Parallel Lecture G: Medico-Legal Issues Arising out of Vaccination

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Medico-legal aspects arising out of vaccination

Vaccination is a complex and difficult area of medico-legal practice. Vaccines have been vital in the eradication of serious diseases such as smallpox and polio and are crucial in public health programmes in preventing disease. The prevailing scientific consensus is that the benefits of vaccines outweigh the risks and the numbers of serious adverse reactions are very small.

However, there have been a number of legal, medical and scientific controversies over the years about adverse events after vaccinations which have played out in the courts.

The UK has a statutory vaccine injury scheme and there are routes to redress against medical practitioners and pharmaceutical manufacturers.

Few clinical negligence practitioners will not have encountered claimants who consider they have suffered adverse reactions to a vaccine and consequently practitioners are called upon to advise about possible routes to redress.

The UK vaccination schedule has grown in recent years and there are now a large number of new additional vaccines which are scheduled for young babies, adolescents and the elderly.

This seminar will give an overview of the current UK vaccination schedule and look at all the additional vaccines that have been added to the programme and new vaccines in the process of being launched.

It will consider the UK statutory vaccine injury scheme, which was established in 1979 and has been updated from time to time. In 2014 it has become the joint responsibility of the Department of Health and DWP. Appeals against refusals are now heard in the First Tier Tribunal of the Courts & Tribunal Service. £93M has been awarded in compensation under the UK scheme – which is rather less than the amount paid in the USA under their statutory scheme ($2.7 Billion).

Alternative routes to redress will be considered including clinical negligence claims against medical practitioners and product liability claims against pharmaceutical manufacturers.

The seminar will look at key cases including Loveday v Renton & the Wellcome Foundation [1990] 1 Med LR, Thompson v Bradford [2005] EWCA Civ 1439, O’Byrne v Aventis Pasteur [2010] UKSC 23, the infamous MMR Vaccine litigation & the currently ongoing Pandemrix swine flu (narcolepsy) claims.

It will also look at key time limits and limitation issues in this area of practice.

Peter Todd, Partner at Hodge Jones & Allen LLP
Medico legal issues arising out of vaccination

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Overview

• The growth of importance of vaccines in public health programmes
• The UK statutory vaccine injury scheme
• Review of key vaccine cases
• Causes of action
• Limitation issues
2014 UK Immunisation Schedule

- Significant increase in recent years in the number of vaccines

"After clean water, vaccination is the most effective public health intervention in the world for saving lives and promoting good health."
- The UK Department of Health

- Further vaccines in the process of being added to the schedule
- More vaccines in development, likely to be added in due course

2014 UK Immunisation Schedule

**Neonates (at risk)**

- BCG vaccine
- Hepatitis B Vaccine

**2 months**

- Diphtheria 1\textsuperscript{st} dose
- Tetanus 1\textsuperscript{st} dose
- Acellular Pertussis 1\textsuperscript{st} dose
- Inactivated Polio 1\textsuperscript{st} dose
- Haemophilus Type b (HIB) 1\textsuperscript{st} dose
- Pneumococcal 1\textsuperscript{st} dose
- Rotavirus 1\textsuperscript{st} dose

**3 months**

- Diphtheria 2\textsuperscript{nd} dose
- Tetanus 2\textsuperscript{nd} dose
- Acellular Pertussis 2\textsuperscript{nd} dose
- Inactivated Polio 2\textsuperscript{nd} dose
- Haemophilus Type b (HIB) 2\textsuperscript{nd} dose
- Meningococcal Group C 1\textsuperscript{st} dose
- Rotavirus 2\textsuperscript{nd} dose

**4th months**

- Diphtheria 3\textsuperscript{rd} dose
- Tetanus 3\textsuperscript{rd} dose
- Acellular Pertussis 3\textsuperscript{rd} dose
- Inactivated Polio 3\textsuperscript{rd} dose
- Haemophilus Type b (HIB) 3\textsuperscript{rd} dose
- Pneumococcal 2\textsuperscript{nd} dose
### 12-13 months
- Measles, Mumps & Rubella (MMR)
- Pneumococcal (single booster dose)
- Haemophilus Typhus b (HIB) (single booster dose)

### 3 yrs 4 months-5 years
- Diphtheria
- Tetanus
- Acellular pertussis
- Inactivated Polio
- Measles, mumps & rubella (MMR)

