several **different** terms / definitions exist

- Marked **inconsistencies** in **what done** and to **whom**
  - Morita et al, JPSM, 2017
In >25 Years, Literature Unclear: Still Hasn’t Clarified ‘Need’

- Terminal / palliative **sedation** is…

- …**standard practice** for refractory symptoms at end-of-life
  » Bobb, Nurs Clin NA, 2016

- …**widely-used** intervention

- …**uncommon**
  » Bodnar, J Pain & Pall Care Pharm, 2017

- …**only rarely** be necessary
  » Twycross, Evid Base Nurs, 2017
In >25 Years, Literature Unclear: As Muddled Different Actions...

- **Terminal / Palliative Sedation** literature unhelpfully combines **good** and **dubious** practices…!

- **Symptom control**, *drugs because of deterioration*  
  - Normal practice, but in increasingly sleepy end-of-life patients

- **Sedation**, *drugs because of deterioration*  
  - Normal practice, but for crises in end-of-life patients

- **Palliative sedation**, *deterioration because of drugs*  
  - Abnormal, changed practice / changed decision making
Reassurances UK SPC, Even if Labelled ‘Palliative Sedation’

• [1] Same symptom control across illness trajectory
  – Individualised assessment
  – Complex decision-making
  – Normal drugs, doses, titration… including last 24-48h

• [2] Same sedation as across any area of healthcare
  – Short-term – specific event / intervention
  – Proportional – light / deep
  – Normal, but not symptom control

• NO change in practice
• NO change in underpinning ethics
My Perspective on Palliative Sedation

• A view…
George Orwell, Outside BBC

"If liberty means anything at all, it means the right to tell people what they do not want to hear."
Palliative Sedation …is Unethical

- The ‘practice’ is unethical
- The ‘term’ is unethical

Sitting on the fence isn’t an option for me!
Palliative Sedation is Wrong on Many Levels

• Fuels misunderstandings
• Fosters misuse
• Allows abuse
If ‘Palliative Sedation’ replaces symptom control

Acceptance symptom control causes ‘sedation’ at EoL

Sedative doses better symptom relief than normal doses

Sedative drugs better symptom relief than targeted drugs

Sedation is a ‘good’

Sedation doesn’t shorten lives

Sedation is evidence-based
If ‘Palliative Sedation’ replaces symptom control

Acceptance symptom control causes ‘sedation’ at EoL
Sedative doses better symptom relief than normal doses
Sedative drugs better symptom relief than targeted drugs
Sedation is a ‘good’
Sedation doesn’t shorten lives
Sedation is evidence-based

[1] Fuels Misunderstandings
Always Symptom Control: Normal Practice / Values

- All medication in palliative care, including sedative medication, is aimed at relief of specific symptoms
  - APM Position Statement
  - Clinical Medicine, 2010
No *Special* Rules are Allowed or Needed for Sedation in EoLC

Our powers made us special

Everyone’s special, Dash

Pixar, 2004 / 2018

One’s rights do not increase or fade, or the need for clinical rigor increase or lessen as death approaches
No ‘Special Case’ Needed for ‘Sedation’ in EoLC

- **No clinical need** to sedate to control symptoms
  - ‘Sophisticated symptom relief’
  - Established ‘best practice’

- **Symptom control controls symptoms**…!
  - Adequate last 6 months, 6 weeks, why not last 6 days…?
  - What changes… to mean drugs don’t work as did… but then a little bit more would work just fine…?!
Don’t Change Terminology 
Just at the Very End of Life…!

• [1] Adding Terminal / Palliative Sedation **not necessary**
  – i) Symptom control and ii) Sedation cover it…!
  – Convention not justification when no help
  – ‘Invented’ to quell misplaced worries with symptom control
Don’t Change Terminology Just at the Very End of Life…!

- [2] Terminal / Palliative Sedation clinically incorrect
  - Symptom control wasn’t ‘sedation’ before (…inconsequential)
  - Drug-induced drowsiness never wanted
  - Drugs aren’t /shouldn’t be a terminal intervention
  - Contradicts: sedation alternative cannot control symptoms
  - Oxymoron, lack of awareness is not control of symptom
Don’t Change Terminology Just at the Very End of Life…!

- [3] Terminal / Palliative Sedation causes fears / risks
  - Pre-palliative care era over-sedation… ‘to death’
  - Reinforces misplaced fear symptom control drugs sedative
  - Avoidable fears unnecessarily doped / sedating everyone
  - ‘Sedation’ particularly dangerous, validating, ‘chemical cosh’
    » Willis, Gannon, Harlow, Baker & George, Pall Med, 2014
Don’t Change Terminology Just at the Very End of Life…!

• [4] Terms Terminal / Palliative Sedation Causes harm
  – Reduces symptom control
  – Dying patients denied relief as legal fears
  – 12% restricted medication feared prosecution
    » 2,311 online survey; Lomas, Nursing Times, 2010
  
  – Care worse with each media storm, LCP / Gosport
  – Over-medicalise
    • More IV fluids unnecessarily
  – Less symptom control of agitation / pain
    • Patients / families refusing syringe pumps
    • GPs refusing to prescribe anticipatory EoLC drugs
Words Convey Meaning
Sadly the Wrong Meaning…!

