

MENTAL HEALTH — DRUG TRIALS

177. Hon Sally Talbot to the Minister for Mental Health:

- (1) How many drug and/or research trials has the Western Australian Mental Health Service conducted since 2000 which included involuntary patients as the subject(s)?
- (2) What were the trials for, what drugs were involved and when were the trials conducted?
- (3) Are there particular ethical guidelines for running drug trails on patients who cannot refuse treatment (i.e. involuntary patients)?
- (4) If so, what are they?
- (5) Were they complied with in all trials?
- (6) If not, for each of these trials, what breaches were there?
- (7) What hospital(s) undertook each of these trials?
- (8) Which doctor was responsible for each of these trials?
- (9) Was the informed consent of involuntary patients obtained to participate in these trials?
- (10) What payments were made in connection with these trials (please provide details of payers, payees, amounts, dates and methods of payment)?
- (11) What was the total income from each of these trials?
- (12) What accounts were the payments directed to?

Hon Helen Morton replied:

- (1) North Metropolitan Health Service (NMHS): There have been 56 trials (48 not involving medication and 8 involving medication), for 2002 onwards.

South Metropolitan Health Service (SMHS): Nil.

WA Country Health Service (WACHS): Nil.

Child & Adolescent Health Service (CAHS): Nil.

- (2) NMHS: The eight trials involving medication were:

Study of safety and effectiveness of <i>intramuscular psychotropic medication</i> in patients who are acutely agitated (2002).
Study examining cardiovascular risk reduction in patients with schizophrenia recently changed to <i>Risperdal</i> (2003).
Study of intramuscular (IM) antipsychotic medications — <i>Olanzapine v's alternative IM medications</i> (2004–2005).
Study of Effectiveness of <i>Olanzapine</i> in Tablet and Wafer Forms on improving negative symptoms in the treatment of Inpatients with Schizophrenia (2003–2005).
Study of Electronic Schizophrenia Treatment Adherence Registry Protocol (<i>Risperdal Consta</i>) (2006).
Trial of <i>Risperdal Consta</i> versus oral atypical antipsychotics in poorly adherent subjects with schizophrenia in a routine care setting (2006–2009).
<i>Risperdal Consta</i> Observation Study After SwiTching (COAST) (2006).
Study looking at the efficacy and safety assessment of <i>Org 5222</i> and <i>Olanzapine</i> in the treatment of patients with schizophrenia or schizoaffective disorder (2003–2004).

The other 48 projects mentioned were research such as de-identified data analysis and data collection.

SMHS: Not applicable.

WACHS: Not applicable.

CAHS: Not applicable.

- (3) NMHS, SMHS, WACHS and CAHS: Yes.
- (4) NMHS, SMHS, WACHS and CAHS: The *National Statement on the Ethical Conduct in Human Research* chapter 3.3 outlines the ethical considerations specific to projects which are “interventions & therapies, including clinical and non clinical trials and innovations”.

- The *National Statement on the Ethical Conduct in Human Research* chapter 4.5 outlines the ethical considerations specific to “people with a cognitive impairment, an intellectual disability or a mental illness”.
- (5) NMHS: Yes.
SMHS: Not applicable.
WACHS: Not applicable.
CAHS: Not applicable.
- (6) NMHS: Not applicable.
SMHS: Not applicable.
WACHS: Not applicable.
CAHS: Not applicable.
- (7) NMHS: Graylands Hospital, Inner City Community (Adult) Mental Health Service and Osborne Park Community (Adult) Mental Health Service.

SMHS: Not applicable.
WACHS: Not applicable.
CAHS: Not applicable.
- (8) NMHS: Names of specific doctors will not be disclosed due to the doctor’s right to confidentiality.
SMHS: Not applicable.
WACHS: Not applicable.
CAHS: Not applicable.
- (9) NMHS: Yes.
SMHS: Not applicable.
WACHS: Not applicable.
CAHS: Not applicable.
- (10) [See paper 613.]
- (11) NMHS: Unable to answer this question as information regarding total income is incomplete or not held by the service.
SMHS: Not applicable.
WACHS: Not applicable.
CAHS: Not applicable.
- (12) NMHS: Two Special Purpose Accounts (0402000 and 0402006) operate for all drug trials undertaken by NMHS MH.
SMHS: Not applicable.
WACHS: Not applicable.
CAHS: Not applicable.