Agony and Autonomy in the Shadow of Montgomery

An investigation into how General Dental Practitioners (GDPs) have negotiated the twin challenges of the new patient-centred standard of consent as laid down in Montgomery and the restrictions to care caused by COVID-19 from June 2020 onwards when treating adult patients suffering with acute dental pain

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List of Abbreviations

AAA	'Advice, Analgesia and Antibiotics': the term used to describe the basis of remote triaging for patients in pain during the lockdown from March to June 2020
AGP	aerosol generating procedure: a medical or dental procedure likely to generate an aerosol spray (a mixture of water and body fluids containing droplet nuclei of less than 5 μm
BDA	British Dental Association
CDO	Chief Dental Officer
CGT	cardiotocography trace
CPD	continuing professional development
CQC	Care Quality Commission
DAS	Dental Anxiety Scale
DBS	Dental Beliefs Survey
ECHR	European Convention of Human Rights
FDS	Faculty of Dental Surgeons
FFP3	fit tested filtered face piece
FGDP	Faculty of General Dental Practice
fMRI	functional magnetic resonance imaging
FTA	free text answer
GDC	General Dental Council
GDP	general dental practitioner

GDS	general dental services
GMC	General Medical Council
HCP	health care professional
IDAN	inferior dental alveolar nerve
IPC	infection prevention control
MADP	management of acute dental pain
MCA	multiple-choice answer
MDU	Medical Defence Union
NICE	National Institute for Clinical Excellence
OCDO	Office of the Chief Dental Officer
ONS	Office for National Statistics
PHE	Public Health England
PPE	personal protective equipment
PSLA	pain, suffering and loss of amenity
RCT	randomised controlled trial
RPE	respiratory protective equipment
SAMS	Self-Assessment Manual and Standards
SARS-CoV2	severe acute respiratory syndrome coronavirus 2
SDCEP	Scottish Dental Clinical Effectiveness Programme
SOP	standard operating procedure
Tv	trigeminal nerve
UDC	urgent dental care centre

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Abstract

Since 2015 and the Montgomery ruling, the courts have informed healthcare workers in the UK of their duty "*to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments*". This legal standard for what constitutes sufficient information disclosure to allow consent to be classed as informed completed a swing from the previous paternalistic stance of the court to one based on a respect for the autonomy of each individual patient. Understanding the ramifications of this ruling and implementing the necessary changes to practice since then have represented a challenge to not just dentists but all healthcare workers.

From March 2020, the impact of the COVID-19 pandemic has had a dramatic impact on dentists in the UK who have faced unprecedented challenges to the provision of every aspect of dental care. Following the first national lockdown that ended in early June 2020, general dental practitioners (GDPs) could reopen their doors and carry out face-to-face dentistry for the first time in more than 10 weeks. The restrictions to care were significant and highly impactful on the provision of urgent dental care in particular.

The aim of this project was to give an informed contribution to our understanding of how GDPs perceive the impact of both the Montgomery ruling and the restrictions imposed upon them following their return to work in June 2020. To achieve this aim, I proposed the following objectives: to explore how much time GDPs routinely allocate for a typical urgent pain appointment; to evaluate how GDPs feel that COVID-19 restrictions have impacted their ability to gain appropriately informed consent for patients in severe, acute pain; and to investigate how GDPs feel that the Montgomery ruling has affected their consent process, with particular reference to how they would go about obtaining consent for a clinical scenario presented in the survey.

The views of GDPs across the UK were gained via a questionnaire-based survey that was distributed via a dental forum on the social media service provider Facebook. Drawing on data from 93 GDPs working in primary care in the UK, who responded to the survey, I was able to reveal the disproportionate impact of COVID-19 restrictions on those GDPs most reliant on NHS funding and the greater likelihood that these GDPs would offer shorter appointments and the lower likelihood that they would offer aerosol generating procedure (AGP) appointments for patients suffering with acute dental pain. The data also revealed that, overall, GDPs had a reasonable awareness and understanding of the Montgomery ruling and how it impacts on their consent processes for patients in pain although their

perceived knowledge and actual knowledge were found to not always be consistent.

Drawing conclusions from these findings, the thesis seeks to explore the ramifications of this unequal impact on the provision of urgent dental care. When looking at the reduced ability of those practices most reliant on NHS funding to provide the conditions for optimal care, the thesis draws into question the courts' ubiquitous approach to consent, applying it equally, as it does, across all clinical settings. It also asks questions relating to how regulatory and authoritative bodies within dentistry offer guidance and advice regarding urgent care when the delivery of it differs from practice to practice. The thesis then seeks to offer solutions in the form of suggesting future research that can help us better understand the training needs of the profession and looks at how regulatory advice and legal rulings can better reflect the disparity in the ability of the profession to deliver optimal urgent care.

Chapter 1: Introduction

The aim of this project is to give an informed contribution to our understanding of how GDPs perceive the impact of both the *Montgomery* ruling and the restrictions imposed following their return to work in June 2020. To achieve this aim, I proposed the following objectives: to explore how much time GDPs routinely allocate for a typical urgent pain appointment; to evaluate how GDPs feel that the COVID-19 restrictions have impacted their ability to gain appropriately informed consent for patients in severe, acute pain; and to investigate how GDPs feel that the *Montgomery* ruling has affected their consent process, with particular reference to how they would go about obtaining consent for a clinical scenario presented in the survey.

In this opening chapter, I explain the nature of toothache and the impact that it can have on a sufferer's cognition and decision making. I also look at how urgent dental care for those in pain should address the cause and symptoms of the pain and why, on occasions, it does not. I also outline the impact of restrictions to the provision of dental care imposed following the onset of the COVID-19 pandemic on the provision of urgent dental care.

This chapter will form the backdrop to the subsequent consideration of informed consent in this particularly challenging area of dental practice and how it operated at this most uniquely challenging of times.

1.1 The torture of toothache

Tooth ache hurts. Sometimes it really, really hurts.

On occasions, it can seem as though there is no upper limit to the suffering that toothache can cause. It is no wonder then that the impact of dental pain has featured so heavily in literature and popular culture (from Shakespeare[1] to Dustin Hoffman[2] and Tom Hanks[3]). As the first animals on earth to outlive the loss of all their teeth and given the relatively minor role that teeth play in terms of our survival these days, it is possible to wonder why such a small part of our body can cause such a disproportionately high level of pain. But when examined more closely, we can see what a pivotal role teeth and the oral cavity played in

[1] "For there was never yet philosopher that could endure the toothache patiently" William Shakespeare, *Much Ado About Nothing* (Act 5, scene i, line 2)
[2] Dustin Hoffman's suffering at the hands of Lawrence Olivier in the torture scene of the 1976 film *Marathon Man* has probably caused more dental phobias than any other movie scene in history
[3] Tom Hanks playing the stranded Chuck Norand in the Robert Zemeckis produced film *Castaway* (2000) memorably extracts an abscessed tooth with an ice skate

evolutionary development and how this central function explains the emphasis that cranial development has put on the dental nerve supply.

The adult dentition is made up of 32 teeth, all of which are innervated by the fifth cranial nerve: the trigeminal nerve (Tv). The Tv is the largest sensory nerve in the body and across its three branches[4] supplies sensation to the oral cavity, peri-orbital tissues, orbit, and the side of the face. The sensory information that the brain receives deals not just with the pressure that teeth are under through chewing but also sensations associated with foreign bodies in the mouth, the presence of toxic or noxious materials, communication (both verbal and non-verbal), threats to the airway and, not least, the intimate pleasures associated with the oral cavity. Given this wide range of signals that on one level are essential to the preservation of life and on another are vital to its enhancement, there can be no surprise that the brain pays so much attention to the sensory input received from this nerve. Indeed, the somatosensory cortex – the area of the brain that encodes incoming sensory information from all over the body – devotes 60% of its processing ability to information received from the Tv[5]. It is small wonder then that, when either the maxillary or mandibular branch starts to register pain from a tooth, the brain pays great attention.

One of the key points to realise when understanding the impact of toothache, or indeed any pain, is that 'all pain is in the brain'; everything that comes before the message reaches the brain is simply nociception.[6]

If we take the example of toothache, then decay caused by bacterial invasion of the tooth results in an inflammatory response in the dental pulp; at this level we are looking at injury rather than pain. The response to bacterial invasion occurs at a cellular level within the pulp and involves an inflammatory process triggered by the immune system. The resultant 'inflammatory soup', as it is known, involves the release of various chemical agents that lower the threshold at which a pain receptor will begin to fire. Once this threshold is breached, pain fibres within the neural network start to send impulses to the somatosensory cortex.

[4] The trigeminal nerve leaves (and enters) the brain at the level of the pons where it forms the trigeminal ganglion. At this point, it divides into three branches, the ophthalmic, maxillary, and mandibular, which carry sensory (and a small motor component) fibres to the associated area of the face

[5] Tara Renton, 'Pain Part 1; Introduction to Pain' (2015) 42 Dental Update 109.

[6] CJ Woolf, 'What is this thing called pain?' (2015) 120 Journal of Clinical Investigation 11 3742. Nociception, by definition, refers to the neural process of detecting, responding to and transmitting information about noxious stimuli. According to CJ Woolf, it is a physiological response that overrides all other neural activity and elicits an immediate response

As soon as the central pain matrix[7] is engaged, we cross from a process of nociceptive responses to noxious stimuli to one of conscious perception. The neural response to stimuli is often likened to an alarm going off. The pain research scientist Clifford Woolf[8] uses an excellent analogy for pain, as follows: "*If pain were a fire alarm then nociception pain would be sensed only as the presence of intense heat, inflammatory pain would be felt with warm temperatures and pathological pain would be felt if there was a fault with the fire alarm itself".*

Taking this analogy one step further, how we respond to the sound of a fire alarm going off will vary greatly from person to person: some will flee the building screaming in panic; others will barely raise their head from their desk.

Given the highly individualistic nature of pain perception, no two toothache experiences are ever the same. Once the somatosensory cortex has received the impulses from the dental pulp, the information is cut and spliced with a vast array of additional inputs drawn in from the previously mentioned pain matrix along with moderating memories and stressors from the nearby amygdala and hippocampus, allowing memories of past experiences to play a huge part in how we rate the threat of this current event.

The biopsychosocial model of thinking in healthcare was first proposed by George Engel in 1977[9] and has been widely adapted to best explain our current understanding of how a person experiences their pain. Everyone's pain experience is dependent on biological, psychological, and social factors, including, amongst other things, their age, gender, ethnicity, culture, personality, stress, depression, and anxiety. Only they can feel their pain and will often struggle to accurately articulate it.[10]

Toothache, then, represents a unique patient experience based on localised pulpal damage that is interpreted through a filter of various emotional and anxiety levels by a pain matrix that has been shaped by a lifetime of experiences and development.

1.2 What does optimal acute pain management entail?

Dealing with an unscheduled patient suffering with acute pain can be the most stressful, difficult, and financially least rewarding appointment that dentists must contend with in

[7] An area of the brain including the anterior cingulated cortex, thalamus and insula that feature heavily in pain responses, especially chronic pain
[8] CJ Woolf, 'What is this thing called pain?' (2015) 120 Journal of Clinical Investigation 11 3742–3744
[9] Professor George Engel, Prof of Psychiatry and Medicine, University of Rochester School of Medicine, New York (Engel, 1977)
[10] T Renton, 'An Update on Pain', 204 BDJ 6 March 22, (2008)

general practice. It can also be the most rewarding treatment we provide and is perhaps the most important thing that we can ever do for that individual, frequently being the benchmark by which we are judged by our patients.

It is first important to differentiate between emergency care and urgent care. Emergency care represents management of a condition with a threat to life, or severe harm at least, whereas urgent care represents treatment to alleviate severe pain, which, whilst extremely unpleasant, does not represent a threat to life. In dentistry it is fortunately a relatively rare event that our treatment is classed as emergency.

According to the Scottish Dental Clinical Effectiveness Programme (SDCEP),[11] approximately 2%[12] of calls to NHS 24[13]in 2005 related to dental pain and/or swelling. Of the 2% of calls relating to dentistry (12, 910), it is estimated that approximately 1% represented an emergency. This equates to 129 cases in a 6-month period for the whole of Scotland (less than one case per day for a population of almost 4 million).

The SDCEP classes emergency care as conditions that include:

- Facial trauma involving dentoalveolar injuries (avulsion of a permanent tooth, fracture of jaw, facial laceration) or prolonged dental bleeding that the patient is not able to control with local measures.
- Oro-facial swelling that is significant and worsening: swelling that is affecting the eye, floor of mouth or impeding swallowing/causing worsening trismus.
- Dental conditions that have resulted in acute systemic illness, for example, pyrexia associated with dental infection greater than 38.1C.
- Oral conditions that likely to exacerbate systemic medical conditions such as diabetes.

The recommendation for such cases is that a clinician is contacted within 60 minutes with a view to any subsequent treatment being provided within a timescale appropriate to the severity of the treatment.

By way of illustration, a patient who is unwell with a raised temperature and a floor of mouth swelling who is finding swallowing and opening wide restricted and painful would be considered a 'blue light' medical emergency, requiring immediate transfer to a specialist

[11] SDCEP, 'Emergency Dental Care' (2007) <https://www.sdcep.org.uk/published-guidance/emergency-dental-care/>

[12] A total of 654,475 calls were received between January and June 2005

[13] NHS 24 operates across Scotland in partnership with local NHS boards to provide confidential health advice throughout the country

maxilla-facial surgical unit in a secondary care facility. By comparison, a patient who has fallen and knocked a tooth entirely out of its socket is not facing a life-threatening event but has a short time frame of 60 minutes or less to have the tooth successfully replanted into the socket. Delays much beyond this time will leave the patient facing significantly greater dental needs for this tooth and site throughout the rest of their lives.

Based on the same study of NHS 24 phone calls, approximately 75% of those relating to dental concerns were classed as urgent dental conditions, which equates to 9,683 calls over the same 6-month period.

The SDCEP categorises urgent care as:

- Dental and soft tissue infections without systemic effect.
- Severe dental and facial pain that cannot be controlled by the patient following self-help advice.
- Fractures to teeth that have exposed the pulp.

It is helpful for the purposes of this thesis that we focus on urgent dental care where we are dealing with patients who are suffering with debilitating levels of pain but who are not systemically unwell.

The currently accepted gold standard of clinical guidance in the UK comes from the Faculty of General Dental Practice (FGDP) and the SDCEP. Both bodies have laid out their standards in print and online for GDPs to access, and keep them regularly updated,[14] and they are covered in greater detail later in this thesis. By way of summary, however, the common ground across both bodies as to what constitutes a basic level of care for patients in need of urgent care can be summarised as follows:

An appropriate examination, including medical and social behaviour history, undertaken (in accordance with FGDP[UK] guidelines[15]) along with a structured pain history, tests, and radiographs as appropriate for assistance with diagnosis and appropriate action taken to relieve pain. Where treatment is provided to relieve pain, it should be done so in a prompt and mutually satisfactory and reasonable time frame and in such a way that resolution of the condition is completed to a level where the patient is satisfied with the procedure and outcome. Treatment may be limited to advice regarding analgesia through to local measures such as drainage of acute infection, dressing of an inflamed nerve or extraction of a tooth. On the rare occasions where an antibiotic prescription is indicated then guidance provided

[14] SDCEP 'Acute Dental Problems' (2013) https://sdcep.org.uk/published-guidance/management-of-acutedental-problems-madp/; and FGDP *Standards in Dentistry* (2018)
[15] FGDP *Clinical Examination and Record Keeping* (2016)

by FGDP[16] and SDCEP[17] must be followed.

Having seen what optimal urgent care should involve, Chapter 2 looks at why optimal care is not always achieved and what happens when these standards are not met.

1.3 What happens when agony threatens autonomy?

As described earlier in this chapter, peripheral responses to insult or injury in the dental pulp cause a response in the somatosensory cortex. The process by which A delta and C fibre nociceptive neurones in the tooth send messages via secondary afferent neurones in the spino-thalamic tract up to the tertiary neurones of the pain matrix is a complex one and beyond the scope of this thesis.[18] However, what happens when the message of dental woe reaches the level of the central nervous system and the impact this has on the individual is an important point to consider, especially when deciding how capacitous that individual truly is when suffering with debilitating pain.

Irrespective of our previous pain experiences, all of us will have experienced the impact of a decision made at a time of heightened mental or physiological stress that has left us with a "what was I thinking?" moment some time subsequent to this decision. Of course, the fact that we may regret a decision made under duress does not mean that it was not an autonomous one; merely one that reflects our current desire autonomy rather than their best or ideal desire.[19]

In neurophysiological terms, the pain impaired decision-making process is easy to understand and can even be seen in action on a functional magnetic resonance imaging (fMRI) scanner.[20]

When mapping brain activity for patients in pain, fMRI studies show a surge in neural activity in the area known as the pain matrix,[21] with the severity of the pain linked to the

[16] FGDP *Antimicrobial Prescribing in Dentistry (*2020)
[17] SDCEP 'Drug Prescribing' (2017, updated May 2020) <https://www.sdcep.org.uk/published-guidance/drug-prescribing/>
[18] Dale Purves Neuroscience (2nd edn, Sinauer Associates 2001). Chapter 10: Pain provides an in-depth description of the central pain pathways and offers clear examination of the perception of pain
[19] J Coggon 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' [2007] 15 Health Care Analysis 3 235–255
[20] fMRI can be used to show blood flow and electrical activity within individual sections of the brain, giving real-time information as to which part is experiencing raised (or lowered) neural activity
[21] Although there is no actual 'pain centre' in the brain, the area that equates to this is known as the pain matrix, which is most commonly explained as being made up of the peri aqua ductal grey, anterior congulate cortex, thalamus, and insula

extent of the activity.[22] The areas of the brain linked with the pain matrix would broadly sit within the area sometimes referred to as the mammalian brain. Whilst Paul Maclean's 'triune brain' model[23] is now largely viewed as being overly simplistic, the concept works well as a description of how the brain functions as a whole. In this model, Layer 1 (reptilian) represents the area mostly concerned with autonomic, regulatory function, while Layer 2 (mammalian) takes charge of physiological input and emotions, leaving Layer 3 (the 'human' or more accurately 'primate') that tackles cognition, sensory inputs, philosophical abstractions and all manner of wistful navel-gazing. Obviously, there is a huge amount of crossover between the areas, and the model does not represent an accurate evolutionary record of how brains developed, but in terms of conceptualising a process within our brains it can still be helpful.

Thinking of the brain as an organisation occupying three floors of an office block with three levels of management can help us see how thought processes can develop within the structure: with Layer 3 the neocortex akin to the CEO of the organisation, Layer 2 representing a raft of middle management that gets most things done and Layer 1 sending out instructions to the rest of the organisation outside of the building.
As with many organisations, Layer 3, the CEO, drains a lot of resources. As described in Robert Sapolsky's exhaustive text *Behave*,[24] the neocortex consumes around 25% of the brain's energy at rest and requires much more than this when deep rational thinking is required. But, as described above, when viewed under fMRI scans, we can see that this area receives a greatly diminished blood supply when Layer 2 is being called upon to think fast and respond to a massive increase in afferent nerve activity, as happens during acute pain.

In times of stress, Layer 2, the middle management, can certainly act without having to get Layer 3's permission and, when it comes to saving our life, this is an essential degree of autonomy within the brain: there is no time for the neocortex to weigh up best desire and future plans when faced with a rustle in the tall grass that might be a lion about to pounce. But what we gain in speed of thought from Level 2 'thinking', relying as it does on stored emotional responses drawn from the amygdala, insula, and hippocampus, we lose in accuracy of information and cognitive decision making.

If we return to the previous section's analogy of a fire alarm to describe pain responses, then a patient in the grips of severe debilitating acute pain can be thought of as being

[22] Legrain and others, 'The pain matrix reloaded' (2011) 93 Progress in Neurobiology 1, 111–124
[23] Maclean, PD, *The triune brain in evolution: role in paleo cerebral functions* (first published 1990, Plenum Press)
[24] Robert Sapolsky, *Behave: The Biology of Humans at Our Best and Worst* (Vintage 2018)

trapped in that house on fire.[25] Level 2 fear-driven thinking focuses purely on current desires only: I need to get out of this building. This desire might be effectively and efficiently served if they jump from the second-floor window, although the ensuing spinal fracture will almost certainly go contrary to their best, future desires. What if there was someone there who could advise the individual against the defenestration option and point them towards the safely protected fire escape? This then is the role of the clinician when advising and treating a patient in pain: they must provide enough information to allow the patient to find a way that will ideally serve their current and best desires (which in many cases will be the same thing). In doing so, the clinician must provide the patient with sufficient time and details to allow them to engage their energy depleted neocortex in a reflective view of what action suits them best and is in keeping with their own value system.

That said, an urgent care patient who is anxious and in pain does not need or want long-winded discussions about extensive treatment plans. But they do need enough information to be able to provide valid and appropriately informed consent for care that is appropriate to them, and the prescribing clinician needs to be assured that the information has been retained, understood, and weighed appropriately by the patient. What counts as sufficient detail to provide 'valid' consent and how much detail is needed for consent to be classed as 'appropriately informed' pose challenging questions that are explored further in Chapter 3 of this thesis.

When considering if a patient has given an autonomous and appropriately informed consent, it is also important to consider if the individual is capacitous at the time of the decision. In terms of the Mental Capacity Act 2005:[26] *"…a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain".*

When indicating who should assess mental capacity, the Act makes clear that the person assessing capacity must understand the decision to be made and be able to provide all of the relevant information to be able to assess the person's ability to make the decision for themselves, for example, a dentist may assess the person's capacity to consent to having a filling. To assist the clinician, the Act lays out a two-stage functional test of capacity[27] and stresses that the greater the implications of the treatment the more rigorous and evidential the assessment needs to be.

[25] Interestingly in dentistry we refer to an acute inflamed tooth as having a 'hot pulp' and it is not unusual to hear a patient describe their toothache as feeling like their head is on fire
[26] Mental Capacity Act 2005, Part 1 section 2
[27] ibid. section 2(4)

In Stage 1 of the test (sometimes known as the diagnostic stage), the clinician should decide if an impairment or disturbance of the mind or brain exists. If they conclude that such a situation does exist, then the clinician needs to complete Stage 2, which addresses whether the impairment or disturbance will prevent the individual from making their own decision. This assessment of capacity comprises the four elements of capacity: can the individual understand, retain, and weigh up the information provided and then communicate their decision (through any means).

In terms of severe, acute, debilitating pain, it is reasonable to describe this as producing an impairment of the mind; albeit one that is likely to be short lived and may be overcome temporarily with appropriate pain relief medication or local anaesthetic. The task of the GDP when managing an acute pain patient is therefore not so much about establishing the individual's capacity (beyond the normal assessments and assumptions) but about judging whether the patient's decision fits with only their current desires but runs contrary to their best (future) desires.

In his 2007 paper,[28] John Coggan discussed the concepts of ideal desire, best desire and current desire autonomy and explains the difference as he sees them. For this discussion, we can agree with the description within this article that an individual is considered autonomous if they make decisions that are based on their value system. Professor Coggan suggests that best desire autonomy leads to actions taken based on an individual's overall desire, reflecting their own values, even if this runs contrary to their immediate desire. The author then goes on to contrast this with current desire autonomy, which leads to actions decided upon as a reflection of the individual's immediate wishes, without a consideration for the future implication and made without further reflection. Best desire autonomy differs from ideal desire in that the best desire will reflect an individual's unique values that may, when viewed by others, seem self-destructive or selfish and so would not represent values that could be expanded to apply to a society at large (as an ideal desire could be) but are settled and consistent for this particular person.

Current desire autonomy can be viewed as dealing with a person's 'first-order desires' and as such may be seen as choices that have involved little, if any, reflection. The article equates this to Lord Donaldson's comments in Re T[29] when he opined that *"this right of choice is not limited to decisions which others might regard as sensible. It exists notwithstanding that the reasons for making the choice are rational, irrational, unknown or even non-existent".*

[28] Coggon J, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15 Health Care Analysis 3 235–255
[29] Re T (Consent to Medical Treatment) CA 1993 at [3]

It is also worth noting, as Professor Coggan does, that current desire autonomy is more likely to get full support from the court when it is regarding negative rights, i.e. the refusal of medical treatment. This right to refuse treatment was highlighted clearly in Re MB,[30] where the Court of Appeal made clear that a mentally competent patient has the right to refuse treatment for whatever reason, even if this decision will lead to their death.

When it comes to positive rights that equate to a patient demanding a certain treatment, the courts are likely to be more restrictive, preferring evidence of best desire, reflective decision making that tallies with an individual's 'second-order desires'. An example of this thinking can be seen in the Court of Appeal's overturning of the findings of Munby J in *R (Burke) v GMC*[31] where a capacitous patient can ask for any form of treatment but no professional can be ordered to provide a form of medical intervention that was in their view not an appropriate form of treatment.

Having considered the neurophysiological aspects of the patient in pain and reflected on their autonomous state, we need to also consider what constitutes an appropriate consent process when dealing with the patient in pain.

When trying to navigate a consent process that allows the patient to give valid and appropriately informed consent, healthcare professionals in the UK must now give due consideration to the Supreme Court ruling in the *Montgomery v Lanarkshire Health Authority* case 2015.[32] This landmark case is seen as the watershed moment when the courts finally cut ties with the historical view that *Bolam* represented the benchmark for consent and completed the swing from a paternalistic, professional-centred view of how much information need be shared with a patient to a far more patient-centred view that considered what information would a reasonable patient expect or should want to hear.

By combining what is required of clinicians under the Mental Capacity Act 2005 with what the law expects of healthcare professionals following *Montgomery*, and by understanding what is happening inside the brain and mind of a patient in pain with consideration for the patient's vulnerability and the voluntary nature of any decisions made and how these fit with their best and current desire autonomy, we are able to see what is required in terms of a discussion during an urgent care visit. We can also see how challenging these discussions can be when the fire alarm is ringing loudly inside the patient's head.

[30] Re MB (Refusal medical treatment) (1997) 8 Med LR 217
[31] *R (Burke) v GMC* [2005] EWCA Civ 1003, [2006] QB 273
[32] *Montgomery v Lanarkshire Health Authority* [2015] UKSC 11

1.4 How has optimal dental care been impacted by COVID-19?

It is hard to overestimate the impact that the SARS-CoV-2[33] virus and the ensuing COVID-19 pandemic has had on the delivery of dental care in the UK from March 2020 onwards. On 26 March 2020, all primary care dental services in the UK were put on notice by a directive from the Office of the Chief Dental Officer (OCDO), supported by the Care Quality Commission (CQC) in England, the Care and Social Inspectorate in Wales, the Care Inspectorate in Scotland and the Regulation and Quality Improvement Authority in Northern Ireland that they were to cease all forms of dental treatment and close their doors to the public with immediate effect. The vast majority of practices remained closed until 8 June 2020. During this period of enforced closure of practices, almost all dental care was provided remotely with dentists using the AAA approach of 'Advice, Analgesia and Antibiotics'. In the first few weeks after lockdown, a very few urgent dental care centres (UDCs) were set up throughout the country to deal with the most severe cases of urgent and emergency care. It is not possible to say exactly how many UDCs were set up across the UK but, by way of indication, NHS services for the South East Region[34] provided 36 UDCs (excluding secondary care facilities such as dental hospitals and maxillo-facial centres in local district general hospitals) for a population of almost 9 million.

When the plan to reopen dental surgeries was announced on 1 June 2020, it was immediately clear that dental practice post lockdown was going to be starkly different to all dental care that had gone on pre lockdown. Guidance on how dental care was to be delivered once surgeries reopened had been evolving over the previous 10 weeks of closure and was based on the scant clinical evidence for cross-infection control for COVID-19 positive patients that had come out of secondary care units. The two major authoritative bodies for GDPs, the FGDP[35] and the SDCEP,[36] issued their guidelines in that first week in June. These guidelines, along with NHS guidelines, as developed by each appropriate body for England,[37] Scotland, Northern Ireland, and Wales, were used as the basis for the standard operating procedures (SOPs) of every primary care dental practice in the UK. These SOPs and their impact on communication, delivery of care and patient experience are examined in greater detail in the next chapter but, by way of a short summary, the key changes of significance were:

[33] Severe Acute Respiratory Syndrome Coronavirus 2
[34] www.england.nhs.uk, n.d.
[35] www.fgdp.org.uk, 2020
[36] SDCEP, *Resuming General Dental Services Following COVID-19 Shutdown A guide and implementation tools for general dental practice for Phases 2 and 3 of dental services remobilisation,* Version 1.1, 2020
[37] www.england.nhs.uk, 2020

- The introduction of the term 'aerosol generating procedure' (AGP), which denoted any dental treatment that generated a high volume of fine particulate spray.
- The mandatory use of fit tested filtered face piece (FFP3)[38] masks, full coverage gowns and face covering visors for all dental team members involved in an AGP.
- An extended fallow time in-between each AGP and enhanced cross-infection control procedures for the surgery after each case.
- Screening of patients before they attended the practice and on entry to the building and restricted numbers of patients to be within the building at any one time.

Implementing these changes, in particular, sourcing enhanced personal protection equipment (PPE) at a time of enormous national and global demand and ensuring that all clinical team members had the FFP3 masks certified as fitting correctly proved to be an enormous challenge and meant that the majority of practices were not able to meet the deadline of opening for business again on 8 June.

Many practices found that the buildings they operated in could not meet the ventilation requirements now imposed or did not have the space to allow social distancing within waiting rooms and reception areas for more than one patient at a time. Dental professionals who have a beard on religious grounds could not meet the requirement to be clean shaven for most standard FFP3 masks so had to source the much more expensive and harder-to-find full facial respiratory protective equipment (RPE).[39] Coupled with the problem that beards presented was the issue that many of the FFP3 masks were sourced from the construction industry where a gender bias means that the majority of masks are designed to fit around larger male faces, which made face fitting for a predominantly female-led dental nursing sector harder still.

These complications and challenges led to a staggered return to dental practices opening their doors to patients. The impact of the COVID-19 restrictions on GDPs' ability to deliver optimal urgent care is explored in detail in the next chapter.

1.5 Outline of thesis narrative

My aim throughout this thesis is to examine and explain the twin issues of consent in general dental practice since the 2015 *Montgomery* ruling and the increased restrictions to the provision of dental care having combined with an almost synergistic impact on GDPs'

[38] An FFF3 mask protects against solid and liquid toxic aerosols to a minimum efficiency of 98%
[39] https://www.hse.gov.uk/pubns/indg479.pdf. RPE equipment was at a premium in June 2020 and some masks were retailing at around £800 per mask; almost twice normal retail price

ability to deliver optimal urgent care. I also reflect on how GDPs have met these challenges and what, if any, impact they may have had on the management of acute dental pain.

To assist in this endeavour, I have divided my thesis into five further chapters that cover, in order:

- Chapter 2: the published clinical articles relevant to the topic and what insight they offer into the topic in hand.
- Chapter 3: the UK law regarding consent, set in a broader comparative context.
- Chapter 4: the methodology of my empirical research into GDPs' knowledge, understanding and experiences of meeting these examined challenges.
- Chapter 5: the findings from the research and how these fit with our existing knowledge on the topic.
- Chapter 6: a concluding chapter in which I hope to summarise the key findings from my research project and review what, if any, additional information this can provide towards informed debate regarding the twin impacts of *Montgomery* and COVID-19 restrictions on the delivery of urgent dental care.

At this time, I will also consider whether the correct amount of weight is being placed on autonomy, with respect to the other three pillars of medical ethics: beneficence, non-maleficence, and justice.[40]

Chapter 2: Literature Review

2.1 Introduction

This chapter sets out the processes involved in my literature search, and in it I discuss the literature I identified as relevant to the investigation and consider how it relates to my research question.

[40] Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics* (8th edn, OUP 2019) is the text most often cited as establishing autonomy, beneficence, non-maleficence, and justice as the four principles that help direct medical (and dental) practice

As part of this process, I established four main research themes, each of which form a section of this chapter. These themes are as follows:

- Clinical challenges relating to the management of acute dental pain.
- Challenges relating to acute dental pain management since the 2020 COVID-19 pandemic.
- The process of gaining valid consent to treatment in dentistry.
- The impact of debilitating pain on a patient's capacity to provide valid consent.