• **Value-laden definitions made** to **support preconceptions**
  – Problematic that **non-neutral** / normative criteria ;
    • Indicative of **own beliefs** / normative position on CDS
  – Make it **difficult / impossible** to agree on **facts** of sedation
    • Leads to disguised circular or tautological statements

• **This language** re Palliative Sedation **impacts on reality**
• **Causes confusion / abuse**
  » Cohen-Almagor & Ely, bmjspc, 2018
Not ‘Sedation’ But Drugs As Needed, Just As Before…

...has anyone mentioned that your mum is likely to get increasingly sleepy as a result of her disease - she’ll need the same sorts of medications as now, which will not noticeably impact on this sleepiness...?
Arguably, *Ongoing* Sedation is Never Desirable in Healthcare…!

- **Consciousness** is the central fact to human existence, but its existence in another can never be known, only inferred
  
  » RCP, 2013
Consciousness defines us as persons
- It allows us to have both pleasurable & painful experiences
  » Glannon, CQHE, 2016

Ongoing Sedation is Never an End in Itself, Never a ‘Good’…!

Sanitized: all nice Hospice Rose-Tinted Glasses

Death is hard The ‘Real World’ Warts and All

Expectation
Ongoing Sedation: Never a ‘Good’ But Can be Acceptable…!

- Consciousness defines us as persons
- It allows us to have both pleasurable & painful experiences
  » Giannon, CQHE, 2016

Iatrogenic lowering of consciousness may be unavoidable, may be necessary, may be common, but this doesn’t make it desirable

Sanitized; all nice
Hospice Rose-Tinted Glasses

Death is hard
The ‘Real World’ Warts and All
Ongoing Sedation Never a ‘Good’ … Though Can be a Means…

- **Denies** opportunities
  - Lose potential for ‘lucid windows’

- Sedation is a **means not an end**… not a good in itself…
  - No net gain in health / well being
  - Autonomy is lost from that point
    » Willis, Gannon, Harlow, Baker & George, Pall Med, 2014

- Consequence of repeating ‘sedation’ misunderstandings
- Well-meaning double whammy:
  - Fosters excessive doses
    - Augmented symptom control
  - And / or fixed sedative medications
    - Sedation

- Consequence of repeating ‘sedation’ misunderstandings

- Well-meaning double whammy:
  - Fosters excessive doses
    - Augmented symptom control

- And/or fixed sedative medications
  - Sedation
Accepting ‘Palliative Sedation’ Fosters Misuse of Drugs

- **Wrong drugs**
  - *Reduced* relief, if don’t hit cause of symptom

- **Excessive doses**
  - *Increased* toxicity… no more gain, just more harm

- **Illogical** – how is this ever a good idea…?
  - *Right* drugs – individually targeted
  - *Right* doses – individually titrated

  - Getting it *right* is *best*…!
Collective Ignorance: Difficult to Shift Cultural Norms

How can you fight stupidity effectively? The answer is simple: it's not easy.

— William C. Brown

American electrical engineer, pioneer in 1950s and 1960s
Spiral: the **Misuse of Drugs** Fosters the **Misuse of Drugs**

- **Inevitable**
  - Endorsing 'sedative doses’ leads to more ‘sedation’

- **HCPs presume ‘higher doses’ needed**
  - Drug-induced drowsiness *expected*
  - *Corroborated* as drowsiness *seen* (disease not drugs)
  - Drowsiness is then *desired*; well meaning
  - Supports ‘*higher-than-needed*’ doses – *more toxic*
  - Sedative drugs *not targeted* drugs – *less symptom control*

- **Over-prescribing used **justify** over-prescribing…!**
By Accepting ‘Palliative Sedation’ We Foster Misuse

• **No sense** in a cocktail of *above-therapeutic* doses of *non-indicated* drugs
  – As if suddenly a “better” option for comfort…?!?
  – *Why didn’t we do that earlier…?!*

• **Opposite** at very end of life…?
  – Drugs do not start to work differently, to become more effective / less toxic…!
  – If anything, *risks higher* and chance of *benefit less*…!
Continuous deep sedation until death (CDS) – scary…!

Thus proposed conceptual frameworks:

- **Gradual** CDS from proportional sedation
- **Rapid** CDS to rapidly induce unconsciousness
- And specific patients' general condition
  - Morita et al, JPSM, 2017

- **Augmented symptom control** (sedation just *not intended*)
- Continuous deep sedation (sedation *intended*)
  - Kettemann et al, ALS & FD, 2017
Yet We Already Know What to Do: Get Basics Right…

- Preparation
  - Know your stuff / that patient scenario
- Assessment
  - Impeccable / comprehensive
- Problem-solving
  - Establish diagnosis
  - Realistic expectations
- Interventions
  - Targeted, proportional, rational
  - Reverse reversible / palliate irreversible
- Follow-up
  - Titrate up / down stop
  - According to response / toxicities

I know it’s not ‘point and shoot’
Terminal Restlessness …is NOT a Diagnosis

- Terminal is ‘presumptive’
- Constellation of signs +/- symptoms
- Multiple causes

….determining which disease or condition explains a person's symptoms and signs

Catherine King, 2008 "Restless II"
“Impeccable Assessment”
It All Starts With a Diagnosis…!

