Partnering with the Healthcare system
A case study in mental health

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Today’s Session

- Overview
  - Janssen’s history in Mental Health
  - Janssen current focus in Schizophrenia

- The Challenge

- Progress so far
  - Successes, challenges and learnings
  - Adapting our approach for Manchester
Janssen- a legacy of making history in psychiatry

- Janssen has a long heritage in mental health, dating back to the 1950’s

- During the last 60 years, we have continued to develop multiple treatments for schizophrenia, with two antipsychotics featuring on the WHO list of essential medicines\(^1\)

- Neuroscience is a key research area for Janssen; part of $4.5 billion investments in research and development annually\(^2\)

- We are involved in a large number of initiatives to support people affected by mental illness and in particular to reduce the stigma of mental health in the community.\(^3\)

- Janssen developed the first response scheme in the UK

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\(^1\) WHO Model List of Essential Medicines, 18\(^{th}\) Edition, April 2013
\(^2\) http://www.janssen.com/uk/about-us/quick-facts-about-janssen
\(^3\) http://www.janssen.com/uk/health/neuroscience
Janssen’s current footprint in Schizophrenia

- Janssen is currently focused in schizophrenia
- Janssen has three licensed Second Generation Long Acting Treatments (SGLATs) for the treatment of Schizophrenia
- Our Paliperidone portfolio is the focus of our attention
  - Paliperidone once-monthly approved in 2011
  - Paliperidone three-monthly - the first 4 times a year maintenance treatment for schizophrenia, approved in 2016
  - Real world evidence across UK sites for Paliperidone once-monthly to support our value proposition around reducing admissions/bed days
Examples of key outcomes in mental health—How could our Value Proposition support achieving these?

Table 1: Outcome measures: Oxfordshire NHS Foundation Trust outcomes-based commissioning model for mental health

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Outcome Description</th>
<th>Indicator</th>
<th>Outcome Points</th>
<th>Indicator Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>People will live longer</td>
<td>Mortality age of the MH adult population (reduction in excess of under 75 age mortality rate)*</td>
<td>3</td>
<td>5</td>
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<tr>
<td>2</td>
<td>People will improve their level of functioning</td>
<td>% aggregated improvement in score on validated recovery evaluation tool (e.g. Star Recovery Tool) amongst service users in clusters 4-17 at most recent cluster review*</td>
<td>20</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>% of service users in clusters 4-17 under the care of OHFT with a reduction in intensity in HeNOS rating score at their most recent cluster review*</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>% of service users who have been discharged from OHFT and are not readmitted to hospital at 28 days after discharge</td>
<td>6</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>% of service users who have been discharged from OHFT and are not readmitted to hospital at 90 days after discharge</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>People will receive timely access to assessment and support</td>
<td>Percentage of all referrals to adult mental health teams that are categorised as crisis/emergency where the patient (and carer where applicable) and the referring GP are contacted within 2 hours.</td>
<td>10</td>
<td>10</td>
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<tr>
<td>4</td>
<td>Carers feel supported in their caring role</td>
<td>% of identified carers who are, as a carer, satisfied with the care and support s/he receives as a carer</td>
<td>15</td>
<td>7.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>% of identified carers who are satisfied with the care and support received by the person s/he cares for</td>
<td></td>
<td>7.5</td>
</tr>
<tr>
<td>5</td>
<td>People will maintain a role that is meaningful to them</td>
<td>50% of service users in paid employment, undertaking a structured education or training programme or undertaking structured voluntary activity with at least 33% of those in paid employment</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>6</td>
<td>People continue to live in stable accommodation</td>
<td>% of service users living in stable accommodation</td>
<td>10</td>
<td>10</td>
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<tr>
<td>7</td>
<td>People will have fewer physical health problems related to their mental health</td>
<td>% of current service users in clusters 4-8 whose impact on the urgent care system will reduce</td>
<td>15</td>
<td>5</td>
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<tr>
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<td></td>
<td>% of service users with BMI between 19 - 25</td>
<td></td>
<td>5</td>
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<tr>
<td></td>
<td></td>
<td>% reduction in the prevalence of smoking amongst the service user population under the care of the contact</td>
<td></td>
<td>5</td>
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</table>

Delivery of agreed milestones within the Trusts Transformation programme e.g. recovery college/SILS 10 | 10
The Challenge

- Patient access mixed and inconsistent
  - Silo budgets in mental health
  - Funding flow in MH makes realising the value proposition a challenge
Funding Flow impacting patient access?