### 12-14 years (females only)
- Human Papillomavirus Vaccine
  - 3 doses; 2nd dose after 1 month; 3rd dose 4-6 months after 1st

### 13-15 years
- Meningococcal Group C – single booster dose

### 13-18 years
- Diphtheria, Tetanus, Inactivated Polio - single booster

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### Women of child bearing age during adult life
Measles, mumps, rubella – (catch up)

### Those at or entering University during adult life
Meningococcal group C – single dose

### 70 years
Herpes Zoster (Shingles) Vaccine – single dose

+seasonal flu vaccines + occupational vaccines (e.g. Hep)
New vaccines on the way

- Candida
- Cytomegalovirus (CMV) Chlamydia
- E Coli
- Genital Herpes
- Hepatitis E
- Strep
- Periodontal Disease
- Respiratory Syncytial virus
- Staph
- New TB
- Malaria
- Mumps
- Hepatitis C
- Herpes Simplex
- Rheumatoid Arthritis
- Peanut Allergy
- Childhood Diabetes
- Allergy
- Multiple Sclerosis
- Anti-cholesterol
- Syphilis
- Listeria
- H Pylori Cat Allergy
- Ringworm
- Gonorrhea
- And many, many more....

Other vaccines on the way

- Malaria
- àCholesterol
- Syphilis
- Listeria
- H Pylori Cat Allergy
- Ringworm
- Gonorrhea
- And many, many more....

Statutory Vaccine Injury Compensation
The Vaccine Damage Payments Act 1979

- In 1970s, UK government stated to make ex gratia payments for vaccine injury compensation
- The 1979 Act put this on a statutory basis
- Originally intended to be a "payment on account" pending outcome of whooping cough vaccine litigation
- Only compensates for "serious permanent disablement"
- Single lump sum to all qualifying applicants, regardless of severity
- Only certain vaccines covered
- Few adult vaccines covered
- 931 awards made to date, worth £93M
- (USA vaccine programme 3,554 awards to 2014 with total of $2,874,524,737.39 awarded)

Coverage

- diphtheria
- tetanus
- pertussis (whooping cough)
- poliomyelitis
- measles
- mumps
- rubella (German measles)
- tuberculosis (TB)
- haemophilus influenzae type B (HIB)
- meningococcal group C (meningitis C)
- pneumococcal infection
- human papillomavirus
- pandemic influenza A (H1N1) 2009 (swine flu) - up to 31 August 2010

Includes babies injured during pregnancy when mother was vaccinated
Persons infected from someone else due to polio vaccine
**Time limit**

Claim must be submitted before the later of:-
- 21st birthday; or
- 6 years of vaccination

This time limit cannot be extended

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**Vaccines not covered**

- All vaccines if over 18 years except
  - Polio, rubella, Men C, HPV & H1N1 (in 2009-10)
- Seasonal flu
- Hepatitis A & B
- Rotavirus
- Herpes Zoster (Shingles)
- Travel vaccines e.g. yellow fever
- All vaccines for a child under 2 years of age

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**Serious permanent disablement**

- 60% disablement on the DWP industrial injuries scale
- 100% = loss of both hands or amputation at higher sites, loss of a hand and a foot, double amputation through leg or thigh or amputation through leg or thigh on one side and loss of other foot, loss of sight to such an extent as to render the Claimant unable to perform any work for which eyesight is essential, very severe facial disfiguration, absolute deafness, forequarter or hindquarter amputation
- 90% Amputation through shoulder joint or at hip or Amputation of both feet resulting in end-bearing stumps
- 80% Amputation below shoulder with stump less than 20.5 cms from tip of acromion
- 70% Amputation from 20.5 centimetres from tip of acromion to less than 11.5 centimetres below tip of olecranon
- 60% Loss of a hand or of the thumb and four fingers of one hand or amputation from 11.5 centimetres below tip of olecranon
- 50% Loss of four fingers of one hand
Reform?