- Pain [opioid-responsive]
- Pain [non-opioid-responsive]
- Anxiety
- Cerebral irritation
- Existential distress
- Dyspnoea
- Delirium [drug-induced]
- Delirium [sepsis]
- Delirium [biochemical]
- Dementia
- Mixed
“Impeccable Assessment”
It All Starts With a Diagnosis…!

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Not “distressed”
Not “not comfy”
Not “restless”
Need an Evidence-Based or at Least Logical Treatment…!

- Pain [opioid-responsive]
- Pain [non-opioid-responsive]
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- Titrate opioids while responds
  - **Avoid** opioids
  - Titrate anxiolytics
  - Titrate anti-epileptics
  - ? Anxiolytics
  - ? Cautious titrate opioids
  - **Reduce** sedative drugs
  - **Avoid** sedative drugs
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NOT... As Dying, Give Random Anything, till Patients Look Flat...!

Priority = symptom control

- Pain [opioid-responsive]
- Pain [non-opioid-responsive]
- Anxiety
- Cerebral irritation
- Existential distress
- Dyspnoea
- Delirium [drug-induced]
- Delirium [biochemical]
- Delirium [sepsis, other]
- Dementia
- Mixed

Priority = not sedate

- Titrate opioids while responds
- Avoid opioids
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- Titrate anti-epileptics
- ? Anxiolytics
- ? Cautious titrate opioids
- Reduce sedative drugs
- Avoid sedative drugs
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“Avoid Sedative Drugs”
But That May Be Inadequate…!
Vagueness of Palliative Sedation Allows an Uncritical Approach

- If want it over quicker,
  - Different debate…PAS / euthanasia…

- If want to reduce delirium
  - Not opioids, not midazolam, cautious antipsychotic
  - What about fluids, even dialysis…?!

- If want to remove awareness
  - Not opioids, possibly midazolam and antipsychotic
  - What about Propofol / general anaesthetic…?!

- We could do more… but convention means we don’t…?
  - Accept priority is sign control…
  - Make patient look better…!
Vagueness of Palliative Sedation Fuels Irrational Use of Drugs

• If want it over quicker,
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Not ‘wrong’, just about being a bit more honest
Terminal Restlessness: Important to Not Fan the Flames

More drugs doesn't mean better, ...in fact, predictably worse...
Repeating ‘Ineffective’ Doses Cannot Work Any Better

Predictably less effective and longer to get to steady state
No ‘Special Case’ as ‘Dying’: Still Cannot Justify Excess

- **Nonsense**; normal approach to drug toxicities
  - *Toxicity is toxic…* still reduces health / well-being

  - ‘Definite downside’ of sedation is profound drug-induced delirium ‘suffering... torturous’
    - Cohen-Almagor & Ely, bmjspc, 2018

- **Likely** outcome is ‘so toxic’ create hypoactive delirium
  - Reassures who…?
  - Though ‘looks better’…!
No ‘Special Case’ as ‘Dying’: Still Cannot Justify Excess

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**Benefit** for family and staff…? Not ‘wrong’, just be aware of who we are helping and of risks...
‘The Last Dose Didn’t Work…
I Know, Let’s Give Some More…!’
‘The Last Dose Didn’t Work… I Know, Let’s Give Some More…!’

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Haematologist</th>
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<tbody>
<tr>
<td>More chemotherapy</td>
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<tr>
<td>Emotive setting</td>
<td>Advanced cancer</td>
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<tr>
<td>Scenario</td>
<td>Deterioration despite EBM chemotherapy</td>
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<tr>
<td>Chance benefit</td>
<td>None: resistant</td>
</tr>
<tr>
<td>Chance harm</td>
<td>High: increase deterioration</td>
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<tr>
<td>Intention</td>
<td>Well-meaning</td>
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<tr>
<td>Reasoning</td>
<td>More must be better, <em>how say ‘no’…?</em></td>
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<tr>
<td>HCP Understanding</td>
<td>Denial / ignorance</td>
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<tr>
<td>Patient / Outcome</td>
<td>Less well</td>
</tr>
<tr>
<td>Palliative Care View</td>
<td>Unacceptable</td>
</tr>
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Warning Shot…
People in Glass Houses…

San Diego, California
<table>
<thead>
<tr>
<th>Intervention</th>
<th>Haematologist</th>
<th>Hospice Staff</th>
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<tbody>
<tr>
<td></td>
<td>More chemotherapy</td>
<td>More morphine</td>
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<tr>
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<td>Scenario</td>
<td>Deterioration despite EBM chemotherapy</td>
<td>Restlessness, despite EBM morphine</td>
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<td>Unacceptable</td>
<td>Standard Practice</td>
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</tbody>
</table>
Sedation is So Emotive / Risky: We Need More Robust Data…?

