APPENDIX 17: HEALTH ECONOMIC EVIDENCE – COMPLETED METHODOLOGY CHECKLISTS

Abbreviations

GDG	Guideline Development Group
HRQoL	health-related quality of life
NA	not applicable
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PSS	personal social services
p.r.n.	pro re nata (take as required)
QALY	quality-adjusted life year

1.1 MODIFICATIONS TO THE ENVIRONMENT

1.1.1 Nanda 2011

Study identification: Nanda U, Eisen S, Zadeh RS, Owen D. Effect of visual art on patient anxiety and agitation in a mental health facility and implications for the business case. Journal of Psychiatric and Mental Health Nursing. 2011;18:386-93.			
Guideline topic: Violence and aggression			
Section 1: Applicability (relevance to specific guideline review question(s) and the NICE reference case)		**Yes/ Partly/ No/Unclear /NA**	**Comments**
1.1	Is the study population appropriate for the guideline?	Yes	
1.2	Are the interventions and services appropriate for the guideline?	Yes	
1.3	Is the healthcare system in which the study was conducted sufficiently similar to the current UK NHS context?	Partly	US study
1.4	Are costs measured from the NHS and personal social services (PSS) perspective?	No	US study
1.5	Are non-direct health effects on individuals excluded?	Yes	
1.6	Are both costs and health effects discounted at an annual rate of 3.5%?	NA	1 year
1.7	Is the value of health effects expressed in terms of quality-adjusted life years (QALYs)?	No	
1.8	Are changes in health-related quality of life (HRQoL) reported directly from patients and/or carers?	NA	
1.9	Is the valuation of changes in HRQoL (utilities) obtained from a representative sample of the general public?	NA	
1.10	**Overall judgement: partially applicable**		
Other comments: None			

Section 2: Study limitations (the level of methodological quality)		**Yes/ Partly/ No/Unclear/ NA**	**Comments**
2.1	Does the model structure adequately reflect the nature of the health condition under evaluation?	NA	Observational study
2.2	Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	No	Each treatment effect only observed for between 16 to 19 days with no long term follow up.
2.3	Are all important and relevant health outcomes included?	No	Service user quality of life not measured
2.4	Are the estimates of baseline health outcomes from the best available source?	No	Observational study with short observation time (16 to 19 days)
2.5	Are the estimates of relative treatment effects from the best available source?	No	Observational study
2.6	Are all important and relevant costs included?	Partly	No long term costs and cost of paintings not included
2.7	Are the estimates of resource use from the best available source?	No	Short observation time
2.8	Are the unit costs of resources from the best available source?	No	Local sources
2.9	Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	Incremental cost per avoided p.r.n. event can be calculated
2.10	Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Partly	Statistical analysis of outcomes only
2.11	Is there no potential conflict of interest?	Yes	
2.12	**Overall assessment**: **very serious limitations**		
Other comments: None			

1.2 RAPID TRANQUILLISATION / PHARMACOLOGICAL INTERVENTIONS

1.2.1 Freeman 2009

Study identification: Freeman DJ, DiPaula BA, Love RC. Intramuscular haloperidol versus intramuscular olanzapine for treatment of acute agitation: a cost-minimization study. Pharmacotherapy. 2009;29:930-36.			
Guideline topic: Violence and aggression			
Section 1: Applicability (relevance to specific guideline review question(s) and the NICE reference case)		**Yes/ Partly/ No/Unclear /NA**	**Comments**
1.1	Is the study population appropriate for the guideline?	Yes	
1.2	Are the interventions and services appropriate for the guideline?	Yes	
1.3	Is the healthcare system in which the study was conducted sufficiently similar to the current UK NHS context?	Partly	US study
1.4	Are costs measured from the NHS and personal social services (PSS) perspective?	No	US study
1.5	Are non-direct health effects on individuals excluded?	Yes	
1.6	Are both costs and health effects discounted at an annual rate of 3.5%?	NA	Episode-based approach
1.7	Is the value of health effects expressed in terms of quality-adjusted life years (QALYs)?	No	
1.8	Are changes in health-related quality of life (HRQoL) reported directly from patients and/or carers?	NA	
1.9	Is the valuation of changes in HRQoL (utilities) obtained from a representative sample of the general public?	NA	
1.10	**Overall judgement: partially applicable**		
Other comments: None			

Section 2: Study limitations (the level of methodological quality)		**Yes/ Partly/ No/Unclear/ NA**	**Comments**
2.1	Does the model structure adequately reflect the nature of the health condition under evaluation?	NA	Alongside medical record review (retrospective design)
2.2	Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	No	Data limited to within 24 hours of receiving medication. No long term effects.
2.3	Are all important and relevant health outcomes included?	No	Service user quality of life not measured
2.4	Are the estimates of baseline health outcomes from the best available source?	No	Retrospective medical record review
2.5	Are the estimates of relative treatment effects from the best available source?	No	Retrospective medical record review
2.6	Are all important and relevant costs included?	No	Does not address treatment of side effects
2.7	Are the estimates of resource use from the best available source?	No	Retrospective medical record review

2.8	Are the unit costs of resources from the best available source?	No	Local sources
2.9	Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10	Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	No	No sensitivity analysis
2.11	Is there no potential conflict of interest?	Yes	
2.12	**Overall assessment**: **very serious limitations**		
Other comments: at the time of producing this guideline olanzapine has gone off patent and is not marketed for rapid tranquilisation in the UK.			

