Addendum to:

Report on Oxevision Evidential Base and Case Study Methodologies

This addendum is prepared by

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Declaration of Interests and Independence

We confirm that we have no financial, professional or personal interest in Oxevision (Oxehealth/LIO), and have not undertaken consultancy work for, or received funding, from these organisations.

We were instructed to undertake this review by the Lampard Inquiry through Oxford University Innovation Limited ("OUI"), which acted solely as an administrative and contracting intermediary. OUI had no role in the design, analysis, interpretation, or conclusion of this report.

We are both employees of the University of Oxford. Oxevision is a product of Oxehealth, a spin-out from the University of Oxford, and OUI forms parts of the University's innovation infrastructure. We recognise that this institutional context may give rise to a perception of proximity and have taken this into account in our assessment.

The evidential base comprised academic literature, case studies, and other materials provided through a range of sources, including Inquiry materials and journal papers. We have taken account of the limitations inherent in this mixed evidential base, including that it was not derived from a fully systematic literature search.

We confirm that our analysis and conclusions were reached independently and have not been influenced by the instruction route or evidential sourcing described above.

In reviewing the evidential base, we also considered relevant institutional and academic contextual relations where those arose within the materials, and these did not affect our assessment or conclusion.

We understand that our overriding duty is to assist the Chair to the Lampard Inquiry on matters within our expertise. In preparing this report we have complied with that duty and have exercised our independent professional judgment at all times.

We confirm that the opinions expressed in this report are our own, represent our true and complete professional opinions on the matters to which they relate, and are based upon the information and materials available to us. Where matters fall outside our expertise, or where there are limitations in the available evidence, we have sought to identify those matters within the report.

We confirm that we have not omitted to consider any material fact or matter of which we are aware that might reasonably be expected to affect the opinions expressed.

We further confirm that neither our opinions nor the conclusions reached in this report have been influenced by any personal, financial, institutional professional or other interest.

Section 1. Illustrative examples of Randomised Controlled Trials

Overview of evidence

1.1 This section summarises a limited selection of randomised controlled trials within the mental health setting, in order to illustrate the extent and diversity of available examples. Even though the focus of each study differs, all six studies have some commonalities both in design and reporting that are associated with randomised controlled trials. These include among others: the implementation (and description in the methods) of randomisation and, where feasible, the description of blinding protocols; the description of an a priori sample size computation; the determination of a single primary outcome; the description of the patient populations in each treatment arm and how the population profiles changed due to attrition or lack of adherence. The overall design standard is high and within the constraints of the study generalisable. With the exception of Rustad Indregard et al. (2024), all remaining studies are multicentre and were determined to provide moderate or moderate-to-high evidential weight.

1.2 Some differences in design highlight the wide applicability of randomised controlled trials. For example, Wykes et al. (2018) used a stepped wedge design in their trial as that ensured fairness in the rollout of additional training and support for staff. As they were examining patient experience, they also actively involved service users in the study design and development. Kallert et al. (2007) demonstrated that cautious design practices can also permit the development of trials in an international setting, developing protocols that ensured the involvement of five European countries. Trials that required a follow-up period outside an inpatient ward, such as Gowers et al. (2007) and Gillard et al. (2022), implemented a variety of processes in order to increase adherence and reduce attrition with varying levels of success depending on the treatment arm and study duration. Rustad Indregard et al. (2024) illustrate a non-inferiority design, where the examination focuses on the treatment under study not performing worse than the comparator. Bryan et al. (2025) implemented a group-sequential design that ensured the study could be terminated early if no clear differences in the treatment arms were detected. This ensured that patient participation and resources were not unnecessarily used.

1.3 Bryan et al. (2025) also presented a strong example on the design and reporting of a clinical trial where multiple authors have a conflict of interest in terms of the technology being tested. The study is adequately powered, the statistical analysis plan presented fully, and the limitations clearly stated.