When carrying out a research project, it is a general requirement to conduct a literature review to see what has been found out previously about the proposed topic.[41] The process for a literature review involves defining the study parameters and refining keywords to assist in identifying relevant sources.[42] I continually revisited the literature search throughout the course of my LLM and the duration of the study, up until 30 September 2021, to ensure identification and inclusion of any new material in the discussion.

2.2 Literature search: initial and iterative

2.2.1. Search terms and search engines

To help guide the literature search, it was helpful to break down the problem into two distinct disciplines: legal cases and publications that comment on them, and clinical publications in scientific literature.

An initial search of the dental literature was carried out using PubMed, SCOPUS, CINHAL and Google Scholar databases using combinations of the terms 'acute dental pain', 'pain', 'irreversible pulpitis', 'consent', 'local anaesthetic', 'antibiotics', 'COVID-19' and 'Montgomery'.

It became clear early on in this search that the dental literature has only limited amounts of material relating to the impact of *Montgomery* on the process of gaining consent within the dental profession, and almost none as it relates to situations involving acute pain management. With this in mind, the search was expanded to include literature that related to medicine, which yielded higher results when searching for issues relating to 'urgent care', 'consent' and '*Montgomery*'. Because my literature search uncovered legal papers as well as

[41] Judith Bell, *Doing Your Research Project: A Guide for First Time Researchers in Education, Health and Social Sciences* (6th edn, Buckingham Open University Press 2014)
[42] Chapter 15 Judith Bell, *Doing Your Research Project: A Guide for First Time Researchers in Education, Health and Social Sciences* (6th edn, Buckingham Open University Press 2014)

clinical ones, I made the decision to focus primarily on clinical matters in Chapter 2 and legal aspects in Chapter 3, although inevitably there is some overlap of these two topics.

2.2.2 Inclusion and exclusion criteria

For the purposes of this literature review, the inclusion and exclusion criteria were as follows:

- Inclusion criteria: The relatively short time period available for literature searches meant that the inclusion criteria were restricted to full-text versions of papers published in peer-reviewed journals in the last 30 years up until 30 September 2021 that could be found via four search sites: PubMed, SCOPUS, CINHAL and Google Scholar. The 30-year period was chosen to allow a perspective on how attitudes towards acute pain management have altered. The search terms mentioned above were used in combination and singularly to try and broaden the search to as many potentially relevant papers as possible.
- Exclusion criteria: the reverse of the above.

2.3 Research themes developed from the medical and dental literature

The initial search across both medical and dental journals produced a list of 128 articles of which 89 were considered sufficiently relevant to the topic to require further scrutiny. These 89 papers were divided across four broad topics: legal aspects of consent; consent in dentistry; *Montgomery* and consent as it relates to COVID-19; and the restrictions to healthcare provision. I have included guidance and advice sheets from regulatory bodies (General Dental Council [GDC]/General Medical Council [GMC]) and authoritative bodies (professional dental organisations such as the aforementioned FGDP and SDCEP) in this chapter when they relate directly to the clinical issues, and again in Chapter 3 when they are more concerned with best practice and regulatory standards that GDPs are required to meet. Where available, greater weight was given to evidence arising from relevant systematic reviews and randomised controlled trials (RCTs), as these are considered to represent the highest level of evidence.[43]

The themes listed above represent four broad areas of interest within the literature search that best answer the research question. By dividing the search under these themes, I was

[43] Nuffield Department of Primary Care Health Sciences, 'Oxford Centre for Evidence-Based Medicine: Levels of Evidence (March 2009) — Centre for Evidence-Based Medicine, University of Oxford' (www.cebm.ox.ac.uk2009) <https://www.cebm.ox.ac.uk/resources/levels-of-evidence/oxford-centre-for-evidence-based-medicine-levels-of-evidence-march-2009>.

able to focus attention on articles most relevant to the area of research whilst gaining a clearer picture of how the research project may help in furthering informed debate on the topic.

2.3.1 Clinical challenges relating to the management of acute dental pain

Providing urgent pain relief for patients with severe pain represents a familiar and formidable challenge in general dental practice.[44] The patient is often sleep deprived, anxious, and emotionally drained following, on average, two to three days of debilitating pain. Dentists must manage such patients when faced with the acknowledged difficulties of achieving adequate local anaesthesia in patients with severe pulpitis.[45] (Success rates as low as 17% for an inferior alveolar nerve block have been reported.[46]) A GDP working under an NHS service contract currently receives a Band 4 fee of £21.60 for providing urgent care for any adult patient in acute pain. This fee applies whether the dentist simply prescribes a course of antibiotics for the patient, which might take 5 minutes, or offers an operative intervention, which might take 45 minutes to complete.[47] By comparison, a private dentist can charge whatever fee they feel is appropriate for their services, within the confines of what the market will bear.

As a full-time GDP with an interest in endodontics (root canal fillings) and the management of acute and chronic dental and oro-facial pain, I have treated thousands of people in pain and have experienced on many occasions the challenges of accommodating and managing urgent care patients in both primary and secondary care settings under both NHS and Private contractual arrangements. It is these many experiences that sparked my interest in research of the topic and led me to my first research project in 2019/2020[48] when I

[44] SS Virdee, D Seymour and S Bhakta, 'Effective Anaesthesia of the Acutely Inflamed Pulp: Part 1. The Acutely Inflamed Pulp' (2015) 219 British Dental Journal 385

[45] Pulpitis is the term given to the inflammatory response of the dental nerve to invasion of the overlaying tooth by bacteria. These bacteria migrate from the oral cavity into the centre of the tooth through dental decay, tooth fracture, trauma, or advanced gum disease. As the pulp becomes increasingly inflamed, the tooth will usually begin to generate the typical symptoms associated with toothache: namely, sensitivity to hot, cold, or sweet substances in the early stages developing into spontaneous pain, constant ache, and tenderness to touch in the later stages. There really is no upper limit to how much pain this process can eventually generate

[46] V Nagendrababu and others, 'Efficacy of Local Anaesthetic Solutions on the Success of Inferior Alveolar Nerve Block in Patients with Irreversible Pulpitis: A Systematic Review and Network Meta-Analysis of Randomized Clinical Trials' (2019) 52 International Endodontic Journal 779

[47] NHS England, 'What Is Included in Each NHS Dental Band Charge?' (9 November 2020) <https://www.nhs.uk/common-health-questions/dental-health/what-is-included-in-each-nhs-dental-band-charge>

[48] MSc (Distinction) Advanced and Specialist Healthcare(ADPP) Stage 3, University of Kent June 2019: research project " A pilot study into possible factors that may correlate to the potential prescription of antibiotics (Abs) by General Dental Practitioners (GDPs) for the urgent treatment of acute dental pain in adults in the primary dental care (PDC) settings in the UK. "

investigated which factors, if any, correlated with inappropriate prescription of antibiotics by GDPs when they treat adult patients in need of urgent care for acute dental pain.[49] The results from my study formed the basis of my published article on the topic[50] and showed that four factors were identified by the survey as having the potential to influence GDPs to offer an inappropriate antibiotic for pain relief: a non UK dental qualification, a lack of any additional postgraduate qualification, the time allocated for the appointment and the GDP's level of confidence in achieving adequate local anaesthesia. Interestingly, the potential bias that the NHS fee might have been imagined as a potential influencer for GDPs' decision making was not shown to correlate with increased inappropriate antibiotic use. (Research into the efficacy of antibiotics in the management of acute dental pain has shown them to be of no benefit[51] in cases where there are no systemic signs or symptoms of spreading infection. The leading authoritative bodies, the FGDP and the SDCEP, both state that there is no indication for the use of antibiotics in the management of acute dental pain.[52]) Despite the clear indications from these authoritative bodies that antibiotics have no part to play in the management of anything other than spreading infection when dealing with urgent care patients, we know from previous studies that inappropriate prescriptions have been shown to be commonplace in dental urgent care settings,[53] albeit with a recent moderate decline in numbers up until 2017.[54] Whether this decline was affected by the lockdown from March to June 2020 and the following restrictions to care imposed as part of the response to COVID-19 is explored further later in this chapter.

[49] Project title '*A pilot study into possible factors that may correlate to the potential prescription of antibiotics (Abs) by General Dental Practitioners (GDPs) for the urgent treatment of acute dental pain in adults in the primary dental care (PDC) settings in the UK'*. Research project for MSc in Advanced and Specialist Health Care, University of Kent, June 2020

[50] Ian Kerr and others, 'An Investigation into Possible Factors That May Impact on the Potential for Inappropriate Prescriptions of Antibiotics: A Survey of General Dental Practitioners' Approach to Treating Adults with Acute Dental Pain' (2021) British Dental Journal

[51] Anwen L Cope and others, 'Systemic Antibiotics for Symptomatic Apical Periodontitis and Acute Apical Abscess in Adults' (2018) 9 Cochrane Database of Systematic Reviews <https://www.cochrane.org/CD010136/ORAL_effects-antibiotics-toothache-caused-inflammation-or-infection-root-tooth-adults>; Anirudha Agnihotry and others, 'Antibiotic Use for Irreversible Pulpitis' (2016) 5 Cochrane Database of Systematic Reviews

[52] Nikolaus SO Palmer, *Antimicrobial Prescribing in Dentistry* (3rd edn, Faculty of General Dental Practice 2019); SDCEP, National Dental Advisory Committee and NHS Education for Scotland, *Drug Prescribing for Dentistry: Dental Clinical Guidance* (SDCEP 2016)

[53] Y Dailey and M Martin, 'Are Antibiotics Being Used Appropriately for Emergency Dental Treatment?' (2001) 191 British Dental Journal 391. This study looked at 55 dentists working in an OoHs clinic over the weekend and found that 75% of the 268 patients treated received an inappropriate prescription

[54] Martin H Thornhill and others, 'Oral Antibiotic Prescribing by NHS Dentists in England 2010-2017' (2019) 227 British Dental Journal 1044. This paper looked at prescription cost analysis data held by NHS Digital and examined all oral antibiotic prescribing by NHS dentists within primary care settings for this period (it did not look at secondary care or private practice prescription patterns). The authors reported an overall decline in antibiotic prescriptions of 14.8%, although not all of these would have been given for acute dental pain

The worrying trend for continued inappropriate care being provided for patients in the most urgent need has been studied to look for potential causes and ways to try and overcome any barriers identified.

Qualitative research by Cope in 2016[55] studied variables within the respondents that might influence how they treated patients in need of urgent care. Cope's work demonstrated that short appointment lengths caused patients to be 10 times more likely to receive an inappropriate antibiotic prescription for dental pain; meaning that the patient was left to suffer additional avoidable pain due to lack of appropriate care at the time of the visit.

Work by Newlands and others,[56] also carried out in 2016, took a theory-informed interview approach to investigate the barriers (and facilitators) that GDPs identified when providing urgent care for adult patients in pain. As with Cope's work and my own, time was seen as a significant barrier, as was the practitioner's belief that they would struggle to overcome patient influence (of an expectation that an antibiotic would resolve the problem) and, in contrast to my work, a lack of incentive to perform local measures under the NHS contract with the previously mentioned potential dilemma of the'5-minute quick fix appointment' versus the '45-minute challenging fix appointment' both receiving the same fee.

The challenges in diagnosing and treating acute dental pain in a short appointment are well known within the profession. Dental pain is often diffuse and can present in the opposing jaw, or even as earache or sinus pain. Research carried out by Bjorndal and others.[57] in 2019 and by Duncan and others.[58] in the same year on behalf of the European Society of Endodontology,[59] and used to form their position statement on the management of caries and the exposed pulp, both highlight the complexity of diagnosis when managing the impact of deep decay on the health of the underlying dental nerve. Further qualitative research by Chevalier and others in 2021[60] has shown that final-year dental students have a fear of approaching the dental nerve when managing deep decay and lack a clear understanding of

[55] Anwen L Cope and others, 'Antibiotic Prescribing in UK General Dental Practice: A Cross-Sectional Study' [2015] 44 Community Dentistry and Oral Epidemiology 145

[56] Rumana Newlands and others, 'Barriers and Facilitators of Evidence-Based Management of Patients with Bacterial Infections among General Dental Practitioners: A Theory-Informed Interview Study' (2015) 11 Implementation Science

[57] L Bjørndal and others, 'Management of Deep Caries and the Exposed Pulp' (2019) 52 International Endodontic Journal 949

[58] HF Duncan and others, 'European Society of Endodontology Position Statement: Management of Deep Caries and the Exposed Pulp' (2019) 52 International Endodontic Journal 923

[59] https://www.e-s-e.eu/

[60] V Chevalier, A Le Fur Bonnabesse and HF Duncan, 'Frightened of the Pulp? A Qualitative Analysis of Undergraduate Student Confidence and Stress during the Management of Deep Caries and the Exposed Pulp' (2020) 54 International Endodontic Journal 130

how best to manage the inflamed pulp. It is likely that this fear spills over into the early years, at least, as a practising professional.

The most recently published research to look at the factors affecting clinical management of acute dental pain[61] was published in September 2020 in the online journal *Antibiotics.* It was an ethnographic study that observed a total of 76 acute dental pain appointments performed by 11 dentists. The researchers identified 31 factors that influenced clinical decision making, which they grouped into 3 categories: Capability, Motivation and Opportunity. The dentists interviewed identified patient safety, lifetime impact of irreversible treatment and running late as the key factors that influenced their decision to give antibiotics for urgent dental care appointments.

Even once the challenges of diagnosing the cause of the pain and identifying the appropriate tooth are met, the difficulty in achieving adequate anaesthesia is one that is recognised by all GDPs who have faced a patient in the throes of severe toothache, especially if the tooth in question is a lower molar. The particular difficulty associated with anaesthetising a lower molar is the requirement to use a block approach to anaesthetise: the inferior dental alveolar nerve (IDAN). An IDAN block is a routine and regular part of dentistry but when the nerve is highly sensitised (the axion potential threshold has been lowered allowing the nerve to fire more freely and rapidly[62]), the success rate for adequate anaesthesia drops significantly.[63] As mentioned above, my research identified a fear of failure when trying to achieve adequate anaesthesia as a potential barrier to the provision of optimal care and a factor likely to trigger inappropriate care. A meta-analysis carried out by two separate research groups in 2018 (Vieira and others[64] and St George and others[65]), who reviewed the available literature on the efficacy of the local anaesthesia in managing acute pulpitis, supported the view that failure rates are high (above 30%) and no one anaesthetic agent or

[61] Wendy Thompson and others, 'Clinician and Patient Factors Influencing Treatment Decisions: Ethnographic Study of Antibiotic Prescribing and Operative Procedures in Out-of-Hours and General Dental Practices' (2020) 9 Antibiotics 575

[62] An in-depth description of the neurological process involved in lowering threshold potentials through an inflammatory mediated response is beyond the scope of this thesis but, if readers would like to advance their knowledge further on this topic, they can read more in articles by K Hargreaves and PV Abbott, 'Drugs for Pain Management in Dentistry' (2005) 50 Australian Dental Journal and Tara Renton, 'Pain Part 1: Introduction to Pain' [2015] 42 Dental Update 109

[63] MRFP Monteiro and others, '4% Articaine Buccal Infiltration versus 2% Lidocaine Inferior Alveolar Nerve Block for Emergency Root Canal Treatment in Mandibular Molars with Irreversible Pulpits: A Randomized Clinical Study' (2014) 48 International Endodontic Journal 145. This research reported failure rates of up to 90% with a single IDAN block administered to patients attending an emergency dental clinic for urgent care

[64] WA Vieira and others, 'Is Mepivacaine as Effective as Lidocaine during Inferior Alveolar Nerve Blocks in Patients with Symptomatic Irreversible Pulpitis? A Systematic Review and Meta-Analysis' (2018) 51 International Endodontic Journal 1104

[65] Geoffrey St George and others, 'Injectable Local Anaesthetic Agents for Dental Anaesthesia' (2018) 2 Cochrane Database of Systematic Reviews

combination of such can claim 100% efficacy. All the articles, however, mention the impact of time and how much must be allowed to give the full opportunity to the anaesthetic agent to reach its maximum outcome. Again, the issue of time is felt when managing urgent care: short appointments do not lend themselves to allow extra time for local anaesthesia to work and the post-COVID-19 additional restrictions in PPE and surgery fallow times do not allow the familiar approach of administering the local anaesthetic agent and asking the patient to return to the waiting room whilst another patient is seen.

A common theme from the three studies by Cope, Newlands and myself discussed previously and those relating to local anaesthetic efficacy is the importance of allowing adequate time for the appointment. Urgent care appointments, by their nature, are often unplanned, unscheduled visits that are squeezed in to busy appointment books. Anything that adds to the workload with this appointment is likely to increase the chances of inappropriate care being delivered.

Given the concerns mentioned in Newlands' work that relate to GDPs' beliefs that they will struggle to overcome patient influence, the issues relating to informed consent become relevant; especially so given *Montgomery's* ruling outlining the need for patients to be informed of material risks. I feel that it is safe to assume that a reasonable patient would want to know that an inappropriate treatment such as an antibiotic prescription for a severe pulpitis is likely to leave them in continuing, worsening pain for several days before the nerve dies off as part of the inflammatory process, after which they are at an increased risk of a dental abscess. (Clearly this would not just be an issue of consent; it would be an issue of inappropriate and potentially negligent treatment, and one that could lead to direct harm to the patient either in the form of excessive painkiller doses[66] and/or acute infection.)

My professional bias may well be clear by this point as my focus thus far in this section has been on the challenges that the GDP faces; it is only right that the words of Lord Kerr and Lord Reed make me focus now on the challenges that the patient faces.

A literature review by Jeres and others in 2007[67] examined the impact of anxiety on pain and reviewed the value of various psychological interventions employed during acute dental pain management. The authors commented on a study carried out by Kunzelmann and Dunninger,[68] who looked not only at a Dental Anxiety Scale (DAS) but also a Dental Beliefs

[66] Dental pain is cited as the commonest cause of admittance to hospital for non-intentional paracetamol overdose (Siddique, Mahmood, and Mohammed-Ali, 2015; O'Sullivan, Ahmed, and Sidebottom, (2018)
[67] W Jerjes and others, 'Psychological Intervention in Acute Dental Pain: Review' (2007) 202 British Dental Journal 337
[68] Karl-Heinz Kunzelmann and Peter Dunninger, 'Dental Fear and Pain: Effect on Patient's Perception of the Dentist' (1990) 18 Community Dentistry and Oral Epidemiology 264

Survey (DBS) when examining 474 patients attending with pain. The findings from Kunzelmann and Dunninger were that patients attending in pain were more anxious and had greater negative beliefs about dentistry than those attending in the absence of pain. When we consider that those individuals most anxious of dentistry are more likely to put off attending a dentist until pain forces them to do so, it is perhaps not surprising then that patients attending for unscheduled urgent treatment are often the most anxious. A consistent finding from all the studies reviewed by Jeres and others was that the anxious patients showed exaggerated expectations of pain compared to non-anxious individuals. The authors also noted that "*individuals differ in their pain perception and reaction according to culture, social environment, gender and individual cognitive and emotional factors".*[69]

Interestingly, the psychological techniques reviewed within the article showed a tendency to lower anxiety, increase patients' perception of control, and improve outcomes in terms of alleviating post-operative pain. Coupled with this finding was the acknowledgement that most of the techniques are relatively simple, low cost, easy-to-apply measures such as distraction techniques, showing patients how they have control over the procedure, giving clear warnings when sensations are likely to be experienced and teaching guided relaxation techniques to the patient. Sadly, there appears to be a view within dentistry, perhaps driven by a lack of understanding, that these techniques take too long to deliver, and time is not allocated to them within the urgent care appointments. A study carried out in 2008[70] looked into the barriers that prevented GDPs from engaging in these and other techniques to help manage the care of anxious patients, and the overwhelming majority (90%) of the 460 respondents indicated a lack of time as a key reason for not providing these measures. Sixty-four per cent indicated a lack of training as a further reason.

The previously mentioned ethnographic research by Thompson and others (2020) and an earlier umbrella review by the same lead author[71] looked at the impact of 'patient beliefs' on prescribing patterns during urgent dental care visits. Both studies identified the impact of having patients with a predetermined approach to the treatment visit as a way of sourcing antibiotics. These patients see antibiotics as a way of managing their pain whilst avoiding the need to engage with operative dentistry. Dentists reported that, when faced with these

[69] ibid. p. 337: Introduction

[70] KB Hill and others, 'Evaluation of Dentists' Perceived Needs Regarding Treatment of the Anxious Patient' (2008) 204 British Dental Journal

[71] W Thompson and others, 'Factors Associated with Antibiotic Prescribing for Adults with Acute Conditions: An Umbrella Review across Primary Care and a Systematic Review Focusing on Primary Dental Care' (2019) 74 Journal of Antimicrobial Chemotherapy 2139

types of patient, the combating issues of 'time' and 'doing the right thing' often lost out to a desire to 'keep the patient happy' and not 'run late'.

Once the increased requirements for cross-infection control were implemented following the COVID-19 pandemic lockdown from March to June 2020, it is easy to see how already time pressed appointments were likely to be further squeezed and, in many cases, how the ability to deliver appropriate care was diminished or removed altogether as many GDPs found themselves unable to meet the regulations imposed upon them. The impact of these restrictions on urgent dental care formed a central theme of my research study and is addressed in greater detail in Chapter 5.

2.3.2 Issues relating to acute dental pain management since the COVID-19 pandemic

Before reviewing the limited literature available on this theme, it is worth having a brief recap of the events which led to the post-pandemic restrictions to dental care.

Towards the latter part of 2019, a novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) was isolated from a patient suffering with pneumonia in Wuhan, China.[72] The virus was reported as being highly contagious and capable of causing a range of symptoms from mild upper respiratory tract infections to severe, often fatal, pneumonia. Within less than six months of the initial reporting of the virus, a global pandemic had occurred with much of the world's population subject to varying levels of government-led societal 'lockdowns'. At the time of writing (October 2021), the impact of these lockdowns can still be felt with some societal restrictions still in place in the UK, particularly within healthcare settings and various countries around the world still imposing restrictions to movement within and across borders.

The Prime Minister Boris Johnson initiated the UK's first lockdown on 23 March 2020 and become enforceable by law at midnight on 25 March 2020 after the Coronavirus Act 2020[73] gained Royal Assent. This national lockdown remained in place until a phased reopening on 1 June 2020 with the full reopening of non-essential services on 15 June 2020 and relaxation of restrictions and a 2-metre social distancing rule on 23 June 2020.

Within the initial government guidance, issued in March 2020, general dental services GDS) were part of the group of business and practices that were exempt from the enforced lockdown. However, the Chief Dental Officers (CDOs) of the four previously mentioned devolved healthcare regulatory bodies in the UK issued advice that all GDPs should stop

[72] Aiping Wu and others, 'Genome Composition and Divergence of the Novel Coronavirus (2019-NCoV) Originating in China' (2020) 27 Cell Host & Microbe 325
[73] 'Coronavirus Act 2020' (www.legislation.gov.uk2020)

providing any form of face-to-face dental care from 26 March 2020. This enforceable guidance resulted in the cessation of all routine dental care, and the vast majority of urgent care until the order was given by the CDOs and the CQC to reopen dental practices from 8 June 2020, one week before non-essential shops were allowed to open.

Given the lack of knowledge surrounding the new threat posed by SARS-CoV2 and the enormous potential threat that it posed, it was inevitable that additional levels of infection prevention control (IPC) were going to be required. And so it was that primary dental care services were closed to the public and, except for a very few UDC centres spread across the UK,[74] patients were denied access to any form of face-to-face dental care for almost three months having to rely instead on so-called 'tele-dentistry' and remote prescribing. With this in mind it made sense to include within the literature search articles that highlighted the impact of the closure of practices. It was not surprising to find that the literature focusing on these events reported that prescription rates for antibiotics in dentistry soared with London seeing a 60% increase in prescription rates during this time[75] and maxilla-facial emergency departments in hospitals seeing a dramatic increase in the number of routine cases that could have been managed in the UDCs: 72% of patients attending a major London hospital for urgent care had tried to access care via a UDC and 52% had been triaged by such a centre and denied access, being given repeat prescriptions of antibiotics instead.[76]

Public Health England (PHE), in collaboration with the NHS and the devolved agencies of Scotland and Wales, provided detailed guidance on the level of precautions required in dentistry,[77] in particular specifying the level of PPE required for AGP services along with the need for additional temporal and spatial separation of patients attending and the use of a fallow time after AGPs to allow aerosols to disperse and/or settle before anyone else entered the room. With a few minor adjustments, these provisions remain in place, 19

[74] Due to the highly devolved funding of NHS services across the UK it is not possible to put an absolute figure on the total number of UDC centres established during this time but, according to an interview with the CDO of England, Sara Hurley (as reported in 'Dentistry' https://dentistry.co.uk/2020/04/20/sara-hurley-speaks-out-about-covid-19/), by 20 April 2020 there were 164 sites across England servicing a population of approximately 54 million. By comparison, the Office for National Statistics (ONS) reported in 2019 that there were more than 12,000 general dental practices across the UK 'Number of dentists and dental practices in the UK Statistics' <https://www.ons.gov.uk/aboutus/transparencyandgovernance/freedomofinformationfoi/numberofdentistsanddentalpracticesintheuk>. Whatever the final figure of UDCs achieved by the end of the dental lockdown, it can be assumed that the reduction in access to dental care experienced by the UK population was enormous

[75] Sagar Shah, Valerie Wordley and Wendy Thompson, 'How Did COVID-19 Impact on Dental Antibiotic Prescribing across England?' [2020] 229 British Dental Journal 601

[76] Kristian K Blackhall and Rabindra P Singh, 'Dental Emergencies Presenting to Maxillofacial Units during the COVID-19 Pandemic: A Five-Centre UK Hospital Study' (2021) British Dental Journal 1 <https://www.nature.com/articles/s41415-020-2499-1> accessed 6 May 2021

[77] 'COVID-19: Infection Prevention and Control' (GOV.UK 2020) <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control>

months later at the time of writing, with no indication being given as to when they might be lifted.

The elements of PPE for AGPs that have been most significant in terms of delivering dental care have been the mandatory requirement for clinical members of the dental team present in the surgery to wear FFP3 respirators, visors, and full coverage surgical gowns. Coupled with this were requirements for a closed-door policy to prevent 'walk-in' patients, remote triaging to assess the clinical need of the individual and to carry out COVID-19 screening checks and the provision of an extended fallow time. This fallow time was initially set at 60 minutes but was then reduced to 10 minutes if sufficient air exchange mechanisms were in place within the surgery to enhance the dispersal time of the aerosol.

The impact that these measures would have on the free flow of patients through the average general dental practice were obvious to all as were the limitations imposed on communication caused by the FFF3 masks, especially to patients with limited understanding of English, high levels of anxiety, impaired hearing or registered deafness. The reopening of general dental services by 8 June proved to be extremely challenging given the severe shortages of the necessary PPE items caused by enormous global demand and the lack of qualified 'mask fitters' to cope with the huge increase in need to cover many tens of thousands of healthcare workers across the UK.

A survey of 455 dentists in England was carried out between 18 August 2020 and 9 September 2020 by the Faculty of Dental Surgeons (FDS)[78] to see how the return to face-to-face care had been managed by GDPs. The findings of the survey indicated a dramatic reduction in the number of patients being seen (93% of respondents were seeing 10 patients or fewer per session, versus 46% who reported seeing this number pre lockdown). Within NHS primary care, less than 40% of respondents had begun AGPs, which compared with 83% in the Private sector. When asked about the principal barrier to resuming services, the primary reason given was the fallow time with lack of staff resources and difficulty of achieving social distancing within the practices being the other main reasons given. It can be assumed that the greater flexibility with setting prices to reflect an increased cost of delivering care and a generally accepted lower number of patients seen per day in the Private sector can explain the difference in impact seen between NHS and Private sectors.

This report gave a clear image of a struggle being felt by GDPs trying to resume normal services post 8 June 2020. It also gave a picture that, for some patients being seen under the NHS in particular, the access to care may have worsened in these first four months because

[78] Faculty of Dental Surgeons, *A Resumption of Dental Services? Dental Surgeons' Experiences of Delivering Care since 8 June 2020* (Faculty of Dental Surgeons 2020)

the UDCs were also being phased out over this time, leaving them unable to get an appointment with either their own dentist or one of the UDCs.

Interestingly, this research did not look into how dentists were finding the experience of working under the new regime of PPE and whether they felt that it was affecting their ability to provide optimal care. Therefore, there can be seen to be value in investigating this topic further, to try and identify any problems encountered by GDPs when delivering acute pain management since June 2020.

A review article published in December 2020[79] looked at the clinical, legal, and economic consequences of withholding dental care in the UK since the first lockdown. The legal position of refusing to treat patients during the official lockdown period of 25 March to 8 June 2020 appears to be relatively clear cut with little prospect of any proceedings being undertaken against a GDP who was accused of withholding face-to-face treatment by a patient denied care at this time. Although the practices in the UK were closed by guidance rather than statute,[80] the four healthcare regulator bodies of the UK made clear their advice to GDPs as to how they were to operate post 26 March onwards: 1) dentists should not provide routine care; 2) dentists were to offer a remote triaging service of AAA; and 3) referral of patients in need of active 'emergency' treatment to a UDC should be considered where appropriate. Subsequent to this advice, the UK dental regulator, the GDC, offered the reassurance to GDPs that *"refusing to treat a patient when it is not safe to do so is perfectly proper professional judgement, which we would not look to question*". The authors of this review article indicated a belief that the risk of litigation was unlikely to increase because of the closure of dental clinics. Even once the practices reopened, a patient would need to show that it was safe for them to be seen by the GDP, which would not be the case if this involved them breaching the practising guidelines in place to help minimise the spread of COVID-19. This article cited *Mulholland v Medway*[81] to stress the point that context is key: as Green J said at [90]: "*in forming a conclusion about the conduct of a practitioner working within triage within an A&E Department context cannot be ignored. The assessment of breach of duty is not an abstract exercise but one formed within a context"*. An earlier paper by Devaney et al in May 2020[82] considered the context issue of consent during the height of the pandemic and suggested that there would situations that might be akin to "battle conditions". The authors indicated that the same reasoning that sees a difference in consent

[79] Paul Coulthard and others, 'The COVID-19 Pandemic and Dentistry: The Clinical, Legal and Economic Consequences - Part 2: Consequences of Withholding Dental Care' (2020) 229 British Dental Journal 801 <https://www.nature.com/articles/s41415-020-2406-9>

[80] Dentistry was not listed in the *Health Protection (Coronavirus, Business Closure [England]) Regulations* 2020

[81] *Mulholland v Medway NHS Foundation Trust* [2015] EWHC 268 (QB)

[82] Sarah Devaney and others, "Healthcare Professional Standards in Pandemic Conditions: The Duty to Obtain Consent to Treatment" (2020) 17 Journal of Bioethical Inquiry 789.

processes involved in a roadside emergency tracheotomy compared to elective surgery would apply in such circumstances. In terms of this research project it should be remembered that we are dealing with urgent dental care not life threatening emergencies. Even in these challenging times and allowing for the context related view of breach of duty mentioned above, it would not be a reasonable expectation to assume that informed consent is not possible when providing treatment choices for dental pain relief. With this in mind, the research sought to investigate how GDPs have met the challenges of gaining informed consent in urgent care situations, contrasting their experiences pre and post COVID-19

Poole J reiterated the point of context in his recent article[83] and cited *Morrison v Liverpool*[84] where Justice Turner said at [24]: *"of course, in the clinical context a balance has to be struck between the needs of any given patient and any other competing professional demands placed upon the clinicians involved .... [Sometimes] the needs of the patient must be deprioritised to allow the clinicians to attend other demands on their time of as a matter of priority".*

Poole J went on to say in his article that he felt sure that courts would take into account the exceptional circumstances under which clinicians are being asked to act.

