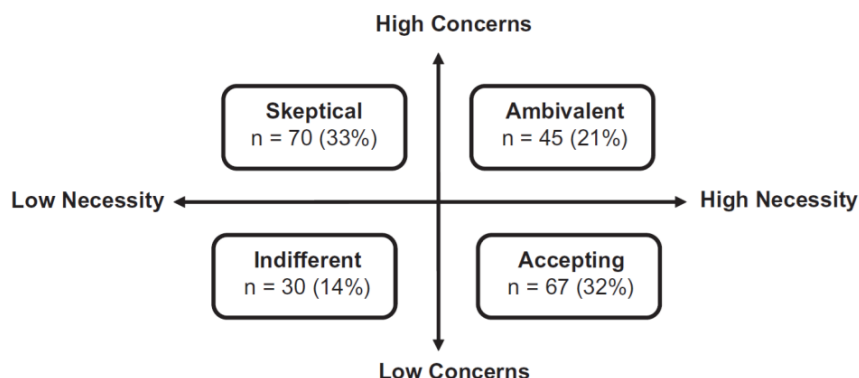


<b>Institution:</b> University College London		
<b>Unit of Assessment:</b> 3 - Allied Health Professions, Dentistry, Nursing and Pharmacy		
<b>Title of case study:</b> Supporting patients' medicines adherence using the Necessity Concerns Framework (NCF)		
<b>Period when the underpinning research was undertaken:</b> 2006 - 2013		
<b>Details of staff conducting the underpinning research from the submitting unit:</b>		
<b>Name(s):</b>	<b>Role(s) (e.g. job title):</b>	<b>Period(s) employed by submitting HEI:</b>
Robert Horne	Professor, Chair in Behavioural Medicine	2006 - Present
<b>Period when the claimed impact occurred:</b> 2014 - 2020		
<b>Is this case study continued from a case study submitted in 2014?</b> No		
<b>1. Summary of the impact</b>  <p>Professor Robert Horne has led the development of the Necessity Concerns Framework – a disease-agnostic framework used to inform the development of pragmatic interventions to improve medicines use and development for acute and chronic disease including HIV and asthma. Horne's work resulted in co-authorship and repeated renewal (current guidelines published in 2019) of National Institute for Clinical Excellence guidelines on adherence and the co-authorship of the 2015 British HIV Association Treatment Guidelines. Based on the framework, Horne has advised the pharmaceutical industry on the development of adherence-enhancing products such as the Astra Zeneca Turbu+™ smart inhaler compliance aid, as well as developing tools to improve patient care including the Reliever Reliance Test.</p>		
<b>2. Underpinning research</b>  <p>The Horne research group is an international leader in the behavioural medicine field, particularly involving the development of reliable methodologies for quantifying patients' perceptions of illness and treatment and developing interventions to support informed choice and adherence by taking account of patient beliefs.</p> <p>Since joining the School of Pharmacy in 2006, Horne has led the validation, application and development of the Necessity Concerns Framework (NCF) [R1, R2, R3]. This body of research is built upon Horne's original conceptual framework for how people perceive pharmaceutical medicines and how those perceptions influence adherence. The Necessity Concerns Framework delineates the fundamental tenets of how patients judge their personal need for the treatment (Necessity beliefs) relative to their concerns about the perceived negative consequences of adherence. Horne's research showed that these perceptions, although logical from the patient's perspective, are often based on common misconceptions about the illness and treatment. An illustration of the tenets of the framework is given in Figure 1. The framework has been widely adopted in the behavioural medicine field for a range of conditions including asthma, HIV, cystic fibrosis, haemophilia, renal disease, hypertension, depression, diabetes, cardiac illnesses, cancer, and stroke. In 2013, these studies and others were included in a meta-analysis which demonstrated the utility of the NCF in explaining non-adherence in 94 peer-reviewed papers involving over 25,000 patients spanning 23 long-term conditions and 18 countries [R4].</p> <p>Since 2006, Horne's work has particularly focused on more detailed studies of the antecedents of treatment Necessity beliefs and Concerns, the framework's wider application across a range of diseases and, crucially, the development of interventions to improve adherence, both via policy and guideline development, as well as product development.</p>		



*Figure 1: Illustration of tenets of NCF: Proportion of the sample allocated to each attitudinal group defined by beliefs about Phosphate Binding Medications (PBM) [R5]*

Horne was also the first to map patient beliefs predicting uptake of and adherence to essential anti-retroviral therapies (ART) for HIV infection [R1], conducting the first longitudinal study to identify patient perceptions influencing initial uptake (or refusal) and subsequent non-adherence up to 12 months later. A similar study conducted in the USA (in collaboration with Horne) [R6] corroborated the findings and reinforced the validity of the NCF as an approach to conceptualising and assessing the key influencing beliefs. This work led to a successful application to NIHR in 2011 to fund the development of an intervention to improve ART adherence and the associated 6-year programme of research (GBP2,412,986; RP-PG-0109-10047; PI Horne).