Even at the end of life…?

Yes, still 'being bothered' is the whole point…!
After >25 Years, Any **Benefit** from Palliative Sedation is **NOT** Clear

- However, remains *questionable* whether:
  - [1] *ethically complex* intervention is
  - [2] *beneficial* for patients

Palliative Sedation is…
Still Ethically Controversial

• Continuous deep sedation until death
  – Highly debated, particularly potential to hasten death
  – Subject of intensive debate concern may hasten death
    » Henry, CO in SPC, 2016
  – Focus of intense debate
    » Morita et al, JPSM, 2017
Palliative Sedation is… Still Clinically Unproven

- **Not** evidence-based
  - **Not** direct research / **not** extrapolation existing knowledge

- Guidance **outdated, non-specific** / **not comprehensive**
- Evidence- and **experience**-based references
- Patient goals in hospital and hospice environments are **different**, use of sedatives can **differ** greatly as well
  - Bodnar, J Pain & Pall Care Pharm, 2017

- Need **evidence-informed** practice guidelines, education, and research on palliative sedation at the end of life
  - Henry, CO in SPC, 2016
Evidence **Inadequate to Use Palliative Sedation**

- **Insufficient** evidence of **benefit**
  - For any efficacy of palliative sedation
  - In quality of life or symptom control
    - Possible partial impact for delirium or breathlessness
    - No hint of difference for other symptoms
- **Insufficient** evidence of **no harm**
  - Under-reporting side effects, thus no major problems…!
  - Weak data did not hasten death - wrongly cited limited use
- **Need studies** to look at quality of life at EoL
  - Compare sedated people vs. non-sedated people
  - Check distressing symptoms, peacefulness and comfort
Evidence of Harm
Can’t Use ‘Blanket’ Sedatives

- **RCT** risperidone, haloperidol, or placebo for delirium
  - Efficacy antipsychotics not established against placebo in palliative care
  - N = 247, intention-to-treat analysis

  - Individualized **supportive care** of delirium reduced **severity** and **duration** of distressing **symptoms** compared to adding risperidone or haloperidol

  - Non-significant **survival disadvantage** with **haloperidol**
    » Agar et al, JAMA Intern Med, 2017
Evidence of Harm
Can’t Use ‘Blanket’ Sedatives

• Highest level, though inevitably some limitations
  – 1 trial – one standardized, 3-day regime
  – Cancer only
  – Oral solution i.e. excluded participants unable to swallow
  – Mild-to-moderate delirium baseline i.e. not severe delirium
  – Irreversible and reversible causes combined

  – Not matched – haloperidol arm had more opioid toxicity risks thus adding drugs likely to be counterproductive
Association is **NOT** Causation…
Our Experience **Misleads Us**

**Terminal Restlessness:**
Delirium, Dying and Drugs…

Timeline, hours / days / weeks

Level of Agitation / Distress
Sadly No Credit: Even if Looks Better…?
Drugs Precipitate the Need for ‘Continuous Deep Sedation’…!

- Compounding error, further over-treatment **irrational**
  - Causes toxicity; *drugs* worsen distress – **vicious cycle**
  - *Opioids* on admission **highly significant association** with receiving *sedation*
    - *Opioids* \((p < 0.001)\) / antipsychotics \((p = 0.003)\)
      » van Deijck et al, JPSM 2016a
  - >65 years, **less opioid** and **less need** for palliative sedation
    » Mercadante et al, Supp Care Cancer, 2016
  - **More** of drug to treat *S/E* of *same* drugs…?!
Fortunately No Blame: Even if a Bit Worse…?

Terminal Restlessness: Delirium, Dying and Drugs...

Level of Agitation / Distress

Timeline, hours / days / weeks

Panic...

Drugs

Drugs

Relief...!
Though **Logic** Goes Out Window: “Just Give **More**”...!

If drug appears to work... **CAN** then **give more**...

If drug doesn’t appear to work... **MUST** give more...

Terminal Restlessness: Delirium, Dying and Drugs...
Yes, we need to be seen to be doing something…
We don’t like ‘discomfort’, so pretend ‘sedation’ is a good
But never forget to check… ‘have we gone too far?’
Collective Ignorance is Not Evidence-Based Practice…!

- We don’t know what to do, so let’s look at what we do and make a guideline…!
  - Sedation used increasingly, expert opinion / case series
  - Little known about actual practice
  - Study of practice will inform nation-wide guidelines for palliative sedation in Austria
    » Schur et al, BMC Pall Care, 2016

- Bad old days: why are we missing out key steps:
  - Literature review; evidence-based guidelines…!
  - Research; emotive, presumptive, convenient etc…?
  - Common-sense; extrapolation of existing knowledge…?
Palliative Sedation

...‘Don’t Ask Questions’...?