1.3 POST-INCIDENT MANAGEMENT

1.3.1 NICE CG25

Study identification: National Collaborating Centre for Nursing and Supportive Care. Violence: the short-term management of disturbed/violent behaviour in in-patient psychiatric settings and emergency departments. Clinical guideline 25. The Royal College of Nursing: London. 2005. [Full guideline]			
Guideline topic: Violence and aggression			
Section 1: Applicability (relevance to specific guideline review question(s) and the NICE reference case)		**Yes/ Partly/ No/Unclear /NA**	**Comments**
1.1	Is the study population appropriate for the guideline?	Yes	
1.2	Are the interventions and services appropriate for the guideline?	Yes	
1.3	Is the healthcare system in which the study was conducted sufficiently similar to the current UK NHS context?	Yes	
1.4	Are costs measured from the NHS and personal social services (PSS) perspective?	Yes	
1.5	Are non-direct health effects on individuals excluded?	Yes	
1.6	Are both costs and health effects discounted at an annual rate of 3.5%?	Partly	3% figure used
1.7	Is the value of health effects expressed in terms of quality-adjusted life years (QALYs)?	Yes	
1.8	Are changes in health-related quality of life (HRQoL) reported directly from patients and/or carers?	No	Utility states based on assumptions
1.9	Is the valuation of changes in HRQoL (utilities) obtained from a representative sample of the general public?	NA	Only values of 1 and 0 employed
1.10	**Overall judgement: directly applicable**		
Other comments: None			

Section 2: Study limitations (the level of methodological quality)		**Yes/ Partly/ No/Unclear/ NA**	**Comments**
2.1	Does the model structure adequately reflect the nature of the health condition under evaluation?	Partly	Proportion surviving with brain damage estimated using GDG opinion.
2.2	Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	Yes	
2.3	Are all important and relevant health outcomes included?	No	Utility values of one for those surviving and 0 for those dying were assumed.
2.4	Are the estimates of baseline health outcomes from the best available source?	Unclear	
2.5	Are the estimates of relative treatment effects from the best available source?	No	GDG opinion
2.6	Are all important and relevant costs included?	Partly	Costs of side effects not included
2.7	Are the estimates of resource use from the best available source?	No	GDG opinion
2.8	Are the unit costs of resources from the best available source?	Unclear	

2.9	Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10	Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	Partly	No probabilistic analysis
2.11	Is there no potential conflict of interest?	Yes	
2.12	**Overall assessment**: **very serious limitations**		
Other comments: None			

1.4 CHILDREN AND YOUNG PEOPLE – NON-PHARMACOLOGICAL MANAGEMENT

1.4.1 LeBel 2005

Study identification: LeBel J, Goldstein R. The economic cost of using restraint and the value added by restraint reduction or elimination. Psychiatric services. 2005;56:1109-14.			
Guideline topic: Violence and aggression			
Section 1: Applicability (relevance to specific guideline review question(s) and the NICE reference case)		**Yes/ Partly/ No/Unclear /NA**	**Comments**
1.1	Is the study population appropriate for the guideline?	Yes	Young people from 13 to 18 years in an inpatient psychiatric facility
1.2	Are the interventions and services appropriate for the guideline?	Yes	
1.3	Is the healthcare system in which the study was conducted sufficiently similar to the current UK NHS context?	Partly	US study
1.4	Are costs measured from the NHS and personal social services (PSS) perspective?	No	US study
1.5	Are non-direct health effects on individuals excluded?	Yes	
1.6	Are both costs and health effects discounted at an annual rate of 3.5%?	NA	Episode-based approach
1.7	Is the value of health effects expressed in terms of quality-adjusted life years (QALYs)?	No	
1.8	Are changes in health-related quality of life (HRQoL) reported directly from patients and/or carers?	NA	
1.9	Is the valuation of changes in HRQoL (utilities) obtained from a representative sample of the general public?	NA	
1.10	**Overall judgement: partially applicable**		
Other comments: Intervention poorly defined			

Section 2: Study limitations (the level of methodological quality)		**Yes/ Partly/ No/Unclear/ NA**	**Comments**
2.1	Does the model structure adequately reflect the nature of the health condition under evaluation?	NA	Alongside before and after study
2.2	Is the time horizon sufficiently long to reflect all important differences in costs and outcomes?	No	Each study period is 1 financial year, this is unlikely to capture long term effects.
2.3	Are all important and relevant health outcomes included?	No	Quality of life not measured
2.4	Are the estimates of baseline health outcomes from the best available source?	Partly	Observational data over 12 months
2.5	Are the estimates of relative treatment effects from the best available source?	No	Before and after study
2.6	Are all important and relevant costs included?	No	Cost of implementation not reported
2.7	Are the estimates of resource use from the best available source?	No	Single before and after study design
2.8	Are the unit costs of resources from the best available source?	No	Local sources
2.9	Is an appropriate incremental analysis presented or can it be calculated from the data?	Yes	
2.10	Are all important parameters whose values are uncertain subjected to appropriate sensitivity analysis?	No	No statistical analysis
2.11	Is there no potential conflict of interest?	Yes	
2.12	**Overall assessment**: **potentially serious limitations**		
Other comments:			