Block contract

No ‘cost’ of admission
Patient stays in secondary care
The Challenge

- **Patient access mixed and inconsistent**
  - Silo budgets in mental health
  - Funding flow in MH makes realising the value proposition a challenge

- What could we do to “back” our value proposition?
- What could we do to increase patient access to treatments
  - Approach using RWE to support appropriate use of our treatments and then outcomes contract based on the value proposition offered...
Building our outcomes scheme

Real World Evidence supporting Medicines Optimisation

Patients initiated on **Janssen’s 1-monthly** Long-Acting Treatment with a diagnosis of schizophrenia

Janssen reimburses on discontinuation within **first 6 months** of treatment due to lack of efficacy or tolerability

Discontinuation in first 3 months = 100% reimbursement on stock used
Discontinuation in months 3 to 6 = 50% reimbursement on stock used

Patients must be stable for a minimum of 4 months on Janssen’s 1-monthly Long-Acting Treatment (the last two doses must be the same) before transitioning to Janssen’s 3-monthly Long-Acting Treatment

Patients transition to **Janssen’s 3-monthly** Long-Acting Treatment

Janssen reimburses within the **first 2 years of treatment** for each patient admitted to an inpatient ward for >72 hours due to a worsening of psychiatric symptoms. There is a 100% reimbursement on the stock used up until the point of admission
Progress, learnings and challenges

- 15 mental health trusts signed up
- Over 600 patients in enrolled in the schemes
- Good feedback on ease of portal and scheme.
- Some sites unable to administer such a scheme
- Uptake of scheme varied across the sites.
- Patient pool is restrictive in the real world
- Evolving the scheme is challenging.
- Over 600 patients in enrolled in the schemes
Partnering to evolve the scheme further: Manchester experience

- Outcomes payment scheme identified by Health Innovation Manchester as one of four schemes to pilot across the area and the only mental health initiative

- Opportunity to evolve scheme as a pilot e.g. different definitions of escalation to be considered and reimbursed (Crisis teams, forensic settings etc)

- Potential to collect further data and evaluate the impact more broadly on the healthcare system

- But...
  - Different service designs commissioned across three distinct Mental Health Providers
  - Data and records not fully joined up
  - Potentially onerous data collection process vs benefits of reimbursement
  - Challenging for Janssen to assess risk of new approach
    - Internal process can be prohibitive
Summary

- We have worked to develop a good base outcomes contract scheme
- Industry and the healthcare system needs to look at how it can better operationalise such approaches
PRESCRIBING INFORMATION

XEPLION® 50 mg, 75 mg, 100 mg & 150 mg prolonged release suspension for injection

ACTIVE INGREDIENT(S): 50 mg, 75 mg, 100 mg or 150 mg paliperidone.

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): XEPLION is indicated for maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, XEPLION may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.

DOSAGE & ADMINISTRATION: Intramuscular use only. Initiation doses (days 1 and 8) must be administered in deltoid muscle for therapeutic concentrations to be rapidly attained. Adults: 150 mg on treatment day 1 and 100 mg one week later (day 8 ± 4), both doses administered in deltoid muscle, using 1½ inch, 22 gauge needle (38.1 mm x 0.72 mm) for patients ≥ 90 kg, or 1-inch, 23 gauge needle (25.4 mm x 0.64 mm) for those < 90 kg. The third dose should be administered one month after the second initiation dose. Recommended monthly maintenance dose is 75 mg (range 50 mg-150 mg) in either deltoid or gluteal muscle. Recommended needle size for maintenance administration of XEPLION into deltoid muscle is as for initiation doses, and for the gluteal muscle is the 1½-inch, 22 gauge needle (38.1 mm x 0.72 mm). To avoid a missed monthly maintenance dose patients may be given injection up to 7 days before or after the monthly time point. Consider maintenance doses in upper range for overweight/obese patients. Adjust maintenance dose at monthly intervals as necessary. Alternate injections between left and right sides. Discontinue previous oral paliperidone or risperidone at time of initiation of XEPLION treatment (gradual withdrawal may benefit some patients). When switching patients from RISPERDAL® CONSTA™, initiate XEPLION in place of next scheduled injection, continue at monthly intervals. Children: No safety or efficacy data available. Elderly: No safety or efficacy data available for patients > 65 years. Renal impairment: Mild (creatinine clearance ≥ 50 to < 80 ml/min): Initiate with 100 mg on treatment day 1 and 75 mg one week later (day 8). Recommended monthly maintenance dose 50 mg. Moderate or severe (creatinine clearance < 50 ml/min): Not recommended. Hepatic impairment: Caution in severe hepatic impairment.

CONTRAINDICATIONS: Hypersensitivity to paliperidone, risperidone or any of the excipients.

SPECIAL WARNINGS & PRECAUTIONS: Do not use in acutely agitated or severely psychotic patients. Caution in cardiovascular disease (including family history of QT prolongation), cerebrovascular disease (especially elderly patients with dementia and risk factors for stroke),
PRESCRIBING INFORMATION
Trevicta® 175 mg, 263 mg, 350 mg & 525 mg prolonged release suspension for injection

ACTIVE INGREDIENT(S): 175 mg, 263 mg, 350 mg & 525 mg paliperidone.