Coulthard and others also voiced an expectation that there would be an overall reduction in litigation given the reduction in the amount of dental treatment being carried out.[85] Further in the same piece the authors indicated that existing indemnity cover persisted through the pandemic for all practitioners. The same authors go on to point out that the UK government extended indemnity cover by way of section 11 of the Coronavirus Act 2020 to ensure that dentists re-tasked to provide medical support at a COVID-19 hospital would have appropriate legal protection for any clinical work provided there. In the article, the authors also addressed the possibility of legal action taken by a claimant against the state for their part in denying access to care. In England and Wales since 2012 the provision of all dental services is the duty of clinical commissioning groups[86] where the rules state that these groups must provide services "*to such an extent as it considers necessary to meet the reasonable requirements of the population*" and, as implied by the courts, "*such as can be provided within the resources available*"; which is referred to by Couthard et al in the

[83] Nigel Poole, 'Coronavirus and Clinical Negligence' (2020) 25 Journal of Patient Safety and Risk Management
[84] *Morrison v Liverpool Women's NHS Foundation Trust* [2020] EWHC 91 QB
[85] The authors took a random of figure for negligent treatment at 1/10,000 cases delivered. If the total number of cases delivered is reduced then the number of negligent cases should fall as well, leaving few exposures to a claim. Anecdotally, working as an expert witness, this has not been my experience since June 2020
[86] 'The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012' (Legislation.gov.uk2012) <https://www.legislation.gov.uk/uksi/2012/2996/regulation/25/made>

previously mentioned article as the 'resources defence'. Whilst courts do have jurisdiction over resource allocation, the authors indicated that they felt that this would be used *"extremely sparingly*". When discussing this point in his article, Nigel Poole cited *University College v MB*[87] in which Justice Chamberlain granted an injunction requiring a patient to vacate a bed. In so doing, the judge considered if any breach of Article 3 of the European Convention of Human Rights (ECHR) might occur. Considering the choice that clinicians were being asked to make at the time, the judge said:[88]

"*Where the decision to discontinue in-patient care involves the allocation of scarce public resources, the positive duty can only be to take reasonable steps to avoid such suffering … It is difficult to conceive of a case in which it could be appropriate for a court to hold a hospital in breach of that duty by deciding, on the basis of an informed clinical assessment and against the background of a desperate need for beds, to discontinue in-patient care in an individual case".*

Coulthard and others considered the risk of a claim being brought for treatment denied via the Human Rights Act 1998, which incorporates most of the rights within the ECHR into UK law but, other than providing medical treatment required to save a life, it is not clear that a breach of ECHR article for failure to provide medical treatment.[89] The conclusion of the article was that, whilst some patients will have to wait longer for dental care and some may lose a tooth that could have been restored had the option of an AGP been available, it is unlikely that this will result in an increased action of regulators or litigators. Nigel Poole matched this conclusion in his paper, as well suggesting that lawyers would be reluctant to take on cases that can be defended on grounds of limited resources or exceptional circumstances.

I think there can be no doubt that the risks of litigation or regulatory sanction against GDPs working in UDCs operating in the depths of the first lockdown or even for practices when they first opened up again can be considered as extremely low indeed. What is less clear, however, is what the situation is now, almost 20 months after a return to work, but when stark differences in access to a full range of services across NHS and Private practices exist. Also, what has not been addressed to date is how GDPs rate the risk of litigation or regulator censure. It may well be the case that the fear of litigation is much more impactful than the actual risks would lead one to expect. One of the aims of the survey was to see

[87] *University College London Hospitals NHS Foundation Trust v MB* [2020] EWHC 882 (QB)
[88] ibid. [57]
[89] Coulthard and others, , 'The COVID-19 Pandemic and Dentistry: The Clinical, Legal and Economic Consequences - Part 2: Consequences of Withholding Dental Care' (2020) 229 British Dental Journal 801 p. 804 'Access to treatment denied by the state'

how GDPs felt about the importance of gaining informed consent for urgent care since June 2020 and if these views had changed since before the lockdown.

2.3.3 The process of consent in dentistry

Because much of this topic crosses into the focus of Chapter 3, I have limited this section of my thesis to the articles discovered during my search and regulatory guidance that is specific to the issues relating to gaining informed consent in dentistry. In Chapter 3, I offer a more detailed discussion of the ethical and legal issues relating to consent.
With regard to the various types of consent,[90] the view in dentistry has long been that 'implied consent' applies only to the degree that a patient voluntarily taking a seat in a dental chair has provided an implied consent that they wish the dentist to carry out an examination of the oral cavity. All other treatment in dentistry requires 'informed consent'.

As we shall see later in Chapter 3, the term 'informed consent' may be undergoing a re-evaluation following the *Montgomery* ruling, with a re-clarification from the courts as to what constitutes 'sufficient' information to class consent as being 'informed'.

Regulatory and authoritative guidance

The regulatory guidance from the GDC on the need for consent is clear. Since 1996,[91] the GDC has provided its members with clear written advice on the behaviours and standards expected of them. The Principles of Consent booklet formed one of six such principles that the GDC first proposed in their 2003[92] update of their 1996 guidance. In the consent booklet, section 1 outlines what is meant by and what is required for informed consent to be given by a patient. The 2005[93] version of GDC guidance (and all future ones) was much less prescriptive as to how the physical act of dentistry should be carried out, leaving this guidance to other authoritative bodies, but it did expand on the consent process. The most recent version, *Standards for the Dental Team*, was published in 2013[94] and updated in 2019.

Whilst these regulatory guidance documents are examined in detail in the next chapter, it is worth highlighting one small section here because it addresses an aspect central to the next section of this chapter. Section 3.2.4 (p. 32) of the 2013 GDC guidance touches on capacity by stating that *"you must always consider whether patients are able to make decisions*

[90] Such as implied, expressed, valid, informed, or unanimous
[91] *Maintaining Standards* 1996
[92] *Standards for Dental Practice*, 2003
[93] *Standards for Dental Professionals*, 2005
[94] *Standards for the Dental Team*, 2013 (updated 2019)

about their care themselves and avoid making assumptions about a patient's ability to give consent". The wording here is interesting, given that the central tenet of the Mental Capacity Act 2005[95] is that there should be an 'assumption of capacity'. This is discussed further in the next section, which looks at the impact of severe pain on capacity.

Other sections that are relevant to the previous aspects of the literature search are those in sections 3 of the same document. Standard 3.3 informs professionals of the need to "*make sure that the patient's consent remains valid at each stage of investigation or treatment*". Section 3.3.1 makes the point that "*giving and obtaining consent is a process, not a one-off event*". Section 3.3.5 deals with situations where it is necessary to change an agreed treatment which, as we will see later, can be particularly relevant to urgent care decisions. The section states: "*if you think that you need to change a patient's agreed treatment or the estimated cost, you must obtain your patient's consent to the changes and document that you have done so*". From personal experience of treating hundreds of toothaches since June 2020, I can state on good authority that communication through enhanced PPE at the time of treatment has been an ongoing and significant challenge with many patients.

The updated version of these Standards became valid from June 2019 but does not differ significantly when addressing the above sections.

Not surprisingly, the advice from authoritative bodies such as the FGDP, the SDECP and the FDS does not stray from the mandatory statements as laid down by the GDC. Likewise, the indemnity providers encourage close adherence to the GDC regulations, although some organisations do offer more detailed explanations of the types of consent, how the process should ideally be carried out and what might make consent invalid. The Dental Protection Organisation, for example, offer a free online booklet on consent in their Dental Advice Series[96] with versions for Scotland and for the rest of the UK. This booklet is covered in more detail in the next chapter.

Probably the most widely accepted published set of standards in dentistry in the UK, outside of the GDC's work, and the one most commonly used by expert witnesses when assessing if a claimant has strayed outside of the standards of care expected of a reasonably competent practitioner are those produced by the FGDP, most significantly the *Standards in Dentistry*[97] and *Clinical Examination & Record Keeping*.[98] Both publications were updated recently with

[95] 'Mental Capacity Act 2005' (Legislation.gov.uk2005) Principle 2: A person must be assumed to have capacity unless it is established that he lacks capacity

[96] https://mpscdnuks.azureedge.net/resources/docs/librariesprovider2/default-document-library/consent-(uk-excl-scotland).pdf

[97] Kenneth Eaton, *Standards in Dentistry* (1st edn, Faculty of General Dental Practice 2006)

[98] Hadden Andrew and others, *Clinical Examination and Record Keeping* (2nd edn, Faculty of General Dental Practice 2009)

Standards in Dentistry getting a second edition in 2018[99] and *Clinical Examination & Record Keeping* getting a third in 2016.[100] As the dates of these older and newer additions straddle the 2015 ruling on *Montgomery*, it made sense to review both sets of publications to see if changes in the editions reflected the shift in the legal landscape, post *Montgomery*. This review is discussed in Chapter 3.

The other major source of authoritative guidance within dentistry for the entire UK comes from the SDCEP. The question of obtaining 'valid consent' is addressed in their *Practice Support Manual* under the General Principles of Ethical Practice[101] in which it states, in reference to the GDC's nine principles outlined in *Standards for the Dental Team*: *"applying these principles to everyday dental practice will ensure that dental teams protect the interests of patients and obtain the respect and trust of their patients, peers and the public".* In other words: do what the GDC tells you to do (which, in rather beautiful tautology is to do what authoritative guidance tells us to do).

In section 2.6 of the SDCEP guidance on management of acute dental pain (MADP),[102] advice is given under the title of *Patient Assessment and Record Keeping* that stresses the need for a tailored clinical assessment and detailed note taking but does not directly address the need for consent prior to treatment. The updated version that was produced as a response to the COVID-19 pandemic[103] again makes mention of the need for accurate record keeping but does not refer to any requirements regarding the need for consent.

When seen in the light of this regulatory and authoritative advice, we get an idea that level of consent[104] gained by a GDP from their patient, as a minimum standard, should involve a clear discussion (in lay terms) of the appropriate treatment options available, along with a descriptions of the advantages and disadvantages of each and a personal recommendation, followed by a time for questions, including the provision of information that the GDP considers the patient ought to know and an evaluation of any future cost and treatment implications of the choices made by the patient at this stage in their care. All of this taking place in a time frame that allows the patient sufficient time to evaluate the information and

[99] David Moles and others, *Standards in Dentistry* (2nd edn, Faculty of General Dental Practice 2018)
[100] Andrew Hadden, *Clinical Examination & Record Keeping: Good Practice Guidelines* (3rd edn, Faculty of General Dental Practice 2016)
[101] SDCEP, National Dental Advisory Committee and NHS Education for Scotland, 'Drug Prescribing for Dentistry: Dental Clinical Guidance' (SDCEP 2016).
[102] 'Acute Dental Problems' (SDCEP 2013) <https://www.sdcep.org.uk/published-guidance/management-of-acute-dental-problems-madp/>
[103] 'Management of Acute Dental Problems during COVID-19 Pandemic' (SDCEP 2020) <https://www.sdcep.org.uk/Management>
[104] As per the above comments, this is taken to mean appropriately informed consent

make a decision that is right for them. But how realistic is this when the patient is suffering with severe pain? How does this impact on their ability to engage in the consent process?

2.3.4 The effect of debilitating pain on a patient's capacity to make informed decisions and the possible legal impacts of this

My literature search on the topic of how acute pain affects patients' cognitive ability produced very few articles relating to dentistry. Most of the articles that dealt with acute pain management in this search tended to look at the types of patients likely to attend in acute pain and how they evaluated their experiences. A scoping review[105] carried out in 2016 looked at the literature available on urgent dental care with a view to identifying research priorities for the organisation and delivery of urgent dental care. It reported that the least studied variables were patient outcomes of evaluated health and quality of life following treatment, indicating that patient-based research is most likely under-represented in the dental press.

Further literature searches identified one article[106] that reported on a cross-sectional study that examined the impact of dental emergencies on the patient's quality of life. The study looked at 189 patients attending a dental teaching hospital for services relating to acute pain. The data showed that the average time patients remained in pain prior to attendance was two weeks, with the trigger for attendance most commonly being the point at which the symptoms reached a level where the individual could no longer cope with the pain or self-medicate it sufficiently. Interestingly, just under half of the patients attending the hospital for treatment did have a regular GDP but 60% of this subgroup reported an inability to get an appointment and a further 13% had been treated by the GDP but the treatment had not resolved the pain. The authors of this study point out that the figures reported from their research are disappointingly similar to those reported 20 years earlier in a previous study.[107] This research suggests that the pain levels being experienced by individuals seeking urgent care are significant and likely to be such that they may impair judgement.

Published research on the question of who is most likely to attend with dental pain was carried out in Gothenburg, Sweden, in 2018[108] where the Department of Behavioural and Community Dentistry looked at patients attending in pain and assessed them for a

[105] DJ Worsley, PG Robinson, and Z Marshman, 'Access to Urgent Dental Care: A Scoping Review' (2017) 34 Community Dental Health 19–26

[106] CC Currie, SJ Stone and J Durham, 'Pain and Problems: A Prospective Cross-Sectional Study of the Impact of Dental Emergencies' (2015) 42 Journal of Oral Rehabilitation 883

[107] C Scully, 'The Pattern of Patient Attendance for Emergency Care in a British Dental Teaching Hospital' (1995) 12 Community Dental Health 151–154

[108] Lisa Svensson, Magnus Hakeberg and Ulla Wide, 'Dental Pain and Oral Health-Related Quality of Life in Individuals with Severe Dental Anxiety' (2018) 76 Acta Odontologica Scandinavica 401

prevalence of severe dental anxiety. The study found that patients with high dental anxiety were more likely to present with pain and were more likely to have a lower oral health-related quality of life, which is perhaps not surprising because these individuals will tend to put off treatment until it is forced upon them due to the severity of the symptoms. The severity of pain, as expressed by the patient, tended to be higher, as a correlation with levels of dental anxiety. Importantly, when procedural pain is investigated (i.e. pain experienced during treatment), this is also reported as being higher by individuals with severe dental anxiety.[109] The significance of this is that anxious patients in pain are more likely to experience pain during treatment and are therefore more likely to have compromised outcomes and be less likely to re-attend for routine care, leaving them at greater risk of returning in the future with further urgent care needs. Patients who are extremely anxious and are suffering with levels of pain that they can no longer cope with, it can reasonably be supposed, are likely to struggle with decision making based around their long-term dental health and will tend to focus on the most immediate pathway to ending their pain and their visit.

According to the Office for National Statistics (ONS), more than one-third of the population will only attend the dentist when they have acute pain.[110] When population studies are carried out to look at who is most likely to attend with pain, we see that dental phobics and severely anxious patients have higher scores for dental infections,[111] more carious (decayed teeth) and lower oral health scores generally[112] and are more likely to attend in pain than the non-phobic population.

When GDPs are examined on their perceptions about treating anxious patients, however, we see that two-thirds (299 of 460) of respondents to a survey[113] asking about their attitudes and experiences of treating anxious patients indicated that they felt that their undergraduate and postgraduate training in this area had been inadequate.

The papers identified helped to build a picture of acute pain patients attending primary (and secondary) care units for urgent treatment as being more likely to score higher on dental anxiety scores than non-pain patients, more likely to be irregular attenders and on a balance

[109] C-S Lin, S-Y Wu, and C-A Yi, 'Association between Anxiety and Pain in Dental Treatment: A Systematic Review and Meta-Analysis' (2016) 96 Journal of Dental Research 153–162

[110] Office for National Statistics (ONS) Social Survey Division, Information Centre for Health and Social Care. (2012). 'Adult Dental Health Survey, 2009' [data collection]. 2nd Edition. UK Data Service. SN: 6884, http://doi.org/10.5255/UKDA-SN-6884-2

[111] PUFA score = Puss, Ulceration, Fistula and Abscess

[112] E Heidari, A Banerjee and JT Newton, 'Oral Health Status of Non-Phobic and Dentally Phobic Individuals; a Secondary Analysis of the 2009 Adult Dental Health Survey' (2015) 219 British Dental Journal

[113] KB Hill and others, 'Evaluation of Dentists' Perceived Needs Regarding Treatment of the Anxious Patient' (2008) 204 British Dental Journal

of probabilities more likely than not to be seen by a dentist who feels that their training in the management of anxious patients has been inadequate. This already paints a picture of a scenario ripe for a challenging consent process, but I did not feel that I had addressed the issue, at a neurophysiological and psychological level, as to what the relationship between acute pain and cognitive ability is.

With this in mind, I decided to expand my keywords to include 'non-dental acute pain' and the 'impact on cognition/capacity 'to see if the medical world had a clear insight into this relationship. Even in the medical world the literature available to review this relationship is sparse, especially when compared to the volume of literature available to examine the relationship between chronic pain and cognition. An extensive literature review in 2011[114] that looked at the clinical and preclinical evidence as it relates to the effect of chronic pain on cognitive function concluded that there was sufficient evidence to support the view that pain is associated with impaired cognitive function. The authors proposed a model to explain this impairment that was based on the three theories of competing limited resources, neuroplasticity, and dysregulated neurochemistry, although they stressed that the exact mechanisms by which pain impairs cognition were not yet fully understood. Because this research was looking at chronic pain, we cannot extrapolate any conclusions directly to acute pain, but it is not unreasonable to imagine that similar processes are at play, albeit in a time frame that has not allowed the sufferers to develop coping strategies.

In papers that focused purely on acute pain, one interesting, if relatively small, study[115] did look directly at the impact of acute pain and executive function.[116] The authors did this by researching a total of 24 otherwise healthy adults who were suffering with acute muscular-skeletal pain following a sporting injury. When the individuals were tested on their digital span (as measured by an ability to recall a string of digits), this function was found to be significantly impaired when pain levels were at their highest. The value of using a digital span test is that it tests the ability of an individual to recall information and then repeat it, which is a key test of capacity when providing consent.[117]

[114] Orla Moriarty, Brian E McGuire, and David P Finn, 'The Effect of Pain on Cognitive Function: A Review of Clinical and Preclinical Research' [2011] 93 Progress in Neurobiology 385

[115] Jenna Morogiello and others, 'The Effect of Acute Pain on Executive Function' (2018) 42 Journal of Clinical and Translational Research

[116] Executive functions are defined in this article as high-level cognition processes that allow a person to successfully engage in an independent and self-fulfilling life. In this context, the definition would include such tasks as planning, control of conflicting thoughts, goal directed behaviour and assessing the consequences of one's actions. Executive functions involve the frontal parts of the brain, which are also involved with pain processing, causing a potential conflict in terms of which part of the brain gets the most attention

[117] Section 3 of the Mental Capacity Act 2005 sets out a two-stage functionality test of capacity. In the second stage, the test highlights the inability to retain information long enough to make a decision as being one of the indicators for a lack of capacity

This topic was looked at in greater detail by David Seminowicz and Karen Davis when they examined the impact of pain intensity on cognitive load.[118] In this study, 23 volunteers were subjected to varying levels of pain intensity and then asked to perform cognitive tasks whilst under fMRI examination. The results showed that cognitive load was only moderately modulated by the presence of pain, although it should be noted that, for ethical reasons, the level of pain intensity and duration in such studies would not be expected to mimic that of severe dental pain.

The authors of all these papers also touch upon the impact of pain medication on cognition and allude to the dramatic rise in opioid prescriptions in the USA. Whilst it is difficult to overestimate the impact of the opioid epidemic in the USA (as reported by Jones and others in their 2019 paper,[119] the US population represents 5% of the world's population but consumes 80% of the world's oxycodone and 90% of the world's hydrocodone, resulting in more than 3,000 deaths a month due to opioid overdose), the prescription rates for opioids are much lower in the UK and, with the exception of codeine, are almost non-existent in dental settings.

The legal and ethical aspects of pain management were looked at by Jukic and Puljak in 2018.[120] The authors used this paper to examine the postulate that pain management is a fundamental human right. They concluded that patients do have rights but that "*these rights have limits which may interfere with other competing rights, and also the rights of their physician*". They also concluded that healthcare workers have an "*obligation to continuously improve their knowledge about pain management, including medical, legal and ethical aspects of pain*". The paper highlights the growing legal opinion in the USA, at least, that pain management is a core ethical duty in medicine, and a prevalent view exists that the unreasonable failure to provide adequate pain management constitutes negligence.[121]

The authors underline this point with reference to the case *Bergman v Chin*[122] where a California court found, in 1999, that the inadequate management of the claimant's pain constituted elder abuse. On the topic of decision-making capacity in pain patients, the

[118] DA Seminowicz and KD Davis, 'Interactions of Pain Intensity and Cognitive Load: The Brain Stays on Task' [2006] 17 Cerebral Cortex 1412
[119] Greg H Jones and others, 'The Opioid Epidemic in the United States—Overview, Origins, and Potential Solutions' (2019) 74 Obstetrical & Gynaecological Survey 278
[120] Marko Jukic and Livia Puljak, 'Legal and Ethical Aspects of Pain Management' [2018] 47 Acta Medica Academia 18
[121] As stated by Margaret Somerville, Professor of Law and Medicine at McGill University in her 1987 interview with Bill Trent in the Canadian Medical Association Journal
[122] *Bergman v Wing Chin and Eden Medical Centre*, No. H205732-1 (Cal App Dept Super Ct 1999)

authors repeat the view stated by the American Academy of Pain Medicine[123] that there is a legal and ethical obligation implicit on physicians to assess and evaluate the decision-making capabilities of their patients in pain. Where the patient cannot meet the usual criteria to establish capacity, a surrogate decision maker may be required. The authors of this paper take a similar view to that of Hall and Boswell in their 2009 review,[124] which states that caution must be applied when stating pain management as a human right. This concept does not equate to patients being able to request any analgesic or pain management strategy that they want. The concept of a right to pain management should not be extrapolated into a right to pain medication or a right to a pain free life. A more balanced view would be to make clear that the right to pain management implies a reasonable and proportionate response, reflective of the severity and pain type that the patient is suffering with. As a broader principal, a patient's right to expect a reasonable standard of care does not expand into a right to be able to demand specific treatments in a way that undermines a clinician's discretion.

2.4 Relevance of the literature reviewed to the research question and thesis

The research question this thesis hopes to investigate is how GDPs have negotiated the twin challenges of the new patient-centred standard of consent as laid down in *Montgomery* and the restrictions to care caused by Covid-19 from June 2020 onwards, when treating adult patients suffering with acute dental pain.

This literature review helped identify appropriate treatment needs for acute dental pain and the impact that not meeting these can have. It also gave a clear insight into the challenges experienced by GDPs in delivering optimal urgent care and the challenges that patients can experience in accessing this care. The regulatory and authoritative dental literature highlighted what is required for consent to be deemed to be valid and appropriately informed while published research gave some insight into the neurophysiological process associated with pain and what impact this might have on patients' cognition.
What the literature search did not reveal, however, was the impact of COVID-19 restrictions on acute dental pain management and the attitude of GDPs to the process of gaining valid consent for adult patients attending for urgent treatment in primary care settings. This offered an opportunity to initiate a study that aimed to explore this further, as outlined in Chapters 4 and 5. I hope that the insights gained from my work will help to lay the

[123] American Academy of Pain Medicine. 'Ethics charter from American Academy of Pain Medicine' (2005) 6 Pain Med 3, 203–12
[124] John K Hall, 'Ethics, Law, and Pain Management as a Patient Right' (2009) 3 Pain Physician 12 499

groundwork for continued work on the implications of COVID-19 on the management of acute dental pain.

This chapter has looked at the published literature relevant to the clinical aspects of the research topic. The next chapter focuses on the impact of the *Montgomery* ruling and reflects on the legal shift from one that supported a paternalistic approach to healthcare to one that now fully supports the view of the patient as an autonomous individual fully in charge of their healthcare decisions. In Chapter 3, I will also compare the stance of the regulatory guidance within healthcare to that of the courts.

Chapter 3: Theoretical, regulatory, and legal underpinning of autonomy and informed consent

3.1 Introduction

The aim of this chapter is to explore the shift in approach towards consent that has taken place within the courts of England, Scotland, and Wales over the past 37 years since the 1984 ruling in *Sidaway v Board of Governors of the Bethlem Royal Hospital* [125] set the professional standard for consent. To assist in the understanding of how this ruling came about, I have included examination of some of the most relevant cases that span from the 1958 landmark case of *Bolam v Friern*[126] until the Supreme Court ruling on *Montgomery*[127] in 2015 unified the UK's view on a patient-centred standard of consent. (In Scotland, the time span is slightly longer, with 60 years spanning the time from *Hunter v Hanley*[128] until the *Montgomery* ruling.) Where appropriate, within this chapter, I have also considered the role of regulatory guidance in establishing what level of information disclosure is considered necessary for informed consent amongst healthcare workers and have identified how this guidance often treads a path for the courts to follow.

The focus of this research project is to see how GDPs have met the challenges of the *Montgomery* ruling, with particular interest in urgent care following the COVID-19 pandemic. In this chapter I will discuss possible impacts that the courts' view on informed consent may have on how the consent process is undertaken during urgent dental care appointments. In Chapters 4 and 5, I will reflect on this discussion when reviewing how the GDPs who responded to my survey feel about the consent process in these circumstances.

3.2 The rise of autonomy in UK law

In this section I have focused on the case law that I understand to be most relevant in shaping the journey to *Montgomery* whilst also considering what is meant by the term 'informed consent'.

3.2.1 A brief history of informed consent

A definition of informed consent in medical case law, as we see it now, is usually based around the prerequisite conditions upon which it stands and was developed in the Re C test

[125] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1984] AC 871
[126] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582
[127] *Montgomery v Lanarkshire Health Authority* [2015] UKSC 11
[128] *Hunter v Hanley* [1955] SC 200

and further enshrined in the Mental Capacity Act 2005. These are that the patient must have capacity, must be competent, must understand the information disclosed to them, appreciating its significance, and must have given their consent freely.[129] The information given, as a bare minimum, must cover: the nature of the procedure; the nature of any risks associated with the proposed treatment; any therapeutic alternatives; and the likely benefits expected from the procedure. When considering the level of detail needed in this information, the clinician must be mindful of any material risks to the patient and must satisfy the objective needs of the information (what the clinician thinks the patient ought to know) and the subjective needs (what a reasonable patient would want to know). The rest of this section outlines how the courts helped, and sometimes hindered, the development of this definition.

Perhaps the earliest example of a legal case relevant to consent is the 1767 case of *Slater v Baker and Stapleton*[130] where the courts found that a surgeon who operated on a case of complex leg fracture was liable for damages when he failed to gain consent for the operation. Fortunately, I have made no attempt to map case law from this point onwards but have skipped forward to the turn of the 20th century.

The case that is commonly quoted as the originator of our modern views of what constitutes legally valid consent is that that of *Schloendorff v Society of NY Hospitals*,[131] which took place in 1914 in the Court of Appeals of New York. In upholding the case for the plaintiff, the appeal court judge stated that "*every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages*".

Although the *Schloendorff* case deals with consent, or the lack thereof, it is not until much later that the first use of the phrase 'informed consent' is seen. Lauren Sutherland QC in her book, *A Guide to Consent in Clinical Negligence Post Montgomery*[132], cites *Salgo v Leyland*[133] as the first example of this. In this 1957 case, the appeal court decision, as expressed by Bray J, stated that the physician must disclose to the patient "*all the facts which mutually*

[129] Re C (Adult Refusal of Treatment) [1994] WLR 290 centred around the case of a 68-year-old paranoid schizophrenic who refused to consent to the removal of his gangrenous right foot. In his ruling, Thorpe J established three stages to a patient making a decision: 1) the need to take in and retain information; 2) to believe it; and 3) to weigh that information, balancing risks and needs. The Mental Capacity Act 2005 expanded on this when establishing its two-stage test for capacity

[130] *Slater v Baker and Stapleton* [1767] CB

[131] *Schloendorff v Society of New York Hospitals* [1914] 105 NE 92,93

[132] Lauren Sutherland, A Guide to Consent in Clinical Negligence Post-Montgomery (Law Brief Publishing 2018).

[133] *Salgo v Leland Stanford Jr. University Board of Trustees* [1957] 317 P.2d 170

affect his rights and interests and of the surgical risk, hazard and danger, if any". According to Lauren Sutherland, it is a further 24 years before the case of *Chatteron v Gerson*[134] brings the term 'informed consent' into use in UK law. This case can also be used to explain the legal difference between valid and informed consent. As Emma Cave explains in her 2020 article,[135] consent can technically be legally valid even if the health care professional (HCP) is found to be clinically negligent. To explain this issue, she uses the Chatterson ruling, which involved a claim for battery and negligence following a competently performed operation on her leg. Bristow J found that the claimant had been informed in broad terms as to the nature of the procedure (that it was a surgical operation on her leg) and, because she had not been deceived, her consent was voluntary and she had capacity, the consent was valid; meaning no action in battery. As Bristow J warned,[136] however, failure to warn of any 'real' risk inherent in the procedure could potentially give rise to liability, but under the law of negligence; not battery.

In English law, an HCP who carries out treatment in the absence of consent could be accused of assault or battery or negligence. In English law, battery and negligence are torts and as such are tried under civil law, whereas assault can fall under criminal law if a person is accused of any act by which a person "*intentionally or recklessly causes another to suffer or apprehend immediate unlawful violence*"[137]. (In Scottish law, no distinction is drawn between assault and battery.)

The distinction between valid and informed consent becomes more interesting because the latter versions of GDC and FGDP guidance (2006) onwards make use of the term 'valid consent' and avoid the use of the term 'informed consent'. The reason for this change in terminology is not clear. For clarity's sake, as explained in Cave's aforementioned 2020 article, in the eyes of the law in England and Wales, valid consent is required to protect against an accusation of battery, whereas informed consent is required to protect against an accusation of negligence (in the context of a lack of information disclosure that led to a decision that would not have been made otherwise). My understanding from discussions with colleagues involved with the drafting of the GDC and FGDP guidelines, however, is that the use of the term 'valid consent' in their documents is taken to mean 'informed consent' because the fine legal distinction between the two terms was not recognised. I should stress that these were unofficial discussions and I have not had this view officially confirmed by the GDC.

[134] *Chatterton v Gerson* [1981] QB 432
[135]. Emma Cave, 'Valid Consent to Medical Treatment' (2020) 47 Journal of Medical Ethics; 47:e31.
[136] at [444]
[137] Common Assault – s.39 Criminal Justice Act 1988

Because of the assumed lack of evil intent in medical consent cases, successful actions brought on the basis of assault or battery are rare, but one example in 1996 is certainly relevant to this thesis. In the case of *Appelton v Garrett*,[138] patients of the defendant dentist brought a case against him for deliberately withholding information about how necessary (or unnecessary) their treatment was, sure in the knowledge that they would not have consented to treatment had he disclosed this information. Eight patients brought cases against him for work that was carried out in the absence of any meaningful information given as to the necessity or likely outcomes of the treatment. The court took the view that the information was withheld in bad faith for purposes of personal profit and accepted the view that they would not have consented to treatment had they been appropriately informed. All the claimants were awarded aggravated damages for pain, suffering and loss of amenity (PSLA).

The consideration as to whether an HCP who provides treatment without consent should face an allegation of assault, battery or negligence is worth considering further as it is reflected in the view taken by the courts in *Sidaway v Board of Governors of the Bethlem Royal Hospital*,[139] which is a ruling that had a profound impact on how the court viewed subsequent cases involving consent for decades to come. From this ruling in 1984 through to the final nail being hammered into its coffin with *Montgomery*, however, the courts have taken the view that issues of consent are most commonly dealt with through claims of negligence, using the professional standard as established by *Hunter* in Scotland and *Bolam* in England (see next section for further discussion). That said, an action in battery could still be undertaken, particularly if a clinician carried out a procedure completely different to the one consented for. In such a situation, an action could be taken in both battery and negligence.

As the most common action taken in UK courts for clinical matters relates to negligence, my focus beyond this point is on this aspect of clinical case law.

3.2.2 Negligence and consent

The most important action for patients who are injured as a result of medical malpractice, including inadequate consent, lies in negligence.

For purposes of medical negligence, the landmark cases of *Hunter v Hanley* in Scotland and *Bolam v Friern,* in 1955 and 1957, respectively, are still seen today as the benchmark to assess whether negligence has occurred. These two cases have provided the 'professional

[138] *Appleton v Garrett* [1996] 5 PIQR P1
[139] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1984] AC 871

standard' governing view for courts when establishing issues of medical negligence for the past six decades with only minor limitations placed upon this.