• Frequent ethical and emotional dilemmas occurred when administering palliative sedation
• Causes general discomfort for nurses
• Nurses need to be confident, competent and supported in palliative sedation

» De Vries & Plaskota, Pall & Supp Care, 2017
Palliative Sedation

...‘MUST Ask Questions’…!

- Frequent ethical and emotional dilemmas occurred when administering palliative sedation
- Causes general discomfort for nurses
- Nurses need to be confident, competent and supported in palliative sedation

De Vries & Plaskota, Pall & Supp Care, 2017

NO...! Always difficult balance
Must not lose moral tension
Dangers of Sedation
Lure of a Simple Solution…!

Very Easy
Reassurances of single answer / guideline, anyone can do it

High Quality
Uncertainties of complex individual decision-making, needing skilled staff
‘Practical Guidance…
…Sedation at End of Life’

- APM refused to support in 2010
  - 'When, how and why?'
  - …But not the ‘if’ or ‘risks’
Global Consultation for PCF3
No Outcry, Yet Ditched in 2007

Sedation Monograph, palliativedrugs.com, 2007
- **Over-simplified** route straight to *coma* for a refractory symptom
- Only 1 *complaint* worldwide…
Global Consultation for PCF3
No Outcry, Yet Ditched in 2007

Sedation Monograph, palliativedrugs.com, 2007
- **Over-simplified** route straight to coma for a refractory symptom
- Only 1 complaint worldwide…
Different Version Out in 2012
No Mention of Sedation / Coma...!

Figure 13.2 Drug treatment used at some centres for irreversible agitated delirium or intolerable distress in the imminently dying.

PCF4, 2012
2007 Version Back in 2015, Is this Commercialism…?

Figure 1 Progressive and proportionate treatment for an intolerable refractory symptom in imminently dying patient.
Palliative Sedation = **Coma**...!

**Figure 1** Progressive and proportionate treatment for an intolerable refractory symptom in imminently dying patient.
PCF6: Ping-Pong in 2017: Back to 2012 Version…!

Figure 1. Drug treatment used at some centres for irreversible agitated delirium or intolerable distress in the imminently dying.

PCF6, 2017
Big Concern: Cannot Balance Literature

• **Misleading** acceptability / consistency
  – Diverse term: contrasting interventions **collated**
  – **One-sided;** cannot publish ‘not doing it’ differently…!
  – **Cannot search** without 'key term'… trying…!
    » Willis, Gannon, Harlow, Baker & George, Pall Med, 2014
Alternative Views Exist…!

- Another perspective…

Rey and Kylo Ren, Star Wars: The Last Jedi, 2017
Consciousness Can Be Seen as Harmful in Some Situations

- **Intraoperative** awareness
- Prolonged disorders of consciousness / locked-in
- Effects of opioids / sedation on terminally ill

- **Ethical significance** of consciousness depends:
  - Content of one’s experience
  - Whether one can report this content to others

- **Disvalue** when one wants or expects to be unconscious
  » Glannon, CQHE, 2016
Potential Disadvantages if DON’T Sedate at EoL…?

• Distressing symptoms may be worse
  – Unnecessary emotional / physical suffering

• Impact of witnessing distress
  – Bereavement issues – family
  – Staff distress

• Increased workload for organisations
  – Need 1-to-1 nursing care
  – 24/7 expertise / specialist palliative care
Strong Case for ‘Palliative Sedation’
Strong Case for ‘Palliative Sedation’

• 42-year-old married, mother of two
  – ‘Concealed’ advanced breast cancer
  – End-stage, but brave façade

• Deteriorated very rapidly
  – Admitted to hospital

• Dying, distressed, twitching, unresponsive
  – No reversible pathology identified
Terminal Restlessness

• Impression – 'terminal restlessness'
  – Prognosis ‘hours / days’ at most

• 'Horrific sight'
  – Husband wanting it over… at least be comfortable
  – Younger, 15-year-old daughter at breaking point

• Sedation, seemingly kinder option…?
  – No grounds to refuse

• Symptom control, tailored…?
  – Risks inadequate response
You Choose…
Sedation or Palliative Care?
Despite Case for Sedation, I Opted **Symptom Control**

- **Assessed** patient
  - Confusional state
  - Muscle spasm
  - Probable pain
- **Treat cause**
  - No option, no target
- **Follow-up**
- **Targeted comfort**
  - Titrated Haloperidol
  - Titrated Midazolam
  - Titrated Diamorphine
- **Involve family**
  - Provide support
- **Re-assess** patient
Was that **Sedation**… or Symptom Control…?