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): TREVICTA, a 3-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly paliperidone palmitate injectable product.

DOSAGE & ADMINISTRATION: Intramuscular injection. Patients who are treated with 1-monthly paliperidone palmitate injectable (4 months or more) and do not require dose adjustment may be switched to TREVICTA. Adults: Administer dose in either deltoid or gluteal muscle. Deltoid administration, use 1½ inch, 22 gauge needle (0.72 mm x 38.1 mm) patients ≥ 90 kg, or 1-inch, 22 gauge needle (0.72 mm x 25.4 mm) patients < 90 kg. For gluteal administration use the 1½-inch, 22 gauge needle (0.72 mm x 38.1 mm). Initiate TREVICTA in place of the next scheduled dose of 1-month paliperidone palmitate injectable (± 7 days). Base TREVICTA dose on the previous 1-month paliperidone palmitate injectable dose using a 3.5-fold higher dose. Thereafter TREVICTA should be administered by intramuscular injection once every 3 months (± 2 weeks). Dose adjustment of TREVICTA can be made every 3 months in increments within the range of 175 mg to 525 mg. Alternate injections between left and right sides. Children: No safety or efficacy data available. Elderly: No safety or efficacy data available for patients > 65 years. Renal impairment: Mild (creatinine clearance ≥ 50 to < 80 ml/min): dose should be adjusted. Stabilise patient using 1-month paliperidone palmitate injectable, and then transition to TREVICTA. Moderate or severe (creatinine clearance < 50 ml/min): Not recommended. Hepatic impairment: Caution in severe hepatic impairment.

CONTRAINDICATIONS: Hypersensitivity to paliperidone, risperidone or any of the excipients.

SPECIAL WARNINGS & PRECAUTIONS: Do not use in acutely agitated or severely psychotic patients. Not recommended in elderly dementia patients. Caution in cardiovascular disease (including family history of QT prolongation), cerebrovascular disease, hypotension, prolactin-dependent tumours, seizures, Parkinson’s disease and in conjunction with medicines that prolong QT interval. May induce orthostatic hypotension. If tardive dyskinesia occurs consider discontinuing all antipsychotics. Events of leucopenia, neutropenia, and agranulocytosis reported with antipsychotics, including TREVICTA, additional monitoring or cessation of treatment may be required. If Neuroleptic Malignant Syndrome (NMS) occurs discontinue all antipsychotics. Rarely, anaphylactic reactions reported in patients previously tolerating oral risperidone/paliperidone. If occur, discontinue TREVICTA, initiate general supportive measures, monitor until resolved. Appropriate clinical monitoring in diabetics and those with risk factors for diabetes advisable. Advise of potential for weight gain, monitor weight regularly. Priapism
reported with oral paliperidone. Caution in patients experiencing conditions which may contribute to core body temperature elevation. Identify all possible risk factors for venous thromboembolism (VTE) before and during treatment and take preventive measures. Antiemetic effect (observed in paliperidone preclinical studies) may mask overdosage with certain medicines, intestinal obstruction, Reye’s syndrome, brain tumour etc. Avoid inadvertent injection into a blood vessel. Intraoperative floppy iris syndrome (IFIS) observed during cataract surgery in patients treated with medicines with alpha1a-adrenergic antagonist effect, such as TREVICTA.

SIDE EFFECTS: Very common: insomnia. Common: upper respiratory tract infection, urinary tract infection, influenza, hyperprolactinaemia, hyperglycaemia, weight increased, weight decreased, decreased appetite, agitation, depression, anxiety, parkinsonism, akathisia, sedation/somnolence, dystonia, dizziness, dyskinesia, tremor, headache, tachycardia, hypertension, cough, nasal congestion, abdominal pain, vomiting, nausea, constipation, diarrhoea, dyspepsia, toothache, transaminases increased, musculoskeletal pain, back pain, arthralgia, amenorrhoea, galactorrhoea, pyrexia, asthenia, fatigue, injection site reaction. Other side effects reported with paliperidone include: pneumonia, respiratory tract infection, cellulitis, thrombocytopenia, diabetes mellitus, electrocardiogram QT prolonged, bradycardia, subcutaneous abscess, neutropenia, inappropriate antidiuretic hormone secretion, diabetic ketoacidosis, NMS, cerebral ischaemia, unresponsive to stimuli, loss of consciousness, depressed level of consciousness, glaucoma, atrial fibrillation, pulmonary congestion, pancreatitis, faecaloma, urinary retention, hypothermia, agranulocytosis, anaphylactic reaction, water intoxication, diabetic coma, pulmonary embolism, pneumonia aspiration, intestinal obstruction, ileus, angioedema, rhabdomyolysis, injection site necrosis. Other side effects reported with risperidone (paliperidone is the active metabolite of risperidone): Weight gain: 10% of TREVICTA-treated subjects experienced weight gain of ≥ 7%. Laboratory tests: Serum prolactin: increases in serum prolactin observed. Class effects: QT prolongation, ventricular arrhythmias, sudden unexplained death, cardiac arrest, and Torsade de pointes may occur with antipsychotics. Cases of venous thromboembolism, including pulmonary embolism and deep vein thrombosis, also reported.