Study summaries

1.4 Kallert et al. (2007) (Trial registration: NCT00153959) present the findings of a multicentre randomised controlled trial in five European countries, focusing on the effectiveness of day hospitals for acutely ill psychiatric patients. Patients in need of acute admission were randomised between inpatient facilities and a day hospital,

with outcomes such as psychopathology, treatment satisfaction, and subjective quality of life collected longitudinally over four time points. Randomisation was undertaken at each centre, with separation between the generation of the randomised allocation and those implementing the allocation. The design also included an a priori sample size computation powered to 95% for a small effect size in the primary outcome (psychopathology). Statistical analysis was conducted by a statistician who was blinded to the service provision. The findings indicate that admission in day hospitals was as effective as inpatient hospital care for clinical outcomes and more effective for social ones. Major strengths of this work include its multinational nature, large sample size (1117 patients), and robust statistical analysis approach. The authors also cite the Consolidated Standards of Reporting Trials (CONSORT) statement in their motivations for design. A limitation is associated with one of those strengths, namely an inconsistency between countries, with the day hospital in one (the United Kingdom) being completely new and as a result more UK patients were randomised to the day hospital when compared to other countries. Another limitation relates to the fact that allocation was made independent of bed availability, meaning that at times patients could not go to their allocated treatment and were therefore excluded from the study. Overall, this work provides high evidential weight for the effectiveness of day hospitals for acutely ill patients.

1.5 Gowers et al. (2007) (Trial registration: ISRCTN39345394) conducted a multicentre randomised controlled trial on the clinical effectiveness of three available treatments for anorexia nervosa in adolescents (inpatient, specialist outpatient, and treatment as usual in the community). The authors follow CONSORT reporting guidelines. Outcomes included interviewer-based measures, such as scoring on Morgan-Russell Average Outcome Scale (MRAOS), and participant ratings, such as the mood and feelings questionnaire. Measurements were collected at three time points. Sample size was calculated a priori focusing on the primary outcome (MRAOS score) using the calculated effect size from previously published pilot study, with an additional contingency for a 15% dropout rate. Statistical analysis was broadly appropriate for the design. Neither of the more intensive treatment approaches (inpatient setting or specialist outpatient) outperformed the community treatment. A primary limitation to this study is the low adherence to treatment. For example, although 57 patients were allocated to the inpatient treatment, only 28 adhered to the 4-week treatment. This limited adherence to inpatient treatment makes it challenging to examine whether the absence of an effect from this setting is due to the treatment itself being ineffective or if it is the result of low adherence. Overall, this work provides moderate evidential weight for the comparison of available treatments for anorexia in adolescents.

1.6 Wykes et al. (2018) (Trial registration: ISRCTN06545047) designed and conducted a randomised controlled trial on the effect of improved staff training on the in-ward experiences of mental health inpatients. The authors follow CONSORT reporting guidelines. The trial used a stepped wedge design in 16 acute mental health wards. In a stepped wedge design, the intervention is rolled out gradually to all wards in the

trial in waves. In this study, the intervention (such as additional staff training and support) was rolled out in three waves. The main outcome was patient self-reported perceptions of care, with patients blinded to the treatment allocation of the ward they were in. Wards were randomised into the intervention every six months of the trial until all wards were part of the intervention. As part of the design, the authors conducted an a priori sample size computation but based the estimation on a cluster randomised design as they had no appropriate pilot studies from stepped wedge designs. Perceptions improved in intervention wards for patients that had been admitted involuntarily but no differences were recorded on those admitted voluntarily. A major strength of this study is the patient involvement in the development of the design, implementation, and dissemination of findings. The study is also extensive, both in terms of wards included and number of service users (1058 participants in the primary outcome survey). The sample size computation mismatch in design is a limitation, the impact of which cannot be fully ascertained from the publication. Overall, this work provides moderate evidential weight for the effect of improved staff training on self-reported perceptions of care.