- All vaccines to be covered
- Adults covered as well as children
- Reduction of 60% threshold to lower level
- DWP Industrial injuries scale to be replaced with vaccine injuries e.g. brain injury, encephalopathy, guillain barre syndrome, narcolepsy, intussusception, thrombocytopenia vasculitis etc
- Tariff for general damages – in line with JC guidelines – not single payment
- Provision for past and future special damages
- Legal costs
Civil action

• Clinical negligence:
  – Defective administration
  – Overdose
  – Contraindication

• Product liability (manufacturer):
  – Consumer Protection Act 1987
  – Strict liability for “defective” product
  – “Defect” – not as safe as consumers are reasonably entitled to expect
  Prove medical causation in both

Limitation

CN: 3 years/21st birthday (never for protected parties)

CPA same but plus 10 year long stop from shipping of product

• Shelf life of 2 yrs can make limitation 8 yrs after vaccination – so 8 year old’s claim may be about to go out of time
• Always issue within 8 years
• Risk of prof neg

Causation in civil actions

• Expert evidence
  – Biologically plausible mechanism
  – Epidemiology (> doubling the risk)
Vaccine litigation in the UK

- The MMR Litigation – 1992 to 2002
- O’Byrne v Aventis Pasteur 2001-2010
- Thompson v Bradford 2004/5
- Pandemrix® Narcolepsy 2009-

Loveday v Renton & Wellcome Foundation

Facts
- Multi party action seeking by several hundred Claimants seeking damages for catastrophic brain injury caused by whole cell pertussis (whooping cough) vaccine (DPT)
- One of the great medico legal controversies of C20th?
- Govt had commissioned NCES which found a weak association between DPT vaccine and brain damage
- Preliminary issue hearing in lead case of Loveday before Murray Stuart-Smith J on whether vaccine was capable of causing brain injury
- Manufacturer (Wellcome) intervened in clinical negligence claim v GP

Loveday

- Judge – NCES unreliable
- Claimants failed to prove causation to the require level of proof
- No appeal – intention to pursue another case
- Attempts to bring the claim back to court ongoing in 2014
- Genetics has since discovered SCN1a defect responsible for some encephalopathies (Dravet syndrome)
Thompson v Bradford

- Hamish Thompson born 1st November 1997, vaccinated with live polio vaccine on 29th December 1997
- A case of VAPP – vaccine-associated paralytic poliomyelitis
- Large spot on left buttock on 19th Nov – mentioned to health visitor (2nd visit)
- 25th Nov (3rd HV visit) – spot on left buttock had faded away but larger spot developed on right buttock. Was gaining weight. Advised to put vaseline on it and to keep an eye on it. Got larger and became more uncomfortable.
- 27/28 dec – called out of hours Dr due to restless night.

Hamish Thompson

- 29th Dec attended GP for 8 week check and imms
- HV checked and noted hard inflamed area on the anal edge – discussed with duty GP who did not examine him
- Saw Practice nurse for imms. Told her Hamish was uncomfortable, miserable and not himself. Nurse asked Dr Bradford to examine Hamish and to advise re imms.
- Dr Bradford established Hamish did not have a fever. Did not see distress save when he pressed the boil gently to express some pus for analysis
- Diagnosed perianal abscess about 1 cm by 0.5 cm and prescribed course of flucloxacillin
- Dr Bradford advised there was no reason not to go on with imms that day. High Ct found Dr B did say “one was at one end and one at the other”.
- Dr B did not go into the question of postponement

Thompson

- By 1st Jan 1998 abscess was larger and more inflamed – parents advised to take Hamish to health centre and then on to hospital
- On call surgeon (who had been advised re imms) lanced the boil under general anaesthetic. Wound then packed
- Wound regularly re-packed
- By 8th Jan high temp
- 9th Jan neck stiffness and photophobia
- Admitted to North Devon hospital – became acutely ill. Semi conscious. Lost all movement in his limbs, became paralysed.
- Eventually diagnosed with vaccine strain poliomyelitis
- Permanent severe injury to all his limbs
Mr Justice Wilkie’s decision

- Dr Bradford was entitled to conclude there was no contra indication to vaccination
- But, he was unnecessarily dismissive of their concerns and brushed them off with an inappropriate analogy which failed to give them the full picture
- Failed to inform them that the recurrent perianal abscess was unique in his experience (of his & two colleagues) and extremely unusual
- Failed to advise them there was a prospect of Hamish having to undergo surgery to lance the abscess within a short period if antibiotics did not succeed
- Therefore he fell below the standard of a reasonably competent GP

Causation

1. Whether parents would have postponed vaccination on correct advice; and
2. Immunisation was the cause; and
3. He would not have contracted vaccine poliomyelitis when vaccinated subsequently

- Wilkie J satisfied that on proper advice parents would have decided to postpone the vaccination
- Wilkie found it was the muscle damage done in the surgical intervention which provided the enhanced opportunity for VAPP to be contracted – which delay would have avoided

