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Knowledge, attitudes and practice toward blood donation

Submission date
16/05/2022

Recruitment status
No longer recruiting

Registration date
27/05/2022

Overall study status
Completed

Last Edited
12/06/2023

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
There is an increasing demand for plasma-derived blood products in the Kingdom of Saudi Arabia (KSA), where about 300,000,000 USD was spent in 2015-2016 on imports of essential medicines derived from plasma. Self-sufficiency in this area is therefore important for the economy of KSA. However, there is no uniform application of national standards or a national monitoring system to guide Blood Establishments (organizations that manufacture products from blood) in KSA. This is made worse by a shortage of voluntary unpaid donors. For example, in 2008 the Saudi Ministry of Health and Saudi Pharmaceutical Society reported that of the existing 251 Blood Establishments only 14 had external accreditation and of over 400,000 donors only 39.5% were voluntary, with most of the remainder being replacement donors, i.e. people who donate directly for family and friends undergoing treatment requiring transfusion. This situation was essentially unchanged when reviewed in 2014. In 2018 the Saudi Food and Drug Authority (SFDA) published Good Manufacturing Practice for Blood Establishments but the majority of Blood Establishments are yet to accreditation due to the newness of this initiative. This study aims to understand the reluctance for voluntary blood donation in KSA since a secure voluntary donor base is a prerequisite for any blood fractionation programme aiming to manufacture medicines from blood. Knowledge, attitudes and practice (KAP) regarding blood donation will be compared between KSA and Wales, where there is over 70 years' experience of voluntary blood donation. Data will be collected from the general public (potential blood donors) and medical professionals to determine any key differences which might explain the different practices. The hypothesis is that socio-cultural factors are the main drivers affecting the likelihood of becoming an altruistic blood donor. If confirmed, the data obtained will inform the process of converting non-donors and replacement donors into regular voluntary donors. Additionally, the research will attempt to quantify key differences in attitudes to regulation to determine current practice by KSA Blood Establishments from the newly introduced SFDA standards in order to determine the likelihood of compliance with the SFDA standards.

Who can participate?
First survey (questionnaire): the general public eligible to donate blood by virtue of age (17-65 years), including university students and staff
Second survey (interview): leaders of blood transfusion establishments including medical consultants, clinical scientists and quality assurance leads

Third survey (questionnaire): professional users of transfusion services (medical and nursing) and professionals working in blood transfusion establishments (typically clinical scientists) but not those in leadership positions

What does the study involve?
The first survey will be conducted online using an online questionnaire tool licensed by Cardiff University ('online surveys' for the English version) and Google Forms (for the Arabic version). The survey takes 15-20 minutes to complete. For the second survey, a semi-structured interview will be employed. A sequence of validated questions would be asked, with two to five sub-questions following each question. The interview should take a maximum of 60 minutes to complete, depending on responses. The third survey will be held on the same online platform as Survey 1 but only in English as outlined above. The survey should take about 10-15 minutes to complete.

What are the possible benefits and risks of participating?
There are no inherent risks for the participants. Data collected will be anonymous and no identifiable data will be collected. The main burden will be the time commitment required to complete the questionnaire or interview. There will be no direct benefit to participants. It is hoped that information gathered from this study will help to identify strategies to increase voluntary blood donation and increase compliance with regulations in the Kingdom of Saudi Arabia. The findings may also be of relevance to other Gulf Cooperation Council states in the Middle East.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
July 2019 to September 2023

Who is funding the study?
Saudi Arabia Cultural Bureau in London (UK)

Who is the main contact?
1. Amr Maqnas (maqnasay@cardiff.ac.uk)
2. Dr Keith Wilson (keith.wilson@wales.nhs.uk)

Contact information

Type(s)
Principal investigator

Contact name
Dr Keith Wilson

ORCID ID
https://orcid.org/0000-0002-6327-9366

Contact details
Department of Haematology
University Hospital of Wales
Heath Park