1.7 Gillard et al. (2022) (Trial registration: ISRCTN10043328) used a randomised controlled trial design to examine whether peer support on discharge reduced readmission in the year post-discharge. Patients from seven study sites were randomly allocated to the peer-support or treatment as usual arms at discharge in a 1:1 ratio, with the primary outcome being readmission within 12 months. An a priori sample size computation was conducted using a similar design to the trial, with an additional 10% contingency to address potential loss to follow-up, although it is unclear in the publication how the effect size was determined. The statistical analysis was appropriate for the design and data characteristics and as the final model was simpler than the one anticipated during the design stage, the study appears adequately powered. The authors follow CONSORT reporting guidelines. Engagement in the peer support intervention varied in the population, suggesting that future adjustments in its implementation may be required. The principal finding was that peer support did not differ from treatment as usual in post-discharge readmission, although a subgroup analysis suggested that peer support in patients of Black ethnicity was significantly associated with lower readmission. Overall, this study provides moderate-to-high evidential weight on the effect of peer support on readmission.

1.8 Rustad Indregard et al. (2024) (Trial registration: ISRCTN16876467) conducted a randomised controlled trial to establish whether an open-door policy could be safely implemented in non-forensic acute mental health wards. The trial protocol was a registered report, meaning that the protocol went through peer-review and publication prior to conducting the study. Five wards were included in the trial, two of which followed an open-door policy for twelve months. In terms of design, this was a non-inferiority trial, which is method used to establish whether a treatment under study does not perform worse than the comparator. In this particular case, the trial aimed to establish whether the amount and type of specific incidents was not

significantly worse in the open-door wards when compared to the controls. The primary outcome was the proportion of patient stays with coercive measures such as isolation or involuntary medication. The main finding from the study was that across outcomes, the open-door policy wards were non-inferior to the treatment as usual wards. An a priori sample size computation was conducted based on published data for similar open-door settings. The statistical analysis conducted was broadly appropriate for the study design. Among the limitations of the study is the fact that all wards are in the same hospital, and the number of wards in each arm is limited. This impacts the generalisability of the work. A further limitation is in the involvement of the principal investigator/study management in both adherence and data monitoring. This goes against current best practice with the [HYPERLINK "https://osp.od.nih.gov/wp-content/uploads/2024/09/DSMB_Brief_20200930_FINAL_508.pdf"] recommending: "To maintain independence, representatives from the sponsor, funder, or study team are not members of the DSMB [Data Safety and Monitoring Board] …". Overall, this study provides low-to-moderate evidential weight on open-door policies in acute mental health wards.

1.9 Bryan et al. (2025) (Trial registration: NCT05144685) examined a digital therapeutic intervention on patients with elevated suicide risk through a multisite double-blind randomised controlled trial. The patients were originally inpatients in a mental health ward, with the intervention commencing just before discharge. Thereafter, patients could access the therapeutic app at their desired frequency and pace. The authors declare that they followed CONSORT in their reporting. The primary outcome was time to suicide attempt during follow up. Randomisation was stratified and developed by an independent biostatistician, and assignment was allocated by researchers not involved in data collection. The study used a group-sequential design, which set boundaries both for efficacy and futility. These boundaries allow the researchers to perform interim examinations of the data as they are collected at pre-specified time points. If the evidence is very strong in rejecting the hypothesis under study, and the efficacy boundary is crossed, then the study can end early. Equivalently, if there is a clear indication that no differences between the groups will be detected, the futility boundary is crossed and the study terminates early. The latter occurred in this particular study, which terminated after collecting data from 339 patients, of which 266 had completed at least one follow up. The statistical analysis was broadly appropriate for the data collected and a complete statistical analysis plan was included in the publication. The primary finding was that the digital therapeutic intervention did not demonstrate a significant difference in time to suicide attempt during follow up when compared with treatment as usual. The authors highlighted some limitations, such as the fact that the study may have been underpowered for patients with no prior suicide attempts and that intervention adherence was lower than anticipated. The study was funded by a digital company that developed the therapeutic tool, and multiple authors were employed by the company. The conflict of interest was clearly declared and the involvement of the funder in the study was

described in the appropriate sections. Overall, this study provides moderate-to-high support for the non-efficacy of the therapeutic digital intervention.