So Wilkie found Dr Bradford liable

Thompson – Court of Appeal

- 29.11.2005
- Waller LJ, Jonathan Parker LJ & Sir Christopher Staughton
- GP appealed against (1) finding of breach (2) factual findings as to whether parents would have postponed vaccination (3) causation.
- Hamish cross-appealed against finding there was no breach in advising jab could proceed
Thompson – Ct of Appeal decision

- GP not in breach of duty to advise the jab could proceed – hence cross-appeal failed
- Appeal against finding of breach succeeded on the basis the Judge failed to consider what Dr Bradford could reasonably have foreseen. Therefore the appeal was allowed and the claim dismissed.
- Hence points on postponement and causation were not dealt with in any detail. Ct of Appeal seems to be of the opinion that the parents would have proceeded with vaccination even had Dr Bradford mentioned how unusual abscess was and possible risk of surgery, had he advised the vaccine to proceed.

O’Byrne v Aventis Pasteur

Facts
- C vaccinated with HIB vaccine on 3.11.92 and suffered serious brain injury
- The vaccine had been put into circulation in Sept 92
- 1.8.01 C issues procs against Aventis Pasteur MSD Ltd.
- Defence filed – AV MSD Ltd denies being the manufacturer
- 1.10.02 C issues new claim against Aventis Pasteur SA.
- Defence filed relying on limitation

High Ct made a preliminary reference to ECJ on interpretation of the EU product Liability Directive
- High Ct & Court of Appeal allows C to substitute Aventis Pasteur SA for Aventis Pasteur MSD Ltd as Defendant, notwithstanding more than 10 years had passed, on the basis this was allowed within national law
- Appeal by AP to the House of Lords.
- Referred back to ECJ for further clarification
- 26th May 2010 Supreme Court decided that substitution could not be allowed as otherwise it would frustrate the 10 year long stop limitation and the claim was therefore statute barred.
- 8 years to determine the claim was issued out of time!
MMR Litigation

- MMR introduced into UK vaccine schedule in October 1988 (3 different brands in use)
- 2 brands withdrawn in 1992 due to mumps encephalitis re the Urabe strain of the mumps virus. However no claims based on mumps encephalitis emerged.
- Andrew Wakefield, Consultant in Gastroenterology at Royal Free Hospital in London suggested the vaccine was causing ulcerative colitis. Then suggested this may also be causing autism.
- Legal Aid Board was persuaded to issue certificates to cover investigating claims. Proceedings issued against Manufacturers, GPs and suppliers
- Claimants represented for the most part by Richard Barr of Dawbarns, HJA, Alexander Harris/Irwin Mitchell, Augustus Ulstein QC & Jeremy Stuart-Smith QC
- Court stayed proceedings apart from re bowel & autism allegations
- Eventually, before trial, LAB area committee decided to withdraw funding
- Judicial review of LAB went to Ct of Appeal but failed
- General scientific consensus that autism not caused by MMR vaccine
- Wakefield struck off
- Many £M spent by LAB
- Conclusions?

+ Prof neg awards for MMR
Pandemrix® (H1N1 vaccine) & Narcolepsy

The facts
- 2009-10 swine flu global pandemic
- UK govt procured a vaccine from GSK
- GSK required UK govt (and governments from all other countries) to indemnify them from product liability claims as otherwise they would not supply the vaccine
- Adjuvant (AS03) squalene was included so that each dose required only 25% of the antigen
- Testing of Pandemrix was limited
- No warnings re lack of testing or need for indemnity
- UK vaccination campaign started in September 2009
- 30 million doses given in 47 countries
- First reports of narcolepsy as an adverse event by August 2010 in Sweden and Finland.
- UK campaign halted in August 2010
- Some stocks used up in 2010-11 flu season

In the UK, the Health Protection Agency (now Public Health England) published UK govt epidemiological study in Feb 2013 which found a 14x increased risk of narcolepsy in pandemrix vaccinated children
- Rate of adverse reaction 1 in 54k – indicates about 100 people affected.
- DWP now accepts Pandemrix causes narcolepsy in children in statutory claims
- Compensation paid already in Sweden and Finland
- Claims now pending in other jurisdictions
- GSK has formally denied liability
- Approx 60 claims pending – mainly children and healthcare workers
- 2 legal aid certs granted pre-LASPO. Exceptional funding apps refused. JR pending.
- Pre action discussions with GSK – update