Cardiff
United Kingdom
CF14 4XW
+44 (0)2921842331
keith.wilson@wales.nhs.uk

Type(s)
Scientific

Contact name
Mr Amr Maqnas

ORCID ID
https://orcid.org/0000-0003-1951-2180

Contact details
Heath Park Way
Cardiff
United Kingdom
CF14 4YS
+44 (0)7985451869
maqnasay@cardiff.ac.uk

Type(s)
Public

Contact name
Mr Amr Maqnas

Contact details
Heath Park Way
Cardiff
United Kingdom
CF14 4YS
+44 (0)7985451869
maqnasay@cardiff.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
271608

Study information

Scientific Title
Establishing a reliable and sustainable blood donation and blood quality system to enable the nationalization of manufacturing of plasma fractionation in the Kingdom of Saudi Arabia

Study objectives

The hypothesis is that socio-cultural factors are the main drivers affecting the likelihood of becoming a voluntary, non-remunerated blood donor. The key question (underlying assumption) is that knowledge affects attitude which in turn affects practice (KAP). The main objective of the research is to compare the knowledge of and attitudes towards voluntary blood donation in the Kingdom of Saudi Arabia (KSA) and Wales to determine if this explains the difference in blood transfusion practice in the two countries with under half of KSA donors being voluntary compared to 100% in Wales.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 28/04/2022, HRA and Health and Care Research Wales (Address: not available; Tel: not available; approvals@hra.nhs.uk, HCRW.approvals@wales.nhs.uk), ref: 22/NI/0066
2. Approved 23/12/2019, School of Medicine, Cardiff University (Main Building, Heath Park, Cardiff, CF14 4XN, Wales, UK; Tel: not available; pgrmedic@cardiff.ac.uk), ref: 19/76
3. Approved 05/02/2020, Faculty of Medicine, King Abdul-Aziz University, KSA (PO Box 80205, Jeddah, 21589, Saudi Arabia; +966 (0)6952446; +966 (0)6952063; Email: not available), ref: 67-20

Study design
Multi-center mixed-method comparative study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Voluntary blood donation among the Welsh and Saudi population

Interventions
This study relies on the mixed method strategy, using both quantitative and qualitative methodologies. Three comparative surveys will be undertaken in the Kingdom of Saudi Arabia and Wales, involving the potential blood donor population (Survey 1); professionals who hold leadership positions in blood transfusion establishments (Survey 2); and medical and nursing professionals who are the main users of blood transfusion services as well clinical scientists who work in blood transfusion establishments but not in leadership positions (Survey 3). The first and third surveys will be quantitative, while the second will be qualitative.

Three surveys have been developed as outlined above, and have been validated for content and understanding. The first survey is available in English and Arabic and the Arabic version has been subjected to both forward (English to Arabic) and backward (Arabic to English) translation using different accredited translation services to confirm accuracy. The second and third surveys are available only in English since the official language for science in KSA is English and the targeted professionals would be sufficiently competent to complete the surveys in English.

The first survey will be conducted online using an online questionnaire tool licensed by Cardiff University ('online surveys' for the English version) and Google Forms (for the Arabic version). The survey takes 15-20 minutes to complete.

For the second survey, a semi-structured interview will be employed. A sequence of validated questions would be asked, with two to five sub-questions following each question. The interview should take a maximum of 60 minutes to complete, depending on the responses.

The third survey will be held on the same online platform as Survey 1 but only in English as outlined above. The survey should take about 10-15 minutes to complete.

A variety of sampling approaches will be used in this research. The first survey will employ the simple random sample method where there is no stratification of potential respondents with all participants having an equal chance of participation. It would be aimed at the general public, particularly those who potentially meet the eligibility criteria to donate blood.

Purposive sampling will be used for the second survey (interview). With this technique the respondents are targeted - in this case leaders of blood establishments. The reason for this is to determine what appetite leaders in the field have for regulation and changing services in response to regulatory requirements. This is because adopting change, even if mandated, would be delegated to the leaders of services. The primary target audience for this poll is medical, scientific and quality assurance professionals working in blood transfusion establishments.

For the third survey, stratified random sampling will be utilized, where responses would be analysed by subgroups. This poll is aimed at blood transfusion laboratory staff as well as medical and using professionals who utilise blood transfusion services, i.e. clinical services with high transfusion rates. These workers would be essential in complying with regulations in the form of adherence to transfusion standards, documentation, reporting and investigating adverse events. Without a willingness to maintain these standards attempts to adopt regulatory standards would be futile.

