

Assessing Patient Safety and Patient Experience of Novel Treatments and Procedures – King’s PSSQ project summary

Medical advances rely on innovative health care staff willing to try new techniques and treatments, and patients who are willing to undergo them. Open-heart surgery, organ transplants and life-saving operations for appendicitis were all developed by doctors trying new things to improve their care of their patients rather than through research. But innovation is not without risk - for patients, health staff and hospitals.

While there are strict rules and laws for developing drugs and medical devices, changes in surgery and clinical procedures are not governed in the same way. Pharmaceutical drugs and devices tend to be tested and assessed in clinical trials before becoming part of everyday care. Surgical and other ‘technique-centered’ innovations tend to arise from adjustments during actual treatment, such as a change to an operation that a surgeon may make to try to benefit one patient.

Grey areas, such as determining which changes are sufficiently different to require monitoring, make regulation harder. Technical innovations may evolve from relatively minor or incremental alterations; at the other end of the scale, they can comprise more obvious and radical change. Hospitals are increasingly under pressure to monitor innovations in surgery and clinical procedures and ensure that patients do not suffer unnecessary risk. But heavy handed regulation might stifle the good will and work of staff who are pushing the boundaries of health care.

We are researching the ways in which one London NHS Foundation Trust tries to balance safety and the risks implicit in advancing medical science. In particular how this hospital might regulate innovation in the best interests of patients, clinicians and management.

Our first step was to look at the work of the teaching hospital’s new committee to assess new procedures. The committee includes senior doctors from across the hospital who assess colleagues’ applications to try out procedures that are significantly different, or new for a particular diagnosis or disease, and have not been tried at this Trust.

We found that:-

The committee is a valuable way of governing innovation, but it needs a higher profile and more clout, so it can, for example, insist that clinicians report back on how the procedure went. We also suggested inviting other health professionals, such as senior nurses and midwives, and lay members onto the committee.

We are now exploring how clinicians see trying to do the best for their patients by innovating, set against their views on risk and attempts to monitor and assess them. Do surgeons, for example, feel progress is hamstrung by bureaucracy? Do they think that internal governance, in the form of the committee, works well? Is there consensus on which technique-centered innovations need regulating?

Next steps:-

Eliciting patients’ views. We will be looking at issues such as informed consent, and why some choose to undergo unproven treatments.