The most famous restriction put upon the professional standard did not come for a further 40 years and was provided by the 1998 *Bolitho v City and Hackney Health Authority*[140] case, although these limitations did not impact on information disclosure; only the diagnostic and treatment elements of healthcare. In his judgement of the appeal in this case, Lord Browne-Wilkinson agreed that a doctor would not escape liability merely because a number of medical experts state that the accused actions were in line with sound medical practice, if this evidence can be shown to be illogical and unreasonable. He went on to caution, however, that a judge should not merely replace medical expert opinion with their own.

When considering matters of diagnosis and treatment, the 'Bolam test' remains in place as the standard by which all HCPs accused of negligence will be held against, even post the 2015 *Montgomery* ruling.[141] Since 1998, the twin tests of *Bolam* and *Bolitho* attest to the view that the professional standard requires not only that a reasonable body of expertise exists but also that it should be seen to be logical in its stance if a defendant is to use it as their defence against negligence.

On the question of the use of the professional standards when considering disclosure of information, *Bolam* was the de facto test and received its most emphatic endorsement in 1981 in *Sidaway v Board of Governors of the Bethlem Royal Hospital*,[142] a ruling that is now, in a post-*Montgomery* world, viewed with some infamy. The problem with the Bolam test and the endorsement given by *Sidaway* when considering information disclosure is that patient rights are seen as secondary to the consensus and standards ascribed by the medical profession. The prevailing legal view remained that 'doctor knows best' (as described in Lord Diplock's summary of the case below) when considering how much information a patient should be provided with, and it wasn't until the early 2000s that this view started to be eroded as a shift in the court's opinion saw the pendulum swing from the paternalism of *Bolam* to the autonomy of *Montgomery*.

[140] *Bolitho v City and Hackney Health Authority* [1998] AC 232

[141] *Bolam's* place in cases of pure diagnosis has come under more recent attack with *Muller v King's College Hospital* [2017] EWHC 1128 (QB). Kerr J wrote [49] about 'pure diagnosis' cases where 'the patient's condition is unknown, and what is alleged to be negligent is a doctor's diagnosis of the condition, in the form of a report, with no decision made or advice given about treatment or further diagnostic procedures. The diagnosis is either right or wrong and, if wrong, either negligently so or not'. His view was that a defence based around the Bolam test was no longer appropriate in such cases

[142] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] UKHL

Interestingly, for much of this time the legal view was out of step with the underlying professional views of the UK healthcare guidance and legal systems around the world regarding information disclosure; a point examined further in the next section.

The *Sidaway* case reached the House of Lords where the Law Lords affirmed the opinion of the Court of Appeal. In his summary Lord Diplock stated[143]

To decide what risks the existence of which a patient should be voluntarily warned and the terms in which such warning, if any, should be given, having regard to the effect that warning may have, is as much an exercise of professional skill and judgement as any other part of the doctor's comprehensive duty of care to the individual patient, and expert medical evidence on this matter should be treated in just the same way. The Bolam test should be applied.

Lord Bridge's view, which is generally seen as the prevailing opinion, was that no distinction between the technical aspects of the role of the clinician and the practice of information disclosure, stating that the role must primarily be a matter of clinical judgement[144]. In the same paragraph, when discussing when the court might consider that "*disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it*" Lord Bridge gave the example of a 10% risk (of stroke) such as the one quoted in *Reibl v Hughes*[145]. By way of comparison the risk of nerve injury quoted in *Sidaway* was 1-2%, a level of risk that a reasonable body of opinion agreed was not a level sufficiently high enough to warrant warning a patient about. On the basis that this expert opinion supported the *Bolam* standard in this case, Lord Bridge dismissed the appeal.

The opposing voice in this appeal came from Lord Scarman, who took a more patient-centred view. He recognised the duty of the doctor to "*provide his patient with the information needed to enable the patient to consider and balance the medical advantages and risks alongside other relevant matters, such as, for example, his family business or social responsibilities of which the doctor may be only partially, if at all informed".*[146] Lord Scarman noted the potential for a contradictory situation where the courts recognise fully the rights of the patient to self-determination as to whether they will accept or reject the proposed treatment but then allow the medical profession to determine "*whether or what*

[143] Ibid. [895]
[144] [24]
[145] Reibl v. Hughes [1980] 114 D.L.R. (3d) 1.
[146] [885-886]

circumstances a duty arises requiring the doctor to warn his patient of the risk inherent in the treatment which he proposes".[147]

Lord Scarman concluded that room existed within the law for a legal duty to warn a patient of the risk inherent in the proposed treatment and that this duty should be seen as an aspect of the duty of care owed by a doctor to their patient. In doing so, Lord Scarman cited *Canterbury v Spence*,[148] to consider if such a duty to warn did exist in law. He referenced the California court's proposition that a doctor must disclose all 'material risks' with materiality being determined by the use of the 'prudent patient' test, which was formulated at [787] as: "*a risk is material when a reasonable person, in what the physician knows or should know to the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy*".

Lord Scarman summed up his feelings on the *Canterbury* ruling and his considerations of the Canadian ruling in *Reibl v Hughes,*[149] which broadly accepted *Canterbury* and the English cases of *Chatterton v Gerson*[150] and *Hills v Potter*,[151] which applied the Bolam test to issues of consent, by saying:

> *The doctor's duty arises from his patient's rights. If one considers the scope of the doctor's duty by beginning with the right of the patient to make his own decision whether he will or will not undergo the treatment proposed, the right to be informed of significant risk and the doctor's corresponding duty are easy to understand: for the proper implementation of the right requires that the doctor be under a duty to inform his patient of the material risks inherent in the treatment. And it is plainly right that a doctor may avoid liability for failure to warn of a material if he can show that he reasonably believed that communication to the patient of the existence of the risk would be detrimental to the health (including of course, the mental health) of his patient.*[152] (The so-called therapeutic exception.)

Lord Scarman went on to acknowledge that the prudent patient test works well in a utopian view but, like the ubiquitous 'man on the Clapham omnibus'[153] are merely representative norms and do not exist in reality. When judging what the prudent patient would want to know, the court must still rely on medical evidence with the materiality of the risk "*medical*

[147] [889-890]
[148] *Canterbury v Spence* 464 F.2d. 772, 782 DC Cir. 1972
[149] *Reibl v Hughes* [1980] 2 SCR 880
[150] *Chatterton v Gerson* [1981] QB 432
[151] *Hills v Potter* [1983] 3 All ER 716
[152] [884]
[153] The man on the Clapham omnibus is a hypothetical ordinary or 'reasonable' man that has existed in English courts since the 1903 case of *McQuire v Western Morning News* [1903] 2 KB, where Sir Richard Henn Collins used it. The character is used as a representation of a reasonably educated, intelligent adult against whom the alleged conduct of the defendant can be judged

evidence will be necessary so that the court may assess the degree of probability and the seriousness of possible injury".

In the final paragraphs of his judgement, Lord Scarman made clear his position:

> *I think that English Law must recognise a duty of the doctor to warn his patient of risks inherent in the treatment which he is proposing. The critical limitation is that the duty is confined to material risk. The test of the materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person in the patient's position would be likely to attach significance to the risk.*

As we will see in the next section, it took more than 30 years for the UK courts to fully acknowledge Lord Scarman's views and provide a legal precedent that established the standard by which disclosure of information should be judged.

3.2.3 The journey from *Sidaway* to *Montgomery*

The 1984 unanimous decision by the Lords Scarman, Diplock, Keith of Kinkel, Bridge of Harwich and Templeman to reject the appeal in *Sidaway* and uphold the English and Wales court view that the Bolam test applied to matters relating to information disclosure went broadly unchallenged until the early years of the 21st century. In fact, cases that followed most closely on the heels of *Sidaway* seemed to reinforce and even extend the power of *Bolam* to control information disclosure. In *Blyth v Bloomsbury Health Authority*,[154] the Court of Appeal concluded that, even where questions are asked about possible side effects, the measure of how much information should be given in reply can be found in the Bolam test. In his summary, Kerr LJ noted: *"the question of what a plaintiff should be told in answer to a general inquiry cannot be divorced from the* Bolam *test, any more than when no inquiry is made"*[155]*.*

At around the same time, the Court of Appeal ruled on *Gold v Haringey*.[156] The Court's reason for denying the claim of negligence was that there existed a body of opinion at the time that, as per the Bolam test requirement, would *not* inform a patient of the risk of pregnancy following the sterilisation procedure on the grounds that this would rob the vast majority of patients of the satisfaction that they would not get pregnant again. Interestingly, as Clare Dyer wrote in her 1987 article,[157] failed sterilisation operations were

[154] *Blyth v Bloomsbury Health Authority* [1993] 4 Med LR 151 CA
[155] Ibid.[155]
[156] *Gold v Haringey Health Authority* [1988] QB 481
[157] C Dyer, 'Failure to Warn' (1987) 294 BMJ 1089

ripe grounds for medicolegal claims during the 1980s (accounting for 29% of claims against gynaecologists in 1984, according to the Medical Defence Union [MDU]).

The highly paternalistic views held in these two cases were largely representative of the next 10 years of UK case law but at roughly the same time the courts elsewhere were starting to swing the pendulum towards autonomy.

Of particular interest is the case of *Rogers v Whitaker*,[158] which reached the Australian High Court in 1992. Mr Rogers, an ophthalmic surgeon who did not warn Mrs Whitaker of a risk of blindness in her one good eye, sought refuge in his defence behind the Bolam test because there existed two respected bodies that would not warn a patient of this risk. The High Court appeal was dismissed because the judges unanimously took the view that the Bolam test no longer stood for matters relating to information disclosure and rejected the narrative of the *Sidaway* judgement.

Gaudron J set out the joint judgement of Mason CJ, Brennan, Dawson, Toohey and McHugh when concluding [at 52] that the scope of a doctor's duty of disclosure is:

To warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of a particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient if warned would be likely to attach significance to it. This is subject to therapeutic privilege.

In reaching this conclusion, the honourable members of the court cited the earlier South Australian ruling in *F v R*,[159] which was heard two years before the *Sidaway* ruling was made and involved the failure to disclose a less than 1% risk of pregnancy following female sterilisation. This case marked the start of the Australian court's rejection of *Bolam* as an appropriate test for matters involving information disclosure and a greater reliance on the 'prudent patient test', as laid out by Lord Scarman in *Sidaway*.

In his judgement of *F v R*, King CJ wrote:[160] "*It is for the court to decide what a careful and responsible doctor would explain to the patient in the circumstances, and I do not regard as decisive the opinions of the medical witnesses on the point or the existence of a practice of non-disclosure in a section of the profession*".

[158] *Rogers v Whitaker* [1992] 109 ALR 625; [1993] 4 Med LR 79 (HC Aus.)
[159] *F v R* (1983) 33 SASR 189 Supreme Court (Full Court) (SA)
[160] ibid. [24]

Rather, as the *Bolitho* case 16 years later would apply a test of 'logicality' to the Bolam test, this case applied a test of 'appropriateness' to it.

As Karen Tickner wrote in her 1995 article[161] about this case, the concern the court felt was that, when applying the Bolam test, it becomes possible to apply weight to patients' questions only if the medical profession attaches significance to them. The title of her article says it best: '*Rogers v Whitaker* – Giving Patients a Meaningful Choice'. The Australian High Court had reached the conclusion that a meaningful choice requires a sharing of information that the patient is likely to want or needs to know; not just what the medical profession thinks they should hear.

By the early 90s, Canadian and Australian courts had rejected *Bolam* as the appropriate test for cases involving information disclosure and the US courts had developed a patient-centred view of informed consent some time before this. Despite a similar shift in the UK regulatory and authoritative guidance for healthcare, the UK courts, however, were slow to embrace such changes and the pendulum swung to patient-centred thinking in matters of information disclosure.

However, by 1999 and the ruling in *Pearce v Bristol*[162] we can see that the thinking had started to shift, in England and Wales at least. Ruling in support of the claimant, Lord Woolf MR noted that "*if there is a significant risk which would affect the judgement of a reasonable patient, then it is the responsibility of a doctor to inform the patient of that significant risk".*[163] Although this ruling held that risks should be disclosed if they are significant to the reasonable patient, the assessment of the risk still rested with the clinician, which falls short of the test finally established in *Montgomery*, 16 years later.

The 'mission creep' towards patient-centred thinking continued through the early years of the 21st century with *Wyatt v Curtis* in 2003,[164] then *Chester v Afshar*[165] in 2004, followed by *Al Hamwi v Johnston and North West London Hospitals NHS Trust*[166] in 2005.

In *Wyatt v Curtis*, Lord Justice Sedley cited[167] Lord Woolf's view in *Pearce* and Lord Bridge's test in *Sidaway* when commenting that "*what is substantial and what is grave are questions on which the doctor's and the patient's perception may differ, and in relation to which the*

[161] Karen Tickner, '*Rogers v Whitaker* – Giving Patients a Meaningful Choice' [1995] 15 Oxford Journal of Legal Studies 109
[162] *Pearce v United Bristol Hospital Governors* [1999] PIQR P53
[163] ibid. [59]
[164] *Wyatt v Curtis* [2003] EWCA Civ 1779
[165] *Chester v Afshar* [2004] UKHL 41
[166] *Al Hamwi v Johnston and North West London Hospitals NHS Trust* [2005] EWHC 206 (QB)
[167] ibid. [16]

doctor must therefore have regard to what may be the patient's perception". In other words, the doctor should have some level of insight into what might most concern the patient in any given situation.

A year later, the House of Lords got to revisit the issue of information disclosure in *Chester v Afshar*, which saw the Appellate Committee split 3:2 in favour of the claimant Miss Chester in her action against Mr Afshar, her neurosurgeon. In rejecting the appeal and supporting Miss Chester's claim, however, Lord Steyn spoke for the majority ruling when he stated: "*standing back from the detailed arguments, I have come to the conclusion that, as a result of the surgeon's failure to warn the patient, she cannot be said to have given informed consent to the surgery in the full legal sense. Her right of autonomy and dignity can and ought to be vindicated by a narrow and modest departure from traditional causation principles".*[168]

Lord Steyn appeared to pick up Lord Scarman's view in *Sidaway* that "*the duty to warn could be seen to be part of the doctor's duty of care only if it were recognized that the duty of care extended beyond the health and well-being of the patient to encompass a proper respect for the patient's rights".*[169]

Lord Steyn's position on informed consent is made clear where he states: "*Surgery performed without the informed consent of the patient is unlawful. The court is the final arbiter of what constitutes informed consent. Usually, informed consent will presuppose a general warning by the surgeon of a significant risk of the surgery"*.[170]

A point from the *Chester* ruling that has some resonance with this research undertaken for this thesis. The risk of injury in the procedure that Miss Chester underwent was put at 1%. All of the Lords sitting in this case agreed with the C of A that a duty existed to warn Miss Chester of this risk and all agreed that the injury had happened in a non-negligent manner. The claimant stated that had she been made aware of the 1% risk of injury she would still have gone ahead with the procedure but on a different day and potentially with a different surgeon. It was accepted by the Court of Appeal and again by the House of Lords that the risks would have been the same even if the operation were performed on another day. Lord Hoffman likened changing the day of the surgery but facing the same risk to changing casino when faced with a 1:37 risk of No7 coming up in roulette.[171]In this respect the "but for" test was not met but Lords Steyn, Hoffman and Hope who agreed in rejecting the appeal felt that the failure to inform of the risk was sufficient cause to find in favour of the claimant. In

[168] ibid. [24]
[169] ibid. [886]
[170] [14]
[171] [31]

the management of urgent care a failure to warn of alternative options that may be available elsewhere or the risks associated with the course of action proposed would certainly represent a breach of duty. But under this ruling, even, if there is a sense that the breach did not have causation attached to it, the failure to inform may be sufficient to result in a court finding for the claimant.

In 2005, the High Court of England and Wales got to consider further the question of disclosure in the case that Mrs Rana al Hamwi brought against Dr Fiona Johnston and the North West London Hospitals NHS trust.[172] The case raised an interesting point relating to a patient's ability to interpret the information that they are given. Simon J also accepted that the act of giving Mrs Al Hamwi a factually correct leaflet (regarding the 1% risk of miscarriage) was sufficient 'imparting of knowledge', without the need for the doctor to check if the patient had understood it.

This stance by Simon J seems to have been at odds with the 1994 ruling by Mooreland J in *Smith v Tunbridge Wells Health Authority*,[173] who took the view that reasonable care must be taken by a doctor to ensure that their explanations have been understood, and suggested that the doctor uses language which is likely to be understandable by the patient. A view that was supported by the information provided by the GMC at around the same time.[174] The GMC's view was that "*effective communication is key to enabling patients to make informed decisions. You must take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment*".[175]

Continuing the slow creep towards truly patient-centred autonomy in the eyes of the law, the question of how much information a patient should be given regarding the comparative risks of alternative procedures was addressed three years later in 2008. The case brought by Mrs Jane Birch against University College London Hospital NHS Foundation Trust[176] centred around Mrs Birch's contention that her treatment at the hands of her neurological team was negligent because it failed to consider and discuss with her the option of a non-invasive approach to her investigation prior to providing an invasive option that ultimately resulted in life altering complications. In his ruling, Cranston J favoured the tone and rulings of *Pearce* and *Chester* when finding the defendants liable to Mrs Birch for failing to properly gain her consent to the invasive procedure. The judge makes plain his thoughts when he expands upon the words of Lord Woolf MR's statement of law in *Pearce*, stating: "*unless the*

[172] *Al Hamwi v Johnston and North West London Hospitals NHS Trust* [2005] EWHC 206 (QB)
[173] *Smith v Tunbridge Wells Health Authority* [1994] 5 Med LR 437
[174] General Medical Council (GMC), *Seeking Patients' Consent: The Ethical Considerations* (GMC 1998)
[175] at [3]
[176] *Birch v University College London Hospital NHS Foundation Trust* [2008] EWCH 2237 QB

patient is informed of the comparative risks of different procedures she will not be in a position to give her fully informed consent to one procedure rather than another".[177]

Cranston J quoted Lord Steyn's words from his ruling in *Chester*[178] when he discussed the need for the law to reject a paternalistic view towards consent, saying: "*The rationale is patient autonomy and respect for the reality that it is the patient who must bear any consequences if a risk transforms into a reality".*

What makes *Birch* such an interesting case in this discussion is that the ruling rested on a failure to gain informed consent with no question of the surgical team being at fault for their procedure and no question of surgical negligence increasing the likelihood of the stroke that ensued. Mrs Birch had been warned of the 1% risk of stroke associated with the procedure that she underwent and had signed a consent form to this effect, but this was not an adequate defence against the allegation of liability due to a failure to properly inform.

The question as to how much weight a court should put upon a signed consent form is a contentious one with a lengthy past. As the question of signed consent forms is addressed in my questionnaire, it is probably worth expanding on this history for one paragraph at least. Bristow J made the point in *Chatterton v Gerson* that, without the accompanying explanations being given in proper form verbally before a patient signs a pro-forma consent form then "*the consent would have been expressed in form only, not in reality".* Lord Donaldson MR made his feelings clear on the subject in Re T (Adult: Refusal of Treatment) when he said:[179]

> *It is clear these forms are designed to primarily to protect the hospital from legal action. They will be wholly ineffective for this purpose if the patient is incapable of understanding them, they are not explained to him and there is no good evidence (apart from the patient's signature) that he had that understanding and fully appreciated the significance of signing it.*

In *Taylor v Shropshire Health Authority*[180], Popplewell J viewed the consent form as 'pure window dressing' but noted that an ineffective signature on a consent form should not be taken as proof that the patient had not actually given valid consent.

Returning to cases linked to the transition towards a patient-centred view on consent, *Jones v North West Strategic Health Authority*[181] (a case highly prescient of *Montgomery* as it

[177] at [74]
[178] at [15]
[179] at [34]
[180] Taylor v Shropshire Health Authority [1998] Lloyd's Rep.Med.395
[181] *Jones v North West Strategic Health Authority* [2010] Med LR 90

involves a claim of failure to warn Mrs Jones of the risk of shoulder dystonia to her unborn son, Jack), Nicol J took Lord Woolf's approach in *Pearce* one step closer to the 'prudent patient test'.

In one final case to consider prior to the 2015 ruling, we get a reminder from the courts, one year earlier, of what role the Bolam test can still fulfil. In *Meiklejohn v St George Healthcare*,[182] the court took the view that Professor Judith Marsh (doctor at the time of the trial) was not at fault and did not have a duty to warn Richard Meiklejohn of a possible alternative diagnosis if there was not good reason to suspect that they would be relevant to the clinical situation. The court held that Professor Marsh's advice and diagnosis, subsequent treatment and any discussion relating to possible side effects should be judged with reference to the Bolam test, and that the ruling in Chester did not apply here. The *Meiklejohn* case involved related to an extremely rare blood disorder that would have been understood and treatable by only a few experts around the world. The claimant's case was based not just on a claim that he should have been informed of a the specific risk of a rare complication associated with the medication prescribed but on a wider basis relating to a breach in Professor Marsh's duty to provide the claimant with all information that might be relevant to the treatment of his condition. To pursue this approach the claimant put reliance on both *Birch* and *Chester*. The court concluded that neither ruling applied here as there was no evidence that delaying the prescription of medication would have made any difference to the outcome (*Chester*). They also concluded that even if the risk had been disclosed the claimant would have taken the medication as no such complication had ever occurred at the hospital involved in the case and the alternative medication carried significant risks of its own (*Birch*).

This case brings us up to the 2015 *Montgomery* ruling, which is now discussed in full along with the impact that has been felt since. I also consider what challenges, if any, the ruling has had on the GDP community and their patients.

3.3. An analysis of the *Montgomery v Lanarkshire Health Authority* ruling and its impact over the following six years to date

The previous section highlights a slow creep change from the paternalist views on consent enshrined in *Sidaway* to the more autonomous views reflected in *Pearce* and *Chester*. The previous chapter revealed the views on consent held by the healthcare regulatory bodies for 15 or more years before the 2015 ruling in *Montgomery* and indicated how these views pre-empted much of what that ruling laid down in UK law. Given these findings it can be seen

[182] *Meiklejohn v St George Healthcare NHS Trust, Homerton University Hospitals Foundation Trust* [2014] EWCA Civ 120

that in some respects the *Montgomery* ruling was neither especially surprising nor particularly impactful. As Lady Hale states in her opening paragraph (at [107]) that a combination of the 2008 GMC guidance and the rulings in *Pearce* and *Chester* meant that it could already be stated "*with a reasonable degree of confidence that the need informed consent was firmly established in English law".* She went on to say, in the same paragraph, that "*this case has provided us with the opportunity, not only to confirm that confident statement, but also to make it clear that the same principles apply in Scotland"*.

In this respect, the *Montgomery* ruling can be seen as the UK courts uniting under the Supreme Court ruling to make clear the standards of informed consent, bringing these views in line with those that were already established in clinical practice guidance and English law. With this in mind, it is surprising, to me at least, how the legal profession has put such great significance on the ruling and how much time and ink has been spent by the healthcare world discussing it. In fact, this current research project reflects my desire to explore the perception within the dental profession that our clinical world has changed dramatically since 2015 and we must now develop hugely convoluted and complex consent processes for all our patients to follow.

The rest of this section details the *Montgomery* case and evaluates if any of the concerns regarding the ruling are justified.

3.3.1 The details of the case

Mrs Montgomery gave birth to her son Sam on 1 October 1999, who was diagnosed with dyskinetic cerebral palsy affecting all four limbs along with Erb's palsy affecting his arms.

At 24, this was Mrs Montgomery's first pregnancy. She was described as petite (1.55m tall) and suffering with insulin dependent diabetes. Her size and her diabetes were relevant to her pregnancy because there is a known risk of larger babies being born to diabetic mothers: large babies in small mothers can represent a risk of complications during childbirth.

Mrs Montgomery claimed that her son's palsies were caused by avoidable complications during labour; risks that Dr McLellan, her consultant obstetrician, had failed to warn her of. The case was first heard in the Outer House of the Court of Session in Scotland by Lord

Bannatyne,[183]who gave his decision in July 2010. The case was heard on a basis of 'consent' and 'failures in management of Mrs Montgomery's labour'.

The failures in management of the labour were based around Dr McLellan's interpretation of the cardiotocography trace (CGT) that was used to monitor the foetus' heart rate during labour. This aspect of the case was unsuccessful for the claimant.

The case for information disclosure was based around three central points:

- Failure to discuss the options of managing her delivery.
- Failure to advise of the risk of vaginal delivery.
- Failure to inform of the specific risks of shoulder dystocia and cephalon-pelvic disproportion.

With respect to the information disclosure aspect of the case, it was noted that Mrs Montgomery was a highly intelligent and articulate, university-educated woman with a parent and sister who were both doctors. It was also reported that Mrs Montgomery had asked specific questions about the risks of vaginal delivery following her concerns regarding the size of the baby.

The claimants team cited *Pearce* and *Chester* when referring to the issue of a "*specific risk which would affect the judgement of a reasonable patient".*[184] They argued that had she been properly informed of the specific risks and, if fully appraised of the delivery options, Mrs Montgomery clearly would have opted for an elective caesarean section.

The defence team acting on behalf of the Lanarkshire health board argued that, although the claimant had asked about her delivery, she should not be viewed as having asked about specific risks. They argued that, because there was no substantial risk of grave consequences, there was no requirement for Dr McLellan to warn Mrs Montgomery about them. The defence team cited *Sidaway*, stating that shoulder dystocia was not an adverse event based on the test laid out in that ruling and, because the risks of permanent disability were reported as being 1:2,000, there was no duty for the doctor to advise of this unilaterally.

The court viewed the question to be addressed as being one that related to the matter of whether a substantial risk of grave consequence existed (as in brain damage or other permanent disability occurring after an incidence of shoulder dystocia). On this matter, Lord

[183] Outer House decision [2010] CSOH Lord Bannatyne 2010 GWD 34–707
[184] *Pearce v United Bristol Healthcare* Lord Bridge at [59]

Bannatyne cited Lord Woolf's summary in *Pearce* when saying:[185] "*Although there is a substantial risk of that problem arising, given the likelihood of an adverse outcome it would not be a risk which would affect the judgement of a reasonable patient"*.

When the court addressed this central question on the basis of *Hunter v Hanley* it viewed Dr McLellan's approach to be in keeping with that of a responsible body of obstetricians and that his approach passed the Bolitho test. On these bases, this aspect of the case failed.

On the question of Mrs Montgomery's concerns about her ability to deliver vaginally, Lord Bannatyne rejected the suggestion that this amounted to specifically raising the question of risk. In his view:[186] "*Only where the patient asks questions specifically related to the risks involved in a particular course of treatment i.e. in this case vaginal delivery that the duty* (to fully explain all risks) *would be engaged".*

His Lordship also rejected the suggestion that, had Mrs Montgomery been aware of the risks, then she would have opted for a caesarean section.

Following these rulings, the claimant failed on all grounds of fault at this first hearing at the Outer House of the Court of Session. Mrs Montgomery appealed to the Inner House of the Court of Session, where her case was heard in 2013. Due to the doctrine of stare decisis[187] the lower courts remained bound to the House of Lord's ruling on *Sidaway* at this time. The claimant's legal team argued that *Pearce* represented a departure from *Sidaway* and expressed the greater focus on patient autonomy in English law, stressing the duty to advise of any substantial risk that would affect the judgement of a reasonable patient.

They argued again that Mrs Montgomery's questions relating to the size of her baby (which had been incorrectly assessed by Dr McLellan) and her ability to deliver it vaginally were sufficient to engage the duty to warn of all significant risks. Again, the claimant failed, and the decision was unanimous. The court ruled that *Hunter* was the correct way to decide if the duty to advise of a risk had been breached. They also ruled that *Sidaway* still applied and, even allowing for Lord Bridge's suggestion that in exceptional circumstances the court could overrule what the medical world consider appropriate in terms of information disclosure, this circumstance did not apply here.

Following this second failure, Mrs Montgomery took her case to the Supreme Court, which issued its decision on 11 March 2015. Of particular importance to the Supreme Court was its awareness that the claimant was trying to bring about an overturning of *Sidaway*; a fact

[185] ibid. [227]
[186] ibid. [263]
[187] Technical term for the rule of common law precedents

reflected in the convening of a bench of seven judges to consider the question. In this respect, the principal submission of the appeal was to ask the court to depart from *Sidaway* and reject the use of the professional standard (*Hunter* or *Bolam*) in consent cases.

Central to all of the arguments made by the claimant's team was the view that consent cannot be accepted as truly informed without adequate information and a patient cannot make a true choice about whether to reject or accept treatment advice without this adequate information. If a doctor withholds information, then the patient's right of choice is usurped. On the question of significant risk, the team argued that the likelihood of the risk and the nature of the harm cannot be separated in an argument about consent. The question of what is significant and what is grave is clearly a subjective one with doctors and patients likely to have differing views, especially as it is the patient who will bear the consequences of any risk that materialises.

Despite its focus on upholding autonomy rights the *Montgomery* ruling it still allows for the therapeutic exception where disclosure of information would "*be seriously detrimental the patient's health*"[188]. As Cave points out in her 2017 article[189]Lords Kerr and Reed do not refer to the "therapeutic privilege" but favour the term "therapeutic exception" (TE) which is taken to signal a narrowing of the courts view on when this approach might be considered acceptable. Professor Cave continues in the same article to highlight the limited role that TE has played in cases relating to consent in England and Wales and argues as to whether the conditions ever exist for it to apply. Given how little use of TE has been shown in the medical world when dealing with life and death issues and given also how it is almost impossible to imagine a scenario where information relating to the relief of dental pain could be "seriously detrimental to the patient's health" the exception was not considered relevant to this research project.

The Supreme Court unanimously found in favour of the claimant in *Montgomery* and in doing so recognised the fundamental importance of patient autonomy and the right of patients to make choices about their lives. As Lords Kerr and Reed stated: "*It would be a mistake to view patients as uninformed, incapable of understanding medical matters, or wholly dependent upon a flow of information from doctors".*[190]

When considering the relative importance that a patient may attach to some aspect of their care the court held: "*The doctor cannot form an objective, 'medical' view of these matters*

[188] Ibid.[88]
[189] Emma Cave, 'The Ill-Informed: Consent to Medical Treatment and the Therapeutic Exception' (2017) 46 Common Law World Review 140.
[190] ibid. [75]

and is therefore not in a position to take the 'right' decision as a matter of clinical judgement".[191]

In rejecting the professional standard of *Bolam* when assessing information disclosure Lady Hale said: "*Once the argument departs from a purely medical consideration and involves value judgements, it becomes clear that the Bolam test of conduct supported by a responsible body of medical opinion becomes quite inapposite".*[192]

When considering the correct test to assess the nature of risk, the Supreme Court reflected the view of the Court in *Rogers v Whitaker*, with further influence from Lord Scarman in *Sidaway* and Lord Woolf MR in *Pearce* to develop the concept of the competent patient and what they would wish to know.

The court then answered the question of what constitutes a material risk thus:[193]

> *A risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position would be likely, if warned of the risk, to attach significance to it* (the so-called objective limb*), or if the medical practitioner is or should reasonably be aware that the particular patient would be likely, if warned of the risk, to attach significance to it (*the so- called subjective limb).

The ruling of the Supreme Court also noted a preference for the adjective 'significant' (as used by Lord Woolf MR in *Pearce*) to 'substantial' (as used by Lord Bridge in *Sidaway*) when discussing risk. The court also took the view expressed in *Sidaway* that a patient needed to ask about a specific risk to get information about it as 'wholly unsatisfactory'. The court repeated Sedley LJ's view in *Wyatt v Curtis* when it said that there was something unreal about "*placing the onus of asking on a patient who may not know there is something to ask about*".[194] The authors Devaney et al discussed the implication of the subjective limb in their 2019 paper.[195] As they point out that while a statistically small risk of say 1:1000 may be dismissed by the majority of patients as theoretical, an individual patient may consider it to be materialistically important to them. From a personal perspective, having to deliver a nerve block to a patient in severe pain who had already experienced a permanent paraesthesia on the other side of their face from a previous administration of local

[191] ibid. [46]
[192] ibid. [115]
[193] ibid. [72]
[194] at [19]
[195] Sarah Devaney and others, "The Far-Reaching Implications of *Montgomery* for Risk Disclosure in Practice" (2018) 24 Journal of Patient Safety and Risk Management 25.

anaesthetic highlighted with great clarity the way a risk quoted as between 1:26,000 and 1:160,000[196] can become highly material to an individual.