Section 2. Comment on retraction of Buckley et al. (2024)

2.1 On the 15th of July 2026, PLOS Digital Health issued a retraction for Buckley et al. (2024). In our original review of the publication, we had established the following limitations:

- The underlying clinical data were from a collection of studies with different designs and without randomisation
- Important model inputs were based on small numbers of trusts or wards and depended on various strong assumptions
- Statistical reporting of findings had severe limitations (e.g., absence of clear confidence intervals)
- Relative change misinterpretation, as suggested by Chua (2026), may have led to substantial cost-savings calculated
- Independence was a material concern because the study was funded by Oxehealth, Oxehealth was involved in data collection and analysis, and the authors' organisation was funded to develop the model and manuscript

2.2 The retraction note, published by the editors of *PLOS Digital Health*, highlighted a further concern that we had been unaware of: the authors had not been given access to the full data. This means that they would not have been able to ascertain whether there were any limitations in the original data that could have led to bias being incorporated in the model inputs. Furthermore, without any access to the original data, neither the authors nor the reviewers would have been able to assess the reliability and validity of modelling decisions. Overall, we consider none of the authors having access to the data of their publication to be highly unorthodox practice. Thus, we suggest this evidence should be given low evidential weight. This is a reduction from low-to-moderate evidential weight, based on our original assessment.

Section 3. Further evidence review from original bundle

3.1 Carey and Steele (2019) (OXHE024284 - LC/109) present a slide deck to support a future project they were intending to design and conduct as part of the Sleep Research Group. The presentation begins with a review of the state of knowledge at the time on the association between sleep, mental illness, and violence. The presenters state that a scoping review would be the expected next step, as the current state of literature is too heterogeneous to conduct a systematic review. Following that, the presenters and their group intended to design a series of experiments to build the evidence base on the effects of sleep for inpatients in forensic psychiatric units, working towards a randomised controlled trial. Oxevision is mentioned as a potential technology for investigation. As this is a presentation of the early stages of research, it does not by itself provide any substantive evidence on Oxevision and its effectiveness within a mental health inpatient setting.

3.2 Freeman et al. (2019) (OXHE025080 - LC/109) is a conference abstract for a presentation to the 2019 Annual Meeting of the American Academy of Neurology. The presentation was to be delivered by William D. Freeman as part of an Advances in Neurology session. The work described in the abstract was a feasibility study on whether an onboard camera based vital signs monitoring system could be used for future space health monitoring. As part of this, Oxevision was used in an unmanned rocket launch. The feasibility findings suggest that the monitoring system would remain functional during launch, apogee, and descent. As this is a feasibility study on the physical robustness of the system, it does not by itself provide any substantive evidence on Oxevision and its effectiveness within a mental health inpatient setting.

3.3 Tardieu et al. (2020) (OXHE025071 - LC109) is a chapter from the book "Deliberately Digital" which examines the impact of digital technologies on businesses. The chapter is a specific case study on the implementation of digital technologies in healthcare, providing wide-ranging examples from personalised medicine to radiology. Oxevision is mentioned briefly within the context of monitoring vital signs that would reduce the pressure of manual monitoring by healthcare workers. The authors describe the technology as being able to determine heart rate through "very small movements" of a patient's face which is not in alignment with our understanding of how Oxevision works. As this is a general review, and due to the possible misunderstanding about how the technology functions, this chapter does not provide any substantive evidence on Oxevision and its effectiveness within a mental health inpatient setting.

Statement of truth

I confirm that I have made clear which facts and matters referred to in this report are within my own knowledge and which are not. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer. I understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

Signed:

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