- Very **settled**, but **unresponsive**
- On syringe pump **continuous infusion** of…
  - Diamorphine
  - Haloperidol
  - Midazolam
She Needed ‘Symptom Control’ …Not 'Sedation'

- **Woke up** 2 days later on **same** medication
  - Normal self

- **Two key lessons**;
  - *Presumption* drugs were **sedative** was **wrong**
  - *Presumption* need **excessive** doses was **wrong**
Strong Case Against 'Sedation'

- Mum spoke openly to young daughter for first time
  - Key exchanges

- Discharged home via hospice
  - Died 4-5 weeks later, ‘uneventfully’
Didn’t Sedate…
Just Normal **Symptom Control**

- Specific **tailored** symptom control
  - **No change** in practice
  - Usual drugs, usual doses, titration, usual care
  - **No compromise** comfort; **as much as needed**

- May **look like** sedation; may **call it** sedation
  - In literature / national surveys…

- But it **wasn’t** sedation
  - Neither in theory or in practice
Biggest Worry… if Had Sedated

• If given excessive doses… to be ‘sure’
  – Outcome would look right
  – Self-fulfilling prophecy

• Never realised;
  – Sedation not needed for comfort
  – Importance lost family exchanges

• Wrongly could assume 'did good'
  – Conveniently no come back
  – Sedation = net loss

• Evidence-based medicine is needed…!
  – Cannot let experiences blind us…
Normally **Looks and Feels Like** ‘Sedation’ But Still Isn’t…!

- Many / most similar patients wouldn’t wake
  - Because of disease **not** drugs
    - Delirium lowers consciousness
    - Dying lowers consciousness

- Association **is not** causation…

Symptom control while a patient dies, *is not sedating the patient until death*
[3] Allows Abuse

- Consequence of normalising ‘Palliative Sedation’
- Lose consciousness – presumed need
- Shortening lives – without safeguards
- Deep ongoing sedation on demand ‘coma’ – autonomy
- Malicious / deliberate / convenient – abuse
[3] Allows Abuse

- Consequence of normalising ‘Palliative Sedation’
- Lose consciousness – presumed need
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- Deep ongoing sedation on demand ‘coma’ – autonomy
- Malicious / deliberate / convenient – abuse
Clinical Concern with ‘Continuous Deep Sedation’

- Debate if akin **physician-assisted suicide** / euthanasia

- Iatrogenic **unconsciousness** negates social function / personhood, leaving patient **effectively ‘dead’**
  - Soh et al, Singapore Medical Journal 2016

- Inefficient ‘slow **euthanasia**’ – what’s the point…?
  - Tännsjö, 2004

- Professionals experience difficulties **distinguishing** use of **sedation** from practice of **euthanasia**
  - Anquinet et al, Pall Med, 2014
Not Clinical, but CDS Can be Social Choice… Even a Right…?!

- More (83%) palliative care patients favour deep ongoing sedation over euthanasia (47%) n=40
- February 2016, France, Claeys-Leonetti Law
- Forbade euthanasia but established right to continuous deep sedation for end-of-life patients
  » Boulanger et al, BMC Pall Care, 2017
Unsafe, open to inappropriate use / abuse
  - No safeguards are 'safe'

Informal guidelines on sedation until death include:
  - Consciousness not lowered more than necessary for preventing suffering
  - Must be impossible to alleviate suffering in any other way
  - Patient’s preference for dying peacefully not enough
  - Some stipulate purely existential suffering not enough

None of arguments for restrictions in literature convincing

While deviation justified by appealing to patient priorities
  » Hartogh, KI EJ, 2016
Concept of ‘Palliative Sedation’
Leads to… More ‘Sedation’…!

• Normalised
  – Different settings in UK different thresholds

• Explicit agenda other countries
  – Deliberate drug-induced coma, for refractory symptoms
  – Most of us have refractory symptoms…!
Disparate Practices
Excessive Doses Get Normalised

- Midazolam 5-10mg/24h
  - UK Palliative Care, terminal agitation, 2nd line

- Midazolam 96mg + morphine 96mg/24h
  - UK ITU, naive not dropped when extubated

- Midazolam >75mg/24h
  - Dutch guidelines starting 1.5-2.5mg/Kg/24h

- Midazolam daily increase 30mg, 60mg, 90mg/24h
  - Ecuador community, neighbouring 'experts'
‘Palliative Sedation’ Fuels Abuse

- ‘Mission creep’ with sedation in palliative care
- ‘Abuse of CDS occurs and seems likely to increase’
  » Twycross, Evid Based Nurs, 2017

- **By-pass** clinical / legal safeguards
- In some cases continuous sedation was alternative to euthanasia, if euthanasia was not possible
  » Robijn et al, EJCC, 2017
• UK Law
• R v Moor [1999]

• Dr David Moor **acquitted** of ending a cancer patient’s life by administering opioids
  – Even though he administered an **overdose**
  – He admitted **helping >300 patients die** “pain-free deaths”
  – On his **day off**, agreed though **list full** [i.e. intent to kill…?]
  – Patient **begged** for a ‘speedy death’
  – As his **claimed intent** was to alleviate suffering and pain
    » Davies, Willis & George EJPC, 2017
Does Sedation Shorten Life…?
It Can, it Does, Even if Not Always
No Risks from *Symptom Control* Fears Are Misplaced