As stated at the start of this chapter, the outcome of this ruling by the Supreme Court has been to focus the law now on the duty of information disclosure to patients and brings it in line with the guidance of the GMC and many other courts around the world. But what has the influence been on cases heard since 2015 and what influence, if any, has it had on clinical practice in dentistry? These questions gain attention in the rest of this section.

Many of the consent cases of note in the immediate aftermath (the rest of 2015 and early 2016) of the *Montgomery* ruling[197] tended to look at what the claimant would have done had they been given the fuller level of information that was originally denied them. Interestingly, the rulings tended to follow the view that the claimant still would have acted the same way as they did, had they been given the greater level of information at the time of making their decision.

One case that is perhaps of increased interest to this thesis is a dental case that was heard in the Scottish courts in 2016[198] and related to the extraction of a wisdom tooth in 2001. In this case, the court considered whether information relating to risks and alternative options for the treatment of the tooth had been appropriately shared with the patient first in the context of *Hunter v Hanley* and then in the context of *Montgomery*. In the context of the former test, the court held that no negligence had occurred as the options had been presented in such a way that the aspects of materiality, as laid out by *Montgomery*, had been met.

In a 2017 case[199] highly reminiscent of *Montgomery*, the Court of Appeal heard the case of Sebastian Webster, who was harmed during complications from his birth that resulted in severe brain injury. The cerebral palsy element of the case was dealt with by an admission of breach. However, the information disclosure element of the case (relating to whether to delay delivery or induce) had originally been dealt with on the basis of the Bolam test and had been rejected by the court on that basis. The Appeal Court held that that test was no longer appropriate and applied the *Montgomery* 'test' of the doctor's obligation to present

[196] MA Pogrel and S Thamby, "Permanent Nerve Involvement Resulting from Inferior Alveolar Nerve Blocks" (2000) 131 J Am Dent Assoc 901.
[197] *Tamsin v Barts Health NHS Trust* [2015] EWHC 3135 (QB), Jay J; *SXX v Liverpool Women's NHS Foundation Trust* [2015] EWCH 4072 (QB), HHJ Collender QC; *Connolly v Croydon Health Services NHS Trust* [2015] EWHC 1339 (QB); *A v East Kent Hospitals University NHS Foundation Trust* [2015] EWCH 1038; *Shaw v Kovac* [2015] EWHC 3335 (QB); *Barrett v Sandwell and West Birmingham Hospitals NHS Trust* [2015] EWHC 2627 (QB); 147 BMLLR 151
[198] *Scott Inglis v Susan Brand* [2016] SC EDIN 63
[199] *Webster v Burton Hospitals NHS Foundation Trust* [2017] EWCA Civ 62

the material risks to allow patients to make decisions that will affect their health and well-being based on proper information of all relevant uncertainties and alternative options. Based on this test and on the basis of questions and concerns raised by Mrs Webster (a qualified medical nurse), the Appeal Court held that she should have been given the additional information (of increased risk of complication in delayed delivery cases) and, had the defendant done so, the claimant would have opted to deliver her baby earlier than she eventually did. The previously mentioned paper by Devaney et al. considered the issue of causation with relation to lack of information disclosure and points out the burden of proving that they would have acted differently had they known all of the relevant alternatives lies with the claimant: they must satisfy the court that they are not just simply being swayed by hindsight.

The Supreme Court, in making their decision in the *Montgomery* case, made clear that the correct way for the court to view information disclosure considerations involved a view that draws substantially upon the words of Lord Scarman in *Sidaway*, Lord Woolf in *Pearce* and the High Court of Australia in *Rogers v Whitaker.* Despite some early cases cited above showing the courts' hesitance to view consent cases this way, it does appear that, six years down the road, this is now the firmly established position of the UK courts.

As we shall see in the next section, however, the ruling in some respects was just the courts' way of catching up with the standards already well embedded in professional practice guidance.

3.4 Regulatory guidance in medicine and dentistry: its view on consent

As stated in Chapter 2 section 2.3.3, the regulatory guidance from the GDC on the need for consent is clear. Since 1996, the GDC has provided its members with clear written advice on the behaviours and standards expected of them. In this original 1996 version of the GDC guidance, section 3.7 directly addresses consent. The guidance states that a dentist *"must explain to the patient the treatment proposed, the risks involved and alternative treatments and ensure that appropriate consent is obtained*". It goes on to state that, as all subsequent versions do, consent for treatment under general anaesthetic and sedation must be recorded in writing.

Of relevance to this thesis, the 1996 version also contained a section on pain and anxiety control (sections 4.8–4.10) where it states that patients have a right to expect adequate and appropriate pain and anxiety control. It also indicates the belief (in section 4.9) that dentists should give due regard "*to all aspects of behavioural management before deciding to prescribe or to proceed with treatment*". In section 4.10, the guidance even goes as far as to

inform dentists that they have "a duty to use the most appropriate and effective method of local anaesthesia for each patient".

The 2005 version of the GDC guidance (and all subsequent ones) was much less prescriptive as to how the physical act of dentistry should be carried out, leaving this guidance to other authoritative bodies, but did expand on the consent process. The Principles of Consent booklet formed one of six such principles that the GDC first proposed in 2003[200]. In the consent booklet, section 1 outlines what is meant by and what is required for informed consent to be given by a patient.

In section 1.2 it states that dentists "*should give patients the information they want and need, in a way they can use so that they are able to make informed decision about their care*". In section 1.4, the guidance informed dentists they should "*find out what your patients want to know as well as telling them what you think they need to know*".

The same section then gave examples of the sort of information a patient may want to know, such as why the dentist thinks the treatment is appropriate, the risk and benefits of the proposed treatment and the alternatives, what might happen if the treatment is not carried out and whether or not the dentist thinks that the treatment is appropriate.

Section 2 covered the aspect of what constituted voluntary decision making. It stressed that the decision as to whether to proceed with the treatment rests with the patient and that the patient has the right to refuse treatment or withdraw consent. The dentist was reminded in section 2.2 to ensure that they *"do not pressure the patient to accept your advice*". The question of ability to give consent was covered in section 3 with a recommendation that dentists consult with their dental defence organisation on what to do if they felt that a patient may not have the ability to give informed consent.

The most recent version, *Standards for the Dental Team*, was published in 2013 and updated in 2019. It listed the nine principles that dental professionals must always adhere to.[201] Within these, it gives notice of the mandatory nature of the consent process within dentistry.

In section 2.1, it states that professionals 'must' *"communicate effectively with patients……and take their individual views and communication needs into account*". Further

[200] Standards for Dental Practice: drat Guidance for Consultation (GDC) September 2003

[201] The nine principles listed are: 1) Put patient's interests first; 2) Communicate effectively with patients; 3) Obtain valid consent; 4) Maintain and protect patients' information; 5) Have a clear and effective complaints procedure; 6) Work with colleagues in a way that is in patients' best interest; 7) Maintain, develop and work within your professional knowledge and skills; 8) Raise concerns if patients are at risk; and 9) Make sure your personal behaviour maintains patients' confidence in you and the dental profession

to this, in section 2.3 (p. 21), it states that professionals 'must' *"give patients the information they need, in a way they can understand, so they can make informed decisions*". The subtle shift in wording here is interesting in context of the *Montgomery* ruling that followed two years later.

Within Principle 3: Obtain valid consent, section 3.1 (p. 29), the guidance states clearly that professionals must *"obtain valid consent before starting treatment, explaining all the relevant options and the possible costs".* This shifts the process from a 'should' in 2005 to a 'must' in 2013. In section 3.2 (p. 29), the guidance makes clear that professionals must "*make sure that patients understand the decisions they are being asked to make*". The document further expands on 3.1 in sections 3.1.1 and 3.1.3 (p. 30), stating that professionals must have valid consent before starting any treatment or investigation: "*whether you are the first member of the team to see the patient or whether you are involved after other team members have already seen them. Do not assume that someone else has obtained the patient's consent*".

Section 3.1.3 lays out what is required for the consent to be considered appropriately informed, stating (in a pre-*Montgomery* ruling world) that "*you should find out what your patients want to know as well as what you think they need to know*". It then lists things that the patient may want to know, which include:

- Options for treatment, the risks, and the potential benefits.
- Why you think a particular treatment is necessary and appropriate for them.
- The consequences, risks, and benefits of the treatment you propose.
- The likely prognosis.
- Your recommended option.
- The cost of the proposed treatment.
- What might happen if the proposed treatment is not carried out.
- Whether the treatment is guaranteed, how long it is guaranteed for and any exclusions that apply.

In section 3.2.1 (p. 31), the guidance states that *"you must provide patients with sufficient information and give them reasonable amount of time to consider the information in order to make a decision".* Section 3.2.4 (p. 32) touches on capacity by stating: "*You must always consider whether patients are able to make decisions about their care themselves and avoid making assumptions about a patient's ability to give consent*".

The wording here is interesting given that the central tenet of the Mental Capacity Act 2005 is that there should be an 'assumption of capacity'.[202] Standard 3.3 (p. 33) informs professionals of the need to "*make sure that the patient's consent remains valid at each stage of investigation or treatment*". Section 3.3.1 makes the point that "*giving and obtaining consent is a process, not a one-off event*". Section 3.3.5 deals with situations where it is necessary to change an agreed treatment which, as we will see later, can be particularly relevant to urgent care decisions. The section states: "*If you think that you need to change a patient's agreed treatment or the estimated cost, you must obtain your patient's consent to the changes and document that you have done so*".

The updated version of these Standards became valid from June 2019 but does not differ significantly when addressing the above sections.

As stated in Chapter 2 section 2.3.3, probably the most widely accepted published set of standards in dentistry in the UK are those produced by the FGDP. The original document published by the Faculty of Dental Surgery, as it then was, to project an accepted set of standards for the dental profession was the *Self-Assessment Manual and Standards (SAMS)*[203] that was first published in 1991. This document and the subsequent *Standards in Dentistry* used a graded system of A, B and C standards of care, as follows: Grade A represents an ideal outcome and describes a situation in a standard of excellence that has been achieved; Grade B (acceptable) represents a minimum acceptable standard of care, below which there is a potential for damage to the patient to occur; and Grade C (unacceptable) describes a situation where the patient concerned has either been damaged or there is potential for them to be damaged. In the 2018 version, these grades had been modified to make A 'aspirational', B 'basic' and C 'conditional', which reflects the context-based aspect to care when, despite everyone's best efforts, it is not always possible to achieve ideal results; a challenge that clinicians face on a daily basis.

The original SAMS version, however, contained a D grade as well as the aforementioned grades that denoted *"a situation where the patient is suffering with or will suffer severe damage as a result of the treatment or lack of treatment provided"*. The D section for 'Management of Acute Pain' records inappropriate diagnosis and inadequate pain relief leading to a worsening situation as evidence of this substandard treatment but makes no mention of consent as an indication of acceptable or unacceptable care. In the Diagnosis and Consultation section (2.1), a D category standard of care for Consent is represented as

[202] 'Mental Capacity Act 2005' (Legislation.gov.uk2005) Principle 2: A person must be assumed to have capacity unless it is established that he lacks capacity

[203] Kenneth Eaton and others, *Self-Assessment Manual and Standards* (Michael Grace ed, 1st edn, Haenor Gate Printing Ltd 1991)

"no explanation of the treatment carried out and no time has been allowed for decision making".

Subsequent to this standalone publication, the Faculty went on to produce additional guidance documents with the two most significant being *Standards in Dentistry*[204] and *Clinical Examination & Record Keeping*.[205] Both publications were updated recently with *Standards in Dentistry* getting a second edition in 2018[206] and *Clinical Examination & Record Keeping* getting a third in 2016.[207] Because the dates of these newer additions straddle the 2015 ruling on *Montgomery*, it made sense to review both sets of publications to see if changes in the editions reflected the shift in the legal landscape, post *Montgomery*.

The 2001, 2006 and 2016 versions of *Clinical Examination & Record Keeping* give clear guidance on what GDPs are expected to provide in terms of clinical history, tests, radiographs, records and treatment planning but they do not give a clear explanation of what constitutes valid and appropriately informed consent or what circumstances might influence this situation.

In section 3.2.2.3 of the 2006 *Standards in Dentistry: Consultation and Diagnosis*, the guidance is that the lowest acceptable standard of care (B) expected of a GDP when gaining consent state is as follows: "*The treatment plan has been explained in lay language together with the advantages and disadvantages of each treatment option. All risks have been explained. Questions have been invited but only immediately prior to treatment*" (as opposed to the aspirational standard [A] where such discussions would happen at a time removed from the treatment).

Clearly in the case of urgent care it is inevitable that much, if not all, of this discussion will happen immediately prior to treatment.

In the equivalent 'Consultation and Diagnosis' section of the 2018 version (section 2.2) the only mention of consent in the Basic standard is as single bullet point stating 'valid consent' (as per previous comments in Chapter 2, the term 'valid consent' has been taken to mean informed consent), which the authors state is a standardisation of a key element of dentistry, for all patients and all treatments, be it a single tooth filling or a full mouth reconstruction of every single tooth and this same standard requirement for 'valid consent' will apply. The 2018 version draws greater attention to the question of standards and how

[204] Kenneth Eaton, *Standards in Dentistry* (1st edn, Faculty of General Dental Practice 2006)
[205] Andrew Hadden and others, *Clinical Examination and Record Keeping* (2nd edn, Faculty of General Dental Practice 2009)
[206] David Moles and others, *Standards in Dentistry* (2nd edn, Faculty of General Dental Practice 2018)
[207] Andrew Hadden, *Clinical Examination & Record-Keeping: Good Practice Guidelines* (3rd edn, Faculty of General Dental Practice 2016)

they should be applied when judging the performance of a practitioner. In section 1.7 of the 2018 *Standards in Dentistry* the authors make clear that

"*any measure of performance has to:*

- *be judged against minimum (basic) standards, not aspirational standards that were acceptable at the time;*
- *be considered within the specific context of the particular patient and environment; and*
- *take account of the practitioner's justification which should be evident from the records"*.

The other major source of authoritative guidance within dentistry comes from the SDCEP. The question of obtaining 'valid consent' is addressed in their *Practice Support Manual* under the *General Principles of Ethical Practice*, in which it states, in reference to the GDC's nine principles outlined in *Standards for the Dental Team*: "*applying these principles to everyday dental practice will ensure that dental teams protect the interests of patients and obtain the respect and trust of their patients, peers and the public*". In other words, do what the GDC tells you to do (which, in a rather beautiful tautology, is to do what authoritative guidance tells us to do).

When seen in the light of this regulatory and authoritative advice, we get an idea that level of consent gained by a GDP from their patient, as a minimum standard, should involve a clear discussion (in lay terms) of the appropriate treatment options available, along with a description of the advantages and disadvantages of each and a personal recommendation followed by a time for questions, including the provision of information that the GDP considers the patient ought to know, and an evaluation of any future cost and treatment implications of the choices made by the patient at this stage in their care. All of this taking place in a timeframe that allows the patient sufficient time to evaluate the information and make a decision that is right for them. Perhaps not surprisingly the regulatory advice from the GMC and GDC has not changed greatly from a pre- and post-*Montgomery* standpoint. The GMC updated their 2008 consent advice in 2020 and the GDC did the same in 2019 for their previously given 2013 advice.
Both pre-*Montgomery* guidance from the GMC and GDC made a point of reminding their members of the mandatory nature of consent and made note of the need to tell patients what they need and want to know; with particular reference to options of treatments, risks, alternatives and the impact of doing no treatment. Given that the ruling in *Montgomery*

mirrors this advice and actually cites GMC Codes of Practice,[208] it would be unlikely that either regulatory body would have made substantial changes post 2015 and, whilst the documents look different and, in the case of the GMC's *Decision Making and Consent* guidance, has changed the headings to reflect a greater reliance on the concept of dialogue, rather than a one-way monologue, the advice remains broadly the same.

The most recent regulatory advice on consent has come from the National Institute for Clinical Excellence (NICE), who published their *Shared Decision Making* guidance in June 2021. This document seeks to embed shared decision making at the board level of trusts downwards; making it intrinsic to any healthcare organisation. At its core is the same basic message that we have seen repeated throughout the latter portions of this section. The guidance defines shared decision making as: "*a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care*" and insists that healthcare workers should ensure that the (person) "*understands the risks, benefits and possible consequences of different options through discussion and information sharing*".

Section 1.4 of the guidance focuses on discussing risk with patients and discourages the use of terms such as 'rare', 'unusual' or 'common' that can be interpreted differently by individuals. It also advises the use of both positive and negative representations when using numerical information, so 97% success can be presented as 'it works in 97 out of 100 people but will not work in 3 out of 100'.

Whilst this sort of advice is helpful it really does not alter what healthcare workers should have been doing and for the most part have been doing for this century at least. Given this finding, it might be expected that the professions that have been following this, or similar, advice for 20 years or more were not too concerned by the 2015 ruling.

An analysis piece in the May 2017 BMJ[209] by SW Chan and others looked at how the medical profession had responded to the ruling two years earlier and concluded that *"The Montgomery ruling has not radically changed the process of consent; it has simply given appropriate recognition to patients as decision makers*". In his May 2019 dental opinion piece,[210] Shaun Sellers asked the question "Has '*Montgomery*' changed anything?" In

[208] *Montgomery* [107] Lady Hale 'A combination of the 2008 Guidance provided by the General Medical Council, the decision of the Court of Appeal in *Pearce v United Bristol Healthcare NHS Trust* [1999] PIQR P53 and the decision of the House of Lords in *Chester v Afshar* [2005] 1 AC 134 meant that it could now be stated 'with a reasonable degree of confidence' that the need for informed consent was firmly part of English law (para 8.70). This case has provided us with the opportunity, not only to confirm that confident statement, but also to make it clear that the same principles apply in Scotland'

[209] Sarah W Chan and others, '*Montgomery* and Informed Consent: Where Are We Now?' (2017) 357 BMJ

[210] Shaun Sellars, 'Has "*Montgomery*" Changed Anything?' (2019) 226 British Dental Journal 719

answering this question, he suggested that the ruling *"changed the legal viewpoint with regard to valid consent*" but he went on to say, "*It could be argued, quite strongly, that from an ethical standpoint, Montgomery did very little, if anything at all".*

A 2021 systematic review[211] that looked at the legal and practical impact of *Montgomery* concluded that the ruling was primarily symbolic and any concerns that it might lead to a rise in defensive medicine and cause a greater workload for doctors were unfounded. Of the 100 papers that met the inclusion criteria for this review (out of 1,134 papers identified), the authors identified one that reflected the patient's view of Montgomery. The title of this single article 'Hobson's choice',[212] gives a hint as to the findings from the qualitative study that looked at patients' experiences of consent prior to urgent medical interventions. Interestingly, the patients interviewed were often unwilling or unable to express material risks as they saw them. For most, the choice was 'have the surgery and have a chance at getting better but with some risk or don't have the surgery with no chance of getting better': a choice Hobson would be proud of.

On the points raised by this systematic review and the aforementioned opinion pieces I am in full agreement. *Montgomery* may have established what the UK courts now view as a basic minimum in terms of information disclosure but it should not have significantly changed how we treat our patients; as healthcare professionals we should always have recognised our patients as individuals worthy of our respect and our full and frank disclosure of all information that is likely to be viewed as materially relevant to them when helping them to make the treatment decisions that are best for them. One would hope that we are all aiming to attain best possible practice standards for our patients, rather than focusing on the minimum standard to avoid legal challenge.

3.5 Conclusion

The 2015 *Montgomery* ruling finally rejected *Sidaway* and the view that the professional standard should determine cases relating to information disclosure. It has defined the courts' view on how patient autonomy should be considered when helping them make treatment decisions and has continued to shape rulings in the civil courts across the UK.

It is likely to be the defining statement on how the courts view information disclosure for some time to come. This ruling mirrors what the medical and dental regulatory bodies had

[211] Isabelle Le Gallez and others, '"*Montgomery*" Legal and Practical Impact: A Systematic Review at 6 Years' (2021) Journal of Evaluation in Clinical Practice

[212] Anthony Howard and others, '"Hobson's Choice": A Qualitative Study of Consent in Acute Surgery' (2020) 10 BMJ Open.

been saying for many years prior and brings the courts in line with the views of the regulatory bodies of doctors and dentists.

That said, there has been, as yet, little work on what difference it has actually made in clinical practice in general and there has been no research in dental practice, in particular. Given the increased challenges GDPs have faced in managing infection control over the past 18 months, this seemed an ideal time to provide research into GDPs' management of consent during urgent dental care appointments against a backdrop of COVID-19 restrictions.

The very more pressing and immediate challenges of the impact of COVID-19 restrictions may have affected GDPs' ability to gain appropriately informed consent, which is why the research question was set to view these twin challenges, in tandem.

Chapter 4 sets out how I went about developing my research project and what conclusions, if any, can be drawn from the analysed data.

Chapter 4: The Research Project Survey: How I did it

4.1 Introduction

As established in the Introduction, the management of acute dental pain can be a challenge for both the dentist and the patient. From personal experience as a full-time GDP, I have found that this challenge has been heightened since the COVID-19 pandemic and the literature available seems to support the view that I am not alone in the profession with this experience. (See Chapter 2, section 2.3.2 for a detailed discussion of the findings of my literature search on this topic.)

With this in mind, and with the backdrop of the 2015 Montgomery ruling continuing to shape our view on consent, the research project question was posed as: 'How have General Dental Practitioners (GDPs) negotiated the twin challenges of the new patient-centred standard of consent as laid down in Montgomery and the restrictions to care caused by Covid-19 from June 2020 onwards when treating adult patients suffering with acute dental pain?'

4.2 Aims and Objectives

It is a basic belief in scientific research that, for a project to be successful, it needs to clearly articulate its aims.[213] With this in mind, the aim of this project is to give an informed contribution to our understanding of how GDPs perceive the impact of both the Montgomery ruling and the restrictions imposed following our return to work in June 2020. To achieve this aim, I proposed the following objectives: to explore how much time GDPs routinely allocate for a typical urgent pain appointment; to evaluate how GDPs feel that the COVID-19 restrictions have impacted their ability to gain appropriately informed consent for patients in severe, acute pain; and to investigate how GDPs feel that the Montgomery ruling has affected their consent process, with particular reference to how they would go about obtaining consent for a clinical scenario presented in the survey.

4.3 Structure of the survey and consideration of bias

The questionnaire-based survey took place within a dental context – an area that has predominantly used a quantitative approach to research – studying that which can be measured and quantified. In dental science, as with most of the rest of the scientific world, the post-positivistic view of science has come to dominate.[214] This view acknowledges the impact of the observer on the observed and recognises that the best we can hope to know

[213] Judith Bell and Stephen Waters, *Doing Your Research Project: A Guide for First-Time Researchers* (London McGraw Hill Education 2014)
[214] Colin Robson and Kieran Mccartan, *Real World Research: A Resource for Users of Social Research Methods in Applied Settings* (4th edn, John Wiley & Sons Ltd 2016)

reality is in an imperfect probabilistic manner. This approach gives us a view of reality that is constrained within the limitations of the researcher's personal characteristics.

The research project can be viewed as providing quantitative descriptive research and was completed via a self-completion questionnaire distributed through a Facebook forum, restricted to UK-based GDPs. The means of distribution and voluntary nature of the respondents' involvement meant that the sampling should be viewed as non-random, convenience sampling that is not necessarily representative of the larger GDP population.

The questions asked are based on the literature, legal analysis undertaken and my intimate knowledge of dentistry practice. The clinical scenario presented in the questionnaire provides an accurate portrayal of symptoms consistent with a clearly diagnosable condition but there was a real risk that I would phrase the questions in a way that would reflect my personal approach to the management of the condition, leaving out answers that would have seemed more appropriate to some of the respondents. When testing the questionnaire in draft form, I asked colleagues from a wide range of clinical environments and checked that they felt the answers given were appropriate to each of them.

With the free text questions there was a risk of treating answers that showed a difference in approach to mine as being wrong because they did not fit with my perspective. I was aware of the possible biases within the deductive element of the research (how I phrased my questions) and tried to minimise the impact of these through an inductive approach to how I examined the responses. As stated by Cresswell,[215] qualitative research requires an interpretive approach and any interpretation I have made in this analysis cannot be separated from my training, personal biases, and prior understanding. Where possible, however, I have tried to keep them all to a minimum and have acknowledged them when I think their influence has been significant. Whilst these FTAs do not represent qualitative research in its most commonly accepted form (involving some level of interviewing of subjects by a researcher), the level of enquiry could perhaps best be described as a blend of narrative and phenomenological research as it seeks to investigate GDPs' experiences within a specific situation (COVID-19 restrictions) whilst asking them to describe their understanding of the processes they are involved in (gaining consent). Because this area of research has not previously been explored, a true qualitative approach using targeted, semi-structured interviews of the respondents would have lent itself to a grounded theory approach.[216] with the hope of generating a new theory based on the data collected that

[215] John W Creswell and J David Creswell, *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches* (5th edn, Sage Publications, Inc 2018) Chapter 9, 164

[216] Barney G Glaser and Anseim Strauss, *The Discovery of Grounded Theory: Strategies for Qualitive Research* (Weidenfeld and Nicolson 1968)

way. As Timmermans and Tavory describe in their 2012 article,[217] grounded theory has become the dominant approach for qualitative data analysis as it provides such a powerful framework with which to construct theories to help understand the phenomenon being examined. Sadly, this approach requires extensive data gathering and analysis and requires an in-depth understanding of technical coding requirements that meant it was beyond the scope of this research project.

To fit within the time limitations of conducting primary research as part of an LLM by Research thesis, my deductive approach was to first identify the type of question to ensure that they were truly open-ended, whilst my inductive approach was to choose codes that offered suitable coverage and flexibility with an awareness of wishing to avoid a large 'other' category or ending up with codes that could apply to all the responses. As explained by Cresswell,[218] coding *"is the process of organising the (recorded) material in to chunks or segments of text before bringing meaning to the information*".

According to Thomas,[219] inductive coding begins with close reading of the text with an aim to consider the multiple meanings within it. It is an iterative process that involves reading and rereading the responses to assess the validity of the chosen codes. As per Cresswell's suggestion, I broke the responses into segments of sentences (after reading all the responses in their entirety) that could be labelled with specific terms (codes). My approach could be thought of as being what Thomas refers to as 'in vivo' coding[220] because I used meaning within the answers to develop my codes.

Whilst this heuristic approach allowed me to quickly develop an understanding of the general nature of the responses given, there are also well-documented limitations with this approach. As Thomas points out,[221] "*any findings are shaped by the assumptions and experiences of the researchers conducting the research and carrying out the data analyses*". In the same section, Thomas goes on to state that the trustworthiness of the findings can be assessed by replication of the research by other independent individuals, with comparison to previous research findings and with feedback from participants. As this is the first such research project looking at this topic, I cannot verify my work against other findings and the anonymous nature of the questionnaire means that I cannot seek feedback from the

[217] Stefan Timmermans and Iddo Tavory, 'Theory Construction in Qualitative Research' [2012] 30 Sociological Theory 167
[218] Chapter 9 p. 173
[219] David R Thomas, 'A General Inductive Approach for Analysing Qualitative Evaluation Data' [2006] 27 American Journal of Evaluation 237 <https://journals.sagepub.com/doi/10.1177/1098214005283748>
[220] ibid. p. 5
[221] ibid. p. 4

respondents. It will require future research by others to see if my findings prove consistent with theirs.

4.4 Data collection

I chose an online, self-completion questionnaire (see Appendix 1) as this has the potential to generate high numbers of responses at no cost to the researcher and has worked well for me and my research colleagues in the past. A systematic review by Edwards and others[222] compared postal and electronic surveys and looked at ways to maximise response rates. Following the advice of this survey, I used shorter questions and imposed a deadline on the survey because both approaches have been shown to improve response rates. I decided to use a mixture of multiple-choice answers (MCAs) and free text answers (FTAs). This approach allowed me to develop data that was amenable to quantitative analysis from the MCAs, at the same time allowing respondents the chance to express themselves in a more nuanced way when answering the FTAs. I decided to make only two questions compulsory within the questionnaire. These were the first two questions, which asked for consent from the respondent to participate in the survey and for confirmation that the respondent was a GDP working in primary care in the UK. So long as the respondents consented and confirmed their working status, they could continue with the rest of the questionnaire and choose which questions to answer. I hoped that this element of choice would encourage respondents to work through all of the questions but had to acknowledge that it had the potential to weaken the analysis of the data because not all questions would be answered by all respondents.

The questionnaire was divided into three broad sections: the first dealing with demographic data such as location of work, experience and qualifications; the second relating to a clinical scenario representative of an acute pain patient that explored attitudes and approaches to pain management before and after the COVID-19 pandemic; and the third relating to the respondents' understanding and approach to consent. In terms of demographic data, I chose to focus on areas such as experience and qualifications (both primary degree and postgraduate) because these factors have been shown in previous studies to influence GDPs' management of acute pain (see Chapter 2 section 2.3.1). I collected data on location of work throughout the four home countries of the UK in the hope that some inferences could be drawn from any differences seen between differing NHS funding or legal systems, although the number of respondents was too low to allow any meaningful analysis of these

[222] Philip James Edwards and others, 'Methods to Increase Response to Postal and Electronic Questionnaires' [2009] Cochrane Database of Systematic Reviews

considerations. I did not collect data on gender because I did not consider this relevant to the questions being considered within the survey.

The clinical scenario presented the case of Jim, a healthy 56-year-old new patient seeking urgent care for pain symptoms that are highly consistent with a diagnosis of severe pulpitis (inflammation of the dental nerve) that requires direct intervention to alleviate the symptoms. It was written in a way to make the diagnosis and optimal treatment clear so that responses could be judged based on an assumption that the GDPs knew what the problem was and how it should be treated.

As per generally accepted guidelines, I piloted the questionnaire prior to disseminating it fully. To this end, I shared the draft questionnaire with 10 colleagues who have experience in research and are representative of the broad demographic of GDPs in the UK. The feedback was helpful and allowed me to refine the questions to minimise any risk of ambiguity or perceived biases in the wording. The feedback helped to shape the clinical scenario so that it provided a concise but accurate representation of an everyday clinical scenario for acute pain management. It also helped with the wording of questions relating to consent and the possible answers where I tried not to relate references to Montgomery and consent too much in the questions so as to avoid giving the respondent a hint as to what the ruling related to.

The population sampled consisted of UK-based GDPs who engage professionally with social media via the Facebook forum, For Dentists by Dentists. According to Statista,[223] Facebook is the most popular medium in social media and, according to research conducted in 2018,[224] approximately 55% of GDPs in the UK engage professionally with social media. It seemed reasonable, therefore, to select the largest UK GDP forum on Facebook as a target for my survey. That said, there are clear limitations to choosing to engage with GDPs solely via social media. Based on the above research, this approach potentially rules out engagement with 45% of GDPs. An additional problem with this approach relates to the algorithms used by Facebook and other social media providers which ensure that users of these services do not get to see all available content. According to Andrew Hutchinson's July 2021 post,[225] the most recent algorithm employed by Facebook uses various signals to determine which post

[223] H Tankovska, 'Topic: Social Media Usage in the UK' (www.statista.comFebruary 25, 2021) <https://www.statista.com/topics/3236/social-media-usage-in-the-uk/>

[224] Nilesh Parmar, Lin Dong and Andreas Benedikt Eisingerich, 'Connecting with Your Dentist on Facebook: Patients' and Dentists' Attitudes towards Social Media Usage in Dentistry' [2018] 20 Journal of Medical Internet Research

[225] Hutchinson Andrew, 'Facebook Provides New Explainer on How Its News Feed Algorithm Works' (Social Media Today 21 July 2021) <https://www.socialmediatoday.com/news/facebook-provides-new-explainer-on-how-its-news-feed-algorithm-works/603189/>

is most relevant to the user. This means that we see a filtered version of the enormous total numbers of posts available. The impact of this is often viewed as the 'echo chamber' of social media where users tend to see posts that are of most interest to them and ally most to their personal opinions. It is reasonable to assume, therefore, that a post placed by me to highlight my questionnaire was more likely to be seen by GDPs who have interacted with me before on Facebook or have shown an interest in questionnaires before or the topic being discussed. As stated at the start of this chapter, the selection of respondents can be seen as non-random, convenience sampling, but can also possibly be seen as targeted, via the algorithms of Facebook, to a group of GDPs who are more inclined to answer professional questionnaires and are possibly more interested in the topic being examined. Despite these limitations, the speed, ease, and no-cost aspects of an online survey delivered via social media meant that this approach remained the mode of delivery of choice for this research project.

