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Increase referrals and organ donors via interoperability

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Introduction: In the United States, national regulatory organizations require that hospitals refer all potential organ and tissue donors to an Organ Procurement Organization (OPO). Secure, direct, electronic donor referral interfaces are being launched across the country to replace the current time-consuming and error-prone telephonic referral process.
Method: The secure technical interface ("iReferral") directly connects the OPO and Hospital systems and is accompanied by seamless donor referral triggers within the Hospital Electronic Medical Record (EMR). These carefully tuned triggers automatically prompt delivery of electronic donor referrals from the Hospital to the OPO, greatly reducing the burden of decision-making and donation knowledge by the hospital staff. An additional trigger option allows staff to "one click" electronically refer for cases such as end-of-life discussions. Immediately the OPO receives a new referral auto populated with actionable patient information and real-time notifications alert OPO staff. The interface automatically returns the associated OPO referral ID number to the patient's EMR to provide confirmation to the referring clinician.
Results: This interface is currently implemented at 67 hospitals across the United States. At a pilot hospital, annualized data after the first year of implementation demonstrated a 49% increase in vented referrals and 78% increase in organs transplanted. At a large hospital network, over 10,000 referrals have been sent electronically since launch in February 2021 which has led to: 1) saving an estimated 3,000 nursing hours; 2) increasing vented referrals by 42%; and 3) a 31% increase in compliance rates (reduced missed referrals).
Conclusions: This interface has increased the number and timeliness of referrals (and thus transplantable organs) and reduced Hospital and OPO resource costs. As the interface was developed utilizing common healthcare interoperability standards there is unlimited potential for expansion and streamlining the referral process, ultimately leading to more donors and transplantations.

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Overcoming the challenges of delivering a national randomised controlled trial in organ donation

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SIGNET Study.
Introduction: SIGNET is a single-blind, randomised controlled trial (RCT) recruiting 2600 organ donors diagnosed dead by neurological criteria, across 76 large hospital trusts in the United Kingdom (UK). The intervention is a single dose of Simvastatin, a safe, affordable, and commonly used drug. The trial utilises the UK's unique infrastructure for organ donation and transplantation, with specialist nurses for organ donation (SNODs) seeking family consent and randomising donors. SIGNET uses UK Transplant Registry (UKTR) data for all recipient outcomes and is a pragmatic trial, assessing not only whether Simvastatin will help limit damage in donor hearts, but also whether it is feasible to deliver an interventional organ donor trial using a risk-adapted approach.
Methods: The trial team held discussions with the Medicines and Healthcare products Regulatory Agency (MHRA) and Health Research Authority to consider risk-adapted approaches appropriate for a study in deceased patients during the organ donation process and to review applicable trial regulations in this context. There were several challenges to overcome including the volume of sites involved, applicable consent for organ donors and recipients, GCP training for SNODs, workload for site research teams and Clinical Trial of an Investigational Medicinal Product (CTIMP) status.
Results: Following these discussions, SIGNET is not considered a CTIMP, and the SIGNET team gained approvals and proceeded with site set-up. Using novel approaches developed for the pandemic for site training and a GCP proportionate approach for SNODs, over 500 people (SNODs and research teams) were trained over a 4-month period, with 79 trusts (126 hospitals) currently open to recruitment. Randomisation, which had not previously been performed by SNODs, has been trouble free and sites have reported very little burden on them.
Discussion: SIGNET will be the largest global RCT in organ donation, benefitting from the unique strengths of the UK NHS infrastructure. We have utilised the MHRA's Innovation office to set precedents for interventional organ donation trials and implement risk-adapted approaches. Using a GCP proportionate approach and methods developed during the pandemic, we trained and set up numerous teams in a short period of time whilst minimising burden on site research departments. We are utilising the SNODs' skills and knowledge of consent to reach a large recruitment target. The centralised nature of the UKTR ensures high data completeness and a low burden on site research teams. These approaches could encourage further research into organ donation and help embed organ donation research into normal practice.
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