- Symptom control drugs **safe** at end-of-life
  - Safe if used **properly**…
  - Evidence shows no impact to hasten death
  - Similar trajectory with / without sedative drugs
    » Thorns & Sykes, 2000; Sykes & Thorns, 2003; Schur et al, BMC Pall Care, 2016; Giles & Sykes, Pall Med, 2017; APM, 2018

- Morphine **safe** in dyspnoea; low-dose, short-term...
  - Even COPD / opioid naïve
  - No respiratory depression
    » Abernethy et al, 2003; Booker, 2005; Estfan et al, 2007
No Risks from *Symptom Control*  
Fears Are *Misplaced*

- Symptom control drugs **safe** at end-of-life  
  - Safe if used **properly**…  
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    » Thorns & Sykes, 2000; Sykes & Thorns, 2003; Schur et al, BMC Pall Care; Sykes, Sykes, Pall Med, 2016; APM, 2018

- Morphine **safe** in  
  - Even COPD / opioid naive  
  - No respiratory depression  
    » Abernethy et al, 2003; Booker, 2005; Estfan et al, 2007

*Symptom control* does **NOT** shorten life
No Risks from *Palliative Sedation* Fears Also Appear Misplaced…?

• ‘*Palliative sedation*’ no impact from RCT evidence
  – When *appropriately indicated* and *correctly used* for *unbearable* suffering, no detrimental effect on survival in *terminal* cancer
  – Medical intervention part of *continuum* of palliative care
    » Systematic Review, Maltoni et al, JCO, 2012

• ‘*Palliative sedation*’ does *not* hasten death
  – However, low quality evidence *interpret with caution*
    » Beller et al, Cochrane Review, 2015
No Risks from *Palliative Sedation* Fears Also Appear **Misplaced**…?

- ‘Palliative sedation’ no impact from RCT evidence
  - When *appropriately indicated* and *correctly used* for *unbearable* suffering, no detrimental effect on survival in *terminal cancer*
  - Medical intervention part of *continuum* of palliative care
    » Systematic Review, Maltoni et al, JCO, 2012

- ‘Palliative sedation’ *should not* shorten life
  - However, low quality evidence *interpret with caution*
    » Beller et al, Cochrane Review, 2015

**Sedation at End of Life SHOULD NOT shorten life**
Continuous deep sedation
- Patient unable face living
- Prognosis potentially months / years

Induce coma; anaesthetic agents / doses
- No food & fluids, hasten death
  » Gormally, 2004

Cannot assume not killing if chance >4-14 days prognosis
- Commission (sedation) not itself life-shortening, but together with simultaneous omission (no fluids), seen as killing
- Hence legal and ethical implications of ‘homicide’
  » den Hartogh, Med, Health Care & Phil, 2016
Be Up Front…
Literature Confirms Media’s Fears

• Continuous deep sedation
  – Patient unable face living
  – Prognosis potentially months / years

• Induce coma; anaesthetic agents / doses
  – No food & fluids, hasten death
    » Gormally, 2004

• Cannot assume not killing
  – Commission (sedation) together with simultaneous omission (no fluids), seen as killing
  – Hence legal and ethical implications of ‘homicide’
    » den Hartogh, Med, Health Care & Phil, 2016

Palliative Sedation WILL shorten life
Hostage to Fortune If Suggest ‘Palliative Sedation’ is Ethical

• Origin
  – Well meaning
  – Need for reassurance
  – Historical opioid phobia …?

• Now
  – Now backfiring…
  – Only safe if in ‘expert’ hands
    • Not needed by experts…!
    • Normal symptom control or sedation
  – Not safe in ‘non-expert’ hands
    • Overall, net harm; best if avoid…
    • Toxicity +/- coma on demand
For Every Complex Question there is a Simple Answer...
...That's Wrong...!

Palliative Sedation...?
Must Better Differentiate Good Care from Bad Practice

• [1] Non-sedating use of medication
  – Within ‘normal’ symptom control
  – As much as needed

• [2] Proportionate sedation
  – Time-limited / intervention-specific – light / deep
  – Targeted, careful dose titration for a ‘very’ end-of-life crisis

• [3] Ongoing supra-therapeutic dose
  – Specific intent anaesthetising patient in advance of what may have proved a peaceful / uneventful death
    » Willis, Gannon, Harlow, Baker & George, Pall Med, 2014
Must Better Differentiate Good Care from Bad Practice

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- **[3] Ongoing supra-therapeutic** dose
  - Specific intent **anaesthetising** patient in advance of what may have proved a peaceful / uneventful death

» Willis, Gannon, Harlow, Baker & George, Pall Med, 2014
Conclusion: EoLC is Ethically and Clinically Complex
‘Palliative Sedation’ is Unacceptable…

- As sedation is **NOT** palliative
- Misleading / dangerous umbrella term
- Spans **good**, but fuels **bad** practice and hides **abuse**
Literature / Language Unhelpful

• ‘Palliative Sedation’ unhelpfully spans:
  – Symptom control                      Good
  – Augmented symptom control            Bad
  – (Clinical) sedation                   Necessary
  – (Social) sedation                    Not medicine