When considering my 'insider-outsider' status as regards this research project, I took the view that, as a UK-based GDP, I could view myself as an insider when conducting research amongst my colleagues. However, as a purely private GDP working in a relatively affluent area of the UK, I could also be viewed as an outsider by GDPs who work in heavily NHS-based practices in areas of high need and privation. Whichever way I choose to view my status, it is important to remember that being an insider or an outsider does not make one a better researcher; merely a different one.[226] Being an insider helped me speak with familiarity regarding the problems associated with pain management and construct a realistic clinical scenario that would most likely be very common place to any GDP. It was also most likely an advantage in terms of recruiting GDPs who may be familiar with me on social media.

Unpublished data from the British Dental Association (BDA) estimates that in 2019/2020 there were 34,180 GDPs working in the UK across the NHS and Private sectors.[227] This compares to a total figure of 43,054 dentists registered with the GDC (December 2020).[228]

According to the forum By Dentists for Dentists, they have 18,100 members, which represents 42% of all dentists. A power calculation based on this figure[229] gave a target

[226] Sonya Corbin Dwyer and Jennifer L Buckle, 'The Space Between: On Being an Insider-Outsider in Qualitative Research' [2009] 8 International Journal of Qualitative Methods 54

[227] The total figure of GDPs currently working in the UK is more difficult to estimate than might be imagined as the GDC register does not record if dentists work in primary or secondary care and there is no official figure for the number of private dentists who do not have an NHS performer number. It is also not possible to give figures for full- and part-time workers in primary care

[228] 'www.gdc-Uk.org/Docs/Default-Source/Registration-Reports/Gdc-Registration-Statistical-Report-2020' (General Dental Council December 2020)

[229] 'www.abs.gov.au/Websitedbs/D3310114.Nsf/Home/Sample+Size+Calculator.

number of responses of 377 (based on a confidence interval of 0.05, and a conservative estimate of variance set at 0.5). The questionnaire was distributed via a link to the onlinesurveys.co.uk site where the questionnaire was held. Reminders were posted on differing days and times on a weekly basis for the 12-week distribution timeframe. (The 12-week limitation reflected the time constraints of completing primary research within a 15-month LLM by Research programme.)

Ethical considerations when carrying out social-media-based research were discussed by Hewson and others in 2017[230] on behalf of the British Psychological Society, and their conclusion was that "*the normal principles of ethical research with human participants apply to internet-mediated research (IMR), and the basics of ethical practice are not changed".* All respondents were made aware that their anonymity would be protected throughout the process and no identifiable data were collected from them. The responses were stored with a secure online survey provider and on a password protected computer with an encrypted hard drive. Consent was given via a tick box response with any respondents who declined consent being directed to the end of the survey without an opportunity to compete the questionnaire.[231] In accordance with the University of Kent, a CPP Full Ethical Application form was completed on 28 April 2021. Approval was granted by the Research Ethics Advisory Group on7 June 2021. I completed the NHS Health Research Authority decision tool for each home nation; all of which confirmed that, because my research did not involve accessing patients or patient sensitive data and did not involve recruitment via the NHS, I did not need NHS Research Ethics Committee approval for this project.

Following 12 weeks of targeted data collection using the above methods, a total of 93 respondents provided useable responses. This number was certainly lower than I had hoped for or expected after my previous research. I attempted to increase numbers by repeatedly reposting the link to the questionnaire at differing times and days to try and reach as many potential respondents as possible. Despite the initial disappointment felt at the lower than expected number of respondents, I was grateful to those who had taken the time to respond and was pleased with the quality of the data gleaned from the questionnaire. The analysis of these responses forms the basis of the next chapter.

The relatively low number of respondents achieved with this survey (a total of 101 respondents with 8 excluded for reasons of lack of consent or not working in the UK as a

[230] Hewson and others, *Ethics Guidelines for Internet-mediated Research* (British Psychological Society, 1NF206 22)

[231] Respondents were informed via a cover sheet that their involvement was entirely voluntary, with no inducement offered to encourage completion other than an expression of gratitude and a belief that their involvement might help develop our understanding of the topic

GDP) means that the sample size is not large enough to make the results generalisable or transferable to the population sampled (UK-based GDPs who engage with the Facebook forum By Dentist for Dentists). The project should be considered to be a pilot study that may help to develop further similar research projects that can be disseminated in both online and conventional postal forms to a larger group of UK-based GDPs.

Chapter 5: The Research Project Survey: What it told us

5.1 Introduction

The questionnaire was available to access for 12 weeks and generated a total of 93 useable responses. Because most of the questions were non-compulsory, some of the respondents completed only certain sections of the questionnaire, meaning that partially completed questionnaires were included as well. Despite the limited number of responses, the quantitative and qualitative data yielded interesting insights into the increased pressures faced by dentists following the implementation of COVID-19 responses. It also shed light on GDPs' knowledge and understanding of Montgomery and provided further examination of how they have implemented this ruling into their consent processes both before and after COVID-19.

This chapter focuses on the analysis of the data provided by these 93 respondents and seeks to review the demographic data and compare this to the FTAs to see if any common themes can be established within the responses.

5.2 Quantitative data

This section provides details with the aspects of the questionnaire that collected responses via drop down answers and can be viewed broadly as providing quantitative data.

5.2.1 Respondents' characteristics

Table 1: Respondents' Characteristics

Year of qualification	Total (percentage)	Location of primary work site	Total (percentage)	Country of qualification	Total (percentage)
1970–1979	3 (3.3)	England	78 (84)	UK	80 (87.9)
1980–1989	13 (14.3)	Scotland	7 (7.6)	Non-UK	11 (12.1)
1990–1999	25 (27.5)	Wales	6 (6.5)		
2000–2009	30 (33)	N Ireland	1 (1.1)		
2010–2020	20 (22)				
Total number of answers	91		92		91

The above figures show that, whilst the overall response rate was low, the characteristics of the respondents were broadly consistent with the GDC data for 2020.[232] The figures from this report show that 74% of dentists on the register are aged 50 or younger, which would equate to a qualification from the early 90s onwards (which would equate to 82.5% of the respondents). The figures from the same report indicate 75% of registrants residing in England and just over 20% in Scotland and Wales. According to the GDC, 77% of the registrants in 2020 qualified in the UK (compared to 80% of respondents in this survey).

In the survey sample population, the proportion of dentists having a secondary postgraduate qualification was approximately the same across both groups (42.3% for UK trained and 45% for Non-UK trained).

Table 2: Respondents' division of services between NHS and Private

Percentage of revenue derived from NHS	Number (percentage)
1-24% NHS	15 (16.3)
25-49% NHS	5 (5.4)
50-74% NHS	20 (21.7)

[232] 'Our Annual Report' (General Dental Council July 4, 2021) <https://www.gdc-uk.org/about-us/our-organisation/our-corporate-strategy-and-business-plans/our-annual-reports>

75-99% NHS	27 (29.3)
100% NHS (No Private income)	6 (6.5%)
100% Private (No NHS Income)	19 (20.7)
Total responses	**92 (99)**

Out of the 19 dentists who earned no income from NHS services, 18 were in England and 1 in Scotland. Because of the way that information regarding individual GDPs is collected by the GDC and other regulatory bodies, it is difficult to state with accuracy how this division of NHS v Private is reflected in the UK GDP population generally. That said, it has been estimated that 40% of practices in the UK (12,500 in total) can be classed as being wholly or predominantly NHS-based[233] (compared to 35.8% of the GDPs in this survey). Overall, the respondents to my survey compare well to the overall distribution of training and NHS participation found in other data sources.

5.2.2 Clinical scenario results

The clinical scenario the respondents were asked to consider presented a typical case of symptomatic irreversible pulpitis causing severe debilitating pain that was limiting the patient's quality of life and ability to function. According to all authoritative bodies in dentistry, the appropriate care for this condition is to remove the inflamed nerve (if the tooth is to be retained) or extraction if retention of the tooth is not appropriate or desired.[234] The scenario and the questions relating to it were designed to try and draw out any tension between GDPs' awareness of what should be done and what they are practically able to deliver, in terms of consent and clinical care. This tension could then be explored in terms of pre and post COVID-19 to see what, if any, impact the restrictions imposed in response to the pandemic have had. For GDPs in England, the management of acute dental pain was drawn into focus by a letter from Sara Huntley, the CDO, in September 2021.[235] This letter informed GDPs of their need to prioritise members of the public in pain above the needs of existing patients of their practices. A subtle word change from previously saying 'patients in pain' to 'people in pain' meant that GDPs' surgeries in England were de facto 'drop-in centres' for people who do not regularly see a dentist. The implications for how dentistry is delivered in England is examined further in the next chapter.

[233] Catherine Rutland, 'The Future of Dentistry Part 1: NHS' (2021) 34 BDJ In Practice 20 <https://www.nature.com/articles/s41404-021-0768

[234] See Chapter 1 section 1.2 for a detailed discussion of the recommendations made by the SDCEP and FGDP on how optimal care for relief acute dental pain should be delivered

[235] NHS, 'Coronavirus» Letters, Updates and Additional Guidance for Dental Teams' (www.england.nhs.uk2020) <https://www.england.nhs.uk/coronavirus/publication/preparedness-letters-for-dental-care/>

The clinical scenario describes the offending tooth as being in a restorable condition and functionally important, so it would seem reasonable to consider retention of the tooth as being in the patient's best interest. The patient does not give a clear clinical preference to how he is treated beyond the need for immediate pain relief. To treat the tooth in such a way that it could be retained would require a treatment that is overwhelmingly likely to involve an AGP, indicating the need for enhanced PPE (full gowns and FFP3 mask) and additional fallow time to cleanse the surgery post treatment.

When asked in Question 9 if they would provide the urgent care appointment as an AGP or a non-AGP appointment the results were divided almost 50:50 (51.1% AGP to 48.9% non-AGP).

This finding is of interest because roughly half of the respondents are providing urgent care appointments that significantly limit the treatment options available to manage the event. The preceding question asked respondents, since June 2020, how long an appointment they would routinely provide for such a patient.

My previously referenced research[236] explored a similar theme, looking at inappropriate antibiotic prescription patterns in urgent care appointments. Using a clinically comparable urgent care scenario, I was able to identify that a significant increase in inappropriate antibiotic prescriptions occurred when GDPs allocated less than 20 minutes for these visits (based on a total of 198 respondents). In the current survey, 18 respondents (19.8%) indicated that they would schedule this amount of time (compared to 47% in the previous survey conducted at the end of 2019). This finding suggests that appointment times have increased since June 2020 although, once we include those respondents who allowed up to 30 minutes, the difference between the two surveys is relatively modest (62.3% for this current sample population versus 76% in the previous one).

Even allowing for the fact that any comparisons between the two surveys needs to be done with caution, it does seem reasonable to suggest that there has been a shift towards slightly longer appointment times in COVID-19 times compared to those unsuspecting pre COVID-19 days. Whether this noted slight increase in appointment time reflects greater treatment time for the patient or a longer appointment scheduled to allow for fallow time cannot be interpreted from this research. It is possible to speculate that GDPs are seeing fewer patients and so have longer appointment times available or GDPs are focusing on more complex cases that have developed as a result of longer waiting times experienced by

[236] Ian Kerr and others, 'An Investigation into Possible Factors That May Impact on the Potential for Inappropriate Prescriptions of Antibiotics: A Survey of General Dental Practitioners' Approach to Treating Adults with Acute Dental Pain' (2021) British Dental Journal

patients but these considerations would require additional research to allow them to be explored further.

Of the 18 respondents who indicated that they would offer an appointment of less than 20 minutes, 15 (83.3%) would offer this as a non-AGP appointment. Those with a high reliance on NHS revenue (75%–100% NHS) were more likely to offer an appointment of less than 20 minutes than those with a low reliance (24% or less NHS): 28% (9 out of 33) of high reliance compared to 17% (6 out of 34) for low reliance. Clearly, the low numbers involved mean that any interpretation should be done with caution. Those with a high reliance were twice as likely to offer the appointment as a non-AGP visit than those with a low reliance: a non-AGP visit limits the treatment choices available to the patient in pain. It is not possible to say from this data why the results point to a potential difference in appointment scheduling between high and low NHS reliance dentists but it could reflect difference in patient numbers seen each day, ease of delivery of AGPs, one sector versus the other or the remuneration on offer for NHS versus Private dentists when treating patients in pain.

In Question 10 the respondents were asked about their likelihood of prescribing antibiotics in this scenario. A concerning figure of 26.4% (24 of 93) indicated that they would issue a prescription as an alternative to an AGP. In my previous study, 4% (7 from 198) indicated that they were highly likely or certain to provide an antibiotic prescription for the equivalent clinical scenario. Again, the figures in both studies were low and any comparison made between the two must be done with caution, but this finding is suggestive of a trend towards a potential increase in inappropriate antibiotic prescription rates and one that may warrant further investigation. As there is no clinical need for the use of antibiotics in this scenario, and their prescription does not reduce the risk of future infection from the tooth, it may be that the potential increase is driven by the relative difficulty in delivering care during this time of heightened restrictions and a misguided belief by the dentist that prescribing the antibiotics on a ‘just in case’ basis will save the patient a repeat visit for treatment.

Of the 18 respondents offering an appointment of 20 minutes or less, 27.8% (5 of 18) would offer antibiotics, with the majority (55.6% or 10 of 18) advising continued painkillers.

Based on the limitations of this survey, the findings suggest that, for patients being seen for an urgent care appointment of less than 20 minutes, 83% (15 of 18) are likely to receive at best no treatment for pain relief and at worst inappropriate care. By comparison, those respondents offering appointments of 30-45 minutes (38.7% or 26 of 93) over half (53.8% or 14 of 26) would provide an AGP treatment to relieve pain. In this group, the likelihood of offering an inappropriate prescription of antibiotics dropped but remained high at 19.2% (5 of 26). Given that the time allocated here represents sufficient opportunity to provide

optimal care, the number of inappropriate prescriptions suggested by this subset is difficult to explain. As discussed in Chapter 1 section 1.2, the delivery of optimal urgent care can be particularly challenging for both the dentist and the patient. Difficulty of diagnosis, problems with achieving adequate anaesthesia and the levels of distress the patient is experiencing can all put pressure on an often times squeezed appointment. Despite these difficulties, it has been well documented within this thesis what the literature and the regulatory and authoritative bodies consider to be optimal care, and patients have a right to expect this at a time when they most need it. When it comes to appointments of less than 20 minutes, it is easier to understand why optimal care may not be achievable in such a short space of time but, when appointments of 45 minutes are allocated and an inappropriate antibiotic prescribed, this may well reflect patient pressure and expectation winning out over antibiotic guardianship.

The real-world implication of appointments scheduled for 20 minutes or less can be seen in the issue of *Commissioning Standards for Urgent Dental Care*.[237] Within this document we see[238] that appointments for UDC are set at a minimum of 15 minutes. The value of 15-minute slots is that it allows for 4 patients an hour to be seen; meaning that access targets can be more readily met. The disadvantage, based on my findings here and in my previous research along with findings published by other researchers,[239] is that, when appointment lengths dip below 20 minutes, the risk of inappropriate treatment increases. Increasing the minimum appointment time to 20 minutes would, of course, cause a reduction of 25% in patient numbers seen but has the potential to decrease the risk of inappropriate care for the fewer patients who are seen. Here the need to achieve acceptable targets for access to a dentist may override the issue of the quality of the care once the patient gets there.

5.2.3 Respondents' attitudes towards consent within the clinical scenario

Questions 11 and 12 explored the respondents' attitude to consent and how these might be affected by the limitations of care imposed since June 2020. Question 11 asked the respondents whether they would inform the patient of any limitations to care that would reduce the treatment options available at that appointment. An overwhelming majority (93.1%: 81 of the 87 respondents who answered this question) indicated that they would inform the patient if they were unable to offer all appropriate treatment choices. Of the 6 respondents (6.9%) who said that they would not inform the patient of the limitations of the

[237] 'NHS England» Commissioning Standard for Urgent Dental Care" (www.england.nhs.ukJuly 2019) <https://www.england.nhs.uk/publication/commissioning-standard-for-urgent-dental-care/>
[238] Section 6.5 p. 18
[239] Wendy Thompson and others, 'Clinician and Patient Factors Influencing Treatment Decisions: Ethnographic Study of Antibiotic Prescribing and Operative Procedures in Out-of-Hours and General Dental Practices' (2020) 9 Antibiotics 575

treatment available, 5 said that they would offer extraction, antibiotics, or no treatment.

Based on the limitations of this survey, these figures suggest that approximately 1 in 14 appointments for urgent care have the potential to result in an inappropriate and uninformed treatment decision for acute pain. As discussed at length throughout Chapter 2, the regulatory advice from the GDC regarding consent makes clear that the dentist has a mandatory duty to inform patients of the risks and appropriate alternative options available. The authoritative advice on urgent care management is unequivocal in its advice that antibiotics are inappropriate for management of dental pain in the absence of spreading infection with systemic impact. To fail to inform a patient about the impact of the restrictions of care specific to that appointment breaches a duty of care to that patient and providing an antibiotic in the clinical scenario provided would represent a standard of care that falls below that expected of a reasonably competent practitioner.

Question 12 asked the respondents how they rated their chances of achieving obtaining valid and appropriately informed consent from the patient in the clinical scenario when treating his acute pain. Almost three-quarters of the respondents (73.7% or 66 of the 90 respondents who answered) rated their chances as highly likely or certain. The remaining 26.7% (24 of 90) viewed their chances as highly unlikely. Again, those with the highest reliance on NHS services for funding reported a greater sense that they would view their chances of gaining valid consent as highly unlikely compared to those with lowest reliance: 14.7% of the low reliance group compared to 33% of the high reliance group. It is not immediately clear why NHS dentists should feel any less confident of achieving informed consent in this scenario than their Private colleagues. It is possible that the impositions of the NHS commissioning contracts that are absent in Private practice may make dentists working in the NHS more anxious regarding their regulatory duties but, again, further research is needed to interpret these findings further.

Based on these figures, it would seem that approximately one quarter of GDPs treating patients suffering with acute pain do so with little or no expectation of having achieved appropriately informed consent for the treatment (or lack of) that they are undertaking.

Concerns relating to gaining consent from patients is certainly not a new finding and not one that is unique to COVID-19 restrictions. When reviewing research looking at confidence levels in medics trying to gain consent, it is interesting to note that Wood and others[240] found similar concerns with their ability to gain informed consent among doctors working in hospital environments. In their 2014 qualitative research, the authors reported that *"many*

[240] Fiona Wood and others, 'Doctors' Perspectives of Informed Consent for Non-Emergency Surgical Procedures: A Qualitative Interview Study' (2014) 19 Health Expectations 751

junior doctors admitted to feeling inexperienced and ultimately lacking confidence to consent for procedures". Earlier research by Yoshihara and Takase[241] highlighted the impact of the clinicians' attitudes towards informed consent on their belief as to whether it could be achieved or not. Perhaps not surprisingly, the authors found that the doctors' belief as to whether patient's self-determination is possible and has a positive influence on outcomes was a significant factor in determining whether they believed gaining informed consent was ever possible. It is likely that dentists have suffered similar concerns and attitudes relating to informed consent prior to COVID-19 restrictions. It is possible that these concerns have worsened due to the difficulties with communication relating to enhanced PPE or paradoxically may have diminished as dentists are forced to focus on issues relating specifically to the restrictions and are paying less attention to their consent processes.

5.2.4 Respondents' understanding of Montgomery and the impact of COVID-19 restrictions on their interpretation of it

Questions 14 and 15 asked the respondents about their awareness and knowledge of the 2015 Montgomery ruling and the results are summarised in the table below.

Table 3: Respondents' knowledge and awareness of Montgomery

Awareness of Montgomery	Number (percentage)	Level of understanding of the changes brought about by the ruling	Number (%)
Yes	72 (80)	Not at all	17 (19.3)
No	18 (20)	A little	35 (39.8)
		A good understanding	26 (29.5)
		Clear and substantial understanding	10 (11.4)
Total	**90 (97)**	**Total**	**88 (94.6)**

The majority of GDPs in this small survey have heard of the *Montgomery* ruling (80% or 72 out of 88) but, of this group, 50% have little or no understanding of the ruling and its impact on our approach to healthcare decisions with our patients. The Le Gallez and others paper[242] mentioned in Chapter 3, as part of its systematic review of the impact of *Montgomery*, looked at doctors' awareness of the ruling and found it to be similarly limited. The review reported a range of familiarity across 11 studies; a range of between 8 and 48% of

[241] Keisuke Yoshihara and Kozo Takase, 'Correlation between Doctor's Belief on the Patient's Self-Determination and Medical Outcomes in Obtaining Informed Consent' (2013) 60 J Med Dent Sci 23
[242] Isabelle Le Gallez and others, '*Montgomery's* Legal and Practical Impact: A Systematic Review at 6 Years' (2021) Journal of Evaluation in Clinical Practice

respondents not being familiar with the ruling. My findings here represent the first time that it has been shown that a similar pattern of awareness exists in dentists.

The latter part of the questionnaire focused on how the respondents perceived the impact of the *Montgomery* ruling on how they conduct urgent care consent processes and how much, if at all, the COVID-19 restrictions had moderated this. The results are summarised below.

Table 4: Results of how GDPs rate the impact of *Montgomery* and how COVID-19 restrictions have affected their attention to these changes

Extent of changes brought about by *Montgomery*	**Numbers (%)**	**Level of attention paid to *Montgomery* post COVID-19 restrictions**	**Number (%)**
Not at all	36 (42.4)	More	14 (16.7%
Minor or slight changes	36 (42.4)	Less	9 (10.7)
Substantial changes	13 (15.3)	The same	61 (72.6%)
Totally changed	2 (2.4)		
Total	**87 (93.5)**	**Total**	**84 (90.3)**

Based on these figures, the impact of both the actual Montgomery ruling and subsequently the impact of COVID-19 restrictions on GDPs' attention to it have been low.

From the detailed discussion of the *Montgomery* ruling in Chapter 3, it could be seen that the ruling did little more than indicate that the courts of the UK now viewed the issue of informed consent in a manner in keeping with the regulatory and authoritative bodies of the healthcare professions. In this respect, one would imagine that the impact of this ruling on GDPs would have been relatively muted and, within the limitations of the findings of the current survey, this has been shown to be the case.

When these responses were compared to those of the previous questions, it was seen that, of the 59.1% of respondents who reported having little or no understanding of the *Montgomery* ruling (Table 3), 75% (39 from 52) indicated that the ruling had slight to no impact on their daily practice. The impact here would seem to be a result of lack of understanding rather than consideration of the ruling.

5.2.5 Impact of COVID-19 restrictions

The final three questions that collected directly quantifiable data (Questions 22–24) explored the consent process and how much, if at all, the respondents felt that the

treatment restrictions post COVID-19 had had on them and their patients. The results are summarised in Table 5 below.

Table 5: Respondents' level of treatment discussion and use of signed consent forms when seeing patients in acute pain

Which treatment discussion are you most likely to have with a patient in pain?	Number of respondents (%)	How often would you get a signed consent form prior to treating a patient in pain?	Number of respondents (%)
Comprehensive of all reasonable options	65 (73%)	Never	41 (46.1)
Immediate pain relief only	21 (23.6%)	Seldom	22 (24.7)
Only options I feel confident to give	3 (3.4%)	Most of the time	13 (14.6)
Only treatments available at my practice	0 (0)	Always	13 (14.6)
Total	**89 (95.6)**	**Total**	**89 (95.6)**

When asked about the discussion of treatment options that the respondents would have with a patient being seen for urgent care, 73% (65 of 89) indicated that they would have a 'comprehensive discussion of all reasonable options'. When this result was compared with an early question regarding how likely the respondents felt about gaining appropriately informed consent, it was found that, of the 24% who indicated that they considered it highly unlikely (see section 5.3.2), the majority (62.5%) indicated in this section that they would provide a comprehensive discussion of all reasonable options. These results suggest that anxiety that surrounds informed consent may well reflect GPs' perceived inability to do the right thing, rather than any actual shortcomings in their process. Another possibility is that it might reflect the respondents' understanding of the impact of pain on cognition, as highlighted by the research discussed in Chapter 2 section 2.3.4, and patient factors may block the path to achieving informed consent.

A small group of three respondents indicated that they would limit the options to those 'that I feel confident delivering'.

The risk of limiting discussions to immediate pain relief or those treatments that 'I feel confident to give' is that the patient receives an incomplete description of the options available and the impact of these treatment choices on later dental needs. If a GDP does not feel confident getting a patient sufficiently numb, they may offer antibiotics as a quick and easy treatment choice that will give the patient a sense that 'something is being done' even

though they will have no beneficial impact and may have a harmful outcome (beyond simply leaving the patient in avoidable pain). If a GDP favours extraction for pain relief in the clinical scenario presented in the questionnaire, then they will certainly end the pain but will leave Jim facing increased future dental needs that could have been avoided. Failure to inform of this impact may leave the GDP receiving an accusation of not gaining appropriately informed consent. As highlighted in the previous section, the regulatory guidance on consent for dentistry is clear, and failure to achieve this could leave the GDP vulnerable to GDC-based sanctions or court findings of negligence that might draw into question the patient's decision to proceed with treatment when uninformed of alternative options. If such a patient became a claimant in a negligence case against the dentist and could convince the court that they would have acted differently, had they been in possession of all the material facts, then the claim may be successful.

Based on the limitations of this questionnaire, 27% of GDPs are potentially leaving themselves exposed to this accusation and are leaving their patients vulnerable to making insufficiently informed decisions that may not have been the best choice for them.

The mandatory requirements for written consent in dentistry are relatively slight. The GDC indicate that only treatment under conscious sedation or general anaesthesia **must** have written consent. All other discussions **should** be documented but do not require mandatory use of signed consent forms. Despite this, there appears to be a belief, anecdotally at least (based on my reading countless social media dental forums) within the profession, that GDPs should seek written consent for all procedures. Question 23 asked respondents how often they obtain a written consent form when treating patients for acute pain. Of the 89 respondents who answered, 26 (29.4%) answered 'most of the time' or 'always', with the largest group (46.1%, 41 of 89) indicating that they 'never' get written consent for acute pain management.

The final multiple-choice question that offered the potential for quantifiable data related to how GDPs felt the COVID-19 restrictions had impacted on their ability to provide optimal treatment for patients suffering with acute pain.

Table 6: How respondents rated the impact of COVID-19 restrictions on their ability to deliver optimal care for patients suffering with severe dental pain

To what extent have the COVID-19 restrictions impacted on your ability to deliver optimal care of patient in pain?	Number of responses (percentage)
Not at all	5 (5.7)
Minimally	26 (29.5)
Significantly	45 (51.1)
Totally changed all aspects	14 (15.9)

Total	**90 (96.7)**

Of the 90 GDPs who responded to this question, just over two-thirds (67%, 59 of 90) indicated that it had 'significantly' or 'totally' changed all aspects of their provision of care. The remaining 33% indicated that it had minimal or no impact on their ability to provide optimal treatment for urgent care. The relationship between a sense of high impact of the restrictions and a high reliance on NHS is explored below. Given the close relationship seen between the two, it is worth considering if the higher volume of patient numbers normally experienced by NHS dentists coupled with a less bureaucratic work environment[243] compared to the Private sector was a factor in this variation.

When this question was coupled with Question 7, relating to the percentage of revenue generated from NHS and from Private, it was interesting to note the differing experience for respondents with a high versus low reliance on NHS income. The results are summarised below.

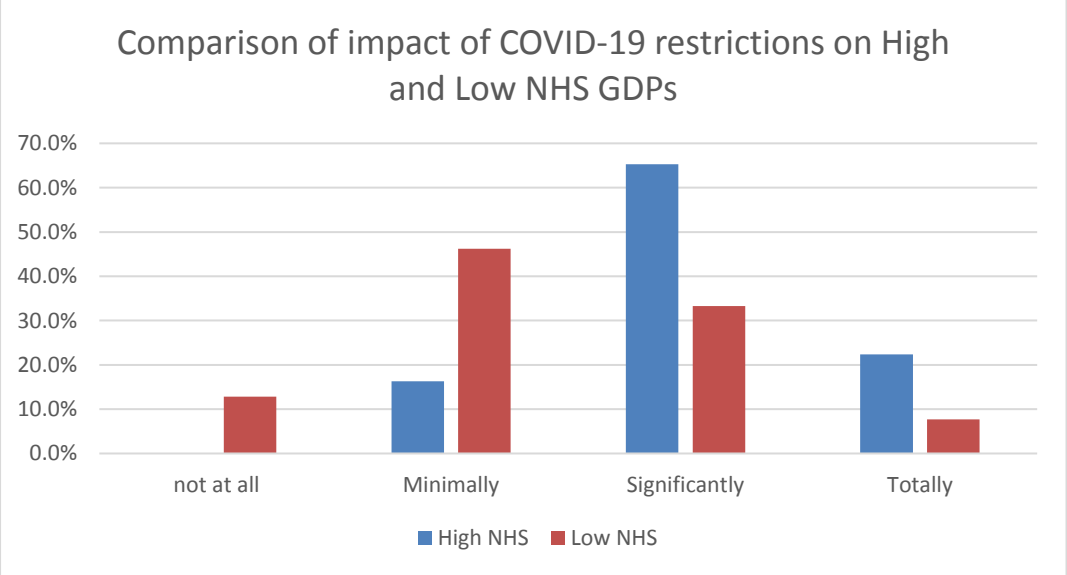

Figure 1: Comparison of how respondents who derived more or less than 50% of their revenue from the NHS felt that COVID-19 restrictions had affected their ability to provide optimal care for adult patients in pain

[243] The Dental Assurance Framework (March 2014) lays out the current contractual obligations for dentists providing NHS dental services. Whilst the clinical standards do not differ from those established via regulatory and authoritative guidance, the framework does lay down an additional layer of bureaucratic requirement in the shape of form completion and standards reviews. The BDA in their 2019/20 *Evidence to the Review Body on Doctors' and Dentists' Remuneration* (para 6.18) cite a 12% reduction in clinical time for NHS dentists over the past 10 years due to an increase in 'red tape' requirements for each clinical process

Whilst the number of respondents in each subset was low (51 and 49 respondents, respectively) the statistical analysis showed that the difference in response between the two groups of high versus low dependence on NHS revenue was statistically significant (see Table 7 below).

Table 7: CHI square table analysis of difference in experience of high versus low reliance on NHS income when examining the impact of COVID-19 restrictions

	Minimal/not at all	Significant/Total	Marginal row totals
High reliance on NHS	8 (15.81) [3.86]	43 (35.19) [1.73]	51
Low reliance on NHS	23 (15.19) [4.02]	26 (33.81) [1.8]	49
Marginal row totals	**31**	**69**	**100**

The chi square statistic with Yates' correction is 9.9967. The p-value is .001568 and Significant at $p < .05$. Those respondents with a 50% or greater reliance on NHS income were significantly more likely to have experienced significant or total changes to their ability to deliver optimal urgent care compared to those with a less than 50% reliance.

The reasons for this observed difference cannot be fully explained by this research but do suggest the need for a larger study to explore the subject matter further. It may be that higher numbers, imposed targets of treatment, limitations in supply of PPE and a disproportionate impact of lockdown on the poorest members of society may help to explain these differences but such an investigation is beyond the limited scope of this research.