Refer to SmPC for other side effects.

PREGNANCY: Should not be used during pregnancy unless clearly necessary.

LACTATION: Should not be used while breastfeeding.

INTERACTIONS: Caution with medicines that prolong QT interval e.g., class IA and class III antiarrhythmics, some antihistaminics, some antibiotics, some other antipsychotics, some antimalarials. Potential for TREVICTA to affect other medicines: Caution in conjunction with: other centrally acting medicines e.g., anxiolytics, antipsychotics, hypnotics, opiates, alcohol; medicines known to lower seizure threshold i.e., phenothiazines, butyrophenones, tricyclics, SSRI’s, tramadol, mefloquine; medicines capable of inducing orthostatic hypotension (an additive effect may be observed when TREVICTA is co-administered); levodopa and other dopamine agonists (paliperidone may antagonize their
effect- use lowest effective dose of each treatment if this combination necessary e.g., end-stage Parkinson’s disease). Interaction of TREVICTA with lithium unlikely. Potential for other medicines to affect TREVICTA: Administration of oral paliperidone and paroxetine (a potent CYP2D6 inhibitor) showed no clinically significant effect on paliperidone pharmacokinetics. Co-administration of oral paliperidone once daily with carbamazepine 200 mg twice daily decreases plasma concentration of paliperidone by 37%. Re-evaluate/increase TREVICTA dose at carbamazepine initiation. No clinically significant interaction expected between valproate and TREVICTA. Caution when TREVICTA is coadministered with risperidone or with oral paliperidone for extended periods of time. Limited safety data for concomitant use of TREVICTA with other antipsychotics.

Refer to SmPC for full details of interactions.

LEGAL CATEGORY: Prescription Only Medicine.

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBERS & BASIC NHS COSTS:

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<td>525 mg pre-filled syringe</td>
<td>1 dose</td>
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<td>£1177.77</td>
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MARKETING AUTHORISATION HOLDER: Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

FURTHER INFORMATION IS AVAILABLE FROM: Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK.

Prescribing information last revised: 09/2017

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Janssen-Cilag Limited on 01494 567447 or at dsafety@its.jnj.com.
hypotension/ hypotensive states, prolactin-dependent tumours, seizures (or conditions that lower seizure threshold), Parkinson’s disease and dementia with Lewy bodies. Discontinue all antipsychotics if neuroleptic malignant syndrome occurs. Consider discontinuation of all antipsychotics if tardive dyskinesia occurs. Monitoring of white cell count (WCC) may be required. Discontinue XEPLION at first sign of clinically significant WCC in absence of other causes or if severe neutropenia (absolute neutrophil count <1 X 10^9/L). Rarely, anaphylactic reactions reported in patients previously tolerating oral risperidone/paliperidone. If occur, discontinue XEPLION, initiate general supportive measures and monitor until resolved. Appropriate clinical monitoring advised in patient with or at risk of diabetes. Advise of potential for weight gain, monitor weight regularly. Advise male patients to seek urgent medical care if priapism not resolved within 4 hours. Appropriate care advised for patients who will experience conditions that elevate core body temperature. Identify all possible risk factors for venous thromboembolism (VTE) before and during treatment and take preventive measures. Antiemetic effect (observed in paliperidone preclinical studies) may mask other conditions including overdose with certain medicines. Avoid inadvertent injection into a blood vessel. Intraoperative floppy iris syndrome (IFIS) has been observed during cataract surgery in patients treated with medicines with alpha1a-adrenergic antagonist effect, such as XEPLION.

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Injection site reactions: mild to moderate pain most commonly reported (tended to lessen in frequency and intensity over time). Weight gain: 12% of XEPLION-treated subjects experienced weight gain of ≥7% (from double-blind phase to endpoint) during 33-week open-label phase of long-term recurrence prevention study. Laboratory tests: Serum prolactin: increases in serum prolactin observed in clinical trial subjects (both genders) with XEPLION. Adverse reactions suggesting increase in prolactin levels reported overall in <1% of subjects. Class effects: Ventricular arrhythmias, sudden unexplained death, cardiac arrest, and Torsade de pointes may occur with antipsychotics. Cases of venous thromboembolism, including pulmonary embolism and deep vein thrombosis, also reported.

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