Recently, the work has evolved to embrace the evaluation of digital technologies for enhancing adherence. The group is currently evaluating NCF-based approaches for other conditions including TB, cancer, hypertension and asthma in research funded by NIHR and HTA and through NIHR North Thames Collaboration for Leadership in Applied Health Research and Care.

### 3. References to the research

- [R1] Horne R, Cooper V, Gellaitry G, Date HL, Fisher M. (2007) Patients' perceptions of highly active antiretroviral therapy in relation to treatment uptake and adherence: the utility of the necessity-concerns framework. *JAIDS*; 45(3): 334-41.  
[doi.org/10.1097/QAI.0b013e31806910e3](https://doi.org/10.1097/QAI.0b013e31806910e3).
- [R2] Clifford S, Barber N, Horne R. (2008) Understanding different beliefs held by adherers, unintentional nonadherers, and intentional nonadherers: application of the Necessity-Concerns Framework. *Journal of Psychosomatic Research*; 64(1): 41-6.  
[doi.org/10.1016/j.jpsychores.2007.05.004](https://doi.org/10.1016/j.jpsychores.2007.05.004).
- [R3] Bucks RS, Hawkins K, Skinner TC, Horn S, Seddon P, Horne R. (2009) Adherence to Treatment in Adolescents with Cystic Fibrosis: The Role of Illness Perceptions and Treatment Beliefs. *Journal of Pediatric Psychology*; 34 (8): 893-902.  
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- [R4] Horne R, Chapman SC, Parham R, Freemantle N, Forbes A, Cooper V. (2013) Understanding patients' adherence-related beliefs about medicines prescribed for long-term conditions: a meta-analytic review of the Necessity-Concerns Framework. *PloS One*; 8(12): e80633. [doi.org/10.1371/journal.pone.0080633](https://doi.org/10.1371/journal.pone.0080633)
- [R5] Chater AM, Parham R, Riley S, Hutchison AJ, Horne R. (2014) Profiling patient attitudes to phosphate binding medication: A route to personalising treatment and adherence support. *Psychology & Health*; 29(12): 1407-1420.  
[doi.org/10.1080/08870446.2014.942663](https://doi.org/10.1080/08870446.2014.942663)

**[R6]** Gonzalez JS, Penedo FJ, Llabre MM, Durán RE, Antoni MH, Schneiderman N, Horne R. (2007) Physical symptoms, beliefs about medications, negative mood, and long-term HIV medication adherence. *Annals of Behavioural Medicine* 2007; 34(1): 46-55. [doi.org/10.1007/BF02879920](https://doi.org/10.1007/BF02879920)

#### 4. Details of the impact

##### **Development of National Institute for Clinical Excellence (NICE) guidelines on Medicine Adherence**

As a direct result of his research, Horne was invited to be an author of NICE Clinical Guideline GC76 “Medicines Adherence: involving patients in decisions about prescribed medicines and supporting adherence”, first published in 2009. These guidelines still remain unchanged following review in 2015 and 2019 [S1], with his work cited ten times in the current document. This comprises the most authoritative guide for industry and the health service in the UK on the issue of medicines adherence as well as being accessible to patients and patient representative groups. Professor Henry Smithson (chair of the NICE Guidelines Development Group) [R3] states that, “Prof Horne’s research on the Necessity Concerns Framework was fundamental in shaping the NICE Guidelines. It is fair to say that this research created a paradigm shift in our approach. It transformed the agenda and scope of the guidelines, placing patients’ beliefs about their illness and treatment at the centre of the consultation”.

##### **Development of guidelines for patients taking anti-retroviral treatments**

The work on adherence to anti-retroviral therapies (ART) [R1] led Horne to be invited to author the British HIV Association guidelines for the treatment of HIV-1-positive adults with antiretroviral therapy in 2015 (with 2016 interim update; further updated in 2019) [S2]. The report features a section (Section 6.1) specifically on adherence and contains recommendations overtly based on the NICE Clinical Guideline CG76. Horne’s work is cited seven times throughout the report, including citation against the recommendations for interventions for patient support to improve adherence. The Perceptions and Practicalities Approach referenced in the guideline [citing R1] was developed by Horne as a framework for incorporating the NCF framework in the design of comprehensive, patient-centred adherence support.

##### **Asthma Medication Adherence: Development of the AstraZeneca digital medication platform and the Turbu+ app**

Horne’s research has been a major influence on AstraZeneca’s digital medication platform. The Executive Director and Head, Biopharmaceuticals R&D Digital Health, Astra Zeneca, states “A peer review of adherence interventions across industry indicates that <1% of all adherence interventions are successful (at a cost of ~USD2.4bn P.A). In the last 4 years using Prof Horne’s behavioural science research as a backbone of our programs we have been successful in >80% of all programs in delivering double digit sustainable increases in adherence both to medication and self-management (adherence to guidelines)” [S3].