5.2.6 Limitations of findings

Any conclusions from this quantitative analysis need to be viewed with caution given the nature of the sampling technique used to attract respondents and the relatively low number of responses achieved. Although the demographic of the sample broadly reflects that of the UK GDP population, the number of responses received means that they are not necessarily generalisable to the population sampled.

5.3 Conclusions from quantitative analysis

The aim of the questionnaire was to gain information that could further help me answer the research question and further understand how GDPs have met the twin challenges of the *Montgomery* ruling and COVID-19 restrictions post June 2020. To this end, I tried to create questions that would help me gain a picture of how GDPs tackle urgent care appointments, with reference to a clinical scenario but also in terms of their everyday practice. The results yielded the following key points:

- The question of whether COVID-19 restrictions have impacted on GDPs' ability to offer optimal treatment for patients in need of urgent care was answered with an emphatic yes with more than two-thirds of GDPs saying that it had had a significantly impact on them, with this figure rising to over 90% in the group of GDPs who receive the majority of their funding from the NHS.
- The impact of high versus low reliance on NHS income showed again when appointment time allocation was examined. In this survey, of the 18 responses who indicated that they would offer an appointment of less than 20 minutes, 3 came from GDPs who work solely within the private sector with the rest coming from those who receive more than half their income from the NHS.
- The majority of GDPs who offer appointments of less than 20 minutes indicated that they would offer the treatment of urgent care as a non-AGP, which is likely to be a significant restriction to the delivery of optimal pain relief treatment. This suggestion gained support from the finding that the group of GDPs who offered the shortest appointments also represented the highest percentage of respondents likely to provide antibiotics (inappropriately) for the clinical scenario presented.

In the responses to the questions that related to *Montgomery* and consent, 80% of GDPs indicated that they were aware of the ruling but more than 50% indicated that they felt they had little or no knowledge of it. When asked how the ruling had impacted on them in their daily practice, almost 85% indicated that it has little or no impact on their daily practice and 72% indicated that the COVID-19 restrictions had not made any difference to how they viewed their ruling within their daily work practices.

Approximately a quarter of the respondents (27%) are leaving themselves vulnerable to accusations of providing treatment without appropriately informed consent because they are not discussing or are not offering appropriate treatment options due to the COVID-19 restrictions to treatment. Whilst it is likely that the concept of 'exceptional circumstances' discussed in Chapter 2 section 2.3.2 would apply to the period of lockdown and perhaps a short time afterwards, it is unlikely that any such defence would be met with much support 15 months after the new practices have become very much the 'new norm' of dentistry. It is

probably also worth remembering at this point that the *Bolitho* ruling would not allow a GDP to hide behind the defence of a 'responsible body of clinical opinion' (as compliance with a 'new norm' might imply) if this opinion does not withstand logical analysis.

The next section focuses on two of the three questions that asked for FTAs. It looks at the responses generated and explores them thematically to try and draw out any similarities and differences in experience evident across the predominantly NHS and wholly Private respondents in terms of understanding of *Montgomery* and how urgent care has been impacted by the COVID-19 restrictions.

5.4 Qualitative data

Due to the time limitations associated with the delivery of an LLM by Research thesis involving primary research, I have elected to focus on the free text questions that relate to the twin questions of *Montgomery* and COVID-19 restrictions because they are most relevant to the research question. The FTAs also generated responses that were interesting on a clinical level but not strictly pertinent to the research question and as such I have chosen to leave them out. The two free text questions being considered further were written as follows in the questionnaire:

> Question 16: In one or two lines please summarise what you understand the case of *Montgomery* v Lanarkshire means in terms of providing dental care.
>
> Question 25: If your treatment options have been reduced because of the imposed restrictions, do you inform patients of this and how is this reflected in your consent process? (please give examples)

Question 16 generated 69 responses and Question 25 a total of 55. To examine the responses further, with a view to see if any themes could be detected, I divided the responses according to the filters described below.

The responses to Question 16 were divided into two subgroups: those relating to how the respondents answered the question relating to their perceived understanding of the *Montgomery* ruling 'little or no understanding' (classified as low understanding), compared to those with 'good to clear and substantial' understanding (classified as high understanding). The number of responses for each subgroup is given in Table 8 below.

Table 8: Response rates for the amalgamated groups in Question 16

Low Understanding	High Understanding
38	31

The responses to Question 25 were divided into three subgroups based on percentage of income derived from NHS and Private contracts. The subgroups were classified as low NHS (0–24% of revenue based on NHS contract), medium (25–74%) and high (75–100%). The number of responses for each subgroup is given in Table 9 below.

Table 9: Response rates for the amalgamated groups in Question 25

Low NHS	Medium NHS	High NHS
18	17	20

To examine the free text responses of each subgroup to try and establish any specific themes evident within them I followed the approach outlined in Chapter 4 section 4.3.

5.4.1 Respondents' perceived understanding of *Montgomery*

I used an inductive flat coding method to analyse the FTAs. The codes I found most effective in terms of selective power and ability to interpret themes within the grouped responses were: 'included words informed consent', 'included words material risks' and 'included words all risks or all options'. I chose these phrases because they are highly representative of the issues at the heart of the *Montgomery* ruling. The response rates are recorded in Table 10 below with further correlations seen with these terms discussed in greater detail below this.

Table 10: Number of coded text responses per each amalgamated group in Question 16

Phrases included words:	Low Understanding 38 respondents Number of responses	High Understanding 31 respondents Number of responses (%)
Informed consent	3	3
Material risk	6	7
All risks or all options	5	4
Total	**14**	**14**

Although the response numbers for 'informed consent' were matched in both groups, the context in which the phase was used differed slightly for each group. In the 'low

understanding' it was seen in responses that included wording such "*discussing all options*" and "*all possible detrimental possibilities explained*", whereas in the 'high understanding' group, the phrase was coupled with wording such as "*certain risks that are weighted more heavily for individual*" and "*to ensure all material risks are given to patient to allow them to decide what is relevant and important to their own personal decision*". This subtle difference suggests a more nuanced understanding of the ruling, which certainly does not require every conceivable risk being explained to a patient. That said, even in the high understanding group, responses were given that perpetuated this belief.

When an additional coding of 'all risks' was applied to both groups, the phrase appeared 4 times in the high understanding group and 5 times in the 'low understanding' with all examples grouped with wording such as "*must discuss all risks"* and "*need to know all risks"*. This misconception may well be at the heart of the belief that gaining informed consent is an impossible task.

Across both groups the code 'material risk' was coupled with phrases such as "*risks material to the individual patient must be explained and discussed*" and "*the onus is on the practitioner to identify what these material risks may be*".

By reading all of the responses it became clear that the 'low understanding' group did contain a core of responses that indicated a genuinely low understanding. This group contained 5 responses (7.2% of all responses across both groups) that indicated either "*never heard of it"* or *"no idea",* and 5 more that indicated a significant misunderstanding such as "*no longer can you say that you did what you thought was best*" or one-word answers such as "*risk*" or "*consent*" that suggest that the respondent had heard of the ruling but knows very little about it.

When these 10 responses are combined, we can see that 14.5% of all respondents to this question do appear to have little or no understanding or awareness of the ruling whilst the remaining 59 responses showed a similar grasp of how the case is reflected in the consent process, irrespective of how they rated their understanding, apart from 5 responses (7.2%) in the 'high understanding' group that offered almost verbatim 'textbook' answers such as: *"Montgomery replaces the old Bolam test for negligence and does not rely on what other medical professionals would have done but the particular risk to that particular patient, so patient rather than professional based" and "To ensure all material risks are given to patient to allow them to decide what is relevant and important to their own personal decision as part of informed consent. It is not for the dentist to decide what the patient may consider to be relevant and/or important".*

Most of the responses in both groups showed a moderate understanding or awareness of the ruling. There is a possibility that respondents who indicated a high understanding of the subject matter may have felt compelled to look up the answer online, but the anonymous nature of the responses means that there is no way of assessing this risk.

The most common theme of misunderstanding noted within the responses was the belief that a clinician needs to give every conceivable treatment option and explain every risk to a patient. The potential implications of this misunderstanding on a clinician's willingness to engage in a consent process with a prospective patient are easy to imagine. Appointments that are, by necessity, time pressured do not lend themselves to lengthy discussions between patient and clinician, especially when the patient is in severe pain and the dentist is wearing a thick, tight-fitting mask that can easily muffle communication. If a dentist believes that they need to discuss every and all possible alternatives and risks, then they may well feel disinclined to enter into the discussion at all. With this consideration in mind, the second FTA examined here attempted to look at this potential concern by asking GDPs how their consent process has been affected by the COVID-19 restrictions.

5.4.2 Respondents' experiences in gaining consent in urgent care scenarios post COVID-19

This analysis related to the responses generated by Question 25: If your treatment options have been reduced because of the imposed restrictions, do you inform patients of this and how is this reflected in your consent process? (please give examples).

Applying the same approach to coding as I did with Question 16, I looked here at the codes: 'includes word yes' and 'includes word no': 'includes words AGP, unable, rebook, reschedule'; and 'includes words antibiotics, prescription or prescribed'.

The coding 'includes word yes' and 'includes word no' was a way of looking specifically at the responses to see if any respondent did not inform their patients that they were being offered a reduced number of treatment options due to the restrictions imposed. (From a clinical point of view, based on the scenario presented, this would most typically present itself where an AGP is not possible, so the optimal option of opening the tooth and treating the inflamed nerve with an appropriate sedative dressing is not offered. The alternative options of continued pain relief medication, antibiotics or extraction would all represent either unnecessary or inappropriate care; information that any reasonable patient would surely want to know.)

The coding for 'yes' showed that 34.5% of all respondents (19 out of 55) responded with a clear affirmation that they would inform patients with a relatively even spread across the three groups (5, 7, 7 across low, medium, high NHS, respectively). The coding for 'no'

produced only 2 responses where it was expressly stated that the respondent would not inform the patient of the limitations of care imposed on them. Both of these responses occurred in the 'medium' group but, given the relatively low numbers of overall responses and, in turn, the very few negative responses, there is no real inference that can be drawn from this distribution. On complete reading of the two negative responses, both contained the caveat that not telling the patient would only occur if it only meant that the patient needed to be rebooked into a slot where optimal treatment could be carried out. In this respect, the consent issue really relates to the need to rearrange the appointment to later the same day or into the next (according to the respondents), which would seem on the face of it to be a much lesser issue than the provision of irreversible and/or inappropriate treatment.

A deeper read of all the responses showed that those that did not contain the word 'yes' or 'no' in reference to the question of information did still address the question in other ways. Again, the overwhelming emphasis (all responses) was on the need to arrange an AGP slot at which optimal care could be provided. The discussion of 'fallow time' and the impact that this would have was prevalent in dental discussions at the time of the return to work in June 2020 but appears to now be less of an issue with only 4 mentions of it across all 55 responses. This perceived reduction in the concern relating to fallow time probably reflects the general roll-out of ventilation systems across dental practices that has allowed surgeries to reduce their time from a maximum of 60 minutes to a more manageable 10 minutes. As the fallow time begins from when the AGP element ends, it is often possible to time the treatment so that the fallow time occurs when other non-AGP treatment is being carried out on the patient; meaning there is now no need to increase the overall length of the appointment.

Many responses showed how GDPs manage a busy treatment schedule to fit in urgent care cases, with the following responses being typical: "*cancelling routine treatment, something I would never have done before* (June 2020)"; "*I will see them in my lunch break or after work*"; and "*because an AGP requires so much extra time and I have to deal with the patient in pain there and then I often have to run very late, affecting staff lunch breaks and having no break at all myself, keeping other non-pain patients waiting".*

As part of the examination, I wanted to see if any similarities or differences in how the groups handled the issue of proving an AGP appointment for urgent care could be identified. Coding for the phrase 'includes word AGP' was not helpful in examining the responses because it was a ubiquitous phrase that appeared repeatedly across all three groups but, when it was combined with the words 'rebook', 'reschedule', 'rearrange' and 'unable', then the search was more helpful in identifying possible themes.

In the ‘high’ group (i.e. those with a heavy reliance on NHS income), the word ‘AGP’ was combined with one or more of these words (or equivalent phrases such as ‘cannot’ or ‘bring patient back’) a total of 13 times out of the 18 responses (72.2%) that addressed the issue (one- or two-word answers excluded from this aspect of the examination). When the same coding was applied to the ‘low’ group (i.e. who treat patients predominantly or wholly on a Private basis), the combinations were seen in 3 of the 13 responses (23%) who addressed this issue (one- or two-word answers excluded). Close reading of the responses from both sections again revealed subtle differences in the emphasis placed on the wording in the relevant responses. In the ‘low’ group, responses commonly expanded on the issue of AGP with comments such as *“it’s harder to find an AGP slot instantly. Patients who are likely to need an AGP slot may have no choice of time. There will be only a few slots available per day*” and “*it hasn’t really changed much. I try to leave emergency appointments to end of session daily where AGPs can be carried out*”, whereas the ‘high’ group responses tended to stress a more restrictive aspect to the AGP provision: “*warn long waiting lists and unable to do unplanned AGPs*”, “*cannot provide AGPs as an emergency appointment”* and *“I would explain the allocated slot doesn't allow for certain things and may need to rebook for an AGP”*. Again, an exact explanation of the differences highlighted here between high and low NHS involvement is not possible from the data, but the generally higher number of patients seen per day by an NHS dentist with the subsequent need for shorter appointments may well be a causative factor.

The final coding word used to help me examine the responses in a methodical manner was ‘antibiotics’. I chose this word because the use of antibiotics can be seen as an inappropriate treatment option that has the potential twin advantages of being quick to deliver and likely to satisfy some patients’ sense that ‘something is being done’ (although also likely to leave them in continued, avoidable pain and at an increased risk of antibiotic-resistant infections and adverse reactions to the prescribed antimicrobial). Given the previously mentioned research by Thompson and others that showed increased antibiotic prescription rates in dentistry during and immediately after the lockdown in March–June 2020, it was also interesting to see if this trend had continued.

Examination of the three groups showed that, across the 55 responses, the word appeared only 4 times with 3 responses in the ‘low’ group and 1 in the ‘mixed’. The additional code words did not reveal any greater detail but full examination of each response that included the word ‘antibiotics’ highlighted the fact that only one response directly reported an increase in antibiotic use: “*we have prescribed more antibiotics than usual*”. The other two responses in the ‘low’ group either stated directly that antibiotics were not appropriate in

this case or suggested that they might "*write out antibiotics to take only in the event of swelling*" (an approach that is also considered inappropriate by authoritative guidance).[244] The single mention of antibiotics in the 'mixed' group indicated that they might be offered as a treatment alternative if an AGP was not possible: "*if can't AGP then the options to come back next day preferably or antibiotics*".

From this examination of this admittedly limited data it would appear that the issue of inappropriate antibiotic prescribing for urgent acute dental pain is not widespread, with only 3 of the 55 responses suggestive of this behaviour. One rather surprising finding within this analysis was that, of the 24 respondents who answered Question 10 (an MCA to a question that asked what alternative treatment options they might consider if they could not provide an AGP) with the option 'antibiotics', 16 provided FTA; none of these responses mentioned the use of antibiotics. Perhaps writing out in free text that you will give an inappropriate treatment option is harder than ticking a multiple-choice box or perhaps those who chose to answer free text questions were more confident in their practice.

5.5 Conclusions from qualitative analysis of Questions 16 and 25

The thematic search of these two questions attempted to draw out any reasonable inferences from the responses because they related to the question central to this research: 'How have General Dental Practitioners (GDPs) met the twin challenges of the *Montgomery* ruling and the restrictions imposed by COVID-19 when delivering urgent care to adult patients in pain?'

To gain greater insight into the answers to this question, I felt that it was first important to investigate how well GDPs understood the *Montgomery* ruling. This aspect of the research was addressed in Questions 15 and 16, which asked respondents to assess their level of understanding and then give a summary of their understanding in one or two lines.

[244] The SRDC and FGDP, as mentioned throughout this thesis, provide authoritative guidance on the prescription of antibiotics in dentistry, and both are firmly in agreement that antibiotics are not to be given prophylactically in the belief that an infection may develop in the future. Direct intervention for the cause of the pain should be provided in a timely fashion with antibiotics used as an adjunct to treatment in cases with signs of spreading infection and systemic involvement (*FGDP Antimicrobial Prescribing for General Dental Practitioners* (first published 2000, 3rd edn, Orchard Press 2020, SDCEP 2013); 'Acute Dental Problems' <https://www.sdcep.org.uk/published-guidance/management-of-acute-dental-problems-madp/>)

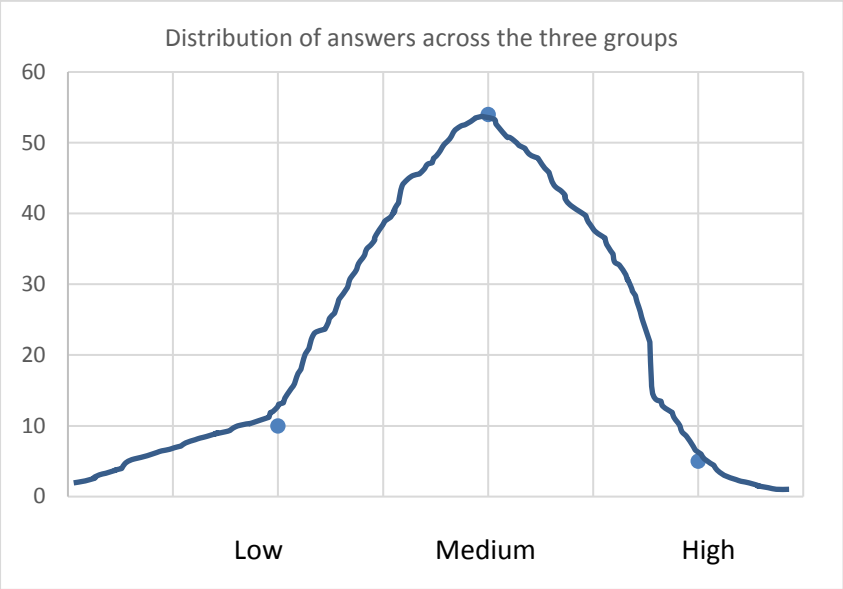

Figure 2: Representative distribution of the answers distributed across low, medium, and high understanding groups

Based on normal Gaussian distribution, how the respondents' answers were positioned along a metric of low to high understanding would be expected to be something akin to a bell-shaped distribution curve, with roughly 10% at each end representing low or high understanding and roughly 80% in the middle showing a moderate level of understanding. Reassuringly, the thematic search did indeed reveal something approaching this distribution, albeit with a slight shift towards low understanding: 14.5% of responses indicating little or no understanding at one end and 7.2% showing a high understanding at the other. For the middle of the 'bell curve', the remaining 78.3% of responses were mostly suggestive of the respondents having a moderate awareness and understanding of the ruling but with a common misconception carried through these responses that clinicians need to cover all and every possible alternative treatment option and risk when discussing care with their patients.

By close examination of all 55 responses, it was possible to see a consistent picture of GDPs' awareness of the limitations under which they now work but providing patients with an honest appraisal of this and the impact that it might have on their treatment choices.

The second theme examined within the responses to this question looked more closely at what that impact might look like; again, viewing this search through the division of high or low involvement with NHS services. Here it was possible to see the influence of NHS involvement with those respondents reporting a high reliance on NHS services tending to pair the phrase 'AGP' with words such as 'rebook', 'reschedule', and 'unable' at a much

higher rate than those with a low reliance (72.2% and 23%, respectively). Again, closer examination of the responses revealed a picture of GDPs working hard to overcome the restrictions for the good of their patients but often having to run late, work late, reschedule other patients and delay seeing patients in pain until they could provide the time needed for optimal care. As mentioned previously, the generally accepted higher number of patients seen per day by NHS practitioners may well have contributed to a disproportionately greater impact among this group of respondents.

The third theme that I explored in the responses to this question was the use of antibiotics. I used this as a theme because it is suggestive of a treatment approach that has increased from the start of lockdown March 2020 and has been identified as the default inappropriate substitute for optimal urgent care when GDPs are unable or unwilling to provide appropriate treatment. It was reassuring to see that only 5.5% (3 out of 55) responses linked the words 'antibiotics', 'prescriptions' or 'prescribed'. Whilst 5% of GDPs providing inappropriate care is of course 5% too many, this represented a small proportion of an already small sample of GDPs working under conditions of unprecedented pressure.

The full conclusions to my thesis are explored in depth in the next chapter but my conclusions to this qualitative analysis of the impact of the *Montgomery* ruling is that the impact on clinical practice has been relatively minor and something that may reflect a lack of understanding of the ruling by the majority of GDPs rather than their studied reflection of it. (Given that the *Montgomery* ruling really followed on from changes within clinical practice, one might always have expected the changes to be slight, so this finding from the research may simply offer a further analysis of an expected result.)

Furthermore, my findings support the view that GDPs are coping well with the twin challenges of *Montgomery* and the COVID-19 restrictions in ways that reflect admirably on the profession by persevering under far from ideal situations with honesty and professional integrity.

Chapter 6: Conclusions

6.1 Introduction

As I stated at the end of Chapter 1, my aim for this concluding chapter is to summarise the key findings from my research project and review what, if any, additional information this can provide towards informed debate regarding the twin impacts of *Montgomery* and COVID-19 restrictions on the delivery of urgent dental care. I will also consider whether the correct amount of weight is being placed on autonomy, with respect to the other three pillars of medical ethics: beneficence, non-maleficence, and justice.

6.2 Summary of the key findings of the literature review

The literature search helped to identify what optimal urgent care should look like but also showed us how and why this optimal outcome is not always met. With my search I was able to identify a great many articles that related to the technical and treatment aspects of acute pain management, reflecting what an important topic this is for the profession, but it also identified the relative dearth of articles that sought to explore dentists' understanding of *Montgomery* or the impact the ruling has had on the profession. The search also highlighted the limited amount of research completed so far with respect to the impact of the COVID-19 restrictions on the delivery of optimal urgent dental care since the return to general dental service in June 2020.

The literature search also identified the potential impact of the length of time of urgent care appointments along with the effect of the dentists' experience, postgraduate qualifications, and confidence in managing acute pain. These factors were all seen to have the potential to increase the risks of patients who are suffering with acute dental pain experiencing inappropriate care. The articles searched showed a pattern of patients most likely to attend suffering with acute dental pain, with irregularly attending, dental phobics and high anxiety patients, most commonly from areas of greater social privation, being those most likely to attend in pain.

With respect to the impact of COVID-19, the papers that were identified showed a pattern of increased inappropriate antibiotic use for pain management, and patients struggling to access care due to the diminished capacity for GDPs to treat patients at pre-pandemic numbers.

Examination of the regulatory and authoritative guidance on consent within dentistry (and medicine) showed that the court's decision on *Montgomery* lagged 15 years or more behind the guidance when it comes to establishing what constitutes appropriate information disclosure to allow patients a true chance at making an autonomous choice and giving appropriate consent.

The literature search extended into the topic of the impact of acute pain on the decision-making process, which surprisingly was found to have been subjected to limited research, even in the medical world. The research that existed did show a common finding that acute pain limits patients' ability to recall and process information given to them. This is a key finding, given the importance of these abilities within the consent process.

Overall, the literature search provided a picture of acute dental pain management as a potential perfect storm of short, unscheduled appointments allocated to dentists who routinely struggle to achieve adequate local anaesthesia in these treatments, and are more likely than not to express a lack of understanding of the psychological techniques best placed to manage the dentally anxious or phobic patients who most commonly attend these appointments. Add to this the COVID-19 restrictions, which have diminished access to care and inhibited communication through enhanced PPE, we can see the challenges that GDPs and patients face when trying to relieve the suffering of those in acute pain.

The focus of my research project was to assess GDPs' understanding of the *Montgomery* ruling and to establish how they felt the restrictions had impacted on their ability to provide optimal care for patients suffering with acute pain. The findings from my research project are discussed more fully in the next section.

6.3 Summary of the research project findings

The research project sought to explore GDPs' attitudes to consent when faced with a typical clinical scenario of an acute pain patient. Although the majority of GDPs who responded gave an indication that they would expect to achieve valid and appropriately informed consent for the procedure, around 27% indicated that they would not expect to do so. Interestingly, around 50% of those who responded indicated having little or no understanding of the *Montgomery* ruling. Published research reported a similar figure for doctors. The real-world implication of this may simply be that GDPs feel confident gaining proper consent, based on their knowledge of the appropriate regulatory guidelines without needing to understand the leading legal authority on what proper consent looks like. An alternative view might equally be that 50% of GDPs are leaving themselves vulnerable to legal accusations of providing treatment without first gaining appropriately informed consent due to a lack of insight into the courts' view on consent.

Qualitative analysis of the FTAs given by respondents to express their understanding of the *Montgomery* ruling revealed that the understanding was more broadly shared than the respondents gave themselves credit for. The spread of correct answers was divided evenly across the groups who expressed either a high or a low understanding of the ruling, which suggests that it may be a problem of perceived lack of understanding rather than an actual

one.

The GDPs who responded to questions relating to how much, if at all, the ruling has affected their management of urgent care scenarios showed a strong majority (84%) indicating that it had had only a minor impact or none at all. This is in line with what would be expected given the previous findings regarding the regulatory advice for dentists since 2003 onwards detailing the need for detailed information disclosure to allow informed consent to take place. In this respect, the *Montgomery* ruling merely gave judicial weight to what the healthcare regulators had been saying for several years before 2015. This lack of change within the respondents' behaviour post *Montgomery* reflects the stance of the profession within published articles, where it has been viewed as legal 'window dressing' to what the professions had already been doing (or should have been doing).

Despite these findings, it is still worth noting that 27% of respondents indicated that, for urgent care patients, they would not discuss all appropriate treatment options with the patient in the clinical scenario. This means that more than a quarter of GDPs in this survey would not provide enough information to allow the patient an opportunity to make well informed decisions. This finding seems in conflict with a duty of candour that is a mandatory regulatory requirement (Principle 1 of the GDC Standards for the Dental Team states that dentists must put patients' interest first and must be honest and act with integrity [1.3]). The information that is potentially being withheld from the patient does not relate to treatment that is unavailable in all circumstances; it is merely unavailable with that particular dentist or at that particular time.

The impact of COVID-19 restrictions on urgent care were clear to see with a particularly marked impact on those dentists who rely most heavily on NHS funding. Overall, 67% of respondents indicated that the restrictions had significantly or totally changed their ability to deliver optimal care for patients suffering with acute dental pain. But, when this figure was assessed to see the impact of NHS revenue, it was seen that those with above 50% reliance on NHS income were significantly more likely to be affected than those who received the majority of their income from private treatments. Again, the qualitative analysis helped to explore this discrepancy further and showed that those with the highest reliance on NHS funding were most likely to express concerns relating to a lack of ability to deliver the appropriate care and were more likely to indicate a need to delay or refer treatment.

6.4 What, if anything, have these findings added to our understanding of the delivery of optimal urgent dental care?

My aim for this section is to try and underpin the ethical standpoints for the delivery of care with what we have learned from this research project.

The four pillars of medical ethics are autonomy, beneficence, non-maleficence, and justice. In terms of autonomy, if an autonomous choice is one that is freely made by a capacious individual who has been given sufficient relevant information to do so, then the *Montgomery* ruling can be seen as the courts' underpinning of this with a legal representation of what constitutes the bare minimum in terms of information disclosure. Most GDPs are aware of the ruling and have a basic understanding of what it means for them and their patients. A small minority, however, remain unaware of its existence.

In the case of urgent dental care, beneficence represents providing a timely diagnosis and prompt resolution of acute pain and infection. The regulatory and authoritative advice is clear and unambiguous on this. As we have seen from the literature search, this simple act of 'doing good' can represent a significant challenge, even under ideal conditions. As we have seen from my research project, this has become even more challenging since the introduction of COVID-19 restrictions. The GDPs who are most reliant on NHS revenue have found these restrictions to have the greatest impact on the provision of optimal urgent care. If we are to have true equality in healthcare, then we need to see those dentists working in the areas with highest privation receiving greater financial and practical support to assist them in this.

The concept of non-maleficence is relatively easy to understand in terms of urgent dental care: a failure to provide timely and appropriate diagnosis or provision of inappropriate care that leaves the patient suffering avoidable, foreseeable, and unnecessary harm. As an additional part of maleficence, we can see a failure to adequately inform as a contributory factor. A patient who is advised that an extraction is the only option may proceed to the loss of the tooth when really the complete wording should have been *"an extraction is the only option that I can offer you under these circumstances"*. An uninformed treatment decision usurps the patient's right to choose and could leave the dentist vulnerable to an accusation of negligence, no matter how expertly the extraction was performed. As we have seen from my research project, more than a quarter of the respondents are leaving themselves vulnerable in this way by not discussing the full range of appropriate treatment options with their patients.

For lack of informed consent to be engaged in a causation argument, it must be shown, however, that the patient would have acted differently had they been given the additional

information. As Turton points out in her 2018 article,[245] when considering the previously discussed ideas of ideal, best and current desires it is the patient's best desire that is being protected by the claim that the additional information would have allowed them to act in a way that reflects their wider values and priorities. In dental terms, this might represent a patient who is a regular attender and works hard to maintain their teeth but consents to the removal of a tooth that they would have, on balance of probabilities, preferred to retain had they been in receipt of all of the relevant information.

When it comes to justice, the consideration of urgent dental care can become more challenging. When this fourth pillar is examined 'normally', it is usual to consider not just the concept of fairness and inequality but also the concepts of distributive justice (fair distribution of healthcare treatments within the confines of a limited budget), legal justice (a respect for the law) and a respect of an individual's right to be protected from discrimination. At the heart of the protection of justice, and ensuring that patients' dignity is respected, is the issue of information disclosure, with a focus above all else on the avoidance of harm.

In their 2016 article,[246] authors Bester, Cole and Kodish considered the patient factors relating to informed consent. They highlighted the concept of a sliding scale of capacity with particular reference to the 'emotionally overwhelmed' patient, who is likely to take longer to process information and requires additional steps be taken by the clinician to ensure that "*a truly autonomous decision has been reached through an informed consent".* The authors also considered the 'information-related factors' with a sliding scale of capacity to understand risk probabilities (which in dental terms might represent the risks associated with a root canal filling to retain a tooth versus those of the procedures used to replace the tooth) and 'communication factors' such as language skills, hearing and, although not mentioned in this article, enhanced PPE; all of which can impair the flow of information if additional steps are not undertaken by the clinician.

Once again, we can see the central importance of the time allocated to treatment when planning for the delivery of optimal care.

From my research project, we could see that the GDPs who are most reliant on NHS fees for revenue were more likely to offer shorter appointments, more likely to offer the urgent care appointment as 'non-AGP' (therefore limiting treatment options available), more likely to view their chances of gaining consent as low, and significantly more likely to view the

[245] Gemma Turton, 'Informed Consent to Medical Treatment Post-Montgomery: Causation and Coincidence' (2018) 27 Medical Law Review 108

[246] Johan Bester, Christie Cole, and Eric Kodish, 'The Limits of Informed Consent for an Overwhelmed Patient: Clinicians' Role in Protecting Patients and Preventing Overwhelm' (2016) 18 AMA Journal of Ethics 869

COVID-19 restrictions as significantly or totally affecting their ability to deliver optimal urgent care compared to their privately-funded counterparts.

Despite these discrepancies in experiences, the regulatory and legal positions are taken as a 'one size fits all' and apply to all dentists equally; no matter the conditions that they conduct their day-to-day practice under. The courts and the GDC do not see a difference between an NHS dentist seeing 50 patients a day in an area of enormous privation and low dental health and a private dentist seeing 10 patients a day in an area of great affluence and low dental need.[247] But is this reasonable and fair?

Professor Newdick, writing on the impact of resource pressures on patient care,[248] talks about the need to balance the rights of an individual against those of public interest. This is not a new theme for debate. Garbutt and Davies[249] considered the balance between the need for finitely funded NHS services to be viewed as a deontological or utilitarian enterprise. They argued, as did Professor Newdick 10 years later, that lofty ideals and the duty driven care of doctors to "*make the care of your patient your first concern*"[250] butt up against the utilitarian need to ensure 'the greater happiness' by treating as many people as possible.