Intervention Type
Other

Primary outcome(s)
Knowledge and attitudes to blood transfusion and regulation amongst the public and relevant professionals (leaders in blood transfusion services and main service users) in Wales and the Kingdom of Saudi Arabia, measured using two online questionnaires and an interview at a single timepoint

Key secondary outcome(s))
The interrelationship between knowledge, attitude, and practice (KAP) of blood transfusion and relevant regulation, as well as differences in this KAP between potential blood donors, workers in blood transfusion establishments, and professionals who use blood transfusion services, such as medical and nursing professionals in surgical specialties in KSA and Wales, measured using two online questionnaires and an interview at a single timepoint

Completion date
29/09/2023

Eligibility

Key inclusion criteria

First survey (questionnaire):
The general public eligible to donate blood by virtue of age (17-65 years), including university students and staff.

Second survey (interview):
Leaders of blood transfusion establishments including medical consultants, clinical scientists and quality assurance leads.

Third survey (questionnaire):
Professional users of transfusion services (medical and nursing) and professionals working in blood transfusion establishments (typically clinical scientists) but not those in leadership positions.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
17 years

Upper age limit
65 years

Sex
All

Total final enrolment
713

Key exclusion criteria
First survey:
Members of the general public not within the permissible age for blood donation, i.e. those not between ages 17-65 years

Second survey:
The general public and workers in blood transfusion establishments who do not occupy positions of leadership

Third survey:
The general public and leaders of blood transfusion establishments

Date of first enrolment
15/06/2020

Date of final enrolment
15/06/2023

Locations

Countries of recruitment
United Kingdom

Wales

Saudi Arabia

Study participating centre
Cardiff University
United Kingdom
CF14 4YS

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
United Kingdom
CF14 4HH

Study participating centre
Swansea Bay University Local Health Board
One Talbot Gateway, Seaway Drive
Seaway Parade Industrial Estate
Baglan
Port Talbot
United Kingdom
SA12 7BR

Study participating centre
Hywel Dda University Lhb
Corporate Offices, Ystwyth Building
Hafan Derwen
St Davids Park, Jobswell Road
Carmarthen
United Kingdom
SA31 3BB

Study participating centre
Cwm Taf Morgannwg University Local Health Board
Dewi Sant Hospital
Albert Road
Pontypridd
United Kingdom
CF37 1LB

Study participating centre
Aneurin Bevan University Lhb
Headquarters - St Cadoc's Hospital
Lodge Road
Caerleon
Newport
United Kingdom
NP18 3XQ

Study participating centre
Powys Teaching Lhb
Bronllys Hospital
Bronllys
Brecon
United Kingdom
LD3 0LS

Study participating centre
Velindre NHS Trust
Unit 2
Charnwood Court
Heol Billingsley
Cardiff
United Kingdom
CF15 7QZ

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Other

Funder Name
Saudi Arabia Cultural Bureau in London

Alternative Name(s)
Royal Embassy of Saudi Arabia Cultural Bureau in London, Royal Embassy of Saudi Arabia - Cultural Bureau in London, Royal Embassy of Saudi Arabia Cultural Bureau, SACB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The two questionnaires will be conducted online using an online questionnaire tool licensed by Cardiff University ('online surveys' for the English version) and Google Forms (for the Arabic version). The interviews will be held via Zoom and the recordings will be kept on Cardiff University's file store service designed specifically for live research data and which is suitable for storing highly confidential (C1) data. This storage benefits from Cardiff University's system of backing-up data to prevent/minimise file corruption. Access would be limited to the researcher (Amr Maqnas) and the lead supervisor via appropriate login credentials. The researchers will not collect any information that will identify participants personally. They will use initials, age and gender to better understand differences (if any) between different age and gender groups.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Donors version 3.2	25/03/2022	18/05/2022	No	Yes
Participant information sheet	Professionals version 3.2	25/03/2022	18/05/2022	No	Yes