• Cannot reasonably allow same term…
  – Misunderstandings – too much worry / too little worry
  – Encourages poor practices – both under-dose / over-dose
  – Extreme problems: as seen with LCP / Mid-Staffs / Gosport
‘Palliative Sedation’ Unacceptable
…As Sedation is NOT Palliative

• Symptom control – at very end of life (hours / days)
  – Targeted / titrated drugs, selected clinical circumstances
  – Sedation due to disease
  – Reduced symptoms, no impact on survival

• Augmented symptom control – lacks logic
  – Higher than symptom control doses and not targeted drugs
  – Sedation due to drugs
  – Increased symptoms, potential impact on survival
‘Palliative Sedation’ Unacceptable …As Sedation is NOT Palliative

- (Clinical) sedation – a ‘necessary evil’ a means
  - Transient / short-term in crisis scenario – light / deep
  - Sedation while improves / dies
  - Reduced awareness, no impact on survival

- (Social) sedation – before end of life – not healthcare…?
  - Ongoing, heavy / fixed doses to induce coma on demand
  - Sedation due to drugs
  - Reduced life, hastens death
Conclusion: ‘Just Say No’ to ‘Palliative Sedation’ Term and Use

Geraint Thomas / Team Sky
Tour de France, 2018
Thank You... Questions

A sleeping, not sedated, animal!
Key References

- Bruinsma SM; van der Heide A; van der Lee ML; Vergouwe Y; Rietjens JA. ‘No Negative Impact of Palliative Sedation on Relatives’ Experience of the Dying Phase and Their Wellbeing after the Patient's Death: An Observational Study’ PLoS ONE, 2016; 11(2):e0149250
- van Deijck RH; Hasselaar JG; Verhagen SC; Vissers KC; Koopmans RT ‘Patient-Related Determinants of the Administration of Continuous Palliative Sedation in Hospices and Palliative Care Units: A Prospective, Multicenter, Observational Study’ Journal of Pain & Symptom Management, 2016; 51(5):882-9
- Davies J, Willis D & George R ‘The double effect is no doctrine: it’s a reflective tool part I’ EJPC, 2017; 24 (4): 178-182
Additional References

- Hong JH; Kwon JH; Kim IK; Ko JH; Kang YJ; Kim HK. ‘Adopting Advance Directives Reinforces Patient Participation in End-of-Life Care Discussion’ Cancer Research & Treatment, 2016; 48(2):753-8
- Giles A; Sykes N. ‘To explore the relationship between the use of midazolam and cessation of oral intake in the terminal phase of hospice inpatients: A retrospective case note review: Does midazolam affect oral intake in the dying?’ Palliative Medicine, 2017; 31(1):89-92
- Henry B. ‘A systematic literature review on the ethics of palliative sedation: an update’ Current Opinion in Supportive & Palliative Care 2016; 10(3):201-7
- Boulanger A; Chabat T; Fichaux M; Destandau M; La Piana JM; Auquier P; Baumstarck K; Salas S. ‘Opinions about the new law on end-of-life issues in a sample of french patients receiving palliative care’ BMC Palliative Care, 2017; 16(1):7
- Kettemann D; Funke A; Maier A; Rosseau S; Meyer R; Spittel S; Munch C; Meyer T. ‘Clinical characteristics and course of dying in patients with amyotrophic lateral sclerosis withdrawing from long-term ventilation’ Amyotrophic Lateral sclerosis & Frontotemporal Degeneration, 2017; 18(1-2):53-59
- De Vries K; Plaskota M. ‘Ethical dilemmas faced by hospice nurses when administering palliative sedation to patients with terminal cancer’ Palliative & Supportive Care, 2017; 15(2):148-157
- Robijn L; Chambaere K; Raus K; Rietjens J; Delliens L. ‘Reasons for continuous sedation until death in cancer patients: a qualitative interview study’ European Journal of Cancer Care, 2017; 26(1):e12405
- Tursunov O; Cherry NI; Ganz FD. ‘Experiences of Family Members of Dying Patients Receiving Palliative Sedation’ Oncology Nursing Forum, 2016; 43(6):E226-E232.
- Soh TL; Krishna LK; Sim SW; Yee AC. ‘Distancing sedation in end-of-life care from physician-assisted suicide and euthanasia’ Singapore Medical Journal, 2016; 57(5):220-7
- Schur S; Weikler D; Gabl C; Kreye G; Likar R; Masel EK; Mayrhofer M; Reiner F; Schmidmayr B; Kirchheiner K; Watzke HH; AUPACS (Austrian Palliative Care Study) Group. Sedation at the end of life - a nation-wide study in palliative care units in Austria’ BMC Palliative Care, 2016;15: 50
- Mercadante S; Aielli F; Masedu F; Valenti M; Verna L; Porzio G. ‘Age differences in the last week of life in advanced cancer patients followed at home’ Supportive Care in Cancer, 2016; 24(4):1889-95