This impact is exemplified by the contribution that Horne’s work has made to the design of the Turbu+ adherence support system for inhalation therapies (co-designed between Horne’s UCL Business consultancy spinout Spoonful of Sugar and AstraZeneca). This is an app that is used in conjunction with the turbuhaler platform (to which a data gathering device is added) that gathers adherence data and offers adherence support, including reminders. An independent assessment of the Turbu+ system in conjunction with the budesonide/ formoterol (Symbicort®) Turbuhaler reported a 71% compliance rate over a 90 day period [S4]; to place this in context, a recent study using conventional inhalers for COPD reported a compliance rate between 22.7% and 31.8% [S5].

As a specific example of the impact of Horne’s research on asthma medication adherence, the Global Initiative for Asthma (GINA) no longer recommends treatment of asthma with short-acting beta<sub>2</sub> agonist (SABA) canisters alone for safety reasons, due to high use of such canisters being associated with severe exacerbations and death [S6]. This

represents a paradigm shift in asthma care necessitating a major change in the behaviour of both patients and health care practitioners. Horne applied the NCF to develop the SABA Reliance Questionnaire (SRQ) [S7] to assess the key beliefs driving SABA over-reliance. The SRQ comprises a set of simple questions, assessing patients' beliefs about their personal necessity for SABA and whether they see SABA use as the best way of managing their asthma. Working with Spoonful of Sugar, the SRQ has been incorporated into the Reliever Reliance Test, a pragmatic tool to help prescribers and patients identify and address overuse of SABA. This has been highlighted on the AstraZeneca website [S8] and will be rolled out globally by the company in 2021-2022. The Biopharmaceuticals R&D Digital Health Head comments that: "Prof Horne's research on the Necessity Concerns Framework has informed global and regional initiatives across the portfolio of AstraZeneca's digital health programme particularly in respiratory disease where it has been central to our behaviour change strategies. We are currently expanding our collaboration to include other areas including initiatives to enhance patients' experience of, and engagement with clinical studies as part of AstraZeneca's commitment to Clinical Trials of the Future" [S3].

#### Establishment of a spin-out company

Horne's spin out company Spoonful of Sugar was established at UCL as a consultancy firm for the pharmaceutical industry and the NHS to help patients and other stakeholders get the best from medicines, and exploit the group's research. Spoonful of Sugar applies behavioural science to help patients and healthcare professionals to get the best from effective treatments by enhancing adherence and optimising health outcomes. The company won two prestigious 'new-comer' Communique awards in 2015 [S9] who stated the company are "delivering through their methodology... bringing some much needed rigor to the discipline of behavioural change", employing 10 staff (full time equivalent) and a wide matrix team of consultants, with an annual turnover of approximately GBP1,000,000.

#### 5. Sources to corroborate the impact (indicative maximum of 10 references)

- [S1] Testimonial from Chair of the NICE Guidelines Development Group - Medicines Adherence (Available upon Request); <https://www.nice.org.uk/guidance/cg76/evidence/full-guideline-242062957> (2009 guidelines); <https://www.nice.org.uk/guidance/cg76> (overview with update statement, 2019)
- [S2] <https://www.bhiva.org/HIV-1-treatment-guidelines>
- [S3] Testimonial from Executive Director and Head, Biopharmaceuticals R&D Digital Health, Astra Zeneca, Intelligent Pharmaceuticals, Astra Zeneca (Available upon Request).
- [S4] G Rumi G, Braido F, Canonica GW, Foster JM, Chavannes NH, Columburo C, Valenti G, Contiguglia R, Rapsomaniki E, de Blas MA, Kocks JWH (2018) Can the turbu+™ adherence programme contribute to improved adherence to asthma controller treatment in Italy? *Thorax*, 73, A194-A195
- [S5] Ngo CQ, Phan DM, Vu GV, Dao PN, Phan PT, Chu HT, Nguyen LH, Vu GT, Ha GH, Tran TH, Tran BX, Latkin CA, Ho CSH, Ho RCM (2019) Inhaler technique and adherence to inhaled medications among patients with acute exacerbation of chronic obstructive pulmonary disease in Vietnam. *International Journal of Environmental Research and Public Health*. 16(2): 185.
- [S6] Global Initiative for Asthma. *Global Strategy for Asthma Management and Prevention*. 2020 Update. Available at: [https://ginasthma.org/wp-content/uploads/2020/06/GINA-2020-report\\_20\\_06\\_04-1-wms.pdf](https://ginasthma.org/wp-content/uploads/2020/06/GINA-2020-report_20_06_04-1-wms.pdf).
- [S7] Chan, A., Katzer, C. B., Horne, R., Haughney, J., Correia de Sousa, J., Williams, S., & Kaplan, A. (2020). SABA Reliance Questionnaire (SRQ): Identifying Patient Beliefs Underpinning Reliever Overreliance in Asthma. *The Journal of Allergy and Clinical Immunology: In Practice*, 8(10), 3482–3489.e1. <https://doi.org/10.1016/j.jaip.2020.07.014>
- [S8] <https://www.astrazeneca.com/media-centre/articles/2020/a-new-tool-to-tackle-saba-over-reliance-in-asthma-management.html#>

[S9] <http://www.uclb.com/2015/07/08/double-win-for-spoonful-of-sugar-at-communique-2015/>