When considering these four pillars of ethics, Garbutt and Davies make the point that the ethical dilemmas at play are most often individual/consultation based and do not reflect the larger system within which these decisions take place.

GDPs who operate within the NHS in primary care in England got a stark illustration of this with the previously mentioned letter from the CDO in September 2021.[251] The letter laid down the urgent care priorities of dentists operating within the confines of an NHS contract for primary care services, and stated that priority needed to be given to members of the public with higher dental needs than existing patients who are on the practice list with the dentist already. From a utilitarian standpoint, the advantage of this approach is clear. All dentists become, in effect, drop-in centres for members of the public in pain, thus allowing the greatest number of people to be treated. But what impact will this have on the GDPs'

[247] Whilst this figure is anecdotal based on my previous personal experiences and on that of a great many colleagues, the average figure of 4.3 NHS dentists per 10,000 UK population (*BDA 2019/20 Evidence Review*) gives an idea of the scope of need for dentists working in areas of low economic prosperity

[248] Chris Newdick, Mark Sheehan, and Michael Dunn, 'Tragic Choices in Intensive Care during the COVID-19 Pandemic: On Fairness, Consistency and Community' (2020) 46 Journal of Medical Ethics 646

[249] G Garbutt and P Davies, 'Should the Practice of Medicine Be a Deontological or Utilitarian Enterprise?' (2011) 37 Journal of Medical Ethics 267

[250] General Medical Council (GMC), 'Good Medical Practice Guidance for Doctors' (2006) <https://www.gmc-uk.org/-/media/documents/good-medical-practice-2006-55612780.pdf?la=en>

[251] NHS, 'Coronavirus» Letters, Updates and Additional Guidance for Dental Teams' (www.england.nhs.uk2020) <https://www.england.nhs.uk/coronavirus/publication/preparedness-letters-for-dental-care/>

duty to "*put your patients' interests before any financial, personal or other gain*"[252] and *"manage patients' pain dental pain and anxiety appropriately*"[253] if the financial aspect of their NHS contract is dependent on the provision of services to the existing patients (calculated on a three-year prediction of need)?

In a finitely funded service, there is a finite number of patients that can be seen. If the pressure on numbers increases as the GDP's ability to deliver optimal care is hampered by additional restrictions, is it fair and reasonable for the regulators and the courts to hold those GDPs under the greatest workload in the areas of highest clinical need to the same idealised standards as those working in a privately-funded service which has suffered little or no impact from the COVID-19 restrictions and is most likely to offer the longest appointments for urgent care?

Whilst it is easy for a hard-working dentist, stretched thin across multiple patients, to blame inappropriate level information disclosure on a lack of time, the ruling in *Montgomery* considered the impact of time-stretched appointments on two occasions.[254] First, Lords Reed and Kerr JJSC made mention of the difficulties felt by patients during time-pressured GP appointments and the intimidation that can be experienced when questioning the information they are being given. In [92] and [93] the conclusions of the court considered the impossibility of discussing the risks associated with a medical procedure within the time available for a healthcare consultation and the risk that trying to do so might result in defensive practices and even an increase in litigation. However, the judges went on to conclude that "*it is nevertheless necessary to impose legal obligations, so that even those doctors who have less skill or inclination for communication, or who are more hurried, are obliged to pause and engage in the discussion which the law requires*".

Whilst the judges acknowledged that some healthcare workers would find this approach as unwelcome as bottled drinks manufacturers no doubt found the ruling of *Donoghue v Stevenson* to be, they felt that the fundamental response to any complaints about their findings is "that respect for dignity of patients requires no less". Given the extreme circumstances of the COVID-19 pandemic and their disproportionate impact on those most reliant on NHS services, perhaps this view of the court needs further consideration?

[252] GDC, 'Standards for the Dental Team' (General Dental Council2018) <https://www.gdc-uk.org/information-standards-guidance/standards-and-guidance/standards-for-the-dental-team>. Section 1.7.1
[253] ibid. 1.2.4
[254] at [58] and [92]

6.5 What are the implications of these findings for GDPs' training, guidance, and future research?

The small number of responses to my survey mean that any findings need to be interpreted with caution and any recommendations made need to be viewed as being tentative, with an acceptance that further research is needed. That said, the key findings from my literature search and research project are as follows:

Appointment length: GDPs and those who fund their services have an obligation to understand the importance of appointment length when planning delivery of optimal urgent dental care. The Commissioning Standard for Urgent Dental Care[255] suggests a minimum appointment length of 15 minutes, despite published evidence linking appointments of less than 20 minutes with an increased risk of inappropriate care. The utilitarian need for greater access needs to be balanced against the negative impact this can have on the deontological need for GDPs to be able to fulfil their duty to manage their patients' pain appropriately. Further research is needed here to explore appointment structuring within NHS primary dental services, looking at the average daily numbers of patients, treatment times and increased costs of delivery compared to remuneration rates with a comparison to the equivalent services within private dentistry. Through this additional research, it might be possible to make evidence-based recommendations to the commissioning services regarding appropriate appointment lengths for urgent dental care.

Communication: In her 2016 article,[256] Suzanne Dintzis quotes the Joint Commission report from 2004–2015 that looked at sentinel events[257] over this time and found that 66% were the result of ineffective communication. From the survey results, more than 25% of GDPs would potentially not routinely inform their pain patients of all reasonable treatment options. It is not possible to say why this group would not effectively communicate with the patient, but it may be that time and training lie at the heart of it. Both the aforementioned Bester, Cole and Kodish article and the Dintzis one stress the need for communication training for clinicians, especially when dealing with patients likely to be emotionally overwhelmed (in dentistry this is likely to be from the emotional impact of anxiety and acute pain rather than the enormity of the decision that they face). Traditionally, communication training for dentists has not been viewed as being a mainstream requirement and remains relatively low priority in postgraduate courses. This may explain

[255] 'NHS England» Commissioning Standard for Urgent Dental Care' (www.england.nhs.ukJuly 2019) <https://www.england.nhs.uk/publication/commissioning-standard-for-urgent-dental-care/>
[256] Suzanne Dintzis, 'Improving Pathologists' Communication Skills' [2016] 18 AMA Journal of Ethics 802
[257] A sentinel event is classed as any unanticipated healthcare event that results in serious harm, psychological injury, or death to a patient during their care

why the majority of dentists who were asked about the use of communication techniques to ease anxiety in patients in pain cited a lack of training as their main reason for not using them. Further research into how this lack of training could best be addressed in primary dental care could help enhance urgent dental care for those most anxious of dental treatment.

Confidence: The GDPs who responded to my survey and indicated either a low understanding of *Montgomery* or a low likelihood of gaining informed consent actually showed (in the FTAs) that they had, on average, a similar understanding to those who indicated that they had a high understanding of the ruling and were informing the patient (in the clinical scenario) with sufficient appropriate information. This mismatch between perception and reality is seen in GDPs' fear of litigation despite falling rates of negligence claims and regulatory hearings over the past five years. Training targeted at correcting the perceptions to be more in line with reality so that GDPs can focus on what is required for informed consent and ignore what isn't would help correct this. Again, this topic is not seen as an important part of current continuing professional development (CPD) programmes.

Understanding: Bester, Cole and Kodish make the point that, when an overwhelmed patient has reached a point that their decision-making capacity has been compromised, they are at risk of making decisions that have the potential to be harmful to themselves and not in keeping with their values. They suggest that, in these circumstances, the clinician's focus should shift from that of informed consent to protecting their patient from harm. This recommendation is broadly in line with the GMC's approach to *Decision Making and Consent*,[258] where the guidance for doctors who are needing to decide how to act in the overall benefit of a patient unable to consent for themselves is that they must: *"consider which option aligns most closely with the patient's needs, preferences, values and priorities"* (89b) and "*which option would be least restrictive of the patient's future options*" (89c).

When GDPs are faced with a patient incapacitated with pain, their focus can safely be aligned to getting the patient out of pain in a way that leaves them with as many future dental treatment options as possible. This knowledge and understanding of what is expected of them can make the GDPs' role much easier for them to identify and remove the confusion and fear of litigation that can drive clinical decision making, especially in UK primary dental care services. As important as autonomy is, the *Montgomery* ruling cannot be used as a blanket approach to every situation. This is particularly the case for those patients whose agony is driving them to make unwise or potentially harmful decisions that

[258] GMC, "Guidance on Professional Standards and Ethics for Doctors Decision Making and Consent" (2020) <https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf>.

they most likely would not have made had they been given appropriate initial care. Allowing patients to make decisions that go against their normally expressed values, simply because of what they say in the throes of acute debilitating pain, is surely closer to maleficence than it is to beneficence. Future research aimed at gaining further understanding into the barriers (and facilitators) to the provision of optimal urgent dental care in the UK should take the form of qualitative analysis of GDPs' actual experiences of their day-to-day practices, which could also be used to shape future training needs, with particular reference to communication skills when treating the anxious and overwhelmed patient in pain. This analysis could also help GDPs recognise their many strengths and skills, which they often underplay.

6.6 Final words

I have been fortunate to have worked for 32 years in a profession that I love, providing treatment across primary and secondary care facilities in both NHS and privately funded arrangements. Over this time, I have treated thousands of patients who were in pain and have spent many years studying the topic of acute and chronic pain.

Throughout my career, I have always been struck by the dedication, care and professionalism of my colleagues, and this research project has done nothing to shake this. Although there will always be a small percentage of professionals who either, through lack of training, understanding, empathy or ability, do not provide a standard of care expected of reasonably competent professionals, the overwhelming majority do and have continued to do so even during these most challenging of times. The legal, regulatory and authoritative guidance provided by the courts to explain what is expected of GDPs in terms of information disclosure for consent, what level of recording of consent is needed and what is expected in terms of urgent care are all clearly laid out, perhaps more than they have ever been before. Despite this clarity, there is still a significant number of GDPs who do not feel confident in their ability to gain informed consent for urgent care patients and do not feel able to deliver optimal care at this time of heightened restrictions. Further research may help shape training that can deliver improved levels of understanding of the pressures felt by GDPs so that they can deliver optimal care within a supportive legal and regulatory framework that recognises the unique pressures that the dental profession is under.

Afterword

I am hugely grateful to my many colleagues who have been so supportive of my efforts with this thesis.

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Appendices

Appendix 1

LLM by Research for Ian Kerr BDS MSc

An investigation into General Dental Practitioners (GDPs) experiences of obtaining valid consent from patients suffering with debilitating pain before and after the impact of COVID 19 related restrictions to care

Participant Information Sheet

Study Title

An investigation into General Dental Practitioners' (GDPs) experiences of obtaining valid consent from patients suffering with debilitating pain before and after the impact of COVID 19 related restrictions to care

Invitation

You are invited to take part in this research project which forms part of my LLM by Research which I am undertaking at the Kent Law School, University of Kent.

You are invited to take part but do not have to if you do not wish to; there are no disadvantages to you if choose not to participate.

What is the purpose of the Study?

The study aims to look at how confident GDPs feel when obtaining valid consent from adult patients suffering with acute dental pain. The questionnaire looks at the impact that

the restrictions placed in response to COVID-19 has had on the delivery of acute pain management and how GDPs have coped with this challenge. It will assess the impact, if any, of various factors that are outlined in the survey.

Why have you been invited to take part?

You are a member of the online dental forum Dentists for Dentists that is run via Facebook. As membership of this forum is restricted to dentists it is being used as a way to access as many GDPs in the UK as possible.

Do I have to take part?

While your help would be greatly appreciated and would assist in furthering our knowledge of how pain requiring urgent care is currently being managed, participation is completely voluntary. You are perfectly entitled not to take the survey, should you wish. You have the right to withdraw from the survey at any time until submission of the completed questionnaire. Due to the anonymous nature of the survey, withdrawal from the survey is impossible once the questionnaire has been submitted by the participant.

I am happy to discuss any aspect of this study and questionnaire with you, and if you are unsure of anything, please do contact me before completing the questionnaire.

Incentives

There are no incentives available for taking part; your participation is entirely voluntary.

Will my participation be confidential?

The questionnaire will remain anonymous. No personal information is collected.

What are the risks and benefits of taking part?

There are no foreseeable risks involved in taking part in this study. It is anticipated that

completing the questionnaire will take approximately 10 minutes. While there is no direct benefit to each individual who completes the questionnaire, it is hoped that the knowledge gained from the research will help dentists identify ways to improve outcomes, for both dentist and patient, when adults attend for emergency appointments.

How is the project funded?

The project is entirely self-funded. There are no sponsors or contributors.

What will happen to the data?

The survey data will be used as part of my LLM by Research and may, if suitable, be used as part of a publication in a peer-reviewed journal.

Can you withdraw from this study if you change your mind?

The questionnaire is entirely anonymous, so it will not be possible to identify any individual response. Any completed questionnaires will remain part of the study once they have been submitted.

What should you do if you have a concern regarding this study?

If any potential participant has any concern or complaint relating to the content of the questionnaire or the approach of the research, then they should contact the supervisor Prof Sally Sheldon S.Sheldon@kent.ac.uk

Principal researcher email: ik262@kent.ac.uk

How will your anonymous responses be stored?

During the data analysis phase of the research all anonymous survey responses and data files will be stored securely on my password protected laptop and backup storage using double authentication system approved by University of Kent.

The final data file will be stored in the University of Kent Data Centre is an onsite secure controlled All data stored at the University of Kent is under Information Compliance - Data Protection Code of Practice:
https://www.kent.ac.uk/infocompliance/downloads/data_protection_CoP.pdf.

Thank you in advance for taking the time to complete this questionnaire

Consent (please complete this questionnaire only once)

CONSENT: I confirm that I have read and understood the purposes of this research and have had the opportunity to consider the information and my involvement: I understand that my involvement is voluntary, and I consent to participate in this study for research purposes * *Required*

More info

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Section 1 Practitioner Background

I currently practice dentistry in the UK as a GDP in a primary care setting (NHS or Mixed or Private practice)

** Required*

- ○ Yes
- ○ No

Which year did you qualify? (Primary Dental Degree) *Optional*

- ☐ 1970-1979
- ☐ 1980-1989
- ☐ 1990-1999
- ☐ 2000-2009
- ☐ 2010-2020

Geographically, which part of the UK is your primary practice based in?

- ○ England
- ○ Scotland
- ○ Wales
- ○ Northern Ireland

Which country did you qualify as a dentist in? *Optional*

- ○ UK

- ○ Non-UK

Do you have any additional university backed post-graduate dental qualifications *Optional*

- ○ Yes
- ○ No

For adult patients only, approximately what percentage of your practice income relates to NHS *Optional*

- ☐ 1-24% NHS
- ☐ 25-49% NHS
- ☐ 50-74% NHS
- ☐ 75-99% NHS
- ☐ 100% NHS (No Private)
- ☐ 100% Private (No NHS)

Section 2: please read the following clinical scenario and answer the few short questions that follow

Jim is a 56 year old new patient with no relevant medical history seeking urgent care for his constant, severe toothache. Jim thinks the pain is coming from his lower right jaw. Painkillers help a bit but the pain kept him up all night. Hot drinks make the pain much worse.

On examination the lower right first molar has deep decay and shows slight periapical change radiographically but is in a restorable condition. The tooth forms part of the only functioning molar pair on that side and he has limited chewing function on the left. There are no significant probing depths, swelling or lymphadenopathy evident.

Jim is clearly distressed by the level of pain that he is in and when questioned on what he wants to do with the tooth Jim says "I don't care what you do, just get me out of pain".

Please answer the questions below that relate to how you might treat Jim as a patient in need of urgent care.

Since June 2020, how long would you expect to allocate to this urgent care visit?
Optional

- ☐ Less than 20 minutes
- ☐ 20-30 minutes
- ☐ 30-45 minutes
- ☐ Over 45 minutes

Would the appointment routinely be offered as an AGP slot or non AGP?

- ○ AGP
- ○ Non AGP

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If you were unable to provide treatment as an AGP at this appointment which of the following treatment options would you be most likely to offer Jim for his pain? *Optional*

- ☐ Continue with painkillers and come back another day
- ☐ Antibiotics
- ☐ Refer to a center where AGPs can be delivered
- ☐ Extraction
- ☐ Not applicable, always offer AGP

If you did not feel able to offer Jim all appropriate options for his pain relief would you discuss this fact as part of the consent process? *Optional*

- ☐ Yes
- ☐ No

How would you rate your chances of obtaining valid and appropriately informed consent for treatment in this case?
Optional

- ☐ No likelihood
- ☐ Highly unlikely
- ☐ Highly likely
- ☐ Certain

In this scenario what risks would you consider to be materially relevant to Jim?

Section 3 Understanding of Montgomery

Are you aware of the ruling of Montgomery v Lanarkshire Health Authority(2015)? *Optional*

- ○ Yes
- ○ No

To what extent do you understand the changes that this ruling has brought about to how we approach healthcare decisions with our patients? *Optional*

- ☐ Not at all
- ☐ A little
- ☐ A good understanding
- ☐ Clear and substantial

In one or two lines please summarise what you understand the case of Montgomery v Lanarkshire means in terms of providing dental care.

When discussing treatment choices for pain relief (extraction V endodontics) what would you identify to be the main material risksthat you most commonly discuss with your patients?

To what extent, if at all,have you changed your daily practice when providing urgent care to adult patients in severe pain to reflect the changes brought about by the Montgomery ruling? *Optional*

- ☐ Not at all
- ☐ Minor or slight changes
- ☐ Substantial changes
- ☐ Total change to our daily practice

Given the additional challenges to delivering dental care post June 2020 do you feel that you now pay more, less or the same level of attention to the impact of the Montgomery ruling when discussing treatment options with patients? *Optional*

- ☐ More
- ☐ Less
- ☐ The same

Final section: Practice strategy for managing acute dental pain as an emergency appointment before and after June 2020

Since June 2020 when dealing with patients requiring urgent care for severe pain do you carry out a remote triage consult (either by phone or video links such as Zoom) prior to the face to face appointment? *Optional*

- ☐ Never
- ☐ Seldom
- ☐ Most of the time
- ☐ Always

Prior to the lock down of March 2020 when dealing with patients requiring urgent care for severe pain did you carry out a remote triage consult (either by phone or video links such as Zoom) prior to the face to face appointment? *Optional*

- ☐ Never
- ☐ Seldom
- ☐ Most of the time
- ☐ Always

When seeing adult patients in severe pain which treatment discussion are you most likely to have with the patient? *Optional*

- ○ Comprehensive discussion of all reasonable options
- ○ Immediate pain relief only
- ○ Only treatments that I feel confident delivering
- ○ Only treatments that are available at my practice

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When treating patients in severe pain how often do you obtain a signed consent form prior to treatment? *Optional*

- ☐ Never
- ☐ Seldom
- ☐ Most of the time
- ☐ Always

In the period following the return to work *after* the closure of dental practices in March-June 2020 to what extent, if at all, have you found the restrictions imposed on treatment have reduced your ability to provide optimal care for patients suffering with severe dental pain? *Optional*

- ☐ Not at all
- ☐ Minimally
- ☐ Significantly
- ☐ Totally changed all aspects

If your treatment options have been reduced because of the imposed restrictions, do you inform your patients of this and how is this reflected in your consent process? (Please give examples)

Submit

That's it, the questionnaire is over. If you are here at the end of working through all the questions, thank you so much: please click "Finish" and you are done!

If you have been redirected here right from the start it is either because you clicked "No" to the consent question or to the question asking if you are working as a GDP in the UK. Sadly a "No" to either question means that you cannot take part in the questionnaire, sorry. If this answer was clicked in error then please just go back to the begining and go again.

Final page

Thank your very much for taking the time to answer this survey. The findings from the survey will be used in my LLM MA dissertation and subsequent publications

Kind regards

Ian

Key for selection options

1 - CONSENT: I confirm that I have read and understood the purposes of this research and have had the opportunity to consider the information and my involvement : I understand that my involvement is voluntary, and I consent to participate in this study for research purposes

Yes
No

Appendix 2 KLS Signed Research Ethics Application Form

KLSResearchEthicsApplicationForm

This form should be completed by all staff and students undertaking research which mightraise ethical issues. Please complete, and submit electronically to KLS Research EthicsCoordinators: Dr Pamela White (p.white-229@kent.ac.uk) and Dr Gbenga Oduntan(o.t.oduntan@kent.ac.uK).

Please note, KLS adheres to Universities UK Concordat to support research integrity. For moredetails on this concordat, please see here:https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Pages/the-concordat-for-research-integrity.aspx

SectionI:Applicantdetails			
Nameof principal researcher	IanKerr		
School/Department:	KentLawSchool		
Email:	Ik262@kent.ac.uk	Telephonenumber:	01580752202
Undergraduate ☐	Taught Postgraduate ☐	ResearchPostgraduate ☒	Staff ☐
Name of others involved androle (e.g.supervisor). Includeaffiliation,ifnotKLS	ProfSallySheldon,Supervisor		
Student detailsifapplicable			
Degreeprogramme:	LLM by Research		
Supervisor'sname:	Sally Sheldon		
Supervisor'semail:	s.sheldon@kent.ac.uk		

SectionII:Project details			
Titleofproject	How have General Dental Practitioners (GDPs) negotiated the twin challenges of the new patient-centredstandardofconsentaslaiddowninMontgomeryandtherestrictionstocarecausedbyCovid-19from June2020onwardswhendealingwithadultpatientssufferingwithseveredentalpain?		
Plannedstartdate:	July 2021	Plannedenddate:	October2021
Funding	**Self**		
Isittheresearchexternallyfunded?	No	If so bywhom?	

- **Summaryofresearch:**

The research project is aiming to explore the impact of severe dental pain when trying to obtain valid consent for treatment. The ruling on Montgomery v Lanarkshire Health Authority in 2015 has given a direction that the consent process should be much more patient centred with a focus on explaining risks that are deemed "material" by the patient given his or her personal circumstances irrespective of how small these risks might be. The impact of COVID-19 felt from March 2020 onwards has made the delivery of dental care more challenging and has led to an increase in the number of patients seeking urgent care, following the closure of all dental practices for 3 months in 2020. These twin challenges have put an increasing burden on GDPs

as they seek to provide
optimal care for their patients and the research project aims to explore how they have managed this and what barriers they have encountered.

- **Locationofresearch**
  The forum is restricted to UK based GDPs and the research is limited to countries within theUK

- **Please describe briefly the methodology/techniques used when dealing with humanparticipantsinyourresearch(suchasquestionnaires,focusgroups,interviewsetc).**

  The project will rely upon an online questionnaire, which will be designed to collect anonymised data relating to time spent inpractice, country of qualification and post graduate experience along with information relatingto their routine working practices. It will then ask questions designed to test the respondents'knowledge on the topic of consent and to explore practices around obtaining valid consent from patients experiencing debilitating pain both before and during COVID. It poses a fictitious but realistic clinical scenario with subsequent questions designed to gauge how GDPs would go about obtaining consent.

- **Pleaseprovide somedetailsontheselectionof participantsandnumbers.**
- The sampling technique will be non-random convenience sampling as the questionnaire willbe distributed freely via the dental forum "Dentists for Dentists" on Facebook and involvement is entirely voluntary. There are roughly17,000 members of the forum and an expected response rate of approximately 250 would beconsideredreasonable. A power calculation based on this population size with an estimated variance of 50% gives a sample size of 374 (standard error<0.05) for the results to be considered generalisable to this population of GDPs.

- **Please give details on how results of your research will be disseminated toparticipants.**

A summary of the findings will be posted on the forum once I have completed my data analysis and LLM thesis; any publication article subsequent to this will also be shared (via a link to the appropriate journal). As the data is collected entirely anonymously there isnowayto specificallytargettherespondents withany information.

SectionIII:Researchethicschecklist

Please note that it is your responsibility to follow, and to ensure that all researchers involved withyour project follow, accepted ethical practice and appropriate academic or professional ethicalguidelines intheconductofyourstudy.Examplesofrelevantguidelines are:

- Socio Legal Studies Association (SLSA) Statement of Principles of Ethical ResearchPractice: https://www.slsa.ac.uk/index.php/ethics-statement
- Economic and Social Research Council (ESRC) Framework for research ethics, UpdatedJan2015: https://esrc.ukri.org/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015/ https://esrc.ukri.org/funding/guidance-for-applicants/research-ethics/
- SocialResearchAssociation(SRA),Researchethicsguidance https://the-sra.org.uk/SRA/Ethics/Research-ethics-guidance/SRA/Ethics/Research-Ethics-Guidance.aspx?hkey=5e809828-fb49-42be-a17e-c95d6cc72da1
- Pleasestatewhichguidelinesyouconsulted:Socio Legal Studies Association (SLSA) Statement of Principles of Ethical ResearchPractice:

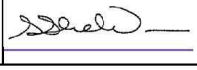
TheChecklist isdesignedtoidentifythenatureofanyethicalissuesraisedbytheresearch. Itmust becompletedbeforepotentialparticipantsareapproachedtotakepartinanyresearch.

Pleaseanswer allquestionsbycheckingtheappropriatebox		Yes	No
Researchsubjects			
a.	Doestheresearchinvolvechildrenor legalminors?		X
b.	Doestheresearchinvolvegroupswhichmaybevulnerableor atrisk?		X
c.	Doestheresearchinvolveparticipantswhoarepotentiallyorinanyway vulnerable or who may have any difficulty giving meaningful consent totheirparticipation ortheuseoftheirinformation?		X
d.	Doestheresearchinvolveparticipantsinadependentrelationshipwith anyoftheinvestigators(e.g.yourownstudents)?		X
e.	Doestheresearchinvolveparticipantsintheircapacityaspatientsofthe NHS, as clientsofsocialservices,orasresidentsofcarehomes?		X
f.	Doestheresearchinvolveparticipantswhoareprisonersorprisonstaff?		X
g.	Willtheresearchrequiretheco-operationof agatekeeperforinitial accessto thegroupsor individualstoberecruited?		X
h.	Will the study involve discussion of sensitive topics? For example (but notlimitedto) sexualactivity;druguse;experienceofviolenceor abuse; criminalactivity?		X
i.	Will the research involve the collection of material that could beconsideredofasensitive,personal,biographical,medical,psychological, socialor physiologicalnature?		X
j.	Couldthestudyinduceunacceptablepsychologicalstressoranxietyor cause harm or negative consequences beyond the risks encountered innormallife?		X
k.	Willtheparticipantsbeinvolvedinaphysicalorvirtualcapacityor both (deleteasappropriate)?		X
ResearchDesign/Methodology			
l.	Doestheresearchmethodologyinvolvetheuseofdeception?		X

m.	Willfinancialinducements(otherthanreasonableexpensesand compensationfortime)beofferedtoparticipants?		X
n.	Doestheresearchinvolveparticipantswhoarebeinginterviewed(in personor virtually)?		X
o.	IfyestotheabovE,is acompletedParticipationInformationSheet& Consent Formattached?		X
Confidentialityanddatamanagement			
p.	Willtheresearchinvolvethesharingofdataorconfidentialinformation beyondtheinitialconsent given?		X
q.	Willtheresearchinvolvethesharingofdatabeyondtheprojectenddate?		X
r.	Willtheresearchinvolveadministrativeorsecuredatathatrequires permissionfromtheappropriateauthoritiesbeforeuse?		X
s.	CompliancewithGeneralDataProtectionRegulation(GDPR):doesyour research participant information sheet include a link to the university'sprivacy policy?	X	
Security-sensitivematerial			
t.	Does your research involve access to or use of material covered by theTerrorismAct? (The Terrorism Act (2006) outlaws the dissemination of records,statements and other documents that can be interpreted as promotingand endorsing terrorist acts. By answering 'yes' you are registering yourlegitimate use of this material with the Research Ethics Advisory Group.Intheeventofapoliceinvestigation,thisregistrationwillhelpyouto demonstratethatyouruseofthismaterialislegitimateandlawful).		X
'Prevent' agenda			
u.	Doestheresearchhavethepotentialtoradicalisepeoplewhoare vulnerabletosupportingterrorismorbecomingterroristsThemselves?		X
v.	Arethereanyparticulargroups whoarelikely tobeharmedby disseminationoftheresultsofthisproject?		X
Anyfurther details			
w.	IfyouhaveansweredYEStoanyoftheabovequestions,pleaseprovidemoreinformation,including details ofmeasureswhichyouwillundertaketoprotecttheparticipants. A link to the university's privacy policy will be included in the questionnaire information sheetthatrespondentsmustread beforebeginningthequestionnaire. The full version of the information relating to retention of anonymised data is copied below: Storage and retention of Anonymised interview/survey data: During the data analysis phase of the research all anonymous survey responses and data files will be stored securely on my password protected laptop and backup storage using double authentication system approved by University of Kent. "The University of Kent Data Centre is an onsite secure controlled facility using a Virtualized Machine environment with built-in computing and power redundancy and resilience. It is guaranteed by 'Cyber Essentials' certification (see https://www.cyberessentials.ncsc.gov.uk/). Data Centre staff ensure that all systems are secure, protected and up-to-date. Certified internal and external penetration tests ensure		

	service security against data corruption and breach. All content is backed-up on nightly, transferred to tape and stored offsite. All data stored at the University of Kent is under Information Compliance - Data Protection Code of Practice: https://www.kent.ac.uk/infocompliance/downloads/data_protection_CoP.pdf. All anonymous interview transcripts will be prepared and stored according to the UKRI 'Common Principles on Data Policy'. Files will be saved in open or standard formats and archived on the University of Kent's Data Repository (KDR). The anonymized data will be allocated DOIs to enable accurate location and citation. Wide and long-term reuse will be promoted by a CC-BY licence and ReadMe documentation detailing the provenance and context of the files. KDR is established to OAIS reference model (ISO14721) specification on an EPrints/recollect platform using DataCite compliant metadata schema and governance in line with FAIR data principles. KDR is fully supported by the University of Kent Information Services who maintain Cyber Essentials certification."
x.	What arrangements have been made to preserve confidentiality for the participants or thosepotentially affected? Noidentifyingdatawillbecollectedbythequestionnaire. In the unlikely event that any GDP shares information in a free text answer that would allow him/her to be identified, this information will be redacted in any quotations, or when the data is cleaned for deposit
y.	If the research raises any ethical issues other than those which you have outlined above,pleasegive information aboutthemhere.

	Consent will be attained by questions at the start of the questionnaire asking whetherrespondents understand that involvement in thequestionnaire is entirely voluntary and thatthey do not have to proceed if they do not wish to. They will also need to answer that theyhave read and understood the purposes of this research and have had the opportunity toconsider the information and their involvement: they will then give a yes or no answer toindicatethattheydoordonotconsenttoparticipateinthestudyforresearchpurposes. The questionnaire is being distributed via a link placed on a closed forum (Dentists for Dentists) on the social media platform Facebook. The questionnaire is hosted by onlinesurveys.ac.uk. As the researcher I am unable to see who responds via the link and the information collected is non-identifiable. The link will be reposted weekly with a request for responses. The link will make clear that, as the researcher, I am unable to engage in any form of online discussion relating to the questionnaire and cannot respond to any personal messages sent to me regarding the questionnaire. Link message: " Please take the time to complete this questionnaire which will form part of my LLM by Research Thesis. I am researching the twin impacts of recent changes to informed consent law and COVID-19 restrictions to care on the management of patients with acute pain. I hope that this research will benefit us all by furthering our understanding of the challenges facing the profession when providing care for those with urgent needs. The questionnaire is entirely voluntary and anonymous so please be as frank and honest as possible. To ensure confidentiality I cannot engage with any online discussions relating to the survey and cannot respond to any personal messages regarding it".

SectionIV:Declarationandsignatures			
Applicant signature		Date	02.06.2021
Supervisorsignature		Date[MOU1]	03.06.2021
Approval byKLSResearchEthicsAdvisoryGroup(REAG)			
Comments	Approved with the addition of the addition of security measures taken during the data analysis phase.		
Signature of Chairs of KLS_REAG	 Gbenga Oduntan by email	Date	07.06.